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03-CV-2023-901109.00

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NOTICE OF ELECTRONIC FILING

IN THE CIRCUIT COURT OF MONTGOMERY COUNTY, ALABAMA

OASIS FAMILY BIRTHING CENTER,LLC, ON BEHALF OF ITSELF AND ITS PATIENTS
03-CV-2023-901109.00

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MONTGOMERY COUNTY, ALABAMA
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03-CV-2023-901109.00
CIRCUIT COURT OF
MONTGOMERY COUNTY, ALABAMA
GINA J. ISHMAN, CLERK

IN THE CIRCUIT COURT OF MONTGOMERY COUNTY, ALABAMA
FIFTEENTH JUDICIAL CIRCUIT – CIVIL DIVISION

OASIS FAMILY BIRTHING CENTER, LLC, on behalf of itself and its patients; HEATHER SKANES, M.D., on behalf of herself and her patients; ALABAMA BIRTH CENTER; YASHICA ROBINSON, M.D., on behalf of herself and her patients; ALABAMA AFFILIATE OF THE AMERICAN COLLEGE OF NURSE-MIDWIVES, on behalf of its members; JO CRAWFORD, CPM, on behalf of herself and her patients; TRACIE STONE, CPM, on behalf of herself and her patients, Plaintiffs, v. **ALABAMA DEPARTMENT OF PUBLIC HEALTH; SCOTT HARRIS, in his official capacity as the State Health Officer at the Alabama Department of Public Health,** Defendants.	Civil Action No. 03-CV-2023-901109.00 - GOG

FIRST AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF[1]

INTRODUCTION

1. In the midst of one of the most severe maternal and infant health crises in the entire country, Defendants Alabama Department of Public Health and Scott Harris, State Health Officer, are prohibiting Plaintiffs from offering critically needed, high-quality prenatal, birthing, and postpartum care (also referred to herein as "pregnancy-related care") that is proven to offer substantial benefits to the health of pregnant people and their babies.

[1] A version of the First Amended Complaint showing track-changes is attached hereto as Ex. E.

2. Plaintiffs are individual health care providers, health care centers, and a professional membership organization that offer or intend to offer midwifery-based care in freestanding (i.e., non-hospital-affiliated) birth centers. Freestanding birth centers provide low-risk pregnant patients with prenatal, birthing, postpartum, and early newborn care from licensed providers in a supportive, homelike environment outside the hospital setting and have been shown to achieve equivalent or better patient outcomes, at a fraction of the cost, when compared to hospital-based care.

3. Despite the proven benefits for maternal and infant health and the critical need for increased access to such care in Alabama—where nearly 40% of counties are classified as "maternity care deserts"[2] and existing hospital-based services are pushed past capacity—Defendants have refused to allow freestanding birth centers, including Plaintiffs, to operate in the state, even threatening Plaintiff Oasis Family Birthing Center with criminal and civil penalties, despite its perfect safety record, and forcing it to close its doors to patients.

4. Far from creating a timely, feasible path to licensure, Defendants' recent birth center regulations (2023 Final Regulations), which took effect October 15, 2023, continue to block freestanding birth centers from opening and operating in Alabama.

5. Defendants' de facto ban on freestanding birth centers, including through the adoption of the 2023 Final Regulations, is a dramatic about-face from their position—taken just three years ago—that they did not regulate birth centers *at all*, and far exceeds their statutory authority under Alabama law to regulate and license "hospitals," as defined under section 22-21-

[2] A "maternity care desert" is a county that lacks access to maternity care providers, including having no hospitals offering obstetric services, no birth centers, and no obstetricians or certified nurse midwives. *See Maternity Care Deserts Report: Nowhere to Go: Maternity Care Deserts Across the U.S. (2022 Report)*, March of Dimes, https://www.marchofdimes.org/maternity-care-deserts-report#divMaps (last visited Jan. 17, 2024).

20(1) of the Alabama Code, and violates the constitutional rights of Plaintiffs, their members, and their patients. Absent relief from this Court, the birth center ban will continue to inflict irreparable harm on Plaintiffs, their members, and their patients, and on the public health and welfare of Alabamians.

JURISDICTION AND VENUE

6. This Court has jurisdiction pursuant to the Alabama Administrative Procedure Act, Ala. Code § 41-22-10, the Alabama Declaratory Judgment Act, *id.* § 6-6-222, and the Due Process and Equal Protection Clauses of the Alabama Constitution, art. I, §§ 1, 13, and the United States Constitution, amend. XIV, § 1.

7. Venue is proper in this Court under Alabama Code section 41-22-10, which provides that the validity or applicability of an agency rule may be determined in an action for a declaratory judgment or its enforcement stayed by injunctive relief in the circuit court of Montgomery County. Venue is also proper in this Court to hear Plaintiffs' constitutional challenges because the government entity and government official defendants officially reside and have their principal place of business in Montgomery County. *See Ex parte Bd. of Water & Sewer Comm'rs of City of Mobile*, 272 So. 3d 635, 639 (Ala. 2018).

PARTIES

A. Plaintiffs

8. Oasis Family Birthing Center, LLC (OFBC), is a freestanding birthing center[3] in Birmingham, Alabama, founded in June 2022, to provide women in the Birmingham area with high-quality, affordable, patient-centered care in an out-of-hospital setting, including prenatal, birthing (i.e., labor and delivery), postpartum, and newborn care. OFBC operates in the midwifery

[3] Plaintiffs use the terms "birth center" and "birthing center" interchangeably.

model of care[4] and is dedicated to creating an inclusive environment for Black women, women of color, gender-non-conforming people, low-income patients, religious families, and other communities who often lack access to affordable, patient-centered care. OFBC began seeing patients in September 2022 but was forced by Defendant Alabama Department of Public Health to cease providing care and stop taking new patients in spring 2023. OFBC sues on behalf of itself and its patients.

9. Heather Skanes, M.D., is a Board-certified obstetrician and gynecologist (OB/GYN) who has provided comprehensive reproductive health care in Alabama for 4 years. She currently provides a broad range of health care to patients at her private practice, Oasis Women's Health in Birmingham, Alabama, including but not limited to general OB/GYN care; minimally invasive outpatient surgery; and management of infertility and menopause treatment. She is also the founder and Executive Director of Plaintiff OFBC. Dr. Skanes sues on her own behalf and on behalf of her patients who seek access to midwifery care and non-hospital birth in a birth center.

10. Alabama Birth Center (ABC) is a freestanding birth center in development and under construction in Huntsville, Alabama, which will provide high-quality, affordable, patient-centered care in an out-of-hospital setting, including prenatal, birthing, postpartum, and newborn care. ABC will operate in the midwifery model of care, with a focus on serving low-income populations who otherwise lack affordable options for out-of-hospital births.

11. Yashica Robinson, M.D., is a Board-certified OB/GYN who has provided comprehensive reproductive health care in Alabama for nearly twenty years. Dr. Robinson currently provides a broad range of health care in her private practice and as Medical Director of Alabama Women's Wellness Center, P.C., in Huntsville, Alabama, including but not limited to

[4] The midwifery model of care is also referred to as the "midwives' model of care" and is further defined below.

general OB/GYN care; major and minor gynecological surgeries; management of infertility; and primary care. She is also the founder and Medical Director of Plaintiff ABC. Dr. Robinson sues on her own behalf and on behalf of her patients who seek access to midwifery care and non-hospital birth in a birth center.

12. The Alabama affiliate of the American College of Nurse-Midwives (ACNM-AL) is the local state affiliate in Alabama of ACNM, the nationwide professional association of certified nurse-midwives (CNMs).[5] ACNM sets the national standards for nurse-midwifery education and practice in the United States. The Alabama affiliate of ACNM is the primary organization representing CNMs in the state of Alabama. It provides professional support and liaises with the national organization on behalf of members with respect to questions about national standards, state laws, and regulations; engages in advocacy on behalf of the nurse-midwifery community in Alabama; and provides a forum for communication and relationship-building among CNMs practicing in the state. Its membership includes all Alabama-based members of ACNM, including members who are dually certified as CNMs and certified professional midwives (CPMs).

13. Jo Crawford is a nationally-certified, Alabama-licensed CPM currently providing midwifery care in Alabama at Plaintiff OFBC and through her home birth practice, Home Sweet Birth, LLC. She also previously provided midwifery care at Plaintiff OFBC when it first opened in 2022, until it was forced to close by ADPH. She is licensed as a CPM in Virginia as well, and provides midwifery care there on a part-time basis in freestanding birth centers. She has over nine years of experience providing midwifery care as a CPM in both freestanding birth centers and

[5] Two kinds of midwives are licensed to practice in Alabama: certified nurse midwives and certified professional midwives. Certified nurse midwives are advanced practice registered nurses specializing in midwifery care and are licensed by the State Board of Nursing. Certified professional midwives are skilled practitioners holding a certification from an accredited organization and are licensed by the State Board of Midwifery. Both kinds of midwives provide care in the midwifery model but complete different educational and training requirements.

home birth settings, in addition to more than fifteen years of experience as a certified doula and childbirth educator. She is also approved by the North American Registry of Midwives as a preceptor and has extensive experience training student midwives in that capacity. Crawford sues on her own behalf and on behalf of her patients who seek access to midwifery care and non-hospital birth in a birth center.

14. Tracie Stone, CPM, is a nationally-certified CPM who obtained a license in December 2023 to practice as a professional midwife in Utah and is in the process of seeking CPM licensure in Alabama. Once licensed in Alabama, she plans to provide midwifery care at Plaintiff ABC. She has spent the last four years completing an apprenticeship as a student midwife with a home birth practice in Alabama. She also has more than six years of experience as a doula and childbirth educator and is completing additional midwifery education through the Midwest Maternity Childbirth Institute. Stone sues on her own behalf and on behalf of her patients who seek access to midwifery care and non-hospital birth in a birth center.

B. Defendants

15. The Alabama Department of Public Health (ADPH) acts for the State Board of Health[6] under section 22-1-1 of the Alabama Code. *See Ex parte Torbert*, 224 So. 3d 598, 598 n.1 (Ala. 2016). ADPH promulgates rules and regulations through the State Board of Health and the State Committee of Public Health. Ala. Code §§ 22-1-1, -2-2, -21-28(a). ADPH's principal place of business is 201 Monroe Street, Montgomery, Alabama.

16. Under section 22-21-22 of the Alabama Code, ADPH has the authority to license

[6] "The terms State Board of Health, State Committee of Public Health, State Department of Public Health, and State Health Officer are used interchangeably except where the context prohibits." Ala. Admin. Code r. 420-1-5-.01. The State Board of Health is constituted of the Medical Association of the State of Alabama, *see* Ala. Code § 22-2-1, which is the professional organization for physicians practicing in Alabama and whose mission includes physician advocacy and education.

and regulate "hospitals," which are defined for these purposes as follows:

> General and specialized hospitals, including ancillary services; independent clinical laboratories; rehabilitation centers; ambulatory surgical treatment facilities for patients not requiring hospitalization; end stage renal disease treatment and transplant centers, including free-standing hemodialysis units; abortion or reproductive health centers; hospices; health maintenance organizations; and other related health care institutions when such institution is primarily engaged in offering to the public generally, facilities and services for the diagnosis and/or treatment of injury, deformity, disease, surgical or obstetrical care. Also included within the term are long term care facilities such as, but not limited to, skilled nursing facilities, intermediate care facilities, assisted living facilities, and specialty care assisted living facilities rising to the level of intermediate care. The term "hospitals" relates to health care institutions and shall not include the private offices of physicians or dentists, whether in individual, group, professional corporation or professional association practice. This section shall not apply to county or district health departments.

§ 22-21-20(1); *see also* Ala. Admin. Code r. 420-5-7-.02(3)(a) (ADPH may grant license to hospitals as "agent" for the State Board of Health).

17. ADPH may issue a license for covered facilities based on compliance with either "the minimum standards provided in [article 2 of title 22, chapter 21] or by regulations issued under its authority." Ala. Code § 22-21-23; *see also id.* § 22-21-25(a). ADPH has adopted a policy of general applicability that freestanding birth centers require a hospital license and has failed to provide any timely, feasible path to such licensure, including by adopting burdensome regulations that make it extremely difficult if not impossible to work in, "establish[]," "construct[]," "maint[ain]," or "operat[e]" freestanding birth centers in Alabama. *See* Ala. Code § 22-21-21. ADPH's actions have resulted in a de facto ban on birth centers in Alabama.

18. Scott Harris, M.D., MPH, is the State Health Officer for ADPH. The State Health Officer is, *inter alia*, the executive officer of the ADPH. *Id.* § 22-2-8. As State Health Officer, Harris is responsible, *inter alia*, for supervising and directing the licensing of hospitals, as defined

under Alabama law. *See id.* § 22-2-2 *et seq.*; Ala. Admin. Code r. 420-5-7-.01 *et seq.* As such, Defendant Harris is responsible for ADPH's policy of general applicability that freestanding birth centers require a hospital license and for its failure to provide any timely, feasible path to such licensure, resulting in a de facto ban on birth centers in Alabama. Defendant Harris is sued in his official capacity.

FACTUAL STATEMENT

A. Establishment of Plaintiffs' Birth Centers

19. Recognizing the lack of access to midwifery and out-of-hospital birthing care in Alabama, as well as the high demand for these services among pregnant Alabamians, the birth center and individual Plaintiffs took various steps over the last several years to establish freestanding birth centers and expand access to this critically needed care.

20. As of the filing of this First Amended Complaint, the only freestanding birth centers that can operate in Alabama are those that receive a temporary license pursuant to this Court's preliminary injunction orders, *see* Order Granting Pls.' Mot. Prelim. Inj., Doc. 110 (Sept. 30, 2023) [hereinafter "Prelim. Inj. Order"], *supplemented by* Suppl. Prelim. Inj. Order, Doc. 119 (Oct. 3, 2023) [hereinafter "Suppl. Prelim. Inj. Order"], *reconsideration denied*, Order Defs.' Mot. Recons., Doc. 131 (Oct. 16, 2023). As of the filing of this First Amended Complaint, one birth center has received a temporary license, effective January 1, 2024, pursuant to the injunction and reopened. Therefore, as set forth further below, but for the temporary relief granted by this Court during the pendency of this lawsuit, the only options for birthing care in Alabama are hospitals, which many areas lack and which are frequently pushed past capacity where they do exist, or home births, which are not accessible to all patients because of lack of access to a suitable or comfortable home space, affordability, or other access challenges.

Oasis Family Birthing Center

21. Dr. Skanes began taking steps to open OFBC in 2021. Over the next year, she spent considerable time and resources getting the birth center ready to operate. This included scouting out and eventually leasing a suitable property; applying for and obtaining numerous grants, including a first-place prize from Magic City Match, a grant program for Black-owned businesses in Birmingham, and a scholarship prize from the American Association of Birth Centers, among others, and completing fellowship programs to fund the birth center; recruiting staff; and sourcing and acquiring equipment.

22. OFBC was officially founded in June 2022. Between June and September 2022, Dr. Skanes completed physical improvements on the property that would become the birth center.

23. Throughout the process of establishing OFBC, Dr. Skanes relied on national standards from the American Association of Birth Centers (AABC),[7] the leading nationwide source for best practices and standards for freestanding birth centers, to ensure that OFBC adhered to evidence-based guidelines for safe, high-quality birthing centers.

24. OFBC opened to patients in September 2022. OFBC provided comprehensive midwifery services for pregnancy-related care, including births, and neonatal care through six weeks after birth, utilizing the midwifery model of care, as defined *infra* Part C. OFBC also provided extensive patient education and counseling, including education on breastfeeding, preparing for childbirth, and newborn care.

25. OFBC's services were primarily provided by CPMs, including Plaintiff Crawford,

[7] *See Birth Center Standards*, Am. Ass'n Birth Ctrs., https://www.birthcenters.org/birth-center-standards (last visited Jan. 17, 2024). These standards are relied on by the Commission for the Accreditation of Birth Centers (CABC), a non-profit organization and the only nationwide accrediting organization for birth centers, as the basis for accrediting birth centers nationwide. *See About the CABC*, Comm'n Accreditation Birth Ctrs., https://birthcenteraccreditation.org/about-commission-accreditation-birth-centers/ (last visited Jan. 17, 2024).

and student midwives training under the supervision of the CPMs and Dr. Skanes. The CPMs conducted the majority of prenatal and postpartum visits and attended births in the birthing center, with assistance from the student midwives, who are also trained as doulas, certified lactation consultants, and birth assistants with training in basic life support and neonatal resuscitation. Dr. Skanes was available for consultation and patient referrals whenever the midwifery staff determined such consultation or referral was necessary or beneficial for the patient. Dr. Skanes also conducted initial patient intakes and provided limited prenatal care to birth center patients throughout their pregnancies. OFBC also intended to employ CNMs in the future. In addition, OFBC collaborated with other birth and pregnancy workers—including educators, nutritionists, prenatal yoga specialists, and additional doulas and lactation consultants—who periodically offered classes or services at OFBC or to whom OFBC made referrals for particular patients.

26. As part of the midwifery care model, all patients received continuous risk assessment to ensure that they remained eligible for birthing care in the birth center. Patients who developed risk factors were either referred for consultation with Dr. Skanes or, for serious risks, transferred to her care for the remainder of their pregnancies and hospital-based births.

27. Between opening and when ADPH forced OFBC to stop offering care to patients at the birth center, twenty-two patients received care at OFBC. Of these, six patients were identified during their pregnancies through OFBC's risk assessment process as having risk factors rendering them ineligible to give birth in the birthing center, and two others elected to deliver in the hospital but received prenatal care in the birth center. These eight patients were referred to Dr. Skanes and delivered with her successfully in the hospital.

28. The remaining fourteen patients delivered successfully and without complication at OFBC, attended by a CPM and with assistance from student midwives. No patients were

transferred to hospital-based care during labor, delivery, or the postpartum period. All mothers and babies treated by OFBC to date are healthy and doing well. One infant's initial screening for sickle cell disease came back positive following a routine newborn screening by OFBC; they were promptly referred to a pediatrician for further care.

29. As set forth below, due to ADPH's actions, OFBC was unable to offer birthing services or other patient care for approximately six months. During that time, OFBC had to tell at least ten established patients that they could no longer continue their care with or give birth at OFBC, and, between March and August 2023 alone, as a result of ADPH's action, OFBC had to turn away more than a dozen prospective patients who inquired about care at OFBC. In the meantime, Dr. Skanes continued to incur significant costs, including monthly rental payments, for a space she was unable to use and may never have been able to resume or continue using absent relief from this Court. While the preliminary injunction entered by this Court provides temporary relief from some of these harms, absent full and final relief from this Court, ADPH's actions will continue to cause irreparable harm to OFBC, Dr. Skanes, and her patients.

30. As further set forth below, it would not be feasible for OFBC to operate under the 2023 Final Regulations.

Alabama Birth Center

31. As early as 2019, Dr. Robinson began exploring opportunities to expand her private OB/GYN practice to include a freestanding birth center, including searching for suitable locations in Huntsville for ABC.

32. In early 2020, she made an initial offer on a property for the birth center and eventually secured a property in December of 2020. Over the next year, she retained and consulted with architects and commenced construction on the planned clinical and educational areas of the

facility, intending to start construction on office space and birthing suites in 2022. When completed, she intends for the birth center to be consistent with AABC standards. Throughout this time, Dr. Robinson also sought grants, engaged in fundraising efforts, hired staff to manage patient inquiries, and took other steps to establish and publicize ABC and the care ABC intended to offer.

33. Because of ADPH's actions, as discussed below, Dr. Robinson halted construction on the birth center because she had no way of knowing whether the property, as planned, would ultimately satisfy ADPH's licensing criteria, and she could not afford to continue to invest money into a business she might never have been permitted to operate. At the time of filing the Original Complaint, Dr. Robinson and the future of the ABC had already been left in a state of arrested development for more than a year, impeding fundraising, necessitating renegotiation of repayment terms for a loan she had taken to help fund ABC, and requiring her to pay a mortgage on an unused space while she waited to see if she would ever be able to open. Between June 2022, when Dr. Robinson was forced to halt construction, and January 2024, ABC received more than two hundred inquiries about services at the birth center. While the preliminary injunction entered by this Court provides temporary relief from some of these harms, absent full and final relief from this Court, ADPH's actions will continue to cause irreparable harm to ABC, Dr. Robinson, and her patients.

34. As set forth below, as of the time of the filing of this First Amended Complaint, ABC is preparing to submit its application for temporary licensure from ADPH pursuant to this Court's preliminary injunction, and to open as soon as possible thereafter once that process is complete. Plaintiff Stone plans to provide midwifery care at ABC once it obtains a temporary license.

35. As further set forth below, it would not be feasible for ABC to operate under the 2023 Final Regulations.

B. Maternal and Infant Health in Alabama

36. The United States has the highest maternal mortality rate of any high-income country in the world, reporting 23.8 deaths per 100,000 live births in 2020.[8]

37. According to Defendant ADPH, Alabama's maternal mortality rate is even higher than the national average, reporting in 2020 a rate of 36.4 deaths per 100,000 live births, the third highest in the country.[9]

38. An analysis of more recent data from the U.S. Centers for Disease Control and Prevention's National Center for Health Statistics shows that Alabama has the worst maternal mortality rate in the country, reporting a rate of 64.6 deaths per 100,000 live births, nearly double the national rate.[10]

39. According to investigations conducted by ADPH, the majority of maternal deaths in Alabama are preventable.[11]

40. Alabama also has the third-highest infant mortality rate in the country.[12] According to Defendant ADPH, in 2021, the infant death rate was 7.6 deaths per 1,000 live births, an increase

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[8] Donna L. Hoyert, Nat'l Ctr. Health Stat., Ctrs. Disease Control & Prevention, *Maternal Mortality Rates in the United States, 2020* at 1 (2022), https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/E-stat-Maternal-Mortality-Rates-2022.pdf [hereinafter *U.S. Maternal Mortality Rates 2020*]. The CDC defines maternal mortality as a maternal death occurring during pregnancy or within 42 days after pregnancy. *Id.* Other sources define maternal mortality to include deaths up to one year after pregnancy.

[9] Bur. Family Health Servs., Ala. Dep't of Pub. Health, *2020 Maternal Mortality Review* 6 (2022), https://www.alabamapublichealth.gov/perinatal/assets/2020_final_annual_mmr.pdf.

[10] Katherine Sacks, Lawson Mansell & Brooke Shearon, Milken Inst., Maternal Mortality Among Vulnerable US Communities 3–4 (Aug. 2023), https://milkeninstitute.org/sites/default/files/2023-07/MaternalMortalityamongVulnerableUSCommunities.pdf.

[11] ADPH, *2020 Maternal Mortality Review*, *supra* note 9, at 10.

[12] *Infant Mortality Rates by State*, Nat'l Ctr. for Health Stat., Ctrs. for Disease Control & Prevention, https://www.cdc.gov/nchs/pressroom/sosmap/infant_mortality_rates/infant_mortality.htm (sort by death rate) (last visited Jan. 17, 2024).

of 8.6% compared to 2020.[13] Alabamians also suffer high rates of preterm birth (13.1%) and low birth weight (10.5%), significant risk factors for infant mortality.[14]

41. Nationwide, Black women are nearly three times more likely to die from pregnancy-associated causes than their white counterparts and twice as likely to suffer severe maternal morbidity.[15] Black women also experience higher rates of fetal death after 20 weeks of pregnancy and stillbirth compared to white women.

42. According to Defendant ADPH, Black Alabamians are likewise disproportionately harmed by the maternal and infant health crisis. Black Alabamians suffer a disproportionate share of maternal deaths in the state,[16] and Black infants die at more than twice the rate of white infants (12.1 vs. 5.8 deaths per 1,000 live births), accounting for almost half of all infant deaths in the state.[17]

43. One significant factor contributing to the maternal and infant health crisis in

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[13] Ala. Dep't of Pub. Health, *Alabama's infant mortality rate for 2021 announced*, Alabama's Health (Nov. 17, 2022), https://www.alabamapublichealth.gov/blog/2022/11/nr-17.html; *see also* Ctr. for Health Statistics, Ala. Dep't of Pub. Health, *Infant Mortality: Alabama 2021* at 2, 5 (2022), https://www.alabamapublichealth.gov/healthstats/assets/infantmortality2021.pdf.

[14] *Infant Mortality: Alabama 2021*, *supra* note 13, at 10–14, 24, 26.

[15] *U.S. Maternal Mortality Rates 2020*, *supra* note 8, at 1; Eugene Declercq & Laurie Zephyrin, Commonwealth Fund, *Severe Maternal Morbidity in the United States: A Primer* 8 (Oct. 2021), https://www.commonwealthfund.org/sites/default/files/2021-10/Declercq_severe_maternal_morbidity_in_US_primer_db.pdf.

[16] *See* ADPH, *2020 Maternal Mortality Review*, *supra* note 9, at 17 (reporting that Black patients make up 36.3% of maternal deaths in Alabama but only 30.6% of all births). Data from the CDC show a maternal mortality rate for Black women in Alabama of 100.07 per 100,000 live births. Ctrs. Disease Control & Prevention, Nat'l Ctr. Health Stat., *Underlying Cause of Death, 2018-2021*, CDC WONDER Online Database (search with parameters Alabama, race Black or African American, and ICD-10 Codes limited to those used in Sacks et al., *supra* note 10, at 3, yields a result of 71 deaths); Ctrs. Disease Control & Prevention, Nat'l Ctr. Health Stat., *Natality*, CDC WONDER Online Database (search with parameters Alabama, years 2018–2021, and mother's race Black or African American yields a result of 70,948 births).

[17] *Infant Mortality: Alabama 2021*, *supra* note 13, at 3, 5.

Alabama is lack of access to pregnancy-related care.

44. More than two-thirds of Alabama counties have inadequate access to such care: 37.3% of counties are classified as "maternity care deserts," defined as areas without any hospitals, birthing centers, obstetricians, or nurse-midwives; and an additional 31.3% have only low or moderate access to care.[18]

45. Moreover, hospital-based services in Alabama are insufficient to meet the need for pregnancy-related care in the state.

46. Hospital-based labor and delivery units, especially in rural hospitals, are closing at an alarming rate in Alabama. As Defendant ADPH reports, the majority of rural counties in the state have lost access to hospital-based obstetrical care in recent decades, and only a third of rural hospitals in Alabama currently offer labor and delivery care.[19] Many of those remaining are losing money and at risk of closure.

47. Hospitals in urban areas, meanwhile, are frequently over-taxed and often lack the staff resources or capacity to meet the high need for care.

48. Three additional hospitals—one in Birmingham, located in a predominantly Black community, another in Shelby County, and one in Monroe County—closed their labor and delivery units in October and November 2023, leaving those communities and counties with either reduced

[18] *Maternity Care Desert: Alabama*, March of Dimes: PeriStats (Oct. 2022), https://www.marchofdimes.org/peristats/data?reg=99&top=23&stop=641&lev=1&slev=4&obj=18&sreg=01.

[19] *Rural Health: At a Glance*, Ala. Pub. Health, https://www.alabamapublichealth.gov/ruralhealth/at-a-glance.html (last visited Jan. 17, 2024); Off. of Primary Care & Rural Health, Ala. Pub. Health, *A Picture of the Loss of Rural Obstetrical Service in Alabama 1980 to 2019* (2019), https://www.alabamapublichealth.gov/healthrankings/assets/a_picture_of_the_loss_of_rural_obstetrical_service.pdf.

options or no options for hospitals providing birthing care.

49. Ensuring maternal and infant health is not solely about access to care during labor and delivery. As Defendant ADPH acknowledges, inadequate access to pregnancy-related care, especially prenatal care, is a significant driver of maternal and infant mortality, increasing the risk of preterm birth and low birthweight.[20] In fact, the vast majority of maternal deaths occur either during pregnancy or within six weeks after birth,[21] not during labor and delivery.

50. According to Defendant ADPH, more than one in four pregnant Alabamians receives inadequate prenatal care during pregnancy.[22]

51. As Defendant Harris has stated, health inequities are frequently driven by race-based disparities in social determinants of health.[23] Research also shows that social and economic factors disproportionately affecting Black communities and other communities of color, such as racism and chronic stress, contribute to poor outcomes for birthing people and their babies. Published research shows that people of color are significantly more likely to report mistreatment during pregnancy and to experience a lower quality of care. Ensuring access to patient-centered and culturally competent care (i.e., care that is tailored to the patient's social and cultural needs) can improve patient experiences and patient outcomes.

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[20] ADPH, *2020 Maternal Mortality Review*, *supra* note 9, at 10; Latoya Hill et al., *Racial Disparities in Maternal and Infant Health: Current Status and Efforts to Address Them*, KFF (Nov. 1, 2022), https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-disparities-in-maternal-and-infant-health-current-status-and-efforts-to-address-them; *Prenatal Care: Why Do I Need Prenatal Care?*, Off. on Women's Health, U.S. Dep't of Health & Hum. Servs., https://www.womenshealth.gov/a-z-topics/prenatal-care (last updated Feb. 22, 2021).

[21] Emily E. Petersen et al., *Vital Signs: Pregnancy-Related Deaths, United States, 2011-2015, and Strategies for Prevention, 13 States, 2013-17*, 68 CDC Morbidity & Mortality Wkly. Rep. 423, 425–26 (2019), https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6818e1-H.pdf.

[22] *Infant Mortality: Alabama 2021*, *supra* note 13, at 20.

[23] *Member Spotlight: Scott Harris*, Assoc. of State & Territorial Health Officials: Blog (Feb. 1, 2018), https://www.astho.org/communications/blog/member-spotlight-scott-harris-alabama.

C. Birth Centers and the Midwifery Model of Care

52. A freestanding birth center provides pregnancy, birthing, postpartum, and newborn care in a homelike environment, utilizing a midwifery model of care, to patients anticipating a low-risk pregnancy and birth. Freestanding birth centers are independent, autonomous health care centers and are not attached to or organized as part of a hospital or other acute care facility.[24]

53. Many patients prefer out-of-hospital births based on their values, beliefs, health needs, or past experiences, or because they live far distances from hospital-based care. For patients seeking an out-of-hospital birth, birth centers provide an alternative to a home birth. While home births are legal in Alabama, birth centers provide an additional option for out-of-hospital care for patients who do not feel safe or comfortable birthing in their own home. Birth centers can also provide important access to high-quality prenatal and postpartum care, even for patients who plan to give birth in a hospital or who, for medical reasons, end up doing so.

54. While the practice of midwifery is part of a centuries-long tradition, the modern midwifery model of care melds that tradition with an evidence-based, patient-centered health care model for pregnancy-related care and newborn care, with a focus on shared-decision making, patient education, and physiological birth[25] with minimal technological interventions. The midwifery model of care centers the physical, psychological, and social wellbeing of birthing people, according to their values, beliefs, and autonomous choices.[26]

55. Midwifery is a distinct health care specialty from obstetrics. It is practiced by trained midwives with a different skill set, education, and training background than obstetricians,

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[24] *What Is a Birth Center?*, Am. Ass'n of Birth Ctrs., https://www.birthcenters.org/what-is-a-bc (last visited Jan. 17, 2024).

[25] Physiological birth means labor and delivery that relies on the innate capacities of the human body for the birthing process, as opposed to the use of medical interventions to initiate, augment, or manage the birth process.

[26] *See* Am. Ass'n of Birth Ctrs., *supra* note 24.

and, where appropriate for the patient, prioritizes physiological birth over medical and technological interventions in the birthing process. Obstetrics, by contrast, emphasizes a medicalized model of care with a focus on identifying and treating pathology or abnormality in pregnancy. Compared to the medicalized model of care, midwifery care also places increased attention on providing patients with access to non-medical support, education, and resources to help address patients' socio-economic and psychological needs and promote overall health and wellbeing.

56. Two kinds of midwives are licensed to practice in Alabama: certified nurse midwives and certified professional midwives. Both provide care in the midwifery model of care.

57. CNMs are advanced practice registered nurses who are certified by the State Board of Nursing to engage in advanced nursing practice as a nurse midwife. CNMs must complete a nursing program qualifying them as a registered nurse, in addition to specialized training and certification in nurse midwifery. Ala. Code § 34-21-81(1), (2)(b).

58. According to national standards, a CNM's scope of practice encompasses "independent provision of care during pregnancy, childbirth, and the postpartum period; sexual and reproductive health; gynecologic health; . . . family planning services, including preconception care," and "primary care for individuals from adolescence throughout the lifespan as well as care for the healthy newborn during the first 28 days of life."[27] A CNM's scope of practice includes conducting patient examinations; prescribing medication independently; making decisions about patient admission, management, and discharge; and ordering and interpreting lab results. They

[27] Am. Coll. of Nurse-Midwives, *Definition of Midwifery and Scope of Practice of Certified Nurse-Midwives and Certified Midwives* 1 (2021), https://www.midwife.org/acnm/files/acnmlibrarydata/uploadfilename/000000000266/Definition%20Midwifery%20Scope%20of%20Practice_2021.pdf.

practice in diverse settings, including hospitals, ambulatory surgical centers, private offices, birth centers, patients' homes, and via telehealth.[28]

59. In accordance with national standards, in the majority of states, CNMs practice autonomously and independently, meaning they do not need to enter into a formal agreement or supervisory relationship with a physician to provide care within their scope of practice.

60. In Alabama, unlike in the majority of states, CNMs are not permitted to practice fully independently and must enter into a collaborative practice agreement (CPA) with a physician. Ala. Code § 34-21-81(1). CPAs are formal agreements between CNMs and physicians setting out prior-approved written protocols under which a CNM may practice. *Id.* § 34-21-81(5).

61. It can be difficult to identify physicians in Alabama willing to enter into such agreements and, if no physician agrees to do so, a CNM may not be licensed in Alabama at all, despite satisfying all other educational, training, and qualification requirements. While the settings in which CNMs may practice are not formally restricted by Alabama law, in practice, CPAs and the need for a physician willing to enter into a formal, supervisory relationship involving that practice setting mean that the vast majority of CNMs in Alabama only attend births in hospital settings.

62. CPMs [29] are skilled practitioners holding a certification from an accredited organization and licensed by the State Board of Midwifery to provide primary maternity care during the pregnancy, birth, and postpartum periods in an out-of-hospital setting. Ala. Code § 34-19-11.[30]

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[28] *Id.*

[29] CPMs are also sometimes referred to as "Licensed Midwives" under Alabama law.

[30] *Who Are CPMs?*, Nat'l Ass'n of Certified Pro. Midwives, https://www.nacpm.org/new-page-2 (last visited Jan. 17, 2024).

63. CPMs must obtain national certification from the North American Registry of Midwives based on a combination of education, training, and a minimum of two years' direct, hands-on clinical experience or apprenticeship with an experienced CPM.[31] The CPM credential is the only national credential requiring training and experience in out-of-hospital birth settings.

64. According to national standards, a CPM's scope of practice encompasses independent provision of care, counseling, and education throughout pregnancy, birth, and the postpartum period, including conducting comprehensive assessments; making diagnoses and treating patients; recognizing conditions requiring consultation or referral to other healthcare providers; administering medications; ordering and interpreting lab and diagnostic tests; providing continuous, hands-on care during labor and delivery; and providing maternal and well-baby care through 6–8 weeks postpartum.

65. In Alabama, CPMs currently provide community-based pregnancy and birthing care. CPMs in Alabama are not subject to any CPA requirement; they practice independently of physicians or CNMs and can attend out-of-hospital births without any formal relationship with, supervision by, or assistance from a physician or CNM. CPMs in Alabama are authorized by law to practice "in the setting of the client's choice, except a hospital." Ala. Code § 34-19-16(a). However, because of the lack of options in Alabama for out-of-hospital births, CPMs in the state primarily provide home birth care.

66. The Board of Midwifery, which has licensing and regulatory authority over the practice of CPMs in Alabama, *id*. §§ 34-19-12, -14, regulates all care provided by CPMs, including home births. Such care is not subject to the vast majority of requirements, discussed further below, that ADPH seeks to impose on out-of-hospital care in birth centers.

[31] For individuals also certified as CNMs, requirements differ but still include hands-on apprenticeship in out-of-hospital births.

67. The practice of midwifery—by both CNMs and CPMs—involves continuous assessment of patients throughout pregnancy, birth, and the postpartum period to proactively identify circumstances when risk factors or complications arise in a low-risk pregnancy that may warrant consultation with or referral to an obstetrician or other skilled provider and to ensure continuity of care in those circumstances.

68. There is extensive evidence showing that midwifery care and birth centers can play an important role in expanding access to pregnancy- and birthing-related care. This is especially critical in places, like many parts of Alabama, where access to skilled providers is limited and maternity care deserts are prevalent.

69. There is also extensive evidence showing that midwifery care and birth centers are as safe as hospitals, reporting similar maternal and infant mortality rates, and, on many factors, reporting better health outcomes, especially for Black, brown and other marginalized communities who are disproportionately affected by inequities in health care access and outcomes.

70. For example, patients giving birth in freestanding birth centers report fewer infant hospitalizations, as well as significantly lower rates of preterm births and low birthweight infants—significant risk factors for poor maternal and infant health outcomes.

71. Research also shows that freestanding birth centers and midwifery-led care achieve significantly lower rates of deliveries by cesarean sections than hospital settings. Cesarean sections are major abdominal surgeries that carry a host of short- and long-term risks for patients, including infection; internal injury to nearby organs; and a risk of complications or repeat cesarean sections in future pregnancies.

72. According to ADPH, Alabama has a statewide rate of cesarean deliveries over 35%

(with some hospitals reporting even higher rates),[32] significantly exceeding the 10–15% rate recognized by the World Health Organization as the maximum associated with medical necessity and improved maternal and infant health outcomes.[33] When patients are subjected to medically unnecessary cesarean sections, they are likewise exposed to unnecessary increased risk of short- and long-term health complications.

73. Midwifery care and birth centers are also associated with significant cost-savings compared to hospital births.

74. Research also shows that patients who receive prenatal and postpartum care in midwife-led birth centers also experience improved maternal and infant health outcomes even if patients end up giving birth in a hospital (either as planned or because of medical necessity).

75. Patients cared for by midwives, including in birth center settings, during pregnancy and birth also report greater satisfaction and a more positive birthing experience, compared to obstetrician-led, hospital-based care.

76. Midwives typically spend more time with patients, both during prenatal and postpartum visits and during labor and delivery, than what obstetricians' schedules typically allow them to provide. Midwives also typically place an increased emphasis on individualized patient education and on addressing non-medical, psychosocial needs that affect health and wellbeing. Patients cared for by midwives report being less rushed, feeling more educated about their experience, and feeling more empowered throughout the birthing process.

77. Evidence demonstrates that states with greater integration of midwifery care into their health systems—including a higher density of practicing midwives and greater access to the

[32] Ala. Ctr. for Health Stat., Ala. Dep't Pub. Health, *Alabama Vital Statistics* 7–8 (2020), https://www.alabamapublichealth.gov/healthstats/assets/avs2020.pdf.

[33] World Health Org., *WHO Statement on Caesarean Section Rates* (2015), https://www.who.int/publications/i/item/WHO-RHR-15.02.

midwifery model of care—achieve better maternal and infant health outcomes. These include significantly lower rates of neonatal death, preterm birth, low birthweight infants, and cesarean section, and significantly higher rates of breastfeeding, spontaneous vaginal birth, and vaginal births after a prior cesarean section.[34]

78. The level of integration of midwifery into the health system in Alabama ranks second-worst out of all fifty states and the District of Columbia.[35]

D. History of Midwifery in Alabama

79. Alabama has a long and rich history of midwifery. Early in the twentieth century, there was a significant community of traditional midwives (also known as lay midwives) practicing in Alabama, the vast majority of whom were Black and Indigenous. Midwives played critical roles within their communities as caregivers, educators, and spiritual leaders.

80. In the 1910s and 1920s, states including Alabama began requiring traditional midwives to be registered with the state and enroll in certain educational programs in order to practice. These formal requirements imposed barriers to some traditional midwives, as a result of geography, literacy, and the impacts of segregation and discrimination in the Jim Crow South. Nonetheless, thousands of traditional midwives completed state requirements and, as a result, began practicing within the state health system.

81. In the decades after state registration, these midwives often played a critical role in expanding access within their communities to health and hygiene education, to vaccinations, and to the formal health system—a system that was otherwise frequently closed to rural and majority-Black communities as a result of geography, racial segregation, and distrust of the predominantly

[34] Saraswathi Vedam et al., *Mapping Integration of Midwives Across the United States: Impact on Access, Equity, and Outcomes*, PLOS ONE, Feb. 2018, at 1–2 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5821332/pdf/pone.0192523.pdf.

[35] *Id.* at 8.

white medical establishment, given the history of forced sterilization and experimentation on Black women by early practitioners of obstetrics.

82. Despite the success and positive outcomes achieved by many traditional midwives in this system, midwives continued to face ongoing discrimination and bias from physicians and the formal medical system, who often devalued the specific skills of traditional midwives and stereotyped the practice of midwifery as primitive and contrary to science. These biases were linked to and compounded by race, gender, and class differences between the predominantly Black women practicing as traditional midwives in low-income and rural communities and the middle-class, white, male physicians who dominated the early practice of obstetrics.

83. Over the course of the twentieth century, restrictive regulation of midwifery, the increasing medicalization of birth under the obstetric model of care, lack of institutional support for traditional midwifery, and ongoing stigma and discrimination against traditional midwives—and Black midwives in particular—decreased the prevalence of midwife-assisted births and the number of known traditional midwives practicing across the South.

84. While traditional midwifery practices were waning during this time, the profession of nurse-midwifery was established. As nurse midwives became more integrated into public health programs in the South, including in Alabama, they were often placed in a supervisory role with respect to traditional midwives.

85. Black women, who for generations had provided the bulk of midwifery care in their communities, encountered serious barriers in attempting to access this newly established profession. Very few accredited nursing programs in the South accepted Black students. When a nurse-midwifery program for Black students opened at the Tuskegee Institute in 1941, it closed after only 5 years due to lack of institutional support. As a result, nurse-midwifery became a

predominantly white profession.

86. In 1976, Alabama passed a law outlawing the practice of all non-nurse midwifery, with the exception of a narrow subset of traditional midwives who held valid permits under the old rules "until such at time as [the midwife's] permit may be revoked." 1976 Ala. Acts 499 (codified at Ala. Code § 34-19-3(a)-(b)). Within five years, the legal practice of non-nurse midwifery effectively ended within Alabama, as state officials revoked or refused to renew or grant any more permits. These regulatory changes disproportionately affected Black midwives practicing in the state, rendering the majority of their practices illegal.

87. For nearly fifty years, the practice of traditional midwifery remained illegal in Alabama, a rule enforced by state prosecution of traditional midwives who attempted to continue practicing. *See, e.g.*, *State v. Kimpel*, 665 So. 2d 990 (Ala. Crim. App. 1995).

88. In 2017, after prolonged advocacy from the midwifery community, the Alabama Legislature passed a law providing a path for non-nurse midwives to practice in the state, with the creation of licensure for certified professional midwives and the creation of a State Board of Midwifery to oversee their practice. 2017 Ala. Laws 383 (effective Aug. 1, 2017) (codified, *inter alia*, at Ala. Code §§ 34-19-11 to -20) (repealing Ala. Code §§ 34-1-1 to -10). In doing so, the Legislature authorized CPMs to provide care in out-of-hospital settings, such as birth centers, and delegated authority to the Board of Midwifery to exercise regulatory oversight of such care. *See* Ala. Code § 34-19-16(a) (licensed CPMs "may provide midwifery care in the setting of the client's choice, except a hospital"); *id.* §§ 34-19-12(a), -14; *see also* Ala. Att'y Gen. Op. No. 2023-12, at 4–5 (Dec. 15, 2022) [hereinafter "Att'y Gen. Op."] (concluding that freestanding birth centers are not hospitals for the purposes of section 34-19-16), https://opinions.alabamaag.gov/Documents/opin/2023-012.pdf.

89. In January of 2019, Alabama granted the first state licenses to Alabama CPMs.

E. Access to Midwifery Care and Birth Centers in Alabama Today

90. Both CNMs and CPMs remain marginalized within the health care system in Alabama today.

91. As noted above, under Alabama law, CNMs are restricted from practicing independently, and both CPMs and CNMs are restricted from practicing to their full scope of practice as set out in national standards and compared to the practice in the majority of states.

92. The lack of freestanding birth centers in Alabama has contributed to this marginalization, as it represents one less practice setting where CNMs and CPMs could see patients and offer much-needed care.

93. According to data from the Alabama Boards of Midwifery and Nursing, as of December 2023, there are only 31 licensed CNMs[36] and 23 licensed CPMs[37] in the entire state.

94. As a result of the limited number of midwives practicing in the state, resistance from the medical establishment, and cost-barriers, access to midwifery-based care remains inaccessible to many Alabamians.

95. Until the events described in this First Amended Complaint, access to freestanding birth centers in Alabama has also been virtually non-existent. While Alabama had regulations in place to license freestanding birth centers between 1987 and 2010, they were eventually repealed because there were no freestanding birth centers operating in the state.

96. Prior to the establishment of OFBC in 2022, there were no known freestanding birth centers operating in the state of Alabama.

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[36] Ala. Bd. of Nursing, Licensee Roster, *available for download at* https://abn.alabama.gov/applications/LicenseLookup.aspx (last visited Jan. 17, 2024).

[37] *Midwives*, Ala. State Bd. of Midwifery, https://alsbm.org/midwives (last visited Jan. 17, 2024) (search by State: Alabama).

97. But for any freestanding birth centers that may be able to obtain temporary licensure pursuant to this Court's preliminary injunction, the only option for patients seeking out-of-hospital births in Alabama is a home birth.

98. While planned home births attended by CPMs can be a safe and appropriate option for certain patients, this option is not accessible to everyone. There are a limited number of CPMs in Alabama offering home birth services, and many patients do not feel that their home environments are suitable for a home birth because of space constraints, needs of other family members, lack of privacy, or location.

F. ADPH's Policies Restricting Birth Centers

ADPH's Attempts to Regulate Freestanding Birth Centers in Alabama between 1987 and 2022.

99. In 1987, ADPH promulgated regulations for the operation of freestanding birth centers in Alabama. Ala. Admin. Code r. 420-5-13 (1987) (repealed 2010).

100. Upon information and belief, few, if any, freestanding birth centers were ever licensed in Alabama under these regulations.

101. In 2010, ADPH repealed the 1987 regulations in full.

102. In 2017, the Alabama legislature explicitly authorized out-of-hospital births and created the Board of Midwifery to oversee these practices. 2017 Ala. Laws 383 (codified, *inter alia*, at Ala. Code §§ 34-19-11 to -20).

103. In 2020, ADPH informed members of Plaintiff ACNM-AL that it did not regulate birth centers.

104. In July 2022, more than two years after Plaintiffs started work on their birth centers—by, e.g., raising funds, securing property, beginning construction, and publicizing their services—ADPH reversed course and announced proposed state regulations for freestanding birth

centers. *See* Birthing Center Rules, (proposed July 18, 2022), attached hereto as Ex. A [hereinafter "2022 Proposed Regulations"].

105. The proposed regulations were met with uniform opposition from national and state-based leaders in midwifery, freestanding birth centers, and pregnancy and birth worker communities, including AABC, the State Board of Midwifery, Plaintiff ACNM-AL members, the Alabama Midwives Association (ALMA),[38] and many individual licensed midwives.

106. Groups and individuals opposing the proposed regulations, including Plaintiffs, pointed out in public comments, both in writing and at the public hearing on August 18, 2022, that the proposed restrictions were not evidence-based, contradicted national standards for birth centers and midwifery care, and would be incredibly burdensome to comply with, making it onerous, if not impossible, for many proposed birth centers to operate.

107. Upon information and belief, ADPH did not consult with the State Board of Midwifery, the State Board of Nursing, ACNM or ACNM-AL, ALMA, AABC, the CNM program at University of Alabama at Birmingham (UAB), or any individual midwives before promulgating the 2022 Proposed Regulations.

108. Upon information and belief, many of these requirements were carried over wholesale from the 1987 regulations, despite those rules being considerably out of step with the best evidence currently available and the prevailing standards of care for midwifery and birth centers.

109. Among the provisions in the proposed regulations that were out of step with evidence-based standards were:

[38] ALMA is the professional organization, similar to ACNM-AL, for Alabama-based CPMs. *See Home*, Ala. Midwives All., http://www.alabamamidwivesalliance.org (last visited Jan. 17, 2024).

- the exclusion of CPMs from working in freestanding birth centers at all, *see* 2022 Proposed Regulations at 420-5-13.03(1), Ex. A at 10, despite their statutory authority under Alabama law to work in any setting of a client's choosing except a hospital and despite their experience and expertise providing out-of-hospital births;

- distance restrictions, preventing any freestanding birth center from operating more than a set distance from an established hospital with a labor and delivery unit, *see id.* at 420.5.13-.01(2)(q), (v), Ex. A at 3, 5, meaning that no freestanding birth centers could operate in the most underserved areas of the state that lack access to hospital-based care and where the need for improved access to pregnancy-related care is greatest;

- onerous requirements for formalized physician supervision and staffing arrangements, *see id.* at 420-5-13-.03, Ex. A at 10–13, which would prevent midwives from operating birth centers independently, despite being qualified to do so by their scope of practice and expertise in the midwifery model of care in which birth centers operate;

- requirements for written transfer agreements with hospitals and emergency medical services (EMS), *see id.* at 420-5-13-.01(2)(v), Ex. A at 5, which essentially give hospitals and EMS providers veto power over the ability of birth centers to operate, and are not necessary to ensure pregnant and laboring patients are safely transferred to hospital-based care when emergencies arise—as evidenced by the fact that hospitals and EMS services are legally obligated to transfer and accept patients in emergent circumstances without any such agreement in place, *see, e.g.*, 42 U.S.C. § 1395dd, and by the fact that CPMs currently conduct home births throughout the state, transferring patients to hospital care when necessary, without any such transfer agreement requirements;

- overly rigid and outdated patient-eligibility criteria, *see* 2022 Proposed Regulations at Appendix A, Ex. A at 47–48, which would exclude many pregnant women with low-risk pregnancies from care in a birthing center, such as those over a particular age and those with more than a set number of prior births, all of whom can be—and are—safely cared for in out-of-hospital settings in other states; and

- cumbersome physical plant requirements, *see id.* at 420-5-.17 to -.19, Ex. A at 35–46, that would drastically increase the cost of operating a birth center and that are unnecessary to provide safe care to low-risk pregnant patients and are inappropriate for birth centers, which are designed to be homelike environments.

110. The proposed regulations not only diverged from modern standards of care, but many of the requirements would have been extremely difficult, if not impossible, for Plaintiffs' birth centers to comply with.

111. For example, OFBC would not have been able to continue operating with CPMs, including Plaintiff Crawford, and student midwives, who together provided the vast majority of care and attended births; would have had to hire additional CNMs and registered nurses; and would have had to undertake costly renovations to retrofit the OFBC property to the regulations' requirements.

112. Dr. Robinson likewise would have had to undertake such extensive and costly physical changes to the property she had acquired for ABC that, as a result of the proposed regulations, she ceased all construction indefinitely and began considering alternative locations for the birth center that would be less prohibitively expensive to retrofit according to the proposed standards. She also would have been prohibited from operating ABC with both CNMs and CPMs independently attending to patients, as she intended and as she felt was most appropriate for the needs of the patient population ABC intended to serve.

113. By state law, ADPH had 90 days from the close of public comment to finalize the regulations. Ala. Code § 41-22-6(b). The state took no action to finalize the flawed proposed regulations within the statutory time frame, thereby allowing them to lapse.

114. ADPH never publicly addressed the many concerns with the proposed regulations raised during the public comment period in 2022.

OFBC Operations After Opening in September 2022

115. With no regulatory barriers in place, OFBC opened and began seeing patients in September 2022. The first birth in the birthing center occurred in October 2022.

116. Shortly thereafter, OFBC staff reached out to ADPH's Center for Health Statistics to inquire about granting OFBC access to the state's centralized system for registering births and deaths. OFBC staff were informed by agency staff that ADPH would work on setting up access

for OFBC and that individual midwives should use their existing credentials to register births in the meantime.

117. Over the next several months, OFBC staff repeatedly reached out to ADPH to inquire about the status of OFBC's account and were assured repeatedly that an account for the facility was in process and would be provided soon.

118. In late February 2023, ADPH reversed course and informed OFBC staff that facility access to the state's birth registry system had been halted. This information was later confirmed in an email by Nicole Henderson Rushing, Director of ADPH's Center for Health Statistics.

Attorney General's December 2022 Opinion and ADPH Actions Against OFBC

119. In December 2022, Alabama Attorney General Steve Marshall issued an Attorney General Opinion, pursuant to Alabama Code section 36-15-1(a), relating to birth centers.

120. The opinion was issued in response to two questions from ADPH: (1) whether birth centers could be considered "hospitals" under section 22-21-20(1) of the Alabama Code, thereby falling within ADPH's regulatory and licensing authority; and (2) whether CPMs were prohibited from practicing in birth centers under section 34-19-16 of the Alabama Code, which allows CPMs to practice "in any setting of the client's choice, except a hospital." Att'y Gen. Op. at 1–2.

121. In response to ADPH's first question, the Attorney General's opinion did not categorically determine whether all freestanding birth centers fell within ADPH's regulatory and licensing authority. Instead, the AG Opinion concluded that, under Alabama law, whether any such facility fell within ADPH's regulatory and licensing authority was a factual determination. *Id.* at 3.

122. Under section 22-21-22 of the Alabama Code, ADPH must require a license for any facility deemed a "hospital" under the licensing statute. "Hospitals," for licensing purposes,

are defined to include, *inter alia*, "health care institutions when such institution is primarily engaged in offering to the public generally, facilities and services for . . . obstetrical care." Ala. Code § 22-21-20(1).

123. Therefore, the Attorney General concluded that freestanding birth centers were "hospitals" requiring an ADPH license to operate *only if* ADPH determined, as a factual matter, that a birth center was "primarily engaged in offering obstetrical care to the public." Att'y Gen. Op. at 5.

124. In response to ADPH's second question, the Attorney General concluded that there was no statutory basis for prohibiting CPMs from working in birth centers because birth centers were *not* "hospitals" as that term is used in section 34-19-16. *Id.* at 4–5. Therefore, under the statute stating that CPMs could practice in any setting "except a hospital," CPMs could lawfully practice in freestanding birth centers.

125. In March 2023, Amber N. Clark-Brown, Medical Director for ADPH's Bureau of Health Provider Standards and Home and Community Services, contacted Dr. Skanes and informed her that ADPH considered her to be operating an "unlicensed hospital." Penalties for operating an unlicensed hospital include criminal misdemeanor penalties and civil liability. Ala. Code § 22-21-33(a)(1)–(3).

126. Dr. Skanes requested that OFBC be permitted to apply for a license, but ADPH refused, saying no such application was available. Dr. Clark-Brown informed Dr. Skanes that she would need to arrange for her existing patients to give birth elsewhere and to cease accepting new patients.

127. Dr. Skanes's counsel at the time met with ADPH's Assistant General Counsel, Dana H. Billingsley, on March 27, 2023. During that meeting, Ms. Billingsley re-confirmed

ADPH's position that freestanding birth centers—even those exclusively offering a midwifery model of care—constitute "hospitals" for licensing purposes under Alabama law. Ms. Billingsley further confirmed that ADPH would not permit OFBC to operate without a license, that no mechanism to seek such a license existed at that time, and that ADPH could not guarantee any particular timeline in which regulations for seeking such a license would be finalized.

128. On April 5, 2023, Dr. Skanes's counsel sent a letter proposing a pathway for OFBC to continue operating based on compliance with national standards for birth centers.

129. On April 7, 2023, Ms. Billingsley sent a letter on behalf of ADPH rejecting Dr. Skanes's proposal, reiterating its position that OFBC could not operate without a license, that no regulatory process for obtaining licensure existed, and that OFBC would need to cease providing birthing services immediately.

130. After additional communications between Dr. Skanes's counsel and ADPH in April 2023, ADPH agreed to let OFBC's existing patients who were already in their third trimester give birth at the birth center but continued to require all other existing patients to arrange to deliver elsewhere. The last patient permitted to give birth at OFBC under this agreement delivered in June 2023.

131. Based on these interactions with ADPH, Dr. Skanes understood that ADPH would not permit OFBC to resume providing birthing services at OFBC unless and until ADPH adopted regulations for freestanding birth centers and OFBC successfully obtained a license pursuant to those regulations.

132. At no point during the interactions with Dr. Skanes did ADPH explain how and on what basis it determined that, by providing midwifery care, OFBC was "primarily engaged in offering obstetrical care to the public." *See* Att'y Gen. Op. at 5. No ADPH employee ever visited

OFBC or spoke to any of OFBC's midwifery team about the type of care they provided at OFBC.

133. As of the date of filing of this First Amended Complaint, and except as ordered by this Court, ADPH has not provided any timely, feasible path to licensure—whether under existing statutory criteria or through their regulatory authority—for freestanding birth centers in Alabama.

134. Currently, the only timely, feasible path to licensure of freestanding birth centers in Alabama is through temporary licensure pursuant to the Preliminary Injunction issued in this case. Prelim. Inj. Order. The injunction prohibits ADPH from refusing to timely license freestanding birth centers, pursuant to its statutory licensing authority, that can demonstrate compliance with nationally-recognized, evidence-based standards set by the American Association of Birth Centers and remaining statutory requirements. *Id.*

ADPH's Proposed 2023 Regulations

135. In late June 2023, ADPH released a new set of proposed regulations, with a public comment period running from July 1 to August 4, 2023. Birthing Centers (proposed June 20, 2023) (to be codified at Ala. Admin. Code r. 420-5-13-.01 to -.19), https://www.alabamapublichealth.gov/about/assets/420-5-13.pdf, attached hereto as Ex. B [hereinafter "2023 Proposed Regulations"]. These 2023 Proposed Regulations not only retained many of the problematic, burdensome, and non-evidence-based requirements as the former proposed regulations but were, in many respects, even more restrictive.

136. For example, the 2023 Proposed Regulations retained or increased restrictions on the degree of physician supervision required, thereby restraining midwives from practicing to the full extent of their training and qualifications. 2023 Proposed Regulations at 420-5-13-.03, Ex. B at 13–16. While ADPH no longer has a legal basis to bar CPMs from practicing in birth centers, *see* Att'y Gen. Op. at 5, the proposed regulations nevertheless restricted CPMs' scope of practice

to providing "assistive care" under the supervision of physicians and CNMs, 2023 Proposed Regulations at 420-5-13-.03(1), Ex. B at 13—even though the Alabama Legislature did not impose any such restriction on CPMs' scope of practice when they enacted the law authorizing CPMs to practice in Alabama in 2017, and even though CPMs currently provide care to home birth patients throughout Alabama without any such restrictions.

137. Other burdensome and irrational requirements—such as written transfer agreements, strict distance limitations to hospital-based obstetric care, and onerous and costly physical plant requirements—also remained. *See* 2023 Proposed Regulations at 420-5-13-.10(1), -.01(v)(5)(x), -.19, Ex. B at 24, 7, 49–52.

138. These requirements would either prevent Plaintiffs from operating their birthing centers entirely or would condition the ability to operate them on significant and potentially cost-prohibitive changes to their facilities and staffing.

139. On July 13, 2023, ADPH held a public hearing for comments on the proposed birth center regulations. Speakers at the public hearing—including AABC, the State Board of Midwifery, ALMA, and many of the plaintiffs in this case—expressed unanimous opposition to the proposed regulations, noting that they continued to contradict evidence-based standards and national guidelines and greatly restricted the ability of freestanding birth centers to operate in Alabama, including in the regions of the state most in need of improved access to pregnancy-related care.

140. No one spoke in favor of the proposed regulations.

Initiation of This Litigation

141. On August 8, 2023, Plaintiffs initiated the present litigation challenging ADPH's unlawful actions and de facto ban on birth centers as violating the Alabama Administrative

Procedure Act and the Alabama and federal Constitutions. *See* Compl. Declaratory & Injunctive Relief, Doc. 002 (Aug. 8, 2023).

142. On August 9, 2023, Plaintiffs filed a motion for preliminary injunction, seeking an order enjoining ADPH from requiring freestanding birth centers operating in the midwifery model of care to seek and obtain a "hospital" license under section 22-21-22 of the Alabama Code or, in the alternative, from refusing to timely license, including through the issuance of temporary licenses, freestanding birth centers operating in the midwifery model of care that can demonstrate compliance with AABC standards and the remaining statutory requirements under ADPH's statutory licensing authority. *See* Pls.' Mot. Prelim. Inj., Doc. 008 (Aug. 9, 2023).

143. After hearing oral argument on September 28, 2023, the Court issued an oral ruling from the bench, followed by a written order the following day, denying Defendants' motion to dismiss and rejecting, *inter alia*, Defendants' argument that the 2023 Final Regulations would moot Plaintiffs' claims were the regulations to take effect. *See* Order, Doc. 104 (Sept. 29, 2023).

144. On September 28 and 29, 2023, the Court heard testimony from multiple witnesses and oral argument on Plaintiffs' motion for a preliminary injunction. *See* Scheduling Order Mot. Prelim. Inj., Doc. 018 (Aug. 10, 2023).

145. On September 30, 2023, the Court issued an order granting Plaintiffs' motion for a preliminary injunction and, on October 3, 2023, a supplemental preliminary injunction order, on Plaintiffs' alternative claims for relief and enjoined Defendants from "refusing to timely license (including but not limited to refusing to timely issue temporary or interim licenses to) freestanding birth centers operating in the midwifery model of care (including [the named Plaintiffs], and/or any birth centers owned or operated by members of Plaintiff Alabama Affiliate of the American College of Nurse-Midwives) that can demonstrate substantial compliance with the standards set

out by the American Association of Birth Centers and can satisfy the remaining statutory requirements, §§ 22-21-23, -24, -29(a), -31, pursuant to the Alabama Department of Public Health's statutory authority under Alabama Code Section 22-21-25(a)." Prelim. Inj. Order at 2; *see also* Suppl. Prelim. Inj. Order at 1–2.

146. On October 13, 2023, OFBC submitted an application for temporary licensure pursuant to this Court's injunction, and, at ADPH's request, supplemented that submission with additional information on November 1, 2023. ADPH conducted an entrance survey with respect to that application on December 1, 2023. On December 20, 2023, OFBC received its temporary license, effective January 1, 2024, and on January 1, it reopened and resumed patient services.

147. As of the filing of this First Amended Complaint, ABC is preparing to submit its application for temporary licensure from ADPH pursuant to this Court's preliminary injunction, and to open as soon as possible thereafter once that process is complete.

Adoption of the 2023 Final Regulations

148. On August 17, 2023, following the initiation of this litigation, ADPH approved the proposed regulations with minimal changes, and the final, approved regulations were published in the Alabama Administrative Monthly on August 31, 2023. A copy of the 2023 Final Regulations is attached hereto as Ex. C.

149. Upon information and belief, ADPH did not consult with the State Board of Midwifery, the State Board of Nursing, ACNM or ACNM-AL, ALMA, AABC, the CNM program at UAB, any of the plaintiffs in this case, or any individual midwives before drafting and issuing the 2023 Proposed Regulations, nor did it consult with any such groups or individuals after receiving public comments in opposition to and prior to approving the 2023 Final Regulations.

150. The 2023 Final Regulations became effective on October 15, 2023, pursuant to Ala.

Code § 41-22-6(c). *See* Ala. Admin. Code r. 420-5-13-.01 to -.19, Ex. C.

151. The extent of opposition to the 2023 Proposed Regulations was evident from an August memo issued by ADPH summarizing oral and written comments—almost all in opposition—received during the public comment period, including that the regulations were inconsistent with best practices, not evidence-based, and would prevent or severely impede the establishment, construction, maintenance, and operation of freestanding birth centers in Alabama. *See* Memorandum from Denise Milledge, MBA, BSN, Dir., ADPH Bureau of Health Provider Standards, to State Comm. of Pub. Health, *Proposed Rules for Birthing Centers, Chapter 420-5-13* (Aug. 8, 2023), attached hereto as Ex. D [hereinafter "Milledge Memo"].

152. However, as approved, the 2023 Final Regulations fail to address the vast majority of these concerns.

153. For example, despite numerous comments in opposition, the 2023 Final Regulations would continue to restrict CPMs, such as Plaintiffs Crawford and Stone, to providing only "assistive" care to a physician or CNM. *See* Ala. Admin. Code r. 420-5-13-.01(2)(b), -.03(1), -.15(2)(c), Ex. C at 2, 15, 43. These restrictions on CPMs prohibit them from providing independent patient care throughout pregnancy, birth, and the postpartum period, including attending deliveries, as CPMs are authorized by the legislature to perform in any out-of-hospital setting, *see* Ala. Code §§ 34-19-14(b)(1), -16(a), and as CPMs including Plaintiff Crawford currently do, and as Plaintiff Stone intends to do once licensed, in home birth settings across Alabama. *See also* Milledge Memo at 2–3, 6–9, 13, 15, 18, 21–22, 26–28, 29–31 (summarizing comments in opposition).

154. This requirement would also prevent Plaintiffs OFBC and ABC from hiring qualified CPMs to provide independent patient care or from leveraging their birth centers to train

CPM students, as intended. OFBC, for example, currently and previously employed CPMs, including Plaintiff Crawford, to train student midwives and to independently manage and attend all patient births in the birth center between October 2022 and June 2023, without additional physician or nurse-midwife supervision, and with a perfect safety record. ABC likewise intends to employ CPMs, such as Plaintiff Stone, to provide independent care to the full scope of their licensed practice within the birth center and to train CPM students.

155. The 2023 Final Regulations further restrict CPMs' and CNMs' ability to practice midwifery consistent with their statutorily-authorized scopes of practice. For example, the Final Regulations require all birth centers either to have a physician on staff or to have an agreement with a consulting physician and require such physicians to meet certain requirements, including but not limited to Board certification, admitting privileges, and physical presence and supervision requirements. Ala. Admin. Code r. 420-5-13-.01(2)(b), (2)(f), (2)(w), Ex. C at 2, 3, 8. Such requirements would prevent CPMs like Plaintiffs Crawford and Stone from engaging in independent practice in birth centers, as they are authorized to do by the legislature, separate and apart from the limitation to "assistive" care, *see* Ala. Code §§ 34-19-14(b)(1), -16(a), and would prevent CNMs, like Plaintiff ACNM-AL's members, from engaging in practice in a birth center pursuant to valid CPAs that satisfy all requirements imposed by the legislature and by the Boards of Medical Examiners and Nursing pursuant to their statutorily-delegated authority, Ala. Code §§ 34-21-83, -84, -85, -90. *See also* Milledge Memo at 1–3, 6–9, 13, 19, 21, 26–27, 29–30 (summarizing comments in opposition).

156. The 2023 Final Regulations also impose burdensome, clinically unnecessary requirements that would be difficult, if not impossible, for Plaintiffs OFBC and ABC to satisfy and that are not required for many other hospital and out-of-hospital settings in Alabama, including

but not limited to certain staffing requirements, *see, e.g.*, Ala. Admin. Code r. 520-5-13-.01(2)(d)–(e), -.03(2)(d), Ex. C at 2–3, 17; *see also, e.g.*, Milledge Memo at 3, 6–7, 10, 13, 18, 22, 26, 27 (summarizing comments in opposition).

157. The 2023 Final Regulations also continue to require birth centers to have written transfer agreements with a hospital within 30 minutes driving distance and with an EMS company, Ala. Admin. Code r. 420-5-13-.01(2)(r), (2)(x), Ex. C at 6, 8, and the staff or consultant physician to have admitting privileges at this hospital, *id.* r. 420-5-13-.01(2)(f), 2(w), Ex. C at 3, 8, thereby giving hospitals and EMS providers a veto power over whether birth centers can open at all—again, despite numerous comments opposing this requirement as unreasonable and unnecessary for patient safety, *see, e.g.*, Milledge Memo at 3, 6, 9–10, 13, 18, 22, 26–27 (summarizing comments in opposition), and despite the fact that CPMs in Alabama, such as Plaintiffs Crawford and Stone, attend home births without any such requirement, consistent with their licensed scope of practice, training, and expertise. Upon information and belief, it would be difficult, if not impossible, for OFBC or ABC to obtain and/or maintain such an agreement with a qualifying hospital or emergency medical service.

158. The distance limitation and other burdensome requirements, *see, e.g.*, Ala. Admin. Code r. 420-5-13-.01(2)(d)–(e), (2)(f), (2)(r), (2)w), (2)(x), Ex. C at 2–3, 6, 8–9, would further prevent birth centers from opening in many maternity care deserts and rural areas where the need for increased access to pregnancy-related care is greatest. *See* Milledge Memo at 2–3, 16, 18, 22, 27, 31 (summarizing comments in opposition).

159. The 2023 Final Regulations also include onerous physical and construction requirements that, as commenters informed ADPH, are not only clinically unjustified and inconsistent with the homelike environment that birth centers provide, but would also be extremely

expensive, if not financially prohibitive, for OFBC or ABC to comply with. *See* Ala. Admin. Code r. 420-5-13-.18 to -.19, Ex. C at 50–60; *see also* Milledge Memo at 3, 6, 15, 18–19 (summarizing comments in opposition).

160. In addition, the 2023 Final Regulations impose requirements that are inconsistent with current standards of care, best practices, and patients' best interests. For example, the regulations exclude many low-risk patients who are otherwise appropriate for midwifery care in an out-of-hospital setting from eligibility based on clinically unjustified risk criteria, such as age, history of miscarriage, or prior number of births, Ala. Admin. Code r. 420-5-13-.01(2)(p), Ex. C at 4–5—restrictions that are not only counter to evidence-based practices but would also narrow the pool of patients that the Plaintiff birth centers could serve, prevent patients from exercising their statutory right to choose the out-of-hospital setting of their choice subject only to Board of Midwifery regulations, *see* Ala. Code § 34-19-16(a), and be inconsistent with midwives' training, expertise, and licensed scope of practice. *See also* Milledge Memo at 2–3, 6, 13–14, 18, 22, 26 (summarizing comments in opposition).

161. The 2023 Final Regulations also fail to provide *timely* access to licenses, creating a catch-22 that similarly makes it difficult, if not impossible, to establish, open, or operate a birth center. For example, the regulations require that birth centers obtain final accreditation from a national accrediting body, Ala. Admin. Code r. 420-5-13-.13(6), Ex. C at 41—despite ADPH's awareness that such a process can take six months to a year or more to complete and that, for this reason, the national accrediting body recommends temporary or interim licensure while such a process is ongoing. *See* Milledge Memo at 13, 19, 21 (summarizing comments in opposition from CABC, among others). Without being able to open and operate while such a process is ongoing, it would be extremely difficult for birth centers to maintain a business (adequate staffing, property

and equipment costs, etc.), while being unable to operate for such an extended period of time. The regulations, however, make no provision for temporary licensure while accreditation is underway. *See* Ala. Admin. Code r. 420-5-13-.13(6), Ex. C at 41.

162. As such, the 2023 Final Regulations not only diverge from modern standards of care, but also impose barriers that would make it extremely difficult, if not impossible, for Plaintiffs to open and operate freestanding birth centers.

G. Harmful Impact of ADPH's Actions on Birth Centers on Plaintiffs and their Patients

163. As a result of ADPH's policy that any and all freestanding birth centers are "hospitals" requiring an ADPH license and ADPH's ongoing failure to provide any timely, feasible path to licensure under either "the minimum standards provided in [article 2 of title 22, chapter 21] or by regulations issued under its authority," Ala. Code § 22-21-23, ADPH has imposed a de facto ban on freestanding birth centers in the state.

164. ADPH's actions are inflicting significant irreparable harm on Plaintiffs, their members, and their current and prospective patients, as detailed below.

165. Because of ADPH's threats and refusal to provide a timely, feasible path to licensure, and despite OFBC's compliance with the national standards for birth centers and perfect record of patient safety, as of the filing of this First Amended Complaint, OFBC was forced to cease providing birthing care to patients in the Birmingham area entirely for six months. Because it was not practical for OFBC to continue providing only prenatal and postpartum care, OFBC lost midwifery personnel and was forced to stop providing *any* care through the birth center during that time.

166. ADPH's actions also forced OFBC to turn away numerous patients seeking access to this critically needed care during the time that the birth center was forced to cease operations.

For example, OFBC had to turn away ten established patients who had selected OFBC for their pregnancy and birthing care, including two patients who were expecting to give birth at the birthing center in August and October 2023. OFBC also had to turn away more than a dozen new patients who inquired about care at OFBC between March and August 2023 alone.

167. By forcing Dr. Skanes and OFBC's midwifery staff, including Plaintiff Crawford, to stop providing care to their patients at OFBC consistent with their training, expertise, and professional judgment, ADPH's actions interfere with their exercise of their professional judgment and their relationships with their patients, including patients with whom they had established provider-patient relationships and to whom they owed professional and ethical obligations.

168. ADPH's actions and forced cessation of OFBC's operations placed years of Dr. Skanes's work in limbo. During the time OFBC was unable to operate, Dr. Skanes incurred considerable financial costs—in addition to the investments she already made to establish OFBC—to maintain an unused space, without knowing if or when she might be able to resume operating her business.

169. Patients turned away from OFBC as a result of ADPH's actions were left without any path to obtaining care in a freestanding birth center in Alabama, despite having previously determined, in consultation with their trusted health care providers, that such care was the optimal care for them, based on their health, values, beliefs, needs, and financial situation. These patients were forced to make other arrangements for either hospital-based care or a home birth, even though this is not the model of care they sought.

170. If OFBC could have operated based on compliance with nationally recognized guidelines from AABC, it would not have had to cease providing patient care.

171. ADPH's actions are also harming Dr. Robinson and her birth center, placing years

of work and investment into limbo.

172. For example, because of ADPH's actions, Dr. Robinson halted construction on ABC entirely and had to turn away interested patients. As a result, during the time that she halted construction, Dr. Robinson incurred considerable financial costs—in addition to the considerable investments she already made in establishing ABC—to maintain an unused space, without knowing if or when she might be able to commence operating her business.

173. More than two hundred patients inquired about care at ABC after Dr. Robinson was forced to halt construction in mid-2022.

174. If ABC could operate based on compliance with nationally recognized guidelines from AABC, it would be able to begin providing patient care as soon as possible once ABC's application for temporary licensure from ADPH pursuant to this Court's preliminary injunction is submitted, and that process is complete.

175. Because of ADPH actions, ACNM-AL's members have been denied the opportunity to open and operate freestanding birth centers, to pursue employment in such birth centers, and to offer this out-of-hospital alternative to their patients, despite considerable interest from the membership and from members' patients in this model of care. This limits their ability to practice to their full scope of practice and to offer their patients the full scope of care they are trained to provide.

176. Because of ADPH's actions, ACNM-AL's members' patients have likewise been denied access to this model of care even if, in consultation with their CNM providers, they determine that such care would be the optimal care for them, based on their health, values, belief, needs, and financial situation.

177. Because of ADPH's actions, Plaintiff Crawford likewise was denied the

opportunity to pursue employment in birth centers during the time OFBC was forced to close. In order to meet her responsibilities to OFBC's patients, Crawford had reduced the volume of home birth patients she took on in her home birth practice. When OFBC was forced to close, this significantly impacted her income. OFBC's closure also denied her the opportunity to offer this out-of-hospital alternative to her patients, despite considerable interest from her patients in this model of care—and she can only do so today by virtue of the Court's injunction. This limits her ability to practice to her full scope of practice and to offer her patients the full scope of care she is trained to provide.

178. Plaintiff Crawford's patients have been denied access to this model of care—and, but for the injunction, would continue to be denied such access—even if, in consultation with her as their trusted provider, they determine that such care would be optimal for them, based on their health, values, beliefs, needs, and financial situation.

179. During her apprenticeship as a student midwife, Plaintiff Stone, like other CPM students in the state, was also denied the opportunity to seek training in birth centers as part of her clinical education, thereby delaying her ability to obtain and complete the necessary training experience within Alabama because of the more limited patient load in the home birth setting.

180. While these irreparable harms may be temporarily abated by this Court's preliminary injunction, that interim relief will only last during the pendency of this litigation. If applied to Plaintiffs, Plaintiffs' members, and their patients, the 2023 Final Regulations would only perpetuate and exacerbate these irreparable harms.

181. If applied to Plaintiffs, their members, and their patients, the 2023 Final Regulations would make it extremely burdensome, if not impossible, for the birth centers to open or continue to operate. The Final Regulations impose some requirements that, in some instances, would be

literally impossible for Plaintiffs to satisfy.

182. Other requirements in the 2023 Final Regulations would render operation of a birth center financially unsustainable, and, therefore, infeasible and impractical to operate.

183. The 2023 Final Regulations are also harming Dr. Skanes, Dr. Robinson, and their birth centers by continuing to place years of work and investment into limbo. They have spent years and made considerable personal and financial investments in establishing their birth centers, without knowing if they will be able to continue operating long term as a result of ADPH's actions and the burdensome and impractical requirements of the 2023 Final Regulations.

184. Plaintiffs, their staff, and their members are also harmed by unlawful and unconstitutional provisions in the 2023 Final Regulations that impose requirements for and limitations to patient care, including but not limited to clinically unjustified risk criteria excluding certain patients from eligibility for birth center care. These requirements are inconsistent with prevailing standards of care, patients' best interests, Plaintiffs' training, expertise, and clinical judgment, and, in some instances, Plaintiffs' ethical obligations to patients. By imposing such requirements, ADPH's actions interfere with Plaintiffs' exercise of professional judgment and disrupt their relationships with their patients, including patients with whom they have established provider-patient relationships and to whom they owe professional and ethical obligations.

185. Plaintiffs Crawford and Stone, the birth centers' other CPM staff, and ACNM-AL's CPM members are further harmed by the limitation in the 2023 Final Regulations restricting CPMs to providing "assistive" care in a birth center, which violates provisions of the Alabama Code authorizing licensed CPMs to practice independently "in the setting of a client's choice except a hospital," § 34-19-16(a); *see also* § 34-19-14(b)(2), and thereby prevents them from practicing their profession in Alabama.

186. Plaintiffs OFBC and ABC are likewise harmed by this limitation. It would be financially and practically unsustainable to employ CPMs in birth centers if limited to only providing "assistive" care under the supervision of a physician or CNM, thereby preventing the birth centers from employing or continuing to employ qualified CPMs to provide independent patient care in their birth centers and making it more expensive—and, in some cases, prohibitively expensive—to operate birth centers at all.

187. Due to the unsustainable and impractical costs, this limitation to "assistive" care for CPMs will likely prohibit CPMs, including Plaintiff Crawford, Plaintiff Stone, and ACNM-AL's CPM members, from practicing in a birth center entirely.

188. Moreover, as a newly-certified and soon-to-be-licensed CPM, Plaintiff Stone would be prohibited by the 2023 Final Regulations from working in a birth center in any capacity for at least a year, despite having fulfilled all qualifications required under Alabama statutory law and Board of Midwifery regulations to practice as a CPM in any setting of her patients' choice other than a hospital.

189. Plaintiffs' and their members' patients will also be harmed by the 2023 Final Regulations. To the extent that the Regulations make it impossible for birth centers to operate at all in Alabama, patients will be denied the option for out-of-hospital care in a birth center entirely, despite having previously determined, in consultation with their trusted health care providers, that such care was the optimal care for them, based on their health, values, beliefs, needs, and financial situation. These patients will be forced to make other arrangements for either hospital-based care or a home birth, even though this is not the model of care they sought.

190. Plaintiffs' and their members' patients will also be harmed by specific requirements in the 2023 Final Regulations—including but not limited to clinically unjustified risk criteria—

that will force birth centers to deny care to low-risk patients who are otherwise clinically appropriate for care in an out-of-hospital setting, despite having previously determined, in consultation with their trusted health care providers, that such care was the optimal care for them, based on their health, values, beliefs, needs, and financial situation. These patients will be forced to make other arrangements for either hospital-based care or a home birth, even though this is not the model of care they sought.

191. The public interest is also considerably harmed by ADPH's actions. Against the backdrop of a severe maternal and infant health crisis, especially for Black Alabamians, prevalent maternity care deserts, and inadequate access to pregnancy-related care in the state, ADPH's actions are preventing skilled providers of pregnancy-related care from offering their much-needed services to help expand access to quality care and improve patient outcomes.

192. Plaintiffs lack an adequate remedy at law.

CLAIMS

Primary Claim

Claim One: Alabama Administrative Procedure Act (AAPA)— Exceeds Statutory Authority

193. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 192.

194. Under Alabama law, a "hospital," for purposes of ADPH's regulatory and licensing authority, includes, *inter alia*, "institution[s] . . . primarily engaged in offering to the public generally . . . obstetrical care." Ala. Code § 22-21-20(1).

195. ADPH's determination that any and all freestanding birth centers are "hospitals" for purposes of its regulatory and licensing authority under section 22-21-20(1), including but not limited to ADPH's enforcement of that determination by threatening Dr. Skanes with criminal and

civil penalties for operating OFBC as an "unlicensed hospital" and adopting regulations for freestanding birth centers, Ala. Admin. Code r. 420-5-13-.01 to -.19, constitutes a rule under the AAPA because it is a "standard[] or statement of general applicability that implements, interprets, or prescribes law or policy." Ala. Code. § 41-22-3(9); *see also Ex parte Traylor Nursing Home, Inc.*, 543 So. 2d 1179, 1183–84 (Ala. 1988).

196. Because a freestanding birth center operating under the midwifery model of care is not engaged in offering obstetrical care to the public generally, it does not fall within ADPH's hospital regulatory and licensing authority.

197. Therefore, ADPH's adoption of the rule that any and all freestanding birth centers operating under the midwifery model of care are "hospitals" for purposes of its regulatory and licensing authority, including through the adoption of regulations for freestanding birth centers, and its application of that rule to Plaintiffs OFBC, ABC, and any other similarly situated birth centers that may be owned, operated, or staffed by the individual Plaintiffs or Plaintiff ACNM-AL's members, exceeds ADPH's statutory authority in violation of Alabama Code § 41-22-10.

Alternative Claims

Claim Two: AAPA—Exceeds Statutory Authority (De Facto Ban)

198. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 192.

199. Plaintiffs bring this claim in the alternative to Claim One.

200. Even if ADPH is authorized to require a freestanding birth center operating in the midwifery model of care to obtain a license under its hospital regulatory and licensing authority, ADPH's adoption of a de facto ban on all freestanding birth centers by refusing to provide any path to licensure constitutes a rule because it is a "standard[] or statement of general applicability

that implements, interprets, or prescribes law or policy." Ala. Code. § 41-22-3(9); *see also Ex parte Traylor Nursing Home, Inc.*, 543 So. 2d at 1183–84.

201. ADPH's hospital regulatory and licensing authority is limited to the authority to "make and enforce . . . reasonable rules and regulations governing the operation and conduct of [regulated facilities]" and to "set uniform minimum standards applicable alike to all [regulated facilities] of like kind." Ala. Code § 22-21-28(a). ADPH lacks the authority under Alabama law to categorically prohibit a particular *type* of "hospital" covered under its regulatory and licensing authority from operating in Alabama entirely.

202. ADPH is authorized by statute to grant a license to operate a "hospital" under section 22-21-25(a) of the Alabama Code to any applicant who demonstrates compliance with minimum statutory criteria, without requiring the promulgation of additional regulations. *See also* Ala. Code § 22-21-23.

203. Except as otherwise ordered by this Court, *see supra* paragraphs 145–47, ADPH has nonetheless categorically refused to consider applications for licensure by freestanding birth centers under the relevant statutory criteria, despite the proven safety record and benefits of freestanding birth centers, and even though Plaintiffs OFBC and ABC have been engaged in public efforts to open freestanding birth centers in Alabama for over three years, and even though Plaintiff OFBC successfully provided prenatal, birthing, and postpartum care to over twenty patients before ADPH forced them to shut down on the grounds that they lacked a "hospital" license from ADPH.

204. Additionally, as discussed *infra* in Claims Three through Thirteen, the current birth center regulations are unlawful, unconstitutional, and make it difficult, if not impossible, to work in, establish, construct, maintain, or operate birth centers. Thus, ADPH has also failed to provide a regulatory path for licensure of freestanding birth centers, despite the proven safety record and

benefits of freestanding birth centers, as described *supra* paragraphs 68–77.

205. ADPH's refusal to provide any statutory or regulatory path for licensure of freestanding birth centers therefore constitutes a de facto ban on freestanding birth centers in Alabama that exceeds ADPH's statutory authority in violation of Alabama Code § 41-22-10.

Claim Three: AAPA—Exceeds Statutory Authority
(Unreasonable Regulatory Scheme)

206. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 192.

207. Plaintiffs bring this claim in the alternative to Claim One.

208. Even if ADPH is authorized to require a freestanding birth center operating in the midwifery model of care to obtain a license under its hospital regulatory and licensing authority, ADPH's adoption of the 2023 Final Regulations for freestanding birth centers, Ala. Admin. Code r. 420-5-13-.01 to -.19, exceeds its statutory authority in violation of the AAPA, Ala. Code § 41-22-10.

209. The purpose of ADPH's hospital regulatory and licensing authority is "to promote the public health, safety and welfare by providing for the development, establishment and enforcement of standards for the treatment and care of individuals in institutions within [its] purview . . . and the establishment, construction, maintenance and operation of such institutions which will promote safe and adequate treatment and care of individuals in such institutions." Ala. Code § 22-21-21.

210. ADPH's hospital regulatory and licensing authority is limited to "the power to make and enforce . . . *reasonable rules and regulations* governing the operation and conduct of hospitals as defined in Section 22-21-20." *Id.* § 22-21-28(a) (emphasis added). "All such regulations shall set uniform minimum standards applicable alike to all hospitals of like kind and

purpose in view of the type of institutional care being offered there and shall be confined to setting minimum standards of sanitation and equipment found to be necessary and prohibiting conduct and practices inimical to the public interest and the public health." *Id.*

211. ADPH's regulatory scheme for freestanding birth centers imposes numerous unreasonable requirements on the Plaintiff birthing centers and their staff, including but not limited to burdensome and clinically unjustified limitations on midwives' scopes of practice, physician supervision and minimum staffing requirements, hospital and transport written transfer agreements, and physical plant prerequisites, that make it extremely burdensome, if not impossible to work in, establish, construct, maintain or operate a freestanding birth center in Alabama.

Claim Four: AAPA—Exceeds Statutory Authority
(Conflict with Childbirth Freedom Act, Act 2017-383)

212. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 192.

213. Plaintiffs bring this claim in the alternative to Claim One.

214. Even if ADPH is authorized to require a freestanding birth center operating in the midwifery model of care to obtain a license under its hospital regulatory and licensing authority, ADPH's adoption of the 2023 Final Regulations for freestanding birth centers, Ala. Admin. Code r. 420-5-13-.01 to -.19, exceeds its statutory authority in violation of the AAPA, Ala. Code § 41-22-10.

215. In exercising its hospital regulatory and licensing authority, ADPH "shall not have power to promulgate any regulation in conflict with law." *Id.* § 22-21-28(a).

216. ADPH's 2023 Final Regulations for freestanding birth centers prohibit CPMs, including Plaintiffs Crawford and Stone, from practicing independently and to their full scope of practice in freestanding birth centers and prohibit the Plaintiff birth centers from employing CPMs

to provide such independent patient care, thereby conflicting with Alabama law authorizing CPMs to practice midwifery independently in out-of-hospital settings, *e.g.*, *id.* §§ 34-19-11 to -21.

217. By statute, Alabama-licensed CPMs are authorized to "practice midwifery care in the setting of the client's choice, except a hospital," *id.* § 34-19-16(a), which includes freestanding birth centers, *see* Att'y Gen. Op. at 4–5 (concluding that freestanding birth centers are not hospitals for the purposes of section 34-19-16).

218. Moreover, when authorizing CPMs to practice in out-of-hospital settings such as birth centers, the Alabama Legislature specifically charged the State Board of Midwifery with licensing and regulating their practice, Ala. Code §§ 34-19-14 to -15, and required that any regulation of CPMs' practice must "ensure independent practice" and be implemented "in a manner consistent with the most current North American Registry of Midwives Job Analysis and with essential documents developed and published by the Midwives Alliance of North America," Ala. Code § 34-19-14(b)(1)–(2); *see also* Ala. Admin. Code r. 582-X-.01 to -.04.

219. Provisions of the 2023 Final Regulations conflict with these statutes including, but not limited to, because they restrict CPMs' scope of practice to only "assistive" care, Ala. Admin. Code r. 420-5-13-.01(2)(b), -.03(1), Ex. C at 2, 15, prohibit their independent practice, and otherwise restrict freestanding birth centers from employing CPMs in accordance with their statutorily-authorized scope of practice, *e.g.*, *id.* r. 420-5-13-.01(2)(b), (e), Ex. C at 2–3.

Claim Five: AAPA—Exceeds Statutory Authority
(Conflict with Certified Nurse Midwife Statutes)

220. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 192.

221. Plaintiffs bring this claim in the alternative to Claim One.

222. Even if ADPH is authorized to require a freestanding birth center operating in the

midwifery model of care to obtain a license under its hospital regulatory and licensing authority, ADPH's adoption of the 2023 Final Regulations for freestanding birth centers, Ala. Admin. Code r. 420-5-13-.01 to -.19, exceeds its statutory authority in violation of the AAPA, Ala. Code § 41-22-10.

223. In exercising its hospital regulatory and licensing authority ADPH "shall not have power to promulgate any regulation in conflict with law." *Id.* § 22-21-28(a).

224. ADPH's 2023 Final Regulations for freestanding birth centers prevent CNMs who meet all statutory requirements for practice in Alabama, including Plaintiff ACNM-AL's members, from owning, operating, or practicing as authorized by Alabama statute in freestanding birth centers and prevent the Plaintiff birth centers from employing CNMs who otherwise meet all requirements for practice in Alabama, thereby conflicting with Alabama law governing the practice of CNMs, *e.g.*, *id.* §§ 34-21-80 to -93.1.

225. Per statute, the Board of Nursing is the "sole state authority designated to establish the qualifications necessary for a registered nurse to be certified to engage in advanced practice nursing," including nurse-midwifery, *id.* § 34-21-84, except to the extent that both the Board of Nursing and the Board of Medical Examiners shall approve protocols for "collaboration with a physician" pursuant to a Collaborative Practice Agreement (CPA), *id.* §§ 34-21-83, -84, -85, -90; *see also* Ala. Admin. Code r. 610-X-5-.14 to -.25.

226. ADPH's 2023 Final Regulations for freestanding birth centers prevent CNMs with a valid CPA from owning, operating, or practicing as authorized by Alabama statute in birth centers and prevent birth centers from employing such CNMs by inappropriately imposing practice requirements beyond those established by the Alabama legislature and the Alabama Boards of Nursing and Medical Examiners pursuant to their statutorily-delegated responsibility, including

but not limited to provisions requiring CNMs to enter into a CPA with the birth center's staff or consultant physician, even if they have another valid CPA already in place, *e.g.*, Ala. Admin. Code r. 420-5-13-.01(2)(d), Ex. C at 2, requiring a CNM's collaborating physician at the birth center to meet requirements not required for other remote practice sites under Alabama law, *e.g.*, *id.* r. 420-5-13-.01(2)(d), (f), (w), Ex. C at 2, 3, 8, and prohibiting CNMs from practicing in birth centers unless certain other qualifications and staffing requirements are met, *e.g.*, *id.* r. 420-5-13-.01(2)(b), (d), Ex. C at 2.

Claim Six: Due Process Right to Pursue Useful Activities under Alabama Constitution

227. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 192.

228. Plaintiffs bring this claim in the alternative to Claim One.

229. The right to due process under Article I, section 13 of the Alabama Constitution protects the right of individuals to "pursu[e] . . . useful activities" free from "restrictions that are unnecessary and unreasonable" and that "do not bear some substantial relation to the public health, safety, or morals, or to the general welfare, the public convenience, or the general prosperity." *Friday v. Ethanol Corp.*, 539 So. 2d 208, 216 (Ala. 1988).

230. ADPH's actions, as set forth above—including but not limited to adopting the 2023 Final Regulations—do not bear any substantial relation to public health and thereby violate Plaintiffs' and their members' constitutional right to pursue useful activities. Certain provisions of the 2023 Final Regulations, individually or collectively, will prevent Plaintiffs and Plaintiffs' members from owning, operating, and/or working at a freestanding birth center and providing critically necessary pregnancy-related care that is proven to improve health outcomes in the midst of one of the most severe maternal and infant health crises in the country, and others impose

burdensome, costly, and clinically unjustified requirements on the operation of birth centers, without any substantial relation to public health.

Claim Seven: AAPA—Violates Constitutional Provisions
(Due Process Right to Pursue Useful Activities under Alabama Constitution)

231. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 192.

232. Plaintiffs bring this claim in the alternative to Claim One.

233. For the same reasons stated in Claim Six ADPH's actions violate the AAPA because the agency's actions "violate[] constitutional provisions." Ala. Code § 41-22-10.

Claim Eight: Right to Procreate under Alabama and U.S. Constitutions

234. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 192.

235. Plaintiffs bring this claim in the alternative to Claim One.

236. The United States Constitution protects the fundamental right to procreate, one of the most "basic civil rights." *Skinner v. State of Oklahoma ex rel. Williamson*, 316 U.S. 535, 541 (1942). The Alabama Constitution protects such a right at least as strongly as its federal counterpart. *Gilbreath v. Wallace*, 292 So. 2d 651, 654–55 (Ala. 1974) ("While the Federal Constitution, as interpreted by the United States Supreme Court, establishes minimum standards, the states have the power and are free to provide greater safeguards and to extend this protection through their own organic law—the State Constitutions.").

237. ADPH's actions, as set forth above—including but not limited to adopting the 2023 Final Regulations—are denying Plaintiffs' patients access to critically needed care that is proven to improve health outcomes in the midst of one of the most severe maternal and infant health crises in the country. By affirmatively preventing birth centers from operating and/or by imposing

clinically unjustified requirements on patient care, amidst a statewide maternal health crisis—and despite birth centers' proven benefits and safety record—ADPH's actions subject Plaintiffs' patients to an increased risk of an unsafe pregnancy and birth and/or fetal or infant death and thereby violate Plaintiffs' patients' fundamental right to procreate under the United States and Alabama Constitutions.

Claim Nine: AAPA—Violates Constitutional Provisions (Right to Procreate under Alabama and U.S. Constitutions)

238. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 192.

239. Plaintiffs bring this claim in the alternative to Claim One.

240. For the same reasons stated in Claim Eight, ADPH's actions violate the AAPA because the agency's actions "violate[] constitutional provisions." Ala. Code § 41-22-10.

Claim Ten: Due Process—Unlawful Private Delegation under Alabama and U.S. Constitutions

241. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 192.

242. Plaintiffs bring this claim in the alternative to Claim One.

243. The Due Process Clause of the U.S. Constitution protects against the unlawful delegation of state power that gives private parties the ultimate authority to determine the nature of property rights in which others have a protectible property interest. *See, e.g.*, *Washington ex rel. Seattle Title Tr. Co. v. Roberge*, 278 U.S. 116 (1928). The Due Process Clause of the Alabama Constitution protects against such unlawful private delegations at least as strongly as its federal counterpart. *Gilbreath*, 292 So. 2d at 654–55.

244. Plaintiffs and Plaintiffs' members have a protectible property interest in practicing

their professions and pursuing useful activities, including working at, opening, operating, and practicing to the full scope of their health care licenses at freestanding birth centers. *See Friday*, 539 So. 2d at 216; *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 577–78 (1972).

245. Several requirements in the 2023 Final Regulations for birth centers, including, but not limited to, those mandating written transfer agreements with hospitals within a certain geographic area, Ala. Admin. Code r. 420-5-13-.01(2)(r), (x), Ex. C at 6, 8–9, physician admitting privileges at such hospitals, *id.* r.420-5-13-.01(2)(f), (w), Ex. C at 3, 8, and written transfer agreements with emergency medical services, *id.* r. 420-5-13-.01(2)(x), Ex. C at 8–9, effectively delegate traditional licensing authority to private parties, including hospitals and emergency medical service companies, who are not bound by due process.

246. In the absence of any standards to govern the decision-making of these private entities regarding whether to enter into a written transfer agreement or to grant privileges, the 2023 Final Regulations unlawfully delegate to private parties—whose interests may be adverse to Plaintiffs'—the authority to deprive Plaintiffs of their protected property interests without due process of law. *See Roberge*, 278 U.S. at 121–22 (delegation must be "[]controlled by [a] standard or rule prescribed by legislative action"); *Eubank v. City of Richmond*, 226 U.S. 137, 143–44 (1912) (requiring a "standard by which the power . . . given is to be exercised").

Claim Eleven: AAPA—Violates Constitutional Provisions
(Unlawful Private Delegation under Alabama and U.S. Constitutions)

247. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 192.

248. Plaintiffs bring this claim in the alternative to Claim One.

249. For the same reasons stated in Claim Ten, ADPH's actions violate the AAPA because the agency's actions "violate[] constitutional provisions." Ala. Code § 41-22-10.

Claim Twelve: Due Process and Equal Protection under Alabama and U.S. Constitutions

250. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 192.

251. Plaintiffs bring this claim in the alternative to Claim One.

252. CNMs and CPMs, including Plaintiffs Crawford and Stone, and Plaintiff ACNM-AL's members, who work or intend to work in freestanding birth centers have a protectible due process property interest in practicing their profession. Ala. Const. art. 1, § 13; U.S. Const. amend. XIV; *see also Barnes v. State ex rel. Ferguson*, 151 So. 2d 619, 623 (Ala. 1963).

253. Dr. Skanes and Dr. Robinson have a protectible due process property interest in operating and maintaining their businesses. Ala. Const. art. 1, § 13; U.S. Const. amend. XIV; *see also supra* paragraphs 244–246.

254. The 2023 Final Regulations deprive Plaintiffs of their protectible property interests by imposing provisions that prevent or impede licensed midwives from practicing their professions in birth centers and prevent or impede Plaintiffs from employing licensed midwives in their birth centers, or impose heightened costs on them for doing so, including, but not limited to, by imposing provisions limiting CPMs to providing only "assistive" care in birth centers, Ala. Admin. Code r. 420-5-13-.01(2)(b), -.03(1), Ex. C at 2, 15, requiring CNMs and physicians working in birth centers to enter into new or more burdensome collaborative practice agreements in order to work in birth centers, *id.* r. 420-5-13-.01(2)(d), (f), Ex. C at 2–3, restricting CPMs' and CNMs' employment in birth centers, *id.* r. 420-5-13-.01(2)(d), (e), Ex. C at 2–3, and requiring CPMs and CNMs who seek to establish and operate birth centers to meet other irrational requirements, despite the fact that midwives safely provide effectively identical services to the same patient populations in a home birth setting without meeting such requirements, *e.g.*, *id.* r. 420-5-13-.01(2)(f), (r), (w),

(x), -.03(2)(a), Ex. C at 3, 6, 7, 8–9, 16–17.

255. The 2023 Final Regulations also impose distinct and heightened requirements on individuals who own, operate, or work in freestanding birth centers—including but not limited to onerous staffing, personnel, and physical plant requirements, *e.g.*, *id.* r. 420-5-13-.01(2)(t), -.03(2)(d), (f), (h)(1), -.16(b)(7), -.19, Ex. C at 6, 17, 18, 46, 56–60—that are not imposed on individuals who establish, operate, or work in similarly situated health care facilities, and/or who provide effectively identical out-of-hospital birthing care, based merely on the location that midwives are providing such care, and without a rational basis for differential treatment.

256. Such differential treatment violates Plaintiffs' and their members' equal protection rights under Article I, section 13 of the Alabama Constitution and the Fourteenth Amendment of the U.S. Constitution. *See also Wallace v. Jones*, No. 2:10-CV-361-MEF, 2013 WL 5406799, at *12 n.11 (M.D. Ala. Sept. 25, 2013).

Claim Thirteen: AAPA—Violates Constitutional Provisions
(Due Process and Equal Protection under Alabama and U.S. Constitutions)

257. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 192.

258. Plaintiffs bring this claim in the alternative to Claim One.

259. For the same reasons stated in Claim Twelve, ADPH's actions violate the AAPA because the agency's actions "violate[] constitutional provisions." Ala. Code § 41-22-10.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court:

1. Issue:

    a. a declaratory judgment, pursuant to the Alabama Declaratory Judgment Act, Ala. Code § 6-6-222, and the AAPA, Ala. Code § 41-22-10, that

freestanding birth centers operating in the midwifery model of care are not "hospitals" under section 22-21-20(1) of the Alabama Code and, therefore, ADPH has no authority to require such birth centers to obtain a license under section 22-21-22 of the Alabama Code or to otherwise regulate such birth centers, and that any such attempts to do so exceed statutory authority in violation of the AAPA;

b. preliminary and permanent injunctive relief enjoining ADPH from requiring freestanding birth centers operating in the midwifery model of care to seek and obtain a "hospital" license under section 22-21-22 of the Alabama Code, and from taking any other adverse action against such entities, their owners, founders, or staff (including Plaintiffs and their members) for failing to seek or obtain such a license, including but not limited to threatening or seeking criminal or civil penalties under section 22-21-33 of the Alabama Code, as further detailed in Plaintiffs' Motion for Preliminary Injunction;

2. Or, in the alternative to (1), issue:

   a. either

      i. a declaratory judgment, pursuant to Alabama Declaratory Judgement Act, Ala. Code § 6-6-222, and the AAPA, Ala. Code § 41-22-10, that the failure to provide a timely, feasible path to licensure for freestanding birth centers operating in the midwifery model of care constitutes a de facto ban on freestanding birth centers that exceeds ADPH's statutory authority in violation of the AAPA

and/or violates Plaintiffs', their members', and their patients' constitutional rights; and

ii. preliminary and permanent injunctive relief enjoining ADPH from refusing to timely license freestanding birth centers operating in the midwifery model of care that can demonstrate compliance with AABC standards and can satisfy the remaining statutory requirements, *see* Ala. Code §§ 22-21-23, 24, 29(a), 31, including, but not limited to refusing to timely grant temporary or interim licenses based on such demonstrated compliance until at least such a time as ADPH adopts final regulations for birth centers and temporary- or interim-licensed facilities have had an opportunity to come into compliance with any such new regulations, as further detailed in Plaintiffs' Motion for Preliminary Injunction.

b. or

i. a declaratory judgment, pursuant to Alabama Declaratory Judgement Act, Ala. Code § 6-6-222, and the AAPA, Ala. Code § 41-22-10, that the 2023 Final Regulations, in whole or in part, exceed ADPH's statutory authority in violation of the AAPA and/or violate Plaintiffs', their members', and their patients' constitutional rights; and

ii. permanent injunctive relief enjoining ADPH from enforcing the 2023 Final Regulations in whole or in part, and from taking any other adverse action against such freestanding birth centers, their

owners, founders, or staff (including Plaintiffs and their members) for failing to comply, in whole or in part, with unlawful provisions of the 2023 Final Regulations, including but not limited to denying a license on that basis or taking other adverse administrative, criminal or civil actions against the birth centers, their owners, founders, or staff (including Plaintiffs and their members).

3. Grant any such further relief as the court deems just and proper.

DATE: January 19, 2024

Respectfully submitted,

/s/ *Robert D. Segall*

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Counsel for Plaintiffs

**Admitted pro hac vice*
***Application for admission pro hac vice filed herewith*

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing has been served upon counsel of record by electronic filing with the Clerk of Court through AlaFile, by e-mail, and/or by placing the same in the U.S. mail on this 19th day of January, 2024.

/s/ *Robert D. Segall*
Of Counsel

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CIRCUIT COURT OF
MONTGOMERY COUNTY, ALABAMA
GINA J. ISHMAN, CLERK

EXHIBIT A

APA-1
4/18

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 420 Alabama Department of Public Health

Rule Number 420-5-13
Rule Title Birthing Center Rules

X New ____ Amend ____ Repeal ____ Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare or safety?	Yes
Is there a reasonable relationship between the state's police power and the protection of the public health, safety or welfare?	Yes
Is there another, less restrictive method of regulation available that could adequately protect the public?	No
Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree?	No
Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule?	No
Are all facts of the rulemaking process designed solely for the purpose of and so they have as their primary effect, the protection of the public?	Yes
Does the proposed action relate to or affect in any manner any litigation which the agency is a party to concerning the subject matter of the proposed rule?	No
Does the proposed rule have an economic impact?	No

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of §41-22-23, Code of Alabama, 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama, 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Services Agency.

Signature of Certifying Officer [signature] Date 7/18/22

REC'D & FILED

JUL 21 2022

LEGISLATIVE SVC AGENCY

FORM APA2
10/17

STATE BOARD OF HEALTH
NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Department of Public Health

RULE NUMBER AND TITLE: 420-5-13, Birthing Centers

INTENDED ACTION: To adopt new rules.

SUBSTANCE OF PROPOSED ACTION: To establish new rules regulating birthing centers in various locations in the state.

TIME, PLACE, AND MANNER OF PRESENTING VIEWS: A public hearing will be held on August 18, 2022 at 10:00 a.m., at the RSA Tower, Suite 982, 201 Monroe Street, Montgomery, AL 36104.

FINAL DATE FOR COMMENTS AND COMPLETION OF NOTICE: Written or oral comments will be received until the close of the record at 5:00 p.m. on September 2, 2022. All comments and requests for copies of the proposed amendments should be addressed to the contact person listed below.

CONTACT PERSON AT AGENCY: Jacqueline D. Milledge, Bureau of Health Provider Standards, Department of Public Health, P.O. Box 303017, Montgomery, Alabama 36130-3017, Telephone number: (334) 206-5366.

P. Brian Hale, Agency Secretary

ALABAMA STATE BOARD OF HEALTH
ALABAMA DEPARTMENT OF PUBLIC HEALTH
ADMINISTRATIVE CODE
CHAPTER 420-5-13
BIRTHING CENTERS

TABLE OF CONTENTS

420-5-13-.01 General.

(1) Legal Authority for Adoption of Rules. The following rules for Birthing Centers are adopted by the Alabama State Board of Health pursuant to § 22-21-20, et seq., Code of Ala. 1975.

(2) Definitions

(a) "Administrator" means a natural person who is the governing authority of a health care facility or a natural person who is designated by the governing authority of a health care facility. Such person must have sufficient authority to interpret and implement all policies of the owner or proprietor and must be qualified to perform those tasks. The Administrator shall be the addressee of all correspondence and inquiries from the State Board of Health.

(b) "Birthing Center" means a health care facility where nonemergency births are planned to occur away from the mother's usual residence following a documented period of prenatal care for a normal uncomplicated pregnancy, which has been determined to be low risk through the Risk Status Criteria for Acceptance of Patients and Continuation of Care. Care provided in a birthing center shall be provided by a licensed physician, or by a duly licensed certified nurse midwife and a licensed registered nurse.

(c) "Board" or "State Board of Health" means the Alabama State Board of Health.

(d) "Certified Nurse Midwife" (CNM) means an advanced practice nurse who is in an active collaborative practice agreement with the licensed physician who is serving as the staff or consultant physician for the birthing center, which includes the birthing center as an approved practice site, and who meets the requirements of and is approved by the Alabama Board of Nursing and the Alabama State Board of Medical Examiners. CNMs in birthing centers shall have at least 1 year of experience in labor and delivery and/or newborn intensive care and be trained and annually certified in adult and infant cardiopulmonary resuscitation (CPR) and infant resuscitation.

(e) "Consultant Physician" means an Alabama licensed physician trained and annually certified in adult and infant CPR and infant resuscitation who has a valid agreement to serve as a consultant to the birthing center or an approved collaborative practice agreement with the CNM employed by or working at the birthing center. The services of a consultant are required for any birthing center which does not have a physician on the medical staff who is currently licensed by and in good standing with the Medical Licensure Commission of Alabama, and who is certified by the American Board of Obstetrics and Gynecology or the American Board of Osteopathic Obstetricians and Gynecologists. The consultant physician must have hospital obstetrical privileges with the hospital that is a party to the Birthing Center's Transfer Agreement and must be readily available within a reasonable time to assist at the birthing center when called. A facility is ineligible for licensure unless it has an Alabama licensed physician on the medical staff or a valid agreement with a consultant physician.

(f) "Department" means the Alabama Department of Public Health.

(g) "Documented Period of Prenatal Care" means prenatal evaluation and care initiated by an appropriate care provider prior to the third trimester, until 38-42 weeks of gestation.

(h) "Family Centered Care" means a philosophy of care that allows family and significant others to participate in the pregnancy, birth, and postpartum period in a homelike environment.

(i) "Freestanding Birthing Center" means a separate and distinct health care facility which is established to provide the services of a birthing center. A freestanding birthing center does not include a separately organized unit of a hospital. Each freestanding birthing center must obtain its own license and comply with all applicable licensing standards promulgated by the State Board of Health and these rules.

(j) "Governing Authority" means the owner or proprietor of a health care facility, or the body, such as a board of directors, which exercises control over a health care facility on behalf of its owner or proprietor.

(k) "Hospital" means a health care facility duly licensed as a hospital by the State Board of Health and operating in compliance with the Department's rules in Chapter 420-5-7. The usual service provided in the obstetric gynecology service of an acute care hospital does not constitute or qualify as a birthing center.

(l) "Hospital Affiliated Birthing Center" means a separate and distinct unit of a hospital or a building owned, leased, rented, or utilized by a hospital for the purpose of providing the service of a birthing center. Hospital affiliated birthing centers that are not located on the hospital campus are required to be separately licensed and may not operate under the license issued to the hospital.

(m) "License" means the legal authority to operate a birthing center, as defined above, to admit patients, and to offer and provide care as permitted under these rules. A license may only be granted by the Board through the actions of its authorized agents.

(n) "Licensed Practical Nurse" (LPN) means a person who holds an active license with the Alabama Board of Nursing or a multistate nursing license which includes a privilege to practice nursing in Alabama. An LPN in a birthing center shall have at least 1 year of experience in obstetrics and be trained and annually certified in adult and infant CPR and infant resuscitation.

(o) "Nonemergency Births" means those births that are planned to occur away from the mother's usual residence and have been determined to be low risk through a formal risk scoring examination.

(p) "Normal Uncomplicated Pregnancy" means a course of pregnancy that is risk scored as such at each patient visit using a written risk scoring method developed by the staff or consultant physician and approved by the Board. See Appendix "A."

(q) "Organized Obstetrical Service" means a hospital which has an obstetrician and a pediatrician on the active staff, a 24-hour emergency room and cesarean section capability, and which provides skilled nursing care, facilities, and equipment appropriate for the patient being transferred from the birthing center. The organized obstetrical service must be located no more than 25 miles driving distance by automobile from the birthing center.

(r) "Registered Nurse" (RN) means a person who holds an active license as such with the Alabama Board of Nursing or a multistate nursing license which includes a privilege to practice nursing in Alabama. An RN in a birthing center shall have at least 1 year of experience in obstetrics and be trained and annually certified in adult and infant CPR and infant resuscitation.

(s) "Risk Status Criteria" means:

1. Birthing center patients are limited to those women who are initially determined to be at low maternity risk and who are evaluated regularly throughout pregnancy to assure that they remain at low risk for a poor pregnancy outcome.

2. Each birthing center shall establish a written risk assessment system which shall be developed by the staff or consultant physician, approved by the Board, and included in the policy and procedure manual. An individual risk assessment for each patient shall form part of the patient's clinical record.

3. The general health status and risk assessment shall be determined by the staff or consultant physician or CNM after obtaining a detailed medical history, performing a physical examination, and considering family circumstances and other social and psychological factors.

4. The criteria upon which the risk status of patients is determined must be approved by the Board and are attached to these rules as Appendix A – Risk Status Criteria for Acceptance of Patients and Continuation of Care. These criteria shall be applied to all patients prior to acceptance for birthing center services and throughout the pregnancy for continuation of services. Patients with any of the risk factors listed in Appendix A shall be ineligible to receive services in a birthing center and shall be referred to a physician for continuing maternity care and hospital delivery.

5. Acceptance for and continuation of care throughout pregnancy and labor is limited to those women for whom it is appropriate to give birth in a setting where anesthesia is limited to local infiltration of the perineum or a pudendal block and where analgesia is limited.

(t) "Services Provided in a Birthing Center" shall be defined and limited as follows:

1. Surgical services shall be limited to those normally performed during uncomplicated childbirth, such as episiotomy and repair, and shall not include operative obstetrics or cesarean sections. Surgical repairs of fourth degree lacerations may only be performed in a birthing center by the staff or consultant physician. Circumcisions of male infants may be performed in a birthing center by the staff or consultant physician or by a CNM who has been approved to perform circumcision of male infants through the collaborative practice approval process.

2. Labor shall not be inhibited, stimulated, or augmented with chemical agents during the first or second stage of labor (i.e., up to and including vaginal delivery).

3. Systemic analgesia may be administered and local anesthesia for pudendal block and episiotomy repair may be performed; however, general and conduction anesthesia shall not be administered.

4. Patients shall not routinely remain in the facility in excess of 24 hours. Exceptional circumstances justifying a stay in excess of 24 hours are set forth in Ala. Admin. Code r. 420-5-13-.09(8).

(u) "Staff Physician" means a person currently licensed by the Alabama Medical Licensure Commission to practice medicine and/or osteopathy in this state and who is certified by the American Board of Obstetrics and Gynecology or the American Board of Osteopathic Obstetricians and Gynecologists. The staff physician must have hospital obstetrical privileges with the hospital that is a party to the Birthing Center's Transfer Agreement and shall be trained and annually certified in adult and infant CPR and infant resuscitation. A birthing center is ineligible for licensure unless it has an Alabama licensed physician on the medical staff or a valid agreement with a consultant physician.

(v) "Transfer Agreement" means a facility's written agreement with a hospital located no more than 25 miles driving distance by automobile from the birthing center, which has an organized obstetrical service, as defined in these rules. The Transfer Agreement shall provide for the hospital's acceptance of referrals from the birthing center and phone consultations as needed to address emergency situations; the agreement shall address financial responsibility for services rendered. A birthing center is ineligible for licensure unless it has a Transfer Agreement with a licensed, qualified hospital. A written agreement with an emergency medical service (EMS) is also required for the transport of a patient or infant to the hospital named in the Transfer Agreement

(3) Type of License.

(a) Regular License. A regular license may be issued by the State Board of Health after the Board has determined that the birthing center is in substantial compliance with these rules.

(b) Probational License. At its discretion, the Board may grant a probational license when it determines that both of the following conditions exist:

1. The birthing center has engaged in one or more deficient practices which are serious in nature, chronic in nature, or which the birthing center has failed to correct; and

2. The birthing center's current governing authority has demonstrated the capability and willingness to correct cited problems and to maintain compliance.

(c) A probational license shall be granted for a specific period which may be extended, but which shall in no case exceed 1 year.

(4) Licensing.

(a) Application. Application for an initial license or renewal of a license shall be made on forms provided by the State Board of Health, including all information required by law, these rules, and the policies and procedures of the Department. An applicant shall submit such

additional information as shall be required by the Department in its discretion to demonstrate that the applicant has the ability and the willingness to comply with these rules. Each application shall be signed by a person authorized to bind the applicant to the representations in the application and shall include any supporting documentation with the application.

(b) Fee. An initial license application, an application for license renewal, or an application for a change in ownership shall be accompanied by the application fee specified in § 22-21-24, Code of Ala. 1975. An application for a name change is not subject to a license application fee. An application fee is non-refundable. Any application fee submitted in the incorrect amount shall nevertheless be deposited. If the fee submitted is too large, a refund for the difference shall be processed using the Department's usual procedures. If the fee submitted is too small, the applicant shall be notified, and the application shall not be considered until the difference is received. Any application submitted without any fee shall be returned to the applicant. If an incomplete application is submitted, the application fee shall be deposited, and the applicant shall be notified in writing of the defects in the application. If the applicant fails to submit all required additional information within 10 working days of the date of the notice, the application shall be denied. The Department may in its discretion extend the deadline for submitting additional information. Denial of an application as incomplete shall not prejudice the applicant from submitting a new application, accompanied by the requisite fee, at a future date.

(c) Renewal. A license, unless suspended or revoked, shall be renewable annually as a matter of course upon submission of a completed renewal application and payment of the required fee. When the Department has served written notice on a birthing center of its intent to revoke or downgrade the license, a renewal application shall be filed, but does not affect the proposed adverse licensure action.

(d) Name. Every birthing center shall be designated by a permanent and distinctive name which shall be used in applying for a license. No birthing center shall change its name without first applying for a change of name approval, nor shall it change its name until such approval is granted. The Department may, in its discretion, deny an initial birthing center application or an application for a change of name if the Department determines that the proposed name is misleading to the public or that the name is overly similar to the name of an already licensed birthing center. Separately licensed birthing centers owned by the same governing authority may have names that are similar to one another and distinguished from one another in some other manner, such as a geographic description. If an initial birthing center application is denied under this rule, the applicant shall be provided a reasonable period of time to submit a revised application with a different name. No freestanding birthing center shall include the word "hospital" in its name.

(e) Issuance of License. All licenses issued by the State Board of Health shall set forth the name of the birthing center, the physical address, the name of the licensee, and the license number.

(f) Separate License. A hospital-affiliated birthing center or facility is required to be licensed separately and may not operate under the license issued to the hospital.

(g) Posting of License. Licenses shall be posted in a conspicuous place on the licensed premises.

(h) License Not Transferable. The license shall not be transferable or assignable and shall be issued for the premises named in the application.

(i) Expiration of License. Each license shall expire on December 31 following the date of issuance.

(j) Condition of Licensure. It is a condition of licensure that the licensee must continuously occupy the licensed premises, remain open to the public as a birthing center, fully staffed and otherwise capable of admitting and treating patients. If a birthing center fails to remain open and staffed as required for 30 days, its license shall become void. If a licensee abandons the licensed premises, the license shall immediately become void.

(k) The following changes in the status of the birthing center will require issuance of a new license.

1. Change in facility ownership or operating entity (application fee required).

2. Change in facility name (no application fee required).

3. Relocation.

The governing authority shall file with the State Board of Health an application for license and application fee (if applicable) 30 days before any proposed change requiring a new license in order to permit processing of the application and issuance of the license prior to the desired effective date of the change.

(l) Denial and Revocation of a License.

1. The Board may deny a license to any applicant or suspend or revoke the license to operate a birthing center in any case in which it finds that there has been a substantial failure to comply with the requirements established under these rules or on grounds of insufficient evidence of the willingness or ability to comply with §§ 22-21-20 through 22-21-34, Code of Ala. 1975, or these rules. Each license shall be returned to the Board immediately upon its revocation or after the birthing center voluntarily ceases operation.

2. Hearing procedures concerning the denial, suspension, or revocation of a license shall be governed by the provisions of the Alabama Administrative Procedure Act, § 41-22-1, et seq., Code of Ala. 1975, and the Board's Rules for Hearing of Contested Cases, Chapter 420-1-3, Ala. Admin. Code.

(5) Failure to Renew a License. Any licensee who fails to renew a license on or before the close of business on the last business day in December shall be assessed a late fee equal to the amount of the original license fee. A license may only be renewed with the payment

of a late fee before the close of business on the last business day in January of any calendar year. A license which has not been renewed by the end of January has expired and shall be void.

(6) Compliance with Federal, State, and Local Laws. The birthing center shall be in compliance with applicable federal, state and local laws, including all applicable zoning ordinances. A birthing center may not be operated in a private residence.

(a) Licensing of Staff. Staff of the facility shall be currently licensed, certified or registered in accordance with applicable laws.

(b) Compliance with Other Laws. The birthing center shall comply with laws relating to fire and life safety, sanitation, communicable and reportable diseases, Certificate of Need review and approval, reporting of health care acquired infections, adverse event reporting, and other relevant health and safety requirements. If a birthing center utilizes the services of a clinical laboratory located outside the state of Alabama, the birthing center shall ensure that, in connection with any work performed for the birthing center, the laboratory complies with the requirements for the reporting of notifiable diseases to the Department, as set forth in state law and the rules of the Board.

(7) A birthing center shall promptly notify the Department in writing when there is any change in its accrediting organization or deemed status.

(8) Exceptions to Regulations. At its discretion, the State Board of Health may grant an exception to, or modify the application of, one or more provisions of these rules or reference codes for a period and under conditions, if any, determined by the Board. The exceptions or modifications shall be based on hardship, impracticality, or economic infeasibility in complying with the rules. The birthing center's request shall be in writing and shall state the specific provisions for which the exception or modification is requested and the reasons for each requested exception or modification.

(9) Disclosure of Information. Official reports, such as statements of deficiencies generated by the State Board of Health as a result of on-site inspections and plans of correction submitted in response to those statements of deficiencies, are subject to public disclosure. Information received through other means and reports, other than statements of deficiencies, shall be deemed to be confidential and shall not be publicly disclosed except in response to a valid subpoena or court order or in proceedings involving the birthing center's license or proceedings involving the license of another facility operated by the same governing authority. Inspection reports will never contain the name or other identification of any patient or client in the inspected facility.

Author: Dana Billingsley, Denise Milledge
Statutory Authority: Code of Ala. 1975, §22-2-2(6), et seq., §22-21-28, et seq.
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420-5-13-.02 Administration.

(1) Governing Authority.

(a) Responsibility. The governing authority is the person or persons responsible for the management, control, and operation of the birthing center, including the appointment of persons to fill the minimum staffing requirements. The governing authority shall ensure that the facility is organized, equipped, staffed, and administered in a manner to provide adequate care for each patient.

(b) The governing body shall be formally organized in accordance with a written constitution, bylaws, rules, or regulations. In the event the governing authority consists of one person, this requirement shall still be met. The written constitution, bylaws, rules, or regulations of the birthing center shall:

1. Specify by name the person to whom responsibility for operation and maintenance of the facility is delegated and methods established by the governing authority for holding such individuals responsible.

2. Provide for at least annual meetings of the governing authority. Minutes shall be maintained of such meetings.

3. Require policies and procedures to include provisions for administration and use of the facility, compliance, personnel, quality assurance, procurement of outside services and consultations, patient care policies, and services offered.

4. Provide for annual reviews and evaluations of the facility's policies and services offered.

(c) Contracted Services. The governing authority shall be responsible for services furnished in the birthing center, whether or not they are furnished under contracts. The governing authority shall ensure that a contractor of services furnishes services that permit the birthing center to maintain compliance with the requirements of these rules.

1. The governing authority shall ensure that the services performed under a contract are provided in a safe and effective manner.

2. The birthing center shall maintain a list of all contracted services, including the scope and nature of the services provided.

(d) The governing authority shall provide for the selection and appointment of the medical or nurse midwifery and nursing staff and the granting of clinical privileges and shall be responsible for the professional conduct of these persons.

(2) Administrator.

(a) Responsibility. The governing authority shall appoint a qualified person as administrator of the facility to represent the governing authority and shall define the administrator's authority and duties in writing. The administrator shall be responsible for the management of the facility, implementation of the policies of the governing authority, and authorized and empowered to carry out the provisions of these rules. Appropriate procedures to enforce these policies, assure proper patient care and safety, and meet requirements of these rules shall be developed in writing by an appropriate committee of professionals and shall be reviewed at least annually.

(b) There is a written plan in place for the operation of the birthing center in the administrator's absence.

(c) The governing authority of the facility shall notify the Department in writing of any change in the birthing center's administrator within 30 days of the effective date of such change.

(3) Personnel Records. The birthing center shall maintain a personnel record of each employee. At a minimum, the personnel record shall include a copy of the application for employment that contains information regarding education, experience, and if applicable, registration and/or licensure information of the applicant, all physical examinations, and evidence of continuing or inservice training and education. Personnel records shall be confidential. Representatives of the Department conducting an inspection of the facility shall have the right to inspect personnel records.

Authors: Dana Billingsley, Denise Milledge
Statutory Authority: Code of Ala. 1975, §22-2-2(6), et seq.; §22-21-20, et seq.
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420-5-13-.03 Medical Staff.

(1) Organization. There shall be an organized medical staff consisting of a minimum of one staff physician or consultant physician, and CNMs and RNs, having overall responsibility for the quality of all clinical care provided to patients, and for the ethical conduct and professional practices of its staff members.

(a) The medical staff shall be accountable to the governing authority and organized in a manner consistent with the facility's documented staff organization and bylaws, rules, and regulations.

(b) The medical staff shall conduct annual appraisals of its members, examine the credentials of candidates for medical staff membership, and make recommendations to the governing authority on the appointment of the candidates.

(2) The medical staff shall develop written policies and protocols for clinical care identifying the roles and responsibilities of each staff member and consultant. The organization

and policies and protocols of the medical staff shall be approved by the facility's governing authority. The policies and protocols shall require that patients are admitted to the birthing center only when they have been prescheduled to deliver there following a documented period of prenatal care for a normal, uncomplicated pregnancy which has been determined to be low risk through a formal risk assessment, and upon immediate evaluation by the medical staff to be low risk.

(a) Consultant Physician.

1. Services of a consultant physician are required in those birthing centers which do not have an Alabama licensed physician on the medical staff who is certified by the American Board of Obstetrics and Gynecology or the American Board of Osteopathic Obstetricians and Gynecologists. The consultant physician must have hospital obstetrical privileges with the hospital that is a party to the Birthing Center's Transfer Agreement and must be readily available within a reasonable time to assist at the birthing center when called.

2. The responsibilities and functions of the consultant physician shall be specifically described in the policy and procedure manual and the patient care protocols.

3. The governing body shall maintain a written agreement with each consultant physician who agrees to provide advice and services to the birthing center as requested.

4. If a birthing center does not have a staff physician and is unable to enter into an agreement with a consultant physician, the license of the birthing center shall be denied or suspended, and no patient services may be rendered until an agreement with a consultant physician is formalized.

(b) The initial appointment and continued medical staff membership shall be dependent upon professional competence and ethical practice in keeping with the qualifications, standards, and requirements set forth in the medical staff policies and protocols and governing authority bylaws, rules, and regulations.

(c) Hospital Privileges. The staff physician and/or consultant physician shall have full active privileges in obstetrics without restrictions at the birthing center's referral hospital.

(d) Staffing. There shall be a minimum of one licensed RN for every two patients. There shall be a staff or consultant physician or CNM at the birthing center when a patient is laboring, during delivery, and for at least 1 hour post-delivery. When the patient census exceeds the above, additional medical staff are to be called in or the patients are to be transferred to a hospital. There shall be an adequate number of medical and support staff on duty and on call to meet demands for services routinely provided and periods of high demand or emergency, to assure that no mother in active labor shall remain unattended.

(e) Licensure. All facility personnel shall be currently licensed to perform the services they render when such services require licensure under the laws of the state of Alabama.

(f) Health Examinations. At a minimum, each employee coming in contact with patients shall have a pre-employment health examination by a physician, certified registered nurse practitioner, or physician assistant. The examination is to be repeated annually and more frequently if indicated to ascertain freedom from communicable diseases. The extent of such examinations shall be determined by the governing authority in consultation with the staff physician or consultant physician and documentation made in the employee's personnel folder. The examination shall include a chest x-ray or a tuberculin test. Each employee must be offered a Hepatitis B vaccine and sign a written declination if the vaccination is refused. Documentation of immunization status for vaccine preventable diseases in pregnancy may be required.

(g) Malpractice Insurance. Medical staff and consulting specialists shall provide evidence of malpractice insurance coverage at the minimum level of $1 million. All medical staff will participate at least annually in staff development, including, but not limited to, recertification of adult and infant CPR training and education programs to maintain knowledge and skills used in birthing center practice.

(h) Nursing Service.

1. Staffing Pattern. There shall be 24-hour availability of qualified nursing staff as defined in these rules. An RN shall be in the birthing center whenever a patient is in labor, during birth, and throughout the postpartum period while a patient is in the center.

2. Nursing Care Plan. An RN must plan, supervise, and evaluate the nursing care of each patient from admission to discharge. Prior to discharge, each patient shall be given a referral with a specific time, date, and place for postpartum, family planning, and infant care. A 2-week health status of the baby shall be documented on the patient's record following review of records evidencing the pediatric or neonatal care provided at the birthing center or other facility.

3. LPNs who are currently licensed to practice within the state may provide nursing care that does not require the skill and judgment of an RN, under the supervision of an RN. LPNs providing such care shall maintain current certification in both adult and infant CPR.

(i) Certified Nurse Midwifery and Physician Service.

1. A CNM or the staff or consultant physician shall be in the birthing center when a patient is in labor, during birth, and for at least 1 hour postpartum, or longer if necessary. A physician obstetrician and pediatrician shall be available 24 hours a day for phone consultation pursuant to a written agreement with the birthing center.

2. There shall be a minimum of one CNM or physician for every two patients in the birthing center, to ensure that every patient in labor is attended.

3. Care policies and procedures shall be consistent with professionally recognized standards of the National Association of Childbearing Centers and shall be in accordance with the Nurse Practice Act and Medical Practice Act of the State of Alabama. Policies shall, at a minimum, include statements relating to the following:

(i) Diagnostic and therapeutic orders.

(ii) Assignment of care of patients.

(iii) Medication orders.

(iv) Charting.

(v) Infection control.

(vi) Patient and personnel safety.

(vii) Family centered maternity care.

(j) Inservice and Continuing Education. An inservice education program shall be provided for all staff members of the birthing center to improve existing practices, obtain new knowledge and skills, keep personnel informed of changes in policies and procedures, and discuss problems in the birthing center.

1. The inservice program shall be planned, scheduled, documented, and held monthly.

2. All medical staff shall participate annually in appropriate training programs for the safe and effective use of diagnostic and therapeutic equipment, for CPR, and infant resuscitation and transport.

3. All personnel shall have training that meets state and federal guidelines, as applicable, including, but not limited to, regulations of the Occupational Safety and Health Administration (OSHA), the Health Insurance Portability and Accountability Act (HIPAA), and Clinical Laboratory Improvement Amendments (CLIA).

Authors: Dana Billingsley, Denise Milledge
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420-5-13-.04 Informed Consent.

(1) Before admission to services, a patient shall be informed of:

(a) The qualifications of the birthing center medical staff.

(b) The risks related to out-of-hospital childbirth.

(c) The benefits of out-of-hospital childbirth; and

(d) The possibility of referral or transfer if complications arise during pregnancy or labor, with additional costs for services rendered by a referral hospital.

(2) The birthing center medical staff shall obtain the patient's written consent for birthing center services using the form, "Consent to Deliver in a Birthing Center," as provided by the Department.

(3) The signed consent form shall be included with the patient's individual clinical record.

Authors: Dana Billingsley, Denise Milledge
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420-5-13-.05 Patient Orientation and Preparation for Childbirth.

(1) Prior to admission for services, patients shall be fully informed of:

(a) The criteria adopted by the birthing center for the selection and admission of patients.

(b) The philosophy of the birthing center's governing body and medical staff regarding childbirth care and management, including the limited use of analgesics and anesthetics.

(c) The scope of services to be provided.

(d) The expectation that the patient and family will be responsible for self-care to the extent feasible and safe. Birthing centers shall not provide the level of care offered in an acute care hospital.

(e) The customary length of stay following delivery.

(f) The policies of the birthing center regarding transfer to hospitals with whom the birthing center has a written agreement.

(g) The qualifications of the medical staff.

(2) During the course of prenatal care, the patient and family, to the extent necessary, shall be counseled or instructed to prepare them for childbirth. At a minimum, the educational topics shall include:

(a) Anticipated changes during pregnancy.

(b) Need for prenatal care.

(c) Nutritional needs during pregnancy.

(d) Effects of smoking and substance abuse.

(e) Danger signs of preterm labor.

(f) What to expect during labor and delivery.

(g) Care and feeding of the newborn, including instruction on lactation (breast feeding).

Authors: Dana Billingsley, Denise Milledge
Statutory Authority: Code of Ala. 1975, §22-2-2(6), et seq.; §22-21-20, et seq.
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420-5-13-.06 Prenatal Visits.

(1) Medical practitioners shall follow the guidelines set forth by the American College of Obstetricians and Gynecologists for testing pregnant women for sexually transmitted diseases.

(2) Initial Visit.

(a) A comprehensive health history of the patient shall be completed, which includes medical, emotional, dietary, and obstetrical data, including a preterm delivery risk assessment.

(b) A physical examination of the patient shall be completed by the staff or consultant physician or CNM, including height and weight measurements; vital signs, including blood pressure; and examination of the skin, head and neck, heart and lungs, breasts, abdomen, pelvis, and neurologic reactions.

(c) The following tests are also required to be performed by a staff member or by qualified personnel:

1. Hemoglobin and hematocrit.

2. Urinalysis by dipstick for protein, sugar, and ketones.

3. Cervical cytology. Results of a cervical cytology done within 6 months is acceptable.

4. Rh determination and blood type.

(2) At a minimum, return visits shall include the following measurements and testing:

(a) Weight, blood pressure, fundal height, and fetal heart rate, as applicable.

(b) Urinalysis by dipstick for protein and sugar.

(c) Hemoglobin and hematocrit should be repeated at least twice and more often if indicated during the course of the pregnancy.

(d) Review of signs and symptoms of complications of pregnancy and risk status.

(e) Examination to determine the estimated weeks of gestation, fetal position, and presentation.

(3) Return prenatal visits shall be scheduled at least every 4 weeks until the 28th week, every 2 weeks until the 36th week, and then every week until delivery, unless more frequent monitoring is required. Patients must be evaluated at their initial prenatal visit and regularly throughout their pregnancy, with a copy of each performed risk assessment retained in their file, to assure that they remain at low risk for a poor pregnancy outcome.

(4) All patients shall receive specific instruction regarding preterm labor, including the potential hazards, preventive measures, symptoms, detection and timing of contractions, and the need for prompt notification of the health provider.

(5) All patients found to be at obstetrical risk pursuant to the Risk Status Criteria set forth in these rules shall be referred to a qualified local physician, certified by the American Board of Obstetrics and Gynecology or the American Board of Osteopathic Obstetricians and Gynecologists, for continued care.

Authors: Dana Billingsley, Denise Milledge
Statutory Authority: Code of Ala. 1975, §22-2-2(6), et seq.; §22-21-20, et seq.
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420-5-13-.07 Intrapartum Care.

(1) A member of the medical staff shall be present or available to the patient at all times throughout her stay in the birthing center.

(2) The medical staff shall monitor the progress of labor and condition of the mother and fetus at sufficiently frequent intervals to identify abnormalities or complications as soon as possible.

(3) The patient shall be transferred to a hospital if complications requiring medical or surgical intervention occur, as set forth in the Risk Status Criteria established in these rules.

(4) The patient's family or persons offering her support shall be instructed as needed to assist the patient during labor and delivery.

(5) Labor shall not be inhibited, stimulated, or augmented with drugs administered in the birthing center except when the patient is to be transported immediately to the hospital and the drug is prescribed by the medical consultant or physician who will manage the continued care of the patient.

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420-5-13-.08 Surgical Services and Use of Analgesics and Anesthetics.

(1) No surgical procedures shall be performed in the birthing center except episiotomy, repair of episiotomy or laceration, or circumcision.

(2) Systemic analgesics and local anesthetics may be administered under the following conditions:

(a) The medical staff member who administers the systemic analgesic is legally authorized to do so and shall be present in the birthing center during the use of intravenous analgesics.

(b) The dosage and drugs are specifically noted in the protocols for clinical services.

(c) The use of such drugs is in conformance with the policies and procedures of the birthing center.

(3) General and conduction anesthesia shall not be administered at birthing centers.

Authors: Dana Billingsley, Denise Milledge
Statutory Authority: Code of Ala. 1975, §22-2-2(6), et seq.; §22-21-20, et seq.
History: Filed November 19, 1987. **Repealed:** Filed April 16, 2010; effective May 21, 2010.
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420-5-13-.09 Postpartum Care.

(1) A prophylaxis shall be instilled into each eye of the newborn.

(2) A cord blood sample shall be secured for laboratory testing for type, Rh determination, and direct Coombs test when the mother is Rh negative.

(3) The newborn shall be weighed, measured, and examined for abnormalities and complications. An identification tape shall be placed on all newborns.

(4) One-half milligram of Vitamin K shall be administered to the newborn within 24 hours after birth.

(5) The newborn shall be referred to a qualified physician or hospital care if the following conditions occur:

(a) Low birth weight (under 2,500 grams).

(b) Apgar score of 7 or less at 5 minutes.

(c) Signs of pre- or post- maturity.

(d) Jaundice.

(e) Persistent hypothermia consisting of a body temperature of less than 97° F for more than 2 hours after birth.

(f) Respiratory difficulties.

(g) Major congenital anomalies.

(h) Exaggerated tremors.

(i) Any other condition requiring medical care.

(6) The condition of the mother shall be monitored frequently to detect signs of hemorrhage or other complications requiring prompt transfer to a physician or hospital.

(7) Adequate nutrition must be provided to the patient during her stay at the birthing center, as evidenced by written dietary requirements on file at the facility.

(8) The mother and infant shall be discharged from the birthing center within 24 hours after the birth occurs, except under the following conditions:

(a) The mother is in a deep sleep when the 24-hour period is completed. In this case, the mother shall be discharged as soon after waking as is feasible; or

(b) The 24-hour period is completed between the hours of 10 p.m. and 6 a.m.

(9) If the mother or infant is retained at the birthing center longer than 24 hours after the birth, a report shall be filed with the Division of Licensure and Certification within 48 hours after the birth, describing the circumstances and reasons for retention.

(10) A postpartum examination shall be performed on the patient within 72 hours after delivery and at approximately 4 to 6 weeks after delivery.

(a) The patient examination within 72 hours shall include, at a minimum:

1. Interval history.

2. Blood pressure measurement.

3. Observation of the breasts, perineum, and abdomen.

(b) The patient examination at 4 to 6 weeks shall include all of the above and:

1. Weight

2. Hemoglobin and hematocrit.

3. Bi-manual pelvic examination.

(11) The mother shall be counseled regarding breastfeeding, perineal care, family planning, signs of common complications, activities and exercises, sex relations, care and feeding of the newborn, and changing family relationships.

(12) Observation of the Newborn at 72 hours and 4 to 6 Weeks. A metabolic screening test shall be performed on the newborn at 72 hours and shall include, at a minimum, hypothyroidism and phenylketonuria. Sickle cell testing should be included if indicated.

(13) The parents shall be instructed in the importance of immunization and a 2-week screening for the newborn in accordance with the American Academy of Pediatrics schedule of visits. Parents shall also be instructed in the importance of repeat metabolic screening starting at several weeks of age. The parents shall be referred to providers of pediatric care if not provided on site.

(14) If complications in the mother or newborn occur during the postpartum period, a consultation or referral shall be made to the appropriate source of secondary or tertiary care.

(15) If the mother refuses to permit eye prophylaxis, Vitamin K injections, or a metabolic screening test prophylaxis for the newborn due to religious beliefs, a waiver indicating this decision shall be signed by the mother, witnessed by a medical staff member, and filed with the clinical record.

Authors: Dana Billingsley, Denise Milledge
Statutory Authority: Code of Ala. 1975, §22-2-2(6), et seq.; §22 - 21-20, et seq.
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420-5-13-.10 Management of Emergencies.

(1) The patient shall be transferred when necessary from the birthing center to a hospital with which a written Transfer Agreement is in effect.

(a) If the patient is unable to ride in an upright position or if the patient's condition is such that she needs observation or treatment by EMS personnel, or if the patient requires transportation on a stretcher, gurney, or cot, the birthing center shall arrange or request transportation services only from providers who are ambulance service operators licensed by the Alabama State Board of Health. For the purposes of this rule, an upright position means no more than 20° from vertical.

(b) A trained RN must accompany the patient and infant when transportation to the referral hospital is required via an emergency vehicle.

(2) The birthing center shall have a written protocol which shall include:

(a) The name, address, telephone numbers, and contact persons of the licensed ambulance service; identify the hospital under written agreement with the birthing center to provide emergency obstetrical and neonatal services; and list other hospitals in the vicinity.

(b) The conditions specified in the arrangements between the birthing center, the ambulance service, and the referral hospital, including financial responsibility for services rendered.

(c) The Risk Status Criteria requiring medical consultation with a qualified physician certified by the American Board of Obstetrics and Gynecology or the American Board of Osteopathic Obstetricians and Gynecologists or transfer to the birthing center's referral hospital, including, but are not limited to:

1. Premature labor, meaning labor occurring at less than 37 weeks gestation.

2. Estimated fetal weight less than 2,500 grams or greater than 4,000 grams.

3. Hypertension.

4. Pre-eclampsia.

5. Failure to progress in labor.

6. Evidence of an infectious process.

7. Premature rupture of the membranes, meaning rupture occurring more than 12 hours before onset of active labor.

8. Suspected placenta praevia or abruption.

9. Non-vertex presentation.

10. Hemorrhage of greater than 500 cc of blood.

11. Anemia, consisting of less than 10 grams of hemoglobin per 100 milliliters of blood or 30 percent hematocrit.

12. Persistent fetal tachycardia (heart rate more than 160 beats per minute), repetitive fetal bradycardia (heartbeat less than 120 beats per minute), or undiagnosed abnormalities of the fetal heart tones.

13. Persistent hypothermia in the newborn.

(d) Criteria to determine risk status which requires immediate emergency transfer include, but are not limited to:

1. Prolapsed cord.

2. Uncontrolled hemorrhage.

3. Placental abruption.

4. Convulsions.

5. Major anomaly of the newborn.

6. Apgar score of 7 or less at 5 minutes.

7. Fetal heart rate of 90 or less beats each minute for 3 minutes.

8. Thick meconium staining at the time of membrane rupture.

9. Respiratory distress in the newborn.

10. Weight less than 2,500 grams.

(e) The criteria and protocols for transfer shall be readily accessible to medical staff members at all times.

(3) The name and telephone numbers of the licensed ambulance services, neonatal transport service, and referral hospital shall be clearly posted at each telephone in the birthing center.

(4) A written report of the transfer shall be provided and retained for quality assurance review and Departmental inspection. The report shall include:

(a) The patient's name.

(b) The date of the event.

(c) The reason for transfer.

(d) The provider and mode of transportation to the hospital.

(e) The exact time of the initial call and of any subsequent calls.

(f) Time of arrival of the emergency personnel.

(g) Time of the patient's departure from the birthing center.

(h) Time of arrival at the hospital.

(i) Name of the receiving hospital.

(j) Details concerning the initiation of EMS.

(k) The condition of the patient at the time of transfer.

(l) Any information regarding the medical care of the patient and outcome.

(5) The medical staff, consultants, and governing authority shall review and evaluate the criteria, protocols, and emergency transfer reports on a monthly basis. The results of the evaluation shall be documented.

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420-5-13-.11 Patient Records.

(1) Medical Records to be Kept. A birthing center shall keep adequate records, including, but not limited to, admission and discharge notes, histories, physical examinations, nurses notes, anesthesia/analgesic records, informed consent, follow-up care, and records of tests performed. The patients' records shall be current and kept with sufficient detail, consistent with good medical and professional practice, based on the services provided to each patient.

(2) Authentication of Records. All records shall be written, dated, and signed in an indelible manner and made part of the patient's permanent record.

(3) Indexes. All health records should be indexed according to patient's name.

(4) Facilities. A room or area shall be designated for maintaining paper copies of patient health records within the birthing center. The area shall be sufficiently large and adequately equipped to permit the proper processing and storing of records and to protect them from fire or water damage. Access to electronic health records shall be properly secured and restricted to the birthing center's medical staff. All health records must be readily accessible to the medical staff.

(5) Ownership. Health records shall be property of the facility and shall not be removed except by subpoena or court order. These records shall be protected against loss, destruction, and unauthorized use; responsibility for the control of all such records shall rest with the administrator and the governing authority. A copy of the health record will accompany the patient at transfer and be made available to the receiving physician or hospital.

(6) Preservation of Records. Health records shall be preserved either in the original form, by microfilm, or in electronic form for a period of not less than 6 years following the most recent discharge of the patient. In the case of a minor, records shall be kept for 6 years after obtaining legal age. Mother and infant records shall be kept together.

(7) Records Are Confidential. Records and information regarding patients shall be confidential. Access to these records shall be determined by the governing authority of the facility; however, patients have a right to access information contained in their medical records within a reasonable timeframe. Inspectors for licensure or other persons authorized by state or federal law shall be permitted to review medical records as necessary to determine compliance.

(8) Individual Patient Records. Each patient's health record shall include, but is not limited to, at least the following information:

(a) Demographic information and patient identification.

(b) Orientation to program and informed consent.

(c) Complete social, family, medical, reproductive, nutrition, and behavioral history.

(d) Initial physical examination, laboratory tests, and evaluation of risk status.

(e) Appropriate referral of ineligible patients with report of findings on initial screening.

(f) Development of a plan for care.

(g) Continuous periodic prenatal examination and evaluation of risk factors including documentation of prenatal care provided outside the center at related practitioner or clinic sites.

(h) Instruction and education including nutritional counseling, changes in pregnancy, self-care in pregnancy, orientation to health record and understanding of findings on

examinations and laboratory tests, preparation for labor, sibling preparation, preparation for early discharge, newborn assessment and care, and feeding and medical evaluation.

(i) History, physical examination, and risk assessment on admission to center in labor (labor graph).

(j) Evaluation of progress in labor with ongoing assessment of maternal and newborn reaction to the process of labor.

(k) Consultation, referral, and transfer for maternal or neonatal problems that elevate risk status.

(l) Physical assessment of newborn including apgar scores, maternal newborn interaction, prophylactic procedures, postpartum monitoring of vital signs, and accommodation to extrauterine life.

(m) Labor summary.

(n) Discharge summary for mother and newborn.

(o) Plan for home care, follow-up, and referral to support groups.

(p) Plan for newborn health supervision and required screening tests.

(q) Late postpartum evaluation of mother, counseling for family planning and other services, and evaluation of mother-child relationships.

(r) Eye care, vitamin K.

(s) All entries shall be dated and signed by the attending professional staff members.

(9) Confidentiality. The clinical record is confidential and shall not be released without the written consent of the patient except under the following conditions:

(a) When the patient is transferred to another source of care.

(b) For audit by the Department during licensure inspection.

(c) In response to a lawfully issued subpoena or court order.

(10) Completion of records. All health records shall be completed promptly. Reports of laboratory tests, treatments, and consultations shall be entered promptly on the health record.

(11) Vital Statistics Report. A record shall be kept of all births, deaths, and stillbirths that occur within the birthing center.

(a) A record shall be kept of all births, deaths, and fetal deaths that occur within the birthing center.

(b) A certificate of birth for each live birth shall be filed with the Office of Vital Statistics, or as otherwise directed by the State Registrar, within 5 days after the birth, in accordance with Code of Ala. 1975, § 22-9A-7 and Ala. Admin. Code r. 420-7-1-.03.

(c) A report of fetal death shall be filed with the Office of Vital Statistics, or as otherwise directed by the State Registrar, within 5 days after the occurrence is known if the fetus has advanced to, or beyond, the 20th week of uterogestation, in accordance with Code of Ala. 1975, § 22-9A-13 and Ala. Admin. Code r. 420-7-1-.03.

(d) A certificate of death shall be filed with the Office of Vital Statistics, or as otherwise directed by the State Registrar, within 5 days of the death, in accordance with Code of Ala. 1975, § 22-9A-14 and Ala. Admin. Code r. 420-7-1-.03 and -.10.

(e) If a record of death or fetal death has not been created in the state's electronic registration system, the person in charge of the birthing center or its designated individual must report to the Office of Vital Statistics, or as otherwise directed by the State Registrar, any dead body or fetal death no later than the 5th day of the following month of which the body was handled by the birthing center.

(f) All records and reports registered by the birthing center with the Office of Vital Statistics shall be in a format prescribed by the State Registrar.

(12) Disposition of Records. When a birthing center ceases to operate either voluntarily or by revocation of its license, the governing body shall develop a proposed plan for the disposition of its medical records. Such plan shall be submitted to the State Board of Health and shall contain provisions for the proper storage, safeguarding, and confidential transfer and/or disposal of patient medical records and x-ray files. Any birthing center that fails to develop a plan for disposition of its records acceptable to the State Board of Health shall dispose of its records as directed by a court of appropriate jurisdiction.

(13) System of Periodic Review. There shall be a system for periodic record review and documentation of issues and outcomes.

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420-5-13-.12 Rights and Responsibilities of the Patient and Her Family.

(1) The rights and responsibilities of the patient and her family, however defined, shall be clearly delineated in the birthing center's policies and procedures and communicated on the patient's admission for care. All patients have a right to:

(a) Be treated with respect, dignity, and consideration.

(b) Be assured of confidentiality.

(c) Be informed of the benefits, risks, and eligibility requirements for care in the birthing center.

(d) Be informed of the services provided by the birthing center and those provided by contract, consultation, and referral.

(e) Be informed of the identity and qualifications of care providers, consultants, and related services and institutions.

(f) Have access to their medical records and all results of screening or diagnostic studies.

(g) Be informed of all diagnostic procedures and reports, recommendations, and treatments.

(h) Participate in decisions relating to the plan for management of the patient's care and all changes in that plan, once established, including referral or transfer to other practitioners or other levels of care.

(i) Receive a written statement of fees for services and responsibilities for payment.

(j) Be informed of the birthing center's plan for the provision of emergency and nonemergency care in the event of complications to mother or newborn.

(k) Receive a written statement of the birthing center's plan and the family's responsibility to ensure adequate supportive home care and follow-up health supervision of the mother and infant.

(l) Be informed of, and reserve the right to refuse, participation in research or student education programs.

(m) Be informed of the birthing center's policy for hearing grievances. The telephone number to register complaints with the Alabama Department of Public Health, Division of Health Care Facilities, shall be posted in a prominent location and shall be included in the written material given to the patient upon discharge. A grievance log, including the nature of the complaint and its resolution, shall be maintained by the birthing center and made available for inspection by the Department on its request.

(n) Be informed of the liability insurance status of the medical staff.

(2) The birthing center shall provide or demonstrate its availability to provide a range of services to meet the physical, emotional, socio-economic, informational, and medical needs of the individual patient while under care, including, but not limited to:

(a) An orientation to the facility fees and services of the birthing center.

(b) Written information, including a glossary of terms, on the established criteria for admission to, and continuation in, the birthing center's program of care.

(c) Prenatal care (may be provided at a related practitioner or clinic site).

(d) A program of education for pregnancy, labor, breastfeeding, infant care, early discharge, parenting, self-care/self-help, and sibling preparation.

(e) Laboratory services.

(f) Twenty-four hour telephone consultation services.

(h) Intrapartum care.

(i) Light nourishment during labor and postpartum.

(j) Immediate postpartum care.

(k) Home or office follow-up for mother and newborn.

1. Additional options:

(i) Exercise programs.

(ii) Parent support groups.

(iii) Postpartum classes.

(iv) Family planning.

(v) Well baby care.

(vi) Circumcision.

(vii) Nursing mother support programs.

(viii) Well woman gynecologic care.

(ix) Public education.

(x) Professional education.

(xi) Clinical investigation and/or research.

(3) The birthing center shall inform patients that drugs for induction or augmentation of labor, vacuum extractors, and forceps are not necessary during normal labor and are not appropriate for use in birthing centers. Patients must be provided with and consent to this policy.

(4) The birthing center's policy and procedure manual shall include all aspects of birthing center practice and care and shall be made available to practitioners and support staff at all times.

(5) The birthing center's practice protocols must be approved by the staff or consultant physician and made available to the hospital receiving transfers upon request.

Authors: Dana Billingsley, Denise Milledge
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420-5-13-.13 Quality Assurance.

(1) There shall be a quality assurance program consisting of an interdisciplinary committee which shall perform quality assurance reviews for maternal and newborn care provided in the birthing center, including, but not limited to:

(a) At least annual review of protocols, policies, and procedures relating to the maternal and newborn care.

(b) The appropriateness of the Risk Status Criteria for determining eligibility for admission to and continuation in the birthing center's program of care.

(c) The appropriateness of diagnostic and screening procedures, including laboratory studies, sonography, and nonstress tests, and their impact on quality of care and patient cost.

(d) The appropriateness of medications prescribed, dispensed, or administered in the birthing center.

(e) Performance evaluations of medical and support staff employed by the birthing center (peer review-self evaluation).

(f) Quarterly meetings of medical staff to review the management of care of individual patients and make recommendations for improving the plan for care.

(g) Quarterly review of all transfers of mothers and neonates to hospital care, to determine the appropriateness and quality of the transfer.

(h) Immediate review and evaluation of all complications of pregnancy, labor, and postpartum periods arising in the birthing center and the appropriateness of medical staff's consultation and treatment of the same.

(i) Evaluation of staff's ability to manage emergency situations via unannounced periodic drills for fire, maternal/newborn emergencies, power failures, etc.

(2) Patient records shall be audited by the medical staff at least every 3 months and a sample audited by the quality assurance committee at least every 6 months. The audit shall evaluate the following:

(a) Initial history, physical examination, risk assessments, and laboratory tests.

(b) Documentation of clinical observations, examinations, and treatments.

(c) Evidence that appropriate actions have been taken in response to clinical findings.

(d) Counseling, education, consultation, and referral activities are recorded.

(e) Consent forms are signed.

(f) All entries are legible, dated, and signed in ink or typed.

(3) The quality assurance committee shall analyze the incidence of maternal and perinatal morbidity and mortality, obstetrical risk assessments, pre-term labor risk assessments, consultant referrals and outcomes, and transfers of care and outcomes.

(4) The quality assurance program ensures quality of care to patients and the community through an effective system for collection and analysis of data, which includes, but is not limited to, utilization of information obtained through the following:

(a) Orientation sessions.

(b) Patient registrations.

(c) Women attending educational programs at the birthing center.

(d) Total number of encounters/visits antepartum.

(e) Number of and reasons for antepartum transfers.

(f) Intrapartum care admissions.

(g) Number of and reasons for intrapartum transfers.

(h) Time in the birthing center before delivery.

(i) Births occurring in the birthing center.

(j) Births occurring en route to the birthing center.

(k) Time in birthing center after delivery.

(l) Number of and reasons for maternal postpartum transfers.

(m) Number of and reasons for newborn transfers.

(n) Postpartum home visits.

(o) Follow-up maternal postpartum office visits.

(p) Follow-up newborn office visits.

(q) Total classes conducted antepartum.

(r) Total classes conducted postpartum.

(s) Outcomes of care provided.

1. Spontaneous abortions.

2. Type of anesthesia/analgesia used.

3. Type of delivery.

4. Place of delivery.

5. Complications of delivery.

6. Episiotomies, lacerations.

7. Infants with birth weight below 2,500 grams or over 4,000 grams.

8. Apgar scores.

9. Neonatal morbidity/mortality.

10. Maternal morbidity/mortality.

11. Maternal or newborn admissions from home to hospital in a 4-week postpartum period.

(5) Professional Accreditation. The birthing center must apply for and obtain accreditation from the Commission for the Accreditation of Birth Centers or another nationally recognized accrediting organization, in addition to acquiring a license.

(6) Yearly Evaluation. The birthing center shall assess the needs of the childbearing community and continue to develop services and programs to address the following:

(a) The general geographical area to be served.

(b) Demographic data and vital statistics of the community to be served.

(c) Availability of and access to maternal and newborn services, including practitioners, hospital obstetrical and newborn services, home birth services, family-centered maternity care programs, birthing rooms/suites, clinics for disadvantaged families, laboratory services, supplementary social and welfare services, childbirth education, and parental support programs.

(d) Periodic market surveys to determine the impact of the birthing center on the community and to assess the needs of childbearing families in the population served, for purposes of program planning and development.

(e) Changes in population, environment, regulations, legislation, reimbursement, and access to and availability of maternal and newborn services in the community.

(7) Reports of the quality assurance committee shall be given to the governing body.

(8) The governing body shall examine the reports of the quality assurance committee and shall make such reports available for inspection by the public and licensing authorities.

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420-5-13-.14 Reports.

(1) An annual report shall be created by the birthing center no later than the 30th day of the month following the end of the calendar year and kept on file by the facility. At a minimum, the report shall contain the following information and shall be made available for inspection by the Department upon its request:

(a) Name and address of the birthing center.

(b) Number of patients accepted for care during the reporting year.

(c) Number of deliveries and number of deliveries of newborns less than 2,500 grams.

(d) Number of transfers to hospitals, the reasons for transfer, and outcomes.

(e) Number of maternal and newborn deaths and stillborns associated with birthing center patients.

(f) Range and average length of stay in hours.

(g) Range and average length of stay after birth in hours.

(h) The nature and number of surgical procedures performed in the birthing center.

(i) Any other additional information the Department may require.

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420-5-13-.15 Pharmaceutical Services.

(1) Administering Drugs and Medicines.

(a) Drugs and medicines shall not be administered to patients unless ordered by a physician duly licensed to prescribe such drugs, or, by a licensed CNM, as authorized by the CNM's collaborative practice protocol or formulary pursuant to the rules of the Alabama Board of Nursing and the Alabama State Board of Medical Examiners, as applicable, and approved protocols. Such orders shall be in writing and signed personally by the prescriber.

(b) All verbal or telephone orders for medication shall be received by a RN, LPN, CNM, physician, or registered pharmacist and shall be placed in writing into the patient's permanent medical record. The order shall include the name of the prescribing physician or CNM, accompanied by the time, date, name, and title of the person making the entry into the record. All verbal or telephone orders shall be countersigned by the prescriber within 48 hours of the order.

(c) All treatments and medications provided to patients shall be recorded in the medical record by the nurse administering the treatment or medication.

(d) Preparation and administration of medications shall be under the supervision of a physician or CNM. Pain control should depend primarily on close emotional support and adequate preparation for the birth experience.

(e) The birthing center shall not dispense any medications to outpatients. The birthing center may procure medications for its patients from community pharmacists through approved contractual agreements. Individual medication containers shall be properly stored in individual patient bins/trays within a lockable area, room or cabinet; or the facility may procure medications via the staff physician's or CNM's registration. Medical staff shall administer or order medications to be administered to patients solely while in the birthing center. Medications for patients to take home shall be provided via written prescription by the attending physician or CNM.

(f) An individual qualified by licensure and experience to meet the requirements of subsections (d) and (g) of this section shall be responsible for the overall supervision of the handling, administration, storage, record-keeping, and final disposition of medications and controlled substances stocked within the birthing center.

(g) Prescribing, dispensing, and administration of medications shall meet all standards required by law and by regulations of the Alabama Board of Medical Examiners, the Alabama Board of Pharmacy, and the Alabama Board of Nursing.

(2) Medicine Storage.

(a) Medicines and drugs maintained in the birthing center shall be stored in a drug room of sufficient size for orderly storage and accurate identification. The room shall be adequately illuminated and maintained at a temperature for safe storage of drugs.

(b) Safety. Drug rooms shall be provided with safeguards to prevent entrance of unauthorized persons, including bars on accessible windows and locks on doors. Controlled drugs and ethyl alcohol, if stocked, shall be stored under double locks and in accordance with applicable federal and state laws.

(c) Only authorized personnel shall have access to the drug/medicine room, as defined by the birthing center.

(d) The drug/medicine room shall be provided with a counter and sink.

(3) Emergency Kit. The birthing center, upon the written advice and written approval of its staff or consultant physician, shall provide an emergency kit or stock supply of drugs and medicines for the exclusive use of the physician or CNM in treating the emergency needs of patients.

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420-5-13-.16 Laboratory Services.

(1) The birthing center may provide a clinical laboratory or make contractual arrangements with a certified laboratory to perform services commensurate with the needs of the birthing center and the laboratory's level of certification.

(a) Outside Laboratory.

1. Qualifications. An approved outside laboratory may be a state licensed hospital laboratory or state licensed independent clinical laboratory and must have a current federal CLIA number.

2. A contractual arrangement shall be deemed as meeting the requirements of this rule so long as the arrangement includes written policies, procedures, and individual chart documentation evidencing that the policies of the birthing center are met and the needs of the patients are being provided, including the processing of specimens and reporting of test results to the birthing center on a 24/7 basis, as the demands of labor and delivery require.

(b) In-House Laboratory.

1. In-house laboratory services shall be well organized and under the direction and supervision of an individual meeting the qualifications set forth in the Department's Rules and Regulations for Independent Clinical Laboratories and CLIA regulations, based on the level of laboratory testing performed.

2. The laboratory must be of sufficient size and adequately equipped to perform the necessary services of the birthing center.

3. Provisions shall be made for a preventive maintenance and an acceptable quality control program covering all types of analyses performed by the laboratory. Documentation must be maintained for both programs.

4. Written policies and procedures shall be developed and approved for all services provided by the laboratory.

5. Documentation of patient laboratory values shall be recorded on appropriate laboratory report forms and duplicate copies of these reports retained for a minimum of 2 years in the laboratory.

6. Contractual arrangements for referral laboratory testing shall be made in accordance with subsection (1)(a) above for laboratory testing procedures not provided by the in-house laboratory.

7. If medical laboratory technologists are employed on staff, such technologists must meet one of the following requirements:

(i) Successful completion of 2 years of academic study (a minimum of 60 semester hours or equivalent) in an accredited college or university, with an associate degree as a medical laboratory technologist; or

(ii) Graduation from high school, and subsequent to graduation, 2 years of documented, hands-on experience as a technician trainee in a clinical laboratory of a hospital, health department, university, or medical research institution, or in a clinical laboratory providing equivalent hands-on training accepted by the Alabama Department of Public Health; or

(iii) Graduation from high school and successful completion of an official military laboratory procedures course of at least 12 calendar months of study, with at least 1 year of hands-on experience as a technician trainee in a clinical laboratory of a hospital, health department, university, or medical research institution, or in a clinical laboratory providing equivalent hands-on training accepted by the Alabama Department of Public Health.

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420-5-13-.17 Physical Environment.

(1) Safety. The governing authority shall develop written policies and procedures designed to safeguard patients, staff, and visitors while in the birthing center and on its grounds. The policies and procedures shall include the following:

(a) Safety rules and practices pertaining to personnel, equipment, liquids, and drugs, with particular attention to hazards of children, such as uncovered electrical outlets, unsafe toys, unprotected stairs, and unlocked storage cabinets, as well as walkways, parking lots, and outside play areas.

(b) Provisions for reporting and investigation of accidental events regarding patients, visitors, and personnel (incidents), and corrective actions taken.

(c) Provision for dissemination of safety-related information to employees and users of the facility.

(d) Provision for syringe and needle storage, handling, and disposal.

(e) Provide a security service and/or specific protocols to screen family members and visitors, restrict entry to the birthing center during certain hours, and prevent newborn abductions.

(2) Housekeeping/Sanitation. The birthing center shall provide a safe and sanitary environment, properly constructed and maintained to protect the health of patients.

(a) The birthing center shall be maintained in a clean condition. The birthing rooms shall be appropriately cleaned after each birth, using appropriate disinfectants to assure asepsis between each use, as approved by the Infection Control Committee.

(b) The premises and equipment shall be kept clean and free of insects, rodents, litter, and rubbish.

(c) There shall be strict shall adherence to regulations of the United States Occupational Safety and Health Administration for handling of medical waste, regulations of the Alabama Department of Environmental Management, and other applicable federal regulations for disposal of medical waste (medical waste includes, but is not limited to disposable gowns, soiled dressings, sponges, surgical gloves, bacteriological cultures, blood and blood products, excretions, secretions, other bodily fluids, catheters, needles, IV tubing with needles attached, scalpel blades, glassware, and syringes that have been removed from their original sterile containers).

(d) Adequate arrangements for housekeeping staff shall be made, or housekeeping staff shall be employed to fulfill the above requirements. Primary patient care personnel shall not perform routine decontamination and housekeeping duties during periods in which they are caring for patients.

(3) Linen and Laundry.

(a) An adequate supply of clean linen or disposable materials shall be available at all times for the proper care and comfort of patients.

(b) Provisions for proper laundering of linen and washable goods shall be made. Linens used for draping must be sterilized. All reusable linens, including those used as sterilizing wrappers, must be laundered before reuse. Linens shall be handled, stored, processed, and transported in such a manner as to prevent the spread of infection. Soiled and clean linen must be handled and stored separately.

(c) A sufficient supply of cloth or disposable towels shall be available so that a fresh towel can be used after each hand washing. Towels shall not be shared.

(4) Disaster Preparedness.

(a) The facility shall have a posted plan for evacuation of patients, staff, and visitors in case of fire or other emergency.

(b) Fire Drills.

1. At least one fire drill shall be held every 3 months to familiarize employees with the drill procedure. Reports of the drills shall be maintained with records of attendance.

2. Records shall show that action has been taken to correct any identified problems with fire drills.

(5) Infection Control.

(a) An Infection Control Committee, or comparable group, comprised of the staff or consultant physician and members of the nurse-midwifery staff, nursing staff, administration, and other services of the birthing center, shall be established and shall be responsible for investigating, controlling, and preventing infections in the birthing center. The Infection Control Committee shall meet quarterly and maintain written documentation and an attendance roster for all such meetings.

(b) There shall be written procedures to govern the use of aseptic techniques and procedures in all areas of the birthing center.

(c) To keep infections at a minimum, such procedures and techniques shall be reviewed on an annual basis by the Infection Control Committee.

(d) Continuing education shall be provided on an annual basis to all birthing center personnel on the causes, effects, transmission, prevention, and elimination of infection.

(e) Reports of infections observed during any follow-up or return visit of the patient shall be made and kept as a part of the patient's medical record. The birthing center shall maintain a surveillance logbook recording all follow-up visits and telephone inquiries in which infections or other complaints are reported or observed. This logbook shall be reviewed at least once quarterly by the facility's staff or consultant physician.

(f) Efforts shall be made to determine the origin of any infection and if the birthing process was found to be related to acquiring the infection, remedial action shall be taken to prevent recurrence.

1. In the event of sustained numbers of infections (3 or more patients in 1 week), the Department shall be immediately notified. Upon order of the Department, operation of the birthing center shall be discontinued until approval for continuation of operation is granted by the Department.

2. If the birthing center wishes to contest such closure, the Department shall provide an opportunity for a hearing under the contested case provisions of the Alabama Administrative Procedure Act. Such hearing shall be held not more than 2 working days after notice of appeal is given to the Department, unless the birthing center agrees otherwise. The birthing center shall be entitled to full rights of appeal from any adverse decision rendered as a result of the hearing, in accordance with state law.

(g) Written policies and procedures shall be developed to ensure that employees with any communicable disease in an infectious stage shall not be on duty in the birthing center.

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420-5-13-.18 Service Facilities, Equipment, and Supplies.

(1) The birthing center shall establish and maintain a safe environment for healthy women anticipating an uncomplicated labor and birth, with adequate space for furnishings, equipment, and supplies necessary to ensure comfortable and private accommodations for the mother and family, and adequate space for personnel, including but not limited to:

(a) Admissions Office. There shall be a room designated as the admissions office, where patients may discuss personal matters in private. The admissions office may be combined with the business office and medical record room if privacy can be maintained when confidential matters are being discussed. This space shall be separated from the treatment area by walls.

(b) Business Office. This space shall be adequate for the number of birthing center personnel.

(c) Reception and Waiting Area. A waiting room shall be provided with sufficient seating for the maximum number of persons that may be waiting at any time, depending on whether prenatal care is provided in the birthing center. Public toilets, telephones, and drinking fountains, accessible to the handicapped, shall be available.

(d) Staff/Employee Locker Rooms and Toilets. The birthing center shall provide male and female toilet and locker rooms, which are centrally located.

(e) Family Room and Play Area for Children. The size and number of family rooms shall be adequate for the patient caseload. A couch, chairs, end table, reading lights, and toy storage area shall be included. Sufficient precautions for child safety shall be observed. Depending on the size of the caseload, the family area may double as a conference room and/or classroom. Toilet facilities shall be available.

(f) Conference/Educational Facilities/Library Area. These areas may be one room or separate rooms; however, each area shall be of sufficient size for the number of personnel in the birthing center and the patient caseload. The conference area may be used for childbirth classes, staff inservice education, meetings, etc.

(g) Clean Utility. A clean workroom for storage and assembly of supplies shall contain storage cabinets or storage carts, a work counter, and a sink.

(h) Soiled Utility. The soiled utility room shall contain a deep sink, work counter, waste receptacle, and soiled linen receptacle.

(i) The Medicine Room shall include a sink, small refrigerator, locked storage, narcotic locker, and work counter. The medicine area may be combined with the clean utility room.

(j) Clean Linen Storage. The clean linen storage shall contain a closet large enough to hold an adequate supply of clean linen. This can be combined with the clean utility room.

(k) Kitchen Facilities. The kitchen/nourishment centers shall have sufficient storage for patients' prepared food and beverages. A centralized kitchen/nourishment center may be shared or individual nourishment centers may be present in each birthing room.

(l) Janitor's closet.

(m) Laundry. A laundry room with a residential washer and dryer shall be provided if an outside laundry contract is not used.

(n) Laboratory. The laboratory area shall contain a counter, sink, and storage area for supplies.

(o) Emergency cart storage.

(p) Examination Rooms. The number of examination rooms shall be adequate for the patient caseload. When used for prenatal care, the examination rooms shall be situated away from the birthing rooms. Each examination room shall contain at least 100 square feet. At least one examination room shall be provided for admission evaluation, containing an examining table with stirrups, stool, goose neck light, equipment table, sink, and supply storage area.

(q) Central Sterile Supply. Written policies and procedures shall be maintained for the sterilization of supplies and water and reprocessing of sterile supplies at specific time periods. The following areas shall be separated:

1. The receiving and clean-up area shall include a two-compartment sink with two drainboards.

2. The area for instrument pack assembly shall have a sterilizer or approved alternate source of sterilization, work counter, and a lavatory or sink. A sterile storage area shall also be provided.

3. When sterilization services are provided via contract outside of the birthing center, there shall be a separately designated area in the facility for dirty, clean, and sterile supplies.

(r) Birthing Rooms.

1. Birthing rooms shall have sufficient space for a double bed, cradle, nightstand, rocking chair, cabinet for supplies, and a sink, with a minimum of 120 square feet. A counter area for infant resuscitation should be lighted in such a manner as to provide at least 100 foot candles at the infant's body surface, and should include an overhead source of radiant heat, a heating pad overlying a thin mattress on which the neonate is placed, and a large wall clock with a clearly visible second hand.

2. Ceiling height of the birthing rooms shall be a minimum of 8 feet.

3. Each birthing room will have immediate access to a bathroom. Tubs are recommended.

4. Birthing rooms shall be designed to provide privacy for the mother and family.

5. All walls and floors shall be suitable for washing.

6. A nurse call outlet or emergency call system shall exist.

7. Portable oxygen and suction shall be available. All outlets shall be grounded.

(2) Equipment.

(a) Testing and Diagnostic Equipment. All testing and diagnostic equipment shall be maintained in good working order at all times.

1. If equipment is obsolete or permanently unusable because of irreparable damage or malfunction to the equipment or any other condition that renders its use detrimental to patient care, it shall be immediately separated from the equipment currently in use, clearly tagged as permanently unusable, and properly disposed of as soon as possible.

2. If equipment is temporarily unusable, it shall be immediately separated from equipment currently in use and clearly tagged as being temporarily unusable until it is repaired or otherwise made fit for use. Equipment is temporarily unusable if in need of repair or if not maintained in accordance with manufacturer standards, regardless of whether there is an apparent defect. Tagged equipment shall not be returned to use until repaired and tested to ensure proper operation.

(b) Preventive Maintenance. There shall be a schedule of preventive maintenance developed for all equipment in the birthing center integral to patient care to assure satisfactory operation thereof. This schedule shall cover at least the following equipment:

1. Ultrasound. All ultrasound machines must be tested and calibrated by a trained, qualified technician in accordance with the manufacturer's recommendations. In no event shall testing and calibration be done less than annually.

2. Autoclave. All autoclaves must be tested and maintained at least annually by a trained, qualified technician in accordance with the manufacturer's recommendations, except that necessary routine weekly cleaning, maintenance, and inspection may be performed by properly trained clinic staff or a trained, qualified technician in accordance with the manufacturer's recommendations. Dated chemical indicators shall be used with every load to ensure sterilization. Biological indicator testing must be performed every 40 service-hours, and the results of the biological indicator testing must be logged.

3. A readily accessible emergency cart or tray for the mother shall be equipped to carry out the birthing center's written emergency procedures. A written log of routine equipment maintenance shall be maintained for the emergency cart. The emergency cart or tray for the mother shall contain mechanical ventilating assistance equipment, airways, manual breathing bag, laryngoscope and endotracheal tubes, suction equipment, emergency drugs and supplies, intravenous equipment, and blood expanders.

4. A readily accessible emergency cart or tray for the newborn shall be equipped to carry out the birthing center's written emergency procedures and shall be securely placed with a written log of routine maintenance. The emergency cart or tray for the newborn shall contain mechanical ventilating assistance equipment, airways, manual breathing bag, laryngoscope and endotracheal tubes, suction equipment, emergency drugs and supplies, and intravenous equipment.

(c) The birthing center must maintain a record for all equipment containing the following information:

1. Manufacturer, make, and model of the equipment.

2. Date of purchase.

3. Any dates on which the equipment was removed from service for repair or maintenance and, if applicable, date equipment was returned to service.

4. Date and description of all tests, maintenance, or repairs performed on the equipment, including all routine inspection and maintenance performed by medical staff.

5. Names and qualifications of the company and technician performing the tests, maintenance, or repairs.

6. Results of any tests, maintenance, or repairs.

7. All manufacturer literature and information. Any missing information shall be noted in the equipment record, and if there is no record of proper maintenance in the last year, the equipment must be immediately tested and, if necessary, calibrated or repaired.

(d) The birthing center shall have properly maintained equipment for routine care of women and neonates, including, but not limited to:

1. A radiant heat source for infant examination.

2. Transfer incubator or isolette.

3. Sterilizer or an approved alternate source of sterilization.

4. Blood pressure equipment, thermometers, fetoscope/doptone.

5. Intravenous equipment.

6. Oxygen equipment for mother and newborn.

7. Instruments for delivery, episiotomy, and repair.

(e) The birthing center shall have properly maintained accessory equipment, which includes, but is not limited to:

1. A conveniently placed telephone and emergency call system.

2. Portable lighting.

3. Kitchen equipment usually found in home for light refreshment.

4. Laundry area for residential washer and dryer if an outside laundry contract is not used.

(3) Supplies.

(a) The inventory of supplies shall be sufficient to care for the number of childbearing women and families registered for care.

(b) Shelf life of all medications and intravenous fluids shall be monitored. Medications and supplies which have deteriorated or reached their expiration dates shall not be used for any reason. All expired or deteriorated items shall be disposed of promptly and properly. The birthing center shall examine all stored medications and supplies no less frequently than once each month and shall remove from its inventory all deteriorated items and all items for which the expiration date has been reached. The birthing center shall maintain a log recording each such examination with its date, time, the person conducting the examination, and a description of each item or group of items removed from inventory and the reason for removal.

Authors: Dana Billingsley, Denise Milledge
Statutory Authority: Code of Ala. 1975, §22-2-2(6), et seq.; §22-21-20, et seq.
History: Filed November 19, 1987. **Repealed:** Filed April 16, 2010; effective May 21, 2010.
New Rule filed XX-XX-XXXX; **effective** XX-XX-XXXX.

420-5-13-.19 Physical Plant.

(1) General.

(a) Location. The birthing center shall be located in a location that is free from undue noise, smoke, dust, or foul odors and shall have sufficient parking spaces to accommodate patients and their families.

(b) Local Requirements. The birthing center shall comply with all local zoning, building, and fire ordinances. A birthing center may not be operated in a private residence.

(c) Accessibility. The birthing center shall be located on streets or roads which can be kept passable at all times.

(d) Communication. The birthing center shall have telephones to summon help in case of fire or other emergency.

(e) Occupancy. No part of the birthing center may be rented, leased, or used for any commercial purpose or for any purpose not necessary or in conjunction with the operation of the birthing center. Food and drink machines may be maintained or a diet kitchen provided for prepared foods.

(2) Submission of Plans and Specifications.

(a) Scope. A facility constructed or renovated after the effective date of these rules shall be classified as Business Occupancy and shall comply with the codes and standards adopted by the State Board of Health and in effect at the time of plan submission.

(b) New Construction, Additions, and Major Alterations. When construction is contemplated for new buildings, conversions, or additions to existing buildings coming within the scope of these rules, plans and specifications shall be submitted for review by the Department in accordance with Alabama Administrative Code Rule 420-5-22, "Submission of Plans and Specifications for Health Care Facilities."

(c) Minor Alterations and Remodeling. Minor alterations and remodeling which do not affect the structural integrity of the building, change functional operation, affect fire safety, and add services to those for which the birthing center is licensed need not be submitted for review.

(d) Water Supply, Plumbing, and Drainage. No system of water supply, plumbing, sewage, garbage, or refuse disposal shall be installed, nor shall any such existing system be materially altered or extended until complete plans and specifications for the installation, alteration, or extension have been submitted to the Department for review.

(e) Inspections. The State Board of Health and its authorized representatives shall have access to the work for inspection wherever it is in preparation or progress.

(3) Building Requirements.

(a) Structural Soundness. The building shall be structurally sound, free from leaks and excessive moisture, in good repair, and painted at intervals to be reasonably attractive inside and out.

(b) Temperature to be Maintained. The mechanical system shall be capable of maintaining a temperature of 70° F to 75° F throughout the birthing center.

(c) Lighting. There shall be general lighting and provision for adequate examination lights in the birthing room.

(d) Screens. All screen doors and non-stationary windows (except in air-conditioned areas) shall be equipped with tight fitting, full length 16 mesh screens. Screen doors shall swing out and shall be equipped with self-closing devices.

(e) Emergency Lighting System. Emergency lighting systems shall be provided to adequately light corridors, exit signs, stairways, and lights at the exterior of each exit in case of electrical power failure.

(f) Emergency Power. An emergency generator shall be provided to operate the emergency lighting system and make life sustaining equipment operable in case of power failure. Emergency outlets shall be provided in all patient care areas.

(g) Floors. All floors in birthing rooms shall be smooth resilient tile, free from cracks, and finished for easy cleaning. All other floors shall be covered with hard tile, resilient tile, carpet, or the equivalent. Carpeting is prohibited as a floor covering in birthing rooms.

(h) Interior Finish and Decorative Materials. All combustible decorative and acoustical material to include wall paneling shall be as follows:

1. Materials on wall and ceiling in corridors and rooms occupied by four or more persons shall carry a flame spread rating of 25 or less and a smoke density rating of 450 or less in accordance with ASIM E-84.

2. Rooms occupied by less than four persons shall have a flame spread rating of 75 or less and a smoke density rating of 450 or less in accordance with ASIM E-84.

(i) Ramps. Ramps shall not be steeper than 1 foot of rise in 12 feet of run, shall be finished with a nonslip surface, and shall be provided with handrails on both sides. Exterior ramps, where installed, shall be provided with handrails on open sides.

(j) Doors.

1. The minimum width of doors to all rooms needing access for stretchers shall be 3 feet 8 inches.

2. Hardware on all toilet and bathroom doors shall be operable from outside the room.

3. Birthing doors shall not be equipped with hardware that will permit a patient to lock herself within the room.

(k) Floor Levels. All differences in floor levels or step-downs within the building shall be accomplished by stairs of not less than three 6-inch risers or ramps and shall be equipped with handrails on both sides.

(1) Ventilation. The building shall be well ventilated at all times. Birthing rooms shall be ventilated in such a manner as to supply fresh air and to prevent accumulation of objectionable odors. Kitchens, laundries, service rooms, toilets, bathrooms, and all inside rooms shall be ventilated by louvers, wall vents, or undercut in doors and by windows, gravity vents, or mechanical means so as to prevent offensive odors from entering other parts of the building.

(m) Fire Extinguisher. An all purpose fire extinguisher shall be provided at each exit and special hazard area and located so a person would not have to travel more than 75 feet to reach an extinguisher. Fire extinguishers shall be of a type approved by the local fire department or State Fire Marshal and shall be inspected at least annually. An attached tag shall bear the initials or name of the inspector and the date inspected.

(n) Elevators. Multi-story facilities shall be equipped with at least one automatic elevator of a size sufficient to carry a patient on a stretcher.

(o) Multi-Story Buildings. All multi-story buildings shall be of fire resistive construction in accordance with NFPA 220, Standard Types of Building Construction.

(p) Exits. Each floor of a facility shall have two or more exit ways remote from each other, leading directly to the outside or to a 2-hour fire resistive passage to the outside. Exits shall be so located that the maximum distance from any point in a floor area, room, or space to an exit doorway shall not exceed 100 feet, except that when a sprinkler system is installed, the distance of travel shall not exceed 150 feet.

(q) Exit Doors. Exit doors shall meet the following criteria:

1. Shall be no less than 44 inches wide.

2. Shall swing in the direction of the exit and shall not obstruct the travel along any required fire exit route.

(r) Exit Signs. Exits shall be equipped with approved illuminated signs bearing the word "Exit" in letters at least 4 1/2 inches high. Exit signs shall be placed in corridors and passageways to indicate the direction of exit.

(s) Carpet. All carpet or pad shall carry a flame spread rating of 75 or less or a radiant flux greater than 0.45 watts per square centimeter and a smoke density rating of 450 or less.

(t) Curtains. All draperies shall be rendered and maintained flame retardant.

(u) Handicapped Facilities. The facility shall be accessible to the physically handicapped and shall comply with ANSI 117.1, "Making Buildings and Facilities Accessible and Useable by the Physically Handicapped, 1981 Edition."

(v) Garbage Disposal. Space and facilities shall be provided for the sanitary storage and disposal of waste by incineration, containerization, removal, or by a combination of these techniques. Infectious waste materials shall be rendered noninfectious on the premises by appropriate measures.

(w) Corridors. Corridors shall comply with the following:

1. All rooms shall open onto a corridor leading to an exit.

2. Corridors used by patients shall be a minimum of 6 feet wide.

3. Service corridors may be a minimum of 4 feet wide.

(x) Water Temperature. Water temperature shall be as follows:

1. Hot water at handwashing facilities shall not exceed 120° F.

2. Hot water at bathing facilities shall not exceed 110° F.

Authors: Dana Billingsley, Denise Milledge
Statutory Authority: Code of Ala. 1975, §22-2-2(6), et seq.; §22-2 1-20, et seq.
History: Filed November 19, 1987. **Amended:** Filed February 20, 1997; effective March 27, 1997. **Amended:** Filed June 18, 2002; effective July 23, 2002. **Repealed:** Filed April 16, 2010; effective May 21, 2010. **New Rule filed** XX-XX-XXXX; **effective** XX-XX-XXXX.

APPENDIX A

RISK STATUS CRITERIA FOR ACCEPTANCE OF PATIENTS AND CONTINUATION OF CARE

Patients with any of the following risk factors shall be referred to a physician for continuing maternity care and hospital delivery.

(1) Less than 16 years of age

(2) Major medical problems, including, but not limited to:

(a) Chronic hypertension, heart disease, pulmonary embolus or congenital heart defects

(b) Severe renal disease

(c) Drug addiction or required use of anticonvulsant drugs

(d) Diabetes mellitus

(e) Bleeding disorder or hemolytic disease

(3) Previous history of significant obstetrical complications, including, but not limited to:

(a) Rh sensitization

(b) Previous uterine wall surgery including Cesarean section

(c) Five or more term pregnancies

(d) Nullipara of greater than 40 years of age or multipara over 45 years of age

(e) Previous placental abruption

(4) Significant signs or symptoms of any of the following:

(a) Hypertension

(b) Toxemia

(c) Poly- or oligo-hydramnios

(d) Placental abruption

(e) Chorioamnionitis

(f) Malformed fetus

(g) Fetal distress

(h) Multiple gestation

(i) Intrauterine growth retardation

(j) Alcoholism or drug addiction

(k) Thrombophlebitis

(1) Pyelonephritis

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MONTGOMERY COUNTY, ALABAMA
GINA J. ISHMAN, CLERK

EXHIBIT B

APA-1
4/18

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 420 Alabama Department of Public Health

Rule Number 420-5-13
Rule Title Birthing Centers

X New ____ Amend ____ Repeal ____ Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare or safety?	Yes
Is there a reasonable relationship between the state's police power and the protection of the public health, safety or welfare?	Yes
Is there another, less restrictive method of regulation available that could adequately protect the public?	No
Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree?	No
Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule?	No
Are all facts of the rulemaking process designed solely for the purpose of and so they have as their primary effect, the protection of the public?	Yes
Does the proposed action relate to or affect in any manner any litigation which the agency is a party to concerning the subject matter of the proposed rule?	No
Does the proposed rule have an economic impact?	Yes

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of §41-22-23, Code of Alabama, 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama, 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Services Agency.

Signature of Certifying Officer Date 6/20/23

REC'D & FILED
JUN 20 2023
LEGISLATIVE SVC AGENCY

FORM APA2
10/17

STATE BOARD OF HEALTH
NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Department of Public Health

RULE NUMBER AND TITLE: 420-5-13, Birthing Centers

INTENDED ACTION: To adopt new rules. The proposed rules fall under an exemption to the moratorium imposed on rulemaking under Governor Ivey's Executive Order 735 because they promote the public health, safety, and welfare.

SUBSTANCE OF PROPOSED ACTION: To establish new rules regulating birthing centers in various locations in the state.

TIME, PLACE, AND MANNER OF PRESENTING VIEWS: A public hearing will be held on July 13, 2023 at 2:00 p.m., at the Montgomery County Health Department, 3060 Mobile Highway, Montgomery, Alabama 36108.

FINAL DATE FOR COMMENTS AND COMPLETION OF NOTICE: Written or oral comments will be received until the close of the record at 5:00 p.m. on Friday, August 4, 2023. All comments and requests for copies of the proposed amendments should be addressed to the contact person listed below.

CONTACT PERSON AT AGENCY: Jacqueline D. Milledge, Bureau of Health Provider Standards, Department of Public Health, P.O. Box 303017, Montgomery, Alabama 36130-3017, Telephone number: (334) 260-5366.

P. Brian Hale, Agency Secretary

APA-6

ECONOMIC IMPACT STATEMENT
FOR APA RULE
(Section 41-22-23(f))

Control No. 420 Department or Agency: Alabama Department of Public Health

Rule No: 420-5-13

Rule Title: Birthing Centers

___x___ New _____ Amend _____ Repeal _____ Adopt by Reference

_____ This rule has no economic impact.

___x___ This rule has an economic impact, as explained below:

1. NEED/EXPECTED BENEFIT OF RULE:

   The purpose of these rules is to establish regulations for the licensure, operation, and survey of health care facilities providing birthing center services throughout the state.

2. COSTS/BENEFITS OF RULE AND WHY RULE IS THE MOST EFFECTIVE, EFFICIENT, AND FEASIBLE MEANS FOR ALLOCATING RESOURCES AND ACHIEVING THE STATED PURPOSE:

   These rules are necessary to establish the regulations for health care facilities, including birthing centers, as authorized under Ala. Code §§ 22-2-2(6) and 22-21-20.

3. EFFECT OF THIS RULE ON COMPETITION:

   N/A

4. EFFECT OF THIS RULE ON COST-OF-LIVING AND DOING BUSINESS IN THE GEOGRAPHICAL AREA WHERE THE RULE IS TO BE IMPLEMENTED:

   These rules will not increase the cost of living in any geographical area of the state, but they will require financial investment and expenditures in order to establish and operate

these health care facilities. Medical staff will need to be employed and buildings will need to meet certain code requirements in order to comply with the new regulations.

5. EFFECT OF THIS RULE ON EMPLOYMENT IN THE GEOGRAPHICAL AREA WHERE THE RULE IS TO BE IMPLEMENTED:

The establishment of birthing centers anywhere in the state should provide increased opportunities for employment. At a minimum, birthing centers must have a staff physician or consultant physician, certified nurse midwife, and registered nurses on staff. Licensed practical nurses and certified professional midwives may provide assistive care in birthing centers within the scope of practice of their professions.

6. SOURCE OF REVENUE TO BE USED FOR IMPLEMENTING AND ENFORCING THIS RULE:

N/A

7. THE SHORT-TERM/LONG-TERM ECONOMIC IMPACT OF THIS RULE ON AFFECTED PERSONS, INCLUDING ANALYSIS OF PERSONS WHO WILL BEAR THE COSTS AND THOSE WHO WILL BENEFIT FROM THE RULE:

In the short term, service providers will incur the costs of establishing and operating a new health care facility. Persons who wish to avail themselves of the services provided by the birthing centers may be initially expected to bear a portion of these costs, so that the business may continue as a viable entity. The licensure fees are not expected to impact provider services given the low cost. In the long-term, any initial investment costs that have been passed on to patients may decrease.

The public will benefit from this rule because the health and safety of mothers and their newborns will be enhanced by the regulations and the Department's oversight. Agreements for the emergency transport of mothers and infants suffering adverse outcomes of childbirth to licensed hospitals with organized obstetrical services must be maintained by the birthing centers; certain medical equipment, including equipment utilized for emergency care, must be included in the inventory and maintained by the birthing center; oversight by qualified physicians, certified nurse midwives, and registered nurses with the requisite training and experience is required; patient assessments must be regularly taken to ensure that patients remain low risk for adverse pregnancy outcomes; and buildings must meet applicable occupancy, building, and life safety codes.

8. UNCERTAINTIES ASSOCIATED WITH THE ESTIMATED BENEFITS AND BURDENS OF THE RULE, INCLUDING QUALITATIVE/QUANTITATIVE BENEFITS AND BURDEN COMPARISON:

At this juncture, the Department is aware of two physicians who have plans to operate a birthing center in north Alabama and the Birmingham area. Both physicians have indicated their willingness to comply with the final regulations and likely have the resources to do so. The locations for both centers are in close proximity to a local hospital with an obstetrical service.

The Department is also aware that other freestanding birthing centers that desire to open in Alabama are being hosted by licensed midwives, who may have fewer available resources. These centers will likely be most heavily impacted by the proposed rules, and the likelihood of locating in rural areas, as some propose, will be greatly lessened.

The Department is unable to estimate the number of persons who would be likely to seek obstetrical care and delivery in a freestanding birthing center, since the services provided there are not eligible for cost reimbursement by the Centers for Medicare and Medicaid Services, not covered by private insurance, and not eligible for coverage by Medicaid, which restricts coverage to delivery by a certified nurse midwife in a licensed hospital. Prenatal and postnatal care and delivery services may still be had in patients' homes by licensed midwives, within their permitted scope of practice.

9. THE EFFECT OF THIS RULE ON THE ENVIRONMENT AND PUBLIC HEALTH:

These rules will have no impact on the environment; however, they will have an impact on the public health. The rules are designed to provide for the health and safety of mothers in the prenatal, delivery, and postnatal stages of the childbirth experience, as well as the health and safety of their newborns. The rules provide an option for mothers to receive obstetrical services in a regulated health care facility that is less restrictive than a hospital, but safer than a home birth.

10. DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE RULE IS NOT IMPLEMENTED:

If these rules are not implemented, there will be fewer safeguards and standards for the operation of these facilities, exposing mothers and their newborns to increased risks to their health and safety.

****Additional pages may be used if needed.**

ALABAMA STATE BOARD OF HEALTH
ALABAMA DEPARTMENT OF PUBLIC HEALTH
ADMINISTRATIVE CODE
CHAPTER 420-5-13
BIRTHING CENTERS

TABLE OF CONTENTS

420-5-13-.01 General.

(1) Legal Authority for Adoption of Rules. The following rules for Birthing Centers are adopted by the Alabama State Board of Health pursuant to § 22-21-20, et seq., Code of Ala. 1975.

(2) Definitions

(a) "Administrator" means a natural person who is the governing authority of a health care facility or a natural person who is designated by the governing authority of a health care facility. Such person must have sufficient authority to interpret and implement all policies of the owner or proprietor and must be qualified to perform those tasks. The administrator shall be the addressee of all correspondence and inquiries from the State Board of Health.

(b) "Birthing Center" means a publicly or privately owned health care facility, place, or institution, constructed, renovated, leased, or otherwise established, where nonemergency births are planned to occur away from the mother's usual residence following a documented period of prenatal care for a low risk patient, as defined herein. Such facility, place, or institution must be a freestanding unit, not part of a hospital or other facility licensed for other purposes by the State Board of Health, and hold itself out to the public as a birthing center by advertising by some public means, such as a newspaper, directory, a website, the Internet, etc. The offices of private physicians assisting births strictly on an emergency basis does not constitute birthing centers for the purposes of this rule. Care provided in a birthing center shall be provided by a licensed physician, or by a duly licensed certified nurse midwife and a licensed registered nurse. Certified professional midwives may also provide care as assistive personnel to staff certified nurse midwives and registered nurses in a birthing center, provided that the staffing requirements of these rules are met when patients are present, laboring, and delivering in the birthing center. Nothing in this rule shall be construed to expand the existing scope of practice for a certified professional midwife.

(c) "Board" or "State Board of Health" means the Alabama State Board of Health.

(d) "Certified Nurse Midwife" (CNM) means an advanced practice nurse who is in an active collaborative practice agreement with the licensed physician who is serving as the staff physician or consultant physician for the birthing center, which includes the birthing center as an approved practice site, and who meets the requirements of and is approved by the Alabama Board of Nursing. CNMs in birthing centers shall have at least 1 year of experience in labor and delivery and/or newborn intensive care, be trained and annually certified in adult and infant cardiopulmonary resuscitation (CPR), and possess a Neonatal Resuscitation Program (NRP) certificate or the equivalent thereof.

(e) "Certified Professional Midwife" (CPM) means a person who holds an active license with the Alabama Board of Midwifery. A CPM in a birthing center shall have at least 1 year of documented experience in providing all phases of prenatal, delivery, and postnatal care, be trained and annually certified in adult and infant CPR, and possess an NRP certificate or the equivalent thereof.

(f) "Consultant Physician" means a person currently licensed by and in good standing with the Medical Licensure Commission of Alabama to practice medicine and/or osteopathy in this state and who has a valid agreement to serve as a consultant to the birthing center. In the absence of a staff physician, the consultant physician must also have an approved collaborative practice agreement with the CNM employed by or working at the birthing center. The services of a consultant physician are required for any birthing center which does not have a physician on the medical staff who is currently licensed by and in good standing with the Medical Licensure Commission of Alabama. Consultant physicians must be either (1) certified by the American Board of Obstetrics and Gynecology or the American Board of Osteopathic Obstetricians and Gynecologists or (2) qualified as family practice physicians with an obstetrical emphasis or fellowship. The consultant physician must be trained and annually certified in adult CPR, equivalent to the American Heart Association's Class C basic life support, infant CPR, and neonatal resuscitation endorsed by the American Academy of Pediatrics/American Heart

Association. The consultant physician must have hospital obstetrical privileges with the hospital that is a party to the birthing center's Transfer Agreement and must be available to be physically present at the birthing center within 30 minutes to provide needed hands-on care to patients at the birthing center when called. A facility is ineligible for licensure as a birthing center unless it has an Alabama licensed physician on the medical staff or a valid agreement with a consultant physician to provide consulting and hands-on services as needed.

(g) "Department" means the Alabama Department of Public Health.

(h) "Documented Period of Prenatal Care" means prenatal evaluation and care initiated by an appropriate care provider prior to the third trimester, until 37-42 weeks of gestation.

(i) "Family Centered Care" means a philosophy of care that allows family and significant others to participate in the pregnancy, birth, and postpartum period in a homelike environment.

(j) "Freestanding" means a separate and distinct health care facility, place, or institution, constructed, renovated, leased, or otherwise established, for purposes of these rules, to provide the services of a birthing center. Each freestanding birthing center must obtain its own license and comply with all applicable licensing standards promulgated by the State Board of Health and these rules; provided, however, that a hospital affiliated birthing center located on the hospital's campus does not constitute a freestanding birthing center and is not required to be separately licensed.

(k) "Governing Authority" means the owner or proprietor of the birthing center, or the body, such as a board of directors, which maintains and controls the operation of the birthing center and who is legally responsible for its operation.

(l) "Hospital" means a health care facility duly licensed by the State Board of Health as a general acute care or specialty hospital with an organized obstetrical service, as defined herein, and operating in compliance with the Department's rules in Chapter 420-5-7. The usual service provided in the obstetric gynecology service of an acute care hospital does not constitute or qualify as a birthing center.

(m) "Hospital Affiliated Birthing Center" means a separate and distinct unit of a hospital or a building owned, leased, rented, or utilized by a hospital for the purpose of providing the services of a birthing center. A hospital affiliated birthing center located on the hospital campus may operate under the general acute care or specialty license issued to the hospital. A hospital affiliated birthing center that is not located on the hospital campus is required to be separately licensed and may not operate under the general acute care or specialty license issued to the hospital.

(n) "License" means the legal authority to operate a birthing center, as defined above, to admit patients, and to offer and provide care as permitted under these rules. A license may only be granted by the Board through the actions of its authorized agents.

(o) "Licensed Practical Nurse" (LPN) means a person who holds an active license with the Alabama Board of Nursing or a multistate nursing license which includes a privilege to practice nursing in Alabama. An LPN in a birthing center shall have at least 1 year of experience in obstetrics, be trained and annually certified in adult and infant CPR and infant resuscitation, and possess an NRP certificate or the equivalent thereof.

(p) "Low Risk Patient" means an individual who does not have any of the listed risk factors for an adverse pregnancy outcome and who is eligible to receive services in a birthing center because the individual:

1. Is in general good health with an uncomplicated prenatal course.

2. Is participating in an ongoing prenatal care and education program that addresses, at a minimum, anticipated changes during pregnancy, the need for prenatal care, nutritional needs during pregnancy, the effects of smoking and substance abuse, the danger signs of preterm labor, what to expect during labor and delivery, and care and feeding of the newborn, including instruction on lactation (breast feeding).

3. Has no major medical problems, including, but not limited to chronic hypertension, heart disease, pulmonary embolus or congenital heart defects; severe renal disease; medication-controlled diabetes; required use of anticonvulsant drugs; bleeding disorder or hemolytic disease; pyelonephritis; or thrombophlebitis.

4. Has no signs or significant symptoms of toxemia, hydramnios, abruptio placenta, chorioamnionitis, malformed fetus, multiple gestation, intrauterine growth retardation, fetal meconium, fetal distress, alcoholism, drug addiction, Rh or other blood group antigen sensitization.

5. Has no history of fetal wastage or premature delivery.

6. Has no previous significant obstetrical complications likely to recur, nor previous uterine wall surgery or Caesarean section.

7. Has given birth to fewer than five children, unless a justification for a variation is approved in writing by the staff physician or consultant physician.

8. If between 36 and 40 years of age and has never before given birth, has been cleared medically by the staff physician or consultant physician, and has both a normal comprehensive sonogram and normal chromosomal testing.

9. Is not less than 16 years of age at the onset of pregnancy.

10. Is appropriate for a setting where anesthesia is limited to local infiltration of the perineum, or a pudendal block, and analgesia is limited.

11. While in active labor:

(i) Demonstrates no significant signs or symptoms or evidence of anemia, significant hypertension, placenta previa, fetal distress, malformed fetus or breech.

(ii) Is progressing normally.

(iii) Is without prolonged ruptured membranes.

(iv) Is not in premature labor.

12. Is no more than 40 years of age at the outset of pregnancy.

(q) "Nonemergency Births" means those births that are planned to occur away from the mother's usual residence and have been determined to be low risk through an ongoing risk assessment from the first prenatal visit throughout admission in labor, and the labor, birth, and postpartum period.

(r) "Organized Obstetrical Service" means a hospital which has an obstetrician (or family practitioner with training and experience in obstetric medicine) and a pediatrician (or family practitioner with training and experience in pediatric medicine) on the active staff, a 24-hour emergency room and Cesarean section capability, and which provides skilled nursing care, facilities, and equipment appropriate for the patient being transferred from the birthing center. The organized obstetrical service must be located no more than 30 minutes driving time by emergency transport vehicle from the birthing center.

(s) "Pediatrician" means a physician who is currently licensed by and in good standing with the Medical Licensure Commission of Alabama, and who is certified in general pediatrics or a pediatric subspecialty by the American Board of Pediatrics. The pediatrician must be trained and annually certified in infant CPR and neonatal resuscitation endorsed by the American Academy of Pediatrics/American Heart Association and possess an NRP certificate or the equivalent thereof.

(t) "Registered Nurse" (RN) means a person who holds an active license as such with the Alabama Board of Nursing or a multistate nursing license which includes a privilege to practice nursing in Alabama. An RN in a birthing center shall have at least 1 year of experience in obstetrics, be trained and annually certified in adult and infant CPR and infant resuscitation, and possess an NRP certificate or the equivalent thereof.

(u) "Risk Criteria" means:

1. Birthing center patients are limited to those women who are initially determined to be at low maternity risk and who are evaluated regularly throughout pregnancy to assure that they remain at low risk for an adverse pregnancy outcome.

2. Each birthing center shall establish a written risk assessment system which shall be developed by the staff physician or consultant physician in accordance with the parameters set forth herein for low risk patients and all applicable standards of good medical practice, to be included in the birthing center's policy and procedure manual. Ongoing written risk assessments from the first prenatal visit throughout admission in labor, and the labor, birth, and postpartum period shall form part of each patient's clinical record.

3. The general health status and risk assessment shall be conducted by the staff physician or consultant physician, CNM, or CPM by obtaining a detailed medical history, performing a physical examination, and considering family circumstances and other social and psychological factors. The patient's health status and risk assessment shall be reviewed by the staff physician or consultant physician or CNM and initially approved as suitable for delivery in the birthing center.

4. The criteria upon which the risk status of patients is determined under the birthing center's written risk assessment system shall be applied to all patients prior to acceptance for birthing center services and throughout the pregnancy for continuation of services. Patients presenting with or later developing any of the risk factors listed under the definition of a low risk patient in these rules shall be ineligible to receive services in a birthing center and shall be referred to another qualified physician for continuing maternity care and hospital delivery.

5. Acceptance for and continuation of care throughout pregnancy and labor is limited to those women for whom it is appropriate to give birth in a setting where anesthesia is limited to local infiltration of the perineum or a pudendal block and where analgesia is limited.

(v) "Services Provided in a Birthing Center" shall be defined and limited as follows:

1. Surgical services shall be limited to those normally performed during uncomplicated childbirth, such as episiotomy and repair, and shall not include operative obstetrics or Cesarean sections. Surgical repairs of fourth degree lacerations may only be performed in a birthing center by the staff physician or consultant physician. Circumcisions of male infants may be performed in a birthing center by the staff physician or consultant physician or by a CNM who has been approved to perform circumcision of male infants through a collaborative practice agreement approved by the Alabama State Board of Medical Examiners and the Alabama Board of Nursing.

2. Labor shall not be inhibited, stimulated, or augmented with chemical agents during the first or second stage of labor (i.e., up to and including vaginal delivery). CPMs are permitted to administer anti-hemorrhagic medication and oxygen in an emergency circumstance.

3. Systemic analgesia may be administered and local anesthesia for pudendal block and episiotomy repair may be performed; however, general and conduction anesthesia shall not be administered. CPMs may not order or administer narcotic analgesia.

4. Vacuum extractors and forceps shall not be used in the birthing center.

5. Patients and their newborns shall not routinely remain in the birthing center in excess of 24 hours. Exceptional circumstances justifying a stay in excess of 24 hours are set forth in Ala. Admin. Code r. 420-5-13-.09(8).

(w) "Staff Physician" means a person currently licensed by and in good standing with the Medical Licensure Commission of Alabama to practice medicine and/or osteopathy in this state and who is (1) certified by the American Board of Obstetrics and Gynecology or the American Board of Osteopathic Obstetricians and Gynecologists or (2) qualified as a family practice physician with an obstetrical emphasis or fellowship. The staff physician must be trained and annually certified in adult CPR, equivalent to the American Heart Association's Class C basic life support, infant CPR, and neonatal resuscitation endorsed by the American Academy of Pediatrics/American Heart Association. The staff physician must have hospital obstetrical privileges with the hospital that is a party to the birthing center's Transfer Agreement and must be available to be physically present at the birthing center within 30 minutes to provide needed hands-on care to patients at the birthing center when called. A birthing center is ineligible for licensure unless it has an Alabama licensed physician on the medical staff or a valid agreement with a consultant physician.

(x) "Transfer Agreement" means a birthing center's written agreement with a hospital located no more than 30 minutes driving time by emergency transport vehicle from the birthing center, which has an organized obstetrical service, as defined in these rules. The Transfer Agreement shall provide for the hospital's acceptance of referrals from the birthing center and phone consultations as needed to address emergency situations; the agreement shall address financial responsibility for services rendered. A birthing center is ineligible for licensure unless it has a Transfer Agreement with a licensed, qualified hospital. A written agreement with at least one currently licensed emergency medical service (EMS) is also required for the rapid response and transport of a patient or infant to the hospital named in the Transfer Agreement.

(3) Type of License.

(a) Regular License. A regular license may be issued by the State Board of Health after the Board has determined that the birthing center is in substantial compliance with these rules.

(b) Probational License. At its discretion, the Board may grant a probational license when it determines that both of the following conditions exist:

1. The birthing center has engaged in one or more deficient practices which are serious in nature, chronic in nature, or which the birthing center has failed to correct.

2. The birthing center's current governing authority has demonstrated the capability and willingness to correct cited problems and to maintain compliance.

(c) A probational license shall be granted for a specific period which may be extended, but which shall in no case exceed 1 year.

(4) Licensing.

(a) Application. Application for an initial license or renewal of a license shall be made on forms provided by the State Board of Health, including all information required by law, these rules, and the policies and procedures of the Department. An applicant shall submit such additional information as shall be required by the Department in its discretion to demonstrate that the applicant has the ability and the willingness to comply with these rules. Each application shall be signed by a person authorized to bind the applicant to the representations in the application and shall include any supporting documentation with the application.

(b) Fee. An initial license application, an application for license renewal, or an application for a change in ownership shall be accompanied by the application fee specified in § 22-21-24, Code of Ala. 1975. An application for a name change is not subject to a license application fee. An application fee is non-refundable. Any application fee submitted in the incorrect amount shall nevertheless be deposited. If the fee submitted is too large, a refund for the difference shall be processed using the Department's usual procedures. If the fee submitted is too small, the applicant shall be notified, and the application shall not be considered until the difference is received. Any application submitted without any fee shall be returned to the applicant. If an incomplete application is submitted, the application fee shall be deposited, and the applicant shall be notified in writing of the defects in the application. If the applicant fails to submit all required additional information within 10 working days of the date of the notice, the application shall be denied. The Department may, in its discretion, extend the deadline for submitting additional information. Denial of an application as incomplete shall not prejudice the applicant from submitting a new application, accompanied by the requisite fee, at a future date.

(c) Renewal. A license, unless suspended or revoked, shall be renewable annually as a matter of course upon submission of a completed renewal application and payment of the required fee. When the Department has served written notice on a birthing center of its intent to revoke or downgrade the license, a renewal application shall be filed, but does not affect the proposed adverse licensure action.

(d) Name. Every birthing center shall be designated by a permanent and distinctive name which shall be used in applying for a license, which shall include the words "birthing center." No birthing center shall change its name without first applying for a change of name approval, nor shall it change its name until such approval is granted. The Department may, in its discretion, deny an initial birthing center application or an application for a change of name if the Department determines that the proposed name is misleading to the public or that the name is overly similar to the name of an already licensed birthing center. Separately licensed birthing centers owned by the same governing authority may have names that are similar to one another and distinguished from one another in some other manner, such as a geographic description. If an initial birthing center application is denied under this rule, the applicant shall be provided a reasonable period of time to submit a revised application with a different name. No freestanding birthing center shall include the word "hospital" in its name.

(e) Issuance of License. All licenses issued by the State Board of Health shall set forth the name of the birthing center, the physical address, the name of the licensee, and the license number.

(f) Separate License. A hospital-affiliated birthing center or facility that is not located on the hospital campus is required to be licensed separately and may not operate under the license issued to the hospital.

(g) Posting of License. Licenses shall be posted in a conspicuous place on the licensed premises.

(h) License Not Transferable. The license shall not be transferable or assignable and shall be issued for the premises named in the application.

(i) Expiration of License. Each license shall expire on December 31 following the date of issuance.

(j) Condition of Licensure. It is a condition of licensure that the licensee must continuously occupy the licensed premises, remain open to the public as a birthing center, fully staffed, and otherwise capable of admitting and treating patients. If a birthing center fails to remain open and staffed as required for 30 days, its license shall become void. If a licensee abandons the licensed premises, the license shall immediately become void. If the facility subsequently wishes to reopen as a birthing center, it shall be required to file an initial licensure application, to include plan review and building inspection, and obtain a certificate of completion before the application can be processed by the Department.

(k) The following changes in the status of the birthing center will require issuance of a new license.

1. Change in facility ownership or operating entity (application fee required).

2. Change in facility name (no application fee required).

3. Relocation.

The governing authority shall file with the State Board of Health an application for license and application fee (if applicable) 30 days before any proposed change requiring a new license in order to permit processing of the application and issuance of the license prior to the desired effective date of the change.

(l) The Department shall be notified in writing within 30 days prior to the effective date of any change in the birthing center's administrator or staff physician and of the birthing center's intent to cease operation.

(m) Denial and Revocation of a License.

1. The Board may deny a license to any applicant or suspend or revoke the license to operate a birthing center in any case in which it finds that there has been a substantial failure to comply with the requirements established under these rules or on grounds of insufficient evidence of the willingness or ability to comply with §§ 22-21-20 through 22-21-34, Code of Ala. 1975, or these rules. Each license shall be returned to the Board immediately upon its revocation or after the birthing center voluntarily ceases operation.

2. Hearing procedures concerning the denial, suspension, or revocation of a license shall be governed by the provisions of the Alabama Administrative Procedure Act, § 41-22-1, et seq., Code of Ala. 1975, and the Board's Rules for Hearing of Contested Cases, Chapter 420-1-3, Ala. Admin. Code.

(5) Failure to Renew a License. Any licensee who fails to renew a license on or before the close of business on the last business day in December shall be assessed a late fee equal to the amount of the original license fee. A license may only be renewed with the payment of a late fee before the close of business on the last business day in January of any calendar year. A license which has not been renewed by the end of January has expired and shall be void.

(6) Compliance with Federal, State, and Local Laws. The birthing center shall be in compliance with applicable federal, state, and local laws, including all applicable zoning ordinances. A birthing center may not be operated in a private residence.

(a) Licensing of Staff. Staff of the birthing center shall be currently licensed, certified, or registered in accordance with applicable laws.

(b) Compliance with Other Laws. The birthing center shall comply with laws relating to fire and life safety, sanitation, communicable and reportable diseases, Certificate of Need review and approval, reporting of health care acquired infections, adverse event reporting, and other relevant health and safety requirements. If a birthing center utilizes the services of a clinical laboratory located outside the state of Alabama, the birthing center shall ensure that, in connection with any work performed for the birthing center, the laboratory complies with the requirements for the reporting of notifiable diseases to the Department, as set forth in state law and the rules of the Board.

(7) A birthing center shall promptly notify the Department in writing when there is any change in its accrediting organization or its status with the accrediting organization.

(8) Waiver and Variance. At its discretion, the State Board of Health may grant an exception to, or modify the application of, one or more provisions of these rules or reference codes for a period and under conditions, if any, determined by the Board. The exceptions or modifications shall be based on hardship, impracticality, or economic infeasibility in complying with the rules. The birthing center's request shall be in writing and meet the requirements of Rule 420-1-2-.09, including a statement regarding the specific provisions for which the exception or modification is requested and the reasons for each requested exception or modification.

(9) Disclosure of Information. Official reports, such as statements of deficiencies generated by the State Board of Health as a result of on-site inspections and plans of correction submitted in response to those statements of deficiencies, are subject to public disclosure. Information received through other means and reports, other than statements of deficiencies, shall be deemed to be confidential and shall not be publicly disclosed except in response to a valid subpoena or court order or in proceedings involving the birthing center's license or proceedings involving the license of another facility operated by the same governing authority. Inspection reports will never contain the name or other identification of any patient or client in the inspected facility.

Author: Dana Billingsley, Denise Milledge
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420-5-13-.02 Administration.

(1) Governing Authority.

(a) Responsibility. The governing authority is the person or persons responsible for the management, maintenance, control, and operation of the birthing center, including the provision of personnel, facilities, equipment, supplies, and services to mothers and families, as well as appointment of persons to fill the minimum staffing requirements. The governing authority shall ensure that the birthing center is organized, equipped, staffed, and administered in a manner to provide adequate care for each patient.

(b) The governing body shall be formally organized in accordance with a written constitution, bylaws, rules, or regulations. In the event the governing authority consists of one person, this requirement shall still be met. The written constitution, bylaws, rules, or regulations of the birthing center shall:

1. Specify by name the person to whom responsibility for operation and maintenance of the birthing center is delegated and methods established by the governing authority for holding such individuals responsible.

2. Provide for at least annual meetings of the governing authority. Minutes shall be maintained of such meetings.

3. Require policies and procedures consistent with professionally recognized standards of practice to include provisions for administration and use of the birthing center, compliance, personnel, medical records, patient rights, emergency care/transfers, emergency preparedness, policy reviews, quality assurance, infection control, procurement of outside services and consultations, patient care policies, and services offered.

4. Provide for annual reviews and evaluations of the birthing center's policies and services offered.

(c) Contracted Services. The governing authority shall be responsible for services furnished in the birthing center, whether or not they are furnished under contracts. The governing authority shall ensure that a contractor of services furnishes services that permit the birthing center to maintain compliance with the requirements of these rules.

1. The governing authority shall ensure that the services performed under a contract are provided in a safe and effective manner.

2. The birthing center shall maintain a list of all contracted services, including the scope and nature of the services provided.

(d) The governing authority shall provide for the selection and appointment of the medical or nurse midwifery and nursing staff and the granting of clinical privileges and shall be responsible for the professional conduct of these persons.

(2) Administrator.

(a) Responsibility. The governing authority shall appoint a qualified person as administrator of the birthing center to represent the governing authority and shall define the administrator's authority and duties in writing. The administrator shall be responsible for the management of the birthing center, implementation of the policies of the governing authority, and shall be authorized and empowered to carry out the provisions of these rules. Appropriate procedures to enforce these policies, assure proper patient care and safety, and meet requirements of these rules shall be developed in writing by an appropriate committee of professionals and shall be reviewed at least annually.

(b) There is a written plan in place for the operation of the birthing center in the administrator's absence.

(c) The governing authority of the birthing center shall notify the Department in writing of any change in the birthing center's administrator within 30 days of the effective date of such change.

(3) Personnel Records. The birthing center shall maintain a personnel record of each employee. At a minimum, the personnel record shall include a copy of the application for employment that contains information regarding education, certification, experience, and if applicable, registration and/or licensure information of the applicant, a current job description, all physical examinations, and evidence of continuing education or inservice training and education. Personnel records shall be confidential. Representatives of the Department conducting an inspection of the facility shall have the right to inspect personnel records.

Authors: Dana Billingsley, Denise Milledge
Statutory Authority: Code of Ala. 1975, §22-2-2(6), et seq.; §22-21-20, et seq.
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420-5-13-.03 Medical Staff.

(1) Organization. There shall be an organized medical staff consisting of a minimum of one staff physician or consultant physician, and CNMs and RNs. CPMs may also provide assistive care to the medical staff of a birthing center while a patient is laboring, during birth, and throughout the postpartum period when in the birthing center. The staff physician shall have overall responsibility for the quality of all clinical care provided to patients, and for the ethical conduct and professional practices of its staff members. In the event the birthing center does not have a qualified staff physician on the medical staff, the consultant physician shall have overall responsibility for the quality of all clinical care provided to patients, and for the ethical conduct and professional practices of its staff members. The staff physician and consultant physician shall maintain independent medical judgment related to the practice of medicine at all times.

(a) The medical staff shall be accountable to the governing authority and organized in a manner consistent with the birthing center's documented staff organization and bylaws, rules, and regulations, provided that only a physician may conduct an annual appraisal or evaluation of another physician.

(b) The medical staff shall conduct annual appraisals of its members, examine the credentials of candidates for medical staff membership, and make recommendations to the governing authority on the appointment of the candidates.

(2) The staff physician shall develop written policies and protocols for clinical care identifying the roles and responsibilities of each staff member and consultant. In the event the birthing center does not have a qualified staff physician on the medical staff, the consultant physician shall develop written policies and protocols for clinical care identifying the roles and responsibilities of each staff member and consultant. Each policy and protocol shall be signed by the staff physician or consultant physician who is a member of the medical staff. The organization and policies and protocols of the medical staff shall be approved by the birthing center's governing authority. The policies and protocols shall require that patients are admitted to the birthing center only when they have been prescheduled to deliver there following a documented period of prenatal care for a patient who has been determined to be low risk, as defined herein, through an ongoing risk assessment from the first prenatal visit throughout admission in labor, and the labor, birth, and postpartum period, and upon immediate evaluation by the medical staff to be low risk.

(a) Consultant Physician.

1. Services of a consultant physician are required in those birthing centers which do not have an Alabama licensed physician on the medical staff who serves as the staff physician. The consultant physician must have hospital obstetrical privileges with the hospital that is a party to the birthing center's Transfer Agreement and must be available to be physically present at the birthing center within 30 minutes to provide needed hands-on care to patients at the birthing center when called.

2. The responsibilities and functions of the consultant physician shall be specifically described in the policy and procedure manual and the patient care protocols.

3. The governing body shall maintain a written agreement with each consultant physician who agrees to provide advice and services to the birthing center as requested.

4. If a birthing center does not have a staff physician and is unable to enter into an agreement with a consultant physician, the license of the birthing center shall be denied or suspended, and no patient services may be rendered until an agreement with a consultant physician is formalized.

(b) The initial appointment and continued medical staff membership shall be dependent upon professional competence and ethical practice in keeping with the qualifications, standards, and requirements set forth in the medical staff policies and protocols and governing authority bylaws, rules, and regulations.

(c) Hospital Privileges. The staff physician and/or consultant physician shall have full active privileges in obstetrics at the hospital that is a party to the birthing center's Transfer Agreement.

(d) Staffing. There shall be a minimum of two licensed RNs at the birthing center at all times when patients are present, with a staffing ratio of one licensed RN for every two patients. There shall be a staff physician or consultant physician or CNM at the birthing center when a patient is laboring, during delivery, and for a minimum of 2 hours post-delivery. When the patient census exceeds the above, additional medical staff are to be called in or the patients are to be transferred to a hospital. There shall be an adequate number of medical and support staff on duty and on call to meet demands for services routinely provided and periods of high demand or emergency, to assure that no mother in active labor shall remain unattended.

(e) Licensure. All birthing center personnel shall be currently licensed to perform the services they render when such services require licensure under the laws of the state of Alabama.

(f) Health Examinations. At a minimum, each employee coming in contact with patients shall have a pre-employment health examination by a physician, certified registered nurse practitioner, or physician assistant. The examination is to be repeated annually and more frequently if indicated to ascertain freedom from communicable diseases. The extent of such examinations shall be determined by the governing authority in consultation with the staff physician and documentation made in the employee's personnel folder. The examination shall include a chest x-ray or a tuberculin test. Each employee must be offered a Hepatitis B vaccine and sign a written declination if the vaccination is refused. Documentation of immunization status for vaccine preventable diseases in pregnancy may be required.

(g) Staff Development. All medical staff will participate in an orientation and training program developed by the birthing center upon hire and at least annually in staff development, including, but not limited to, recertification of adult and infant CPR training and education programs to maintain knowledge and skills used in birthing center practice.

(h) Nursing Service.

1. Staffing Pattern. There shall be 24-hour availability of qualified RNs and CNMs as defined in these rules. A minimum of two RNs shall be in the birthing center whenever a patient is in labor, during birth, and throughout the postpartum period while a patient is in the center.

2. Nursing Care Plan. An RN must plan, supervise, and evaluate the nursing care of each patient from admission to discharge. Prior to discharge, each patient shall be given a referral with a specific time, date, and place for postpartum, family planning, and infant care. A 2-week health status of the baby shall be documented on the patient's record following review of records evidencing the pediatric or neonatal care provided at the birthing center or other facility.

3. LPNs who are currently licensed to practice within the state may provide nursing care that does not require the skill and judgment of an RN, under the supervision of an RN. LPNs providing such care shall maintain current certification in both adult and infant CPR.

(i) Certified Nurse Midwifery and Physician Service.

1. A CNM or the staff physician or consultant physician shall be in the birthing center when a patient is in labor, during birth, and for a minimum of 2 hours postpartum, or longer if necessary. A physician obstetrician and pediatrician shall be available 24 hours a day for phone consultation pursuant to a written agreement with the birthing center.

2. There shall be a minimum of one CNM or physician for every two patients in the birthing center, to ensure that every patient in labor is attended.

3. Care policies and procedures shall be consistent with professionally recognized standards and shall be in accordance with the Nurse Practice Act and Medical Practice Act of the State of Alabama. Policies shall, at a minimum, include the following:

(i) Diagnostic and therapeutic orders.

(ii) Assignment of care of patients.

(iii) Medication orders.

(iv) Charting.

(v) Infection control.

(vi) Patient and personnel safety.

(vii) Family centered maternity care.

(j) Inservice and Continuing Education. An inservice education program shall be provided for all staff members of the birthing center to improve existing practices, obtain new knowledge and skills, keep personnel informed of changes in policies and procedures, and discuss problems in the birthing center.

1. The inservice program shall be planned, scheduled, documented, and held monthly.

2. All medical staff shall participate annually in appropriate training programs for the safe and effective use of diagnostic and therapeutic equipment, for CPR, and infant resuscitation and transport.

3. All personnel shall have training that meets state and federal guidelines, as applicable, including, but not limited to, regulations of the Occupational Safety and Health Administration (OSHA), the Health Insurance Portability and Accountability Act (HIPAA), and Clinical Laboratory Improvement Amendments (CLIA).

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420-5-13-.04 Informed Consent.

(1) Before admission to services, a patient shall be informed of:

(a) The qualifications of the birthing center medical staff.

(b) The risks related to out-of-hospital childbirth.

(c) The possibility of referral or transfer if complications arise during pregnancy or labor, with additional costs for services rendered by any hospital to which the patient may be transferred.

(2) The birthing center medical staff shall obtain the patient's written consent for birthing center services using the form, "Consent to Deliver in a Birthing Center," as provided by the Department.

(3) The signed consent form shall be included with the patient's individual clinical record.

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Statutory Authority: Code of Ala. 1975, §22-2-2(6). et seq.; §22-21-20, et seq.
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420-5-13-.05 Patient Orientation and Preparation for Childbirth.

(1) Prior to admission for services, patients shall be fully informed of:

(a) The criteria adopted by the birthing center for the selection and admission of patients.

(b) The philosophy of the birthing center's governing body and medical staff regarding childbirth care and management, including the limited use of analgesics and anesthetics.

(c) The scope of services to be provided.

(d) The expectation that the patient and family will be responsible for self-care to the extent feasible and safe. Birthing centers shall not provide the level of care offered in an acute care hospital.

(e) The customary length of stay following delivery.

(f) The policies of the birthing center regarding transfer to hospitals with whom the birthing center has a written agreement.

(g) The qualifications of the medical staff.

(2) During the course of prenatal care, the patient and family, to the extent necessary, shall be counseled or instructed to prepare them for childbirth. At a minimum, the educational topics shall include:

(a) Anticipated changes during pregnancy.

(b) Need for prenatal care.

(c) Nutritional needs during pregnancy.

(d) Effects of smoking and substance abuse.

(e) Danger signs of preterm labor.

(f) What to expect during labor and delivery.

(g) Care and feeding of the newborn, including instruction on lactation (breast feeding).

Authors: Dana Billingsley, Denise Milledge
Statutory Authority: Code of Ala. 1975, §22-2-2(6), et seq.; §22-21-20, et seq.

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420-5-13-.06 Prenatal Visits.

(1) The birthing center's medical practitioners shall follow the guidelines set forth by the American College of Obstetricians and Gynecologists for testing pregnant women for sexually transmitted diseases.

(2) Initial Visit.

(a) The birthing center shall at a minimum conduct one prenatal visit in which a comprehensive health history of the patient shall be completed, which includes medical, emotional, dietary, and obstetrical data, including a preterm delivery risk assessment.

(b) A physical examination of the patient shall be completed by qualified staff, within their scope of practice, including height and weight measurements; vital signs, including blood pressure; and examination of the skin, head and neck, heart and lungs, breasts, abdomen, pelvis, and neurologic reactions.

(c) The following tests are also required to be performed by a staff member or by other of the birthing center's qualified personnel:

1. Hemoglobin and hematocrit.

2. Urinalysis by dipstick for protein, sugar, and ketones.

3. Cervical cytology. Results of a cervical cytology done within 6 months is acceptable.

4. Rh determination and blood type.

5. Prenatal screening recommended by the American Academy of Pediatrics and American College of Obstetricians and Gynecologists Guidelines for Perinatal Care and the rules and regulations of the Department, to include, but not be limited to, HIV, syphilis, and Hepatitis B surface antigen screening.

(2) At a minimum, return visits to the birthing center shall include the following measurements and testing:

(a) Weight, blood pressure, fundal height, and fetal heart rate, as applicable.

(b) Urinalysis by dipstick for protein and sugar.

(c) Hemoglobin and hematocrit should be repeated at least twice and more often if indicated during the course of the pregnancy.

(d) Review of signs and symptoms of complications of pregnancy and risk status.

(e) Examination to determine the estimated weeks of gestation, fetal position, and presentation.

(3) If prenatal visits subsequent to an initial visit are offered at the birthing center, they should be scheduled at least every 4 weeks until the 28th week, every 2 weeks until the 36th week, and then every week until delivery, unless more frequent monitoring is required. Patients must be evaluated by qualified medical staff at the birthing center at their initial prenatal visit and regularly throughout their pregnancy, with a copy of each performed risk assessment retained in their file, to assure that they remain at low risk for an adverse pregnancy outcome. If prenatal visits subsequent to the initial visit are conducted at a location other than the birthing center, visit summaries must be obtained by the birthing center and reviewed as part of the continuing risk assessment for that patient. Prenatal visits conducted by a provider other than the birthing center must be scheduled and conducted with the same frequency as the visits conducted by the birthing center under these rules and must meet the same evaluation and risk assessment requirements for each visit in order for the patient to remain eligible for delivery in the birthing center.

(4) All patients shall receive specific instruction regarding preterm labor, including the potential hazards, preventive measures, symptoms, detection and timing of contractions, and the need for prompt notification of the health provider.

(5) At least one prenatal visit in the second trimester of pregnancy shall be overseen by the staff physician or consultant physician, to certify that the patient remains eligible for delivery in the birthing center. All patients found to be at obstetrical risk pursuant to the criteria set forth in these rules shall be referred to a qualified local physician, certified by the American Board of Obstetrics and Gynecology or the American Board of Osteopathic Obstetricians and Gynecologists, for continued care.

Authors: Dana Billingsley, Denise Milledge
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420-5-13-.07 Intrapartum Care.

(1) A member of the medical staff shall be present or available to the patient at all times throughout her stay in the birthing center.

(2) The medical staff shall monitor the progress of labor and condition of the mother and fetus at sufficiently frequent intervals to identify abnormalities or complications as soon as possible.

(3) The patient shall be transferred to a hospital if complications requiring medical or surgical intervention occur, as set forth in the criteria established in these rules.

(4) The birthing center shall be able to respond to medical emergencies that may arise during the provision of services to patients, including adult basic life support, neonatal resuscitation, and initial management of postpartum complications.

(5) The patient's family or persons offering her support shall be instructed as needed to assist the patient during labor and delivery.

(6) Labor shall not be inhibited, stimulated, or augmented with drugs administered in the birthing center except when the patient is to be transported immediately to the hospital and the drug is prescribed by the medical consultant or physician who will receive the patient and manage her continued care. All such drugs shall be administered solely by appropriate, qualified staff within each staff member's permissible scope of practice.

Authors: Dana Billingsley, Denise Milledge
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420-5-13-.08 Surgical Services and Use of Analgesics and Anesthetics.

(1) No surgical procedures shall be performed in the birthing center except episiotomy, repair of episiotomy or laceration, or circumcision. Surgical repairs of fourth degree lacerations may only be performed in a birthing center by the staff physician or consultant physician. Circumcisions of male infants may be performed in a birthing center by the staff physician or consultant physician or by a CNM who has been approved to perform circumcision of male infants through a collaborative practice agreement approved by the Alabama State Board of Medical Examiners and the Alabama Board of Nursing.

(2) Systemic analgesics and local anesthetics may be administered under the following conditions:

(a) The medical staff member who administers the systemic analgesic is legally authorized to do so and shall be present in the birthing center during the use of intravenous analgesics. CPMs may not order or administer narcotic analgesia.

(b) The dosage and drugs are specifically noted in the protocols for clinical services.

(c) The use of such drugs is in conformance with the policies and procedures of the birthing center.

(3) General and conduction anesthesia shall not be administered at birthing centers.

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420-5-13-.09 Postpartum Care.

(1) Immediate postpartum care shall be provided to the mother at the birthing center by qualified members of the medical staff.

(2) The condition of the mother shall be monitored frequently to detect signs of hemorrhage or other complications requiring prompt transfer to a hospital.

(3) Adequate nutrition must be provided to the mother during her stay at the birthing center, as evidenced by written dietary requirements on file at the birthing center.

(4) Qualified members of the birthing center's staff shall perform a postpartum examination on the mother, as permitted within the staff member's legal scope of practice, prior to discharge and within 72 hours after delivery, and an additional examination of the mother shall be performed at approximately 4 to 6 weeks after delivery by the birthing center, a referral facility, or a qualified medical professional.

(a) The patient examination prior to discharge and within 72 hours shall include, at a minimum:

1. Interval history.

2. Blood pressure measurement.

3. Observation of the breasts, perineum, and abdomen.

(b) The patient examination at 4 to 6 weeks shall include all of the above and:

1. Weight.

2. Hemoglobin and hematocrit.

3. Bi-manual pelvic examination.

(5) Immediate postpartum care shall be provided to the newborn at the birthing center by qualified members of the medical staff as permitted within that staff member's legal scope of practice.

(a) A prophylaxis shall be instilled into each eye of the newborn.

(b) A cord blood sample shall be secured for laboratory testing for type, Rh determination, and direct Coombs test when the mother is Rh negative. The newborn shall also receive umbilical cord care.

(c) Newborn screening monitoring as recommended by the American Academy of Pediatrics and American College of Obstetricians and Gynecologists Guidelines for Perinatal Care and the rules and regulations of the Department, to include, but not be limited to, testing for Group B Streptococcal infection, HIV, syphilis, and metabolic screening, to include newborn hearing screening and congenital cardiac screening, as required by state law.

(d) The newborn shall be weighed, measured, and examined for abnormalities and complications, and an Apgar score shall be obtained and recorded at 1 and 5 minutes. An identification tape shall be placed on all newborns.

(e) One-half milligram of Vitamin K shall be administered to the newborn within 24 hours after birth.

(f) The newborn must be examined by a qualified medical staff member, pursuant to each one's scope of practice, prior to discharge and shall be immediately referred to a qualified physician or hospital care if any of the following conditions occur:

1. Low birth weight (under 2,500 grams).

2. Apgar score of 7 or less at 5 minutes.

3. Signs of pre- or post-maturity.

4. Jaundice.

5. Persistent hypothermia consisting of a body temperature of less than 97° F for more than 2 hours after birth.

6. Respiratory difficulties.

7. Major congenital anomalies.

8. Exaggerated tremors.

9. Any other condition requiring medical care.

(6) Discharge Criteria.

(a) Prior to discharge of the newborn, recommendations and care consistent with the American Academy of Pediatrics and American College of Obstetricians and Gynecologists Guidelines for Perinatal Care and the rules and regulations of the Department must be followed, to include, but not be limited to, any required treatment for congenital syphilis, post-exposure

prophylaxis for HIV, Hepatitis B immune globulin, and Hepatitis B vaccination. The newborn should also be evaluated for the risk for hyperbilirubinemia by either blood or transcutaneous measurement, with a written plan for medical follow up.

(b) The mother and newborn shall be discharged from the birthing center within 24 hours after the birth occurs, except under the following conditions:

1. The mother is in a deep sleep when the 24-hour period is completed. In this case, the mother shall be discharged as soon after waking as is feasible; or

2. The 24-hour period is completed between the hours of 10 p.m. and 6 a.m.

(7) If the mother or newborn is retained at the birthing center longer than 24 hours after the birth, a report shall be filed with the Department's Division of Licensure and Certification within 48 hours after the birth, describing the circumstances and reasons for retention.

(8) The mother shall be counseled and receive written information regarding breastfeeding, perineal care, family planning, signs of common complications, activities and exercises, sex relations, care and feeding of the newborn, and changing family relationships prior to discharge from the birthing center.

(9) Prior to discharge, the parents shall be instructed by the birthing center in the importance of immunization and a 2-week screening for the newborn in accordance with the American Academy of Pediatrics schedule of visits. Parents shall also be instructed in the importance of repeat metabolic screening starting at several weeks of age. The parents shall be referred to providers of pediatric care if not provided on site.

(10) Observation of the Newborn at 72 Hours and 4 to 6 Weeks. A metabolic screening test shall be performed on the newborn by the birthing center, a referral facility, or a qualified medical professional at 72 hours and shall include, at a minimum, hypothyroidism and phenylketonuria. Sickle cell testing should be included if indicated. An examination of the newborn should also be made at 4 to 6 weeks by qualified members of the birthing center's medical staff, pursuant to each staff member's legal scope of practice, or a licensed pediatrician, family medicine practitioner, or pediatric nurse practitioner.

(11) If complications in the mother or newborn occur during the postpartum period, a consultation or referral shall be made to the appropriate source of secondary or tertiary care.

(12) If the mother refuses to permit eye prophylaxis, Vitamin K injections, or a metabolic screening test prophylaxis for the newborn due to religious beliefs, a waiver indicating this decision shall be signed by the mother, witnessed by a medical staff member, and filed with the clinical record.

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420-5-13-.10 Management of Emergencies.

(1) When necessary, patients shall be transferred from the birthing center to a hospital with which a written Transfer Agreement is in effect. A complete copy of the health record of both the mother and newborn, maintained up to and including the time of transfer, shall be provided to the referred provider or facility upon transfer.

If the mother is unable to ride in an upright position, or the mother's condition is such that she needs observation or treatment by EMS personnel, or the mother requires transportation on a stretcher, gurney, or cot, the birthing center shall arrange or request transportation services only from providers who are ambulance service operators licensed by the Alabama State Board of Health and with whom the birthing center has a written agreement for the transport of a patient to the hospital named in the Transfer Agreement. For the purposes of this rule, an upright position means no more than 20° from vertical.

(2) The birthing center shall have a written protocol for emergency situations, which shall include:

(a) The name, address, telephone numbers, and contact persons of the licensed ambulance service; identify the hospital under written agreement with the birthing center to provide emergency obstetrical and neonatal services; and list other hospitals in the vicinity.

(b) The conditions specified in the arrangements between the birthing center, the ambulance service, and the hospital, including financial responsibility for services rendered.

(c) The criteria requiring medical consultation with a qualified physician who is (1) certified by the American Board of Obstetrics and Gynecology or the American Board of Osteopathic Obstetricians and Gynecologists or (2) qualified as a family practice physician with an obstetrical emphasis or fellowship, or transfer to the hospital under written agreement with the birthing center, including, but not limited to:

1. Premature labor, meaning labor occurring at less than 37 weeks gestation.

2. Estimated fetal weight less than 2,500 grams. Newborns weighing more than 4,000 grams may require referral in the clinical judgment of the staff physician or consultant physician.

3. Hypertension.

4. Pre-eclampsia.

5. Failure to progress in labor.

6. Evidence of an infectious process.

7. Premature rupture of the membranes, meaning rupture occurring more than 12 hours before onset of active labor.

8. Suspected placenta previa or abruption.

9. Non-vertex presentation.

10. Hemorrhage of greater than 500 cc of blood.

11. Anemia, consisting of less than 10 grams of hemoglobin per 100 milliliters of blood or 30 percent hematocrit.

12. Persistent fetal tachycardia (heart rate more than 160 beats per minute), repetitive fetal bradycardia (heartbeat less than 120 beats per minute), or undiagnosed abnormalities of the fetal heart tones.

13. Persistent hypothermia in the newborn.

(d) Criteria to determine risk status which requires immediate emergency transfer include, but are not limited to:

1. Prolapsed cord.

2. Uncontrolled hemorrhage.

3. Placental abruption.

4. Convulsions.

5. Major anomaly of the newborn.

6. Apgar score of 7 or less at 5 minutes.

7. Fetal heart rate of 90 or less beats each minute for 3 minutes.

8. Thick meconium staining at the time of membrane rupture.

9. Respiratory distress in the newborn.

10. Weight less than 2,500 grams.

(e) The criteria and protocols for transfer shall be readily accessible to medical staff members at all times.

(3) The name and telephone numbers of the licensed ambulance services providing transport for the birthing center, the Children's Hospital Critical Care Transport Team, and the hospital accepting transfer shall be clearly posted at each telephone in the birthing center.

(4) A written report of the transfer shall be provided and retained for quality assurance review and Departmental inspection. The report shall include:

(a) The patient's name.

(b) The date of the event.

(c) The reason for transfer.

(d) The provider and mode of transportation to the hospital.

(e) The exact time of the initial call and of any subsequent calls.

(f) Time of arrival of the emergency personnel.

(g) Time of the patient's departure from the birthing center.

(h) Time of arrival at the hospital.

(i) Name of the receiving hospital.

(j) Details concerning the initiation of EMS.

(k) The condition of the patient at the time of transfer.

(l) Any information regarding the medical care of the patient and outcome.

(5) The medical staff, consultants, and governing authority shall review and evaluate the criteria, protocols, and emergency transfer reports on a monthly basis. The results of the evaluation shall be documented.

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420-5-13-.11 Patient Records.

(1) Medical Records to be Kept. A birthing center shall keep comprehensive, organized, and readily accessible records for each patient (mother and newborn), including, but not limited to, admission and discharge notes, histories, physical examinations, nurses notes, procedure schedules, anesthesia/analgesic records, informed consent, follow-up care, and records

of tests performed. The patients' records shall be current and kept with sufficient detail, consistent with good medical and professional practice, based on the services provided to each patient.

(2) Authentication of Records. All records shall be written, dated, and signed in an indelible manner, with the identity of the writer indicated, and made part of the patient's permanent record.

(3) Indexes. All health records should be indexed according to the patient's name.

(4) Facilities. A room or area shall be designated for maintaining paper copies of patient health records within the birthing center if a paper record is prepared. The area shall be sufficiently large and adequately equipped to permit the proper processing and storing of records and to protect them from fire or water damage. Access to electronic health records shall be properly secured and restricted to the birthing center's medical staff. All health records must be easily retrievable and readily accessible to the medical staff.

(5) Ownership. Health records shall be property of the facility and must be protected against loss, destruction, and unauthorized use; responsibility for the control of all such records shall rest with the administrator and the governing authority.

(6) Preservation of Records. Health records shall be preserved either in the original form, by microfilm, or in electronic form for a period of not less than 6 years following the most recent discharge of the patient. In the case of a minor, records shall be kept for 6 years after obtaining legal age. Mother and newborn records shall be kept together.

(7) Records are Confidential. Records and information regarding patients shall be confidential; however, patients may access and request copies of their own and their newborn's medical records, consistent with the provisions of HIPAA. The clinical record shall not be released without the written consent of the patient except under the following conditions:

(a) When the patient is transferred to another source of care. A complete patient record shall accompany the mother or newborn in the event of an emergent or non-emergent transfer of care.

(b) For audit by the Department during licensure inspection.

(c) In response to a lawfully issued subpoena or court order.

(d) As otherwise provided or required by HIPAA or other applicable state or federal law.

(8) Individual Patient Records. Each patient's health record shall include, but is not limited to, at least the following information:

(a) Demographic information and patient identification.

(b) Orientation to program and informed consent.

(c) Complete social, family, medical, reproductive, nutrition, and behavioral history.

(d) Initial physical examination, laboratory tests, and evaluation of risk status.

(e) Appropriate referral of at risk patients with report of findings on risk assessment.

(f) Development of a plan for care.

(g) Continuous periodic prenatal examination and evaluation of risk factors including documentation of prenatal care provided outside the center at related practitioner or clinic sites.

(h) Instruction and education including nutritional counseling, changes in pregnancy, self-care in pregnancy, orientation to health record and understanding of findings on examinations and laboratory tests, preparation for labor, sibling preparation, preparation for early discharge, newborn assessment and care, and feeding and medical evaluation.

(i) History, physical examination, and risk assessment on admission to the birthing center in labor (labor graph).

(j) Ongoing assessment of maternal and fetal status after admission to care and during the intrapartum period.

(k) Evaluation of progress in labor with ongoing assessment of maternal and newborn reaction to the process of labor.

(l) Consultation, referral, and transfer for maternal or neonatal problems that elevate risk status.

(m) Physical assessment of newborn, including apgar scores, gestational age, maternal newborn interaction, feeding, prophylactic procedures, postpartum monitoring of vital signs, and accommodation to extrauterine life. The birthing center must perform an ongoing postpartum assessment of both mother and newborn.

(n) Labor summary.

(o) Discharge summary for mother and newborn.

(p) Plan for home care, follow-up, and referral to support groups.

(q) Plan for newborn health supervision and required screening tests.

(r) Late postpartum evaluation of mother, counseling for family planning and other services, and evaluation of mother-child relationships.

(s) Eye care, vitamin K.

(t) All entries shall be dated and signed by the attending professional staff members.

(9) Completion of records. All health records shall be completed promptly. Reports of laboratory tests, treatments, and consultations shall be entered promptly on the health record.

(10) Vital Statistics Report. A record shall be kept of all births, deaths, and stillbirths that occur within the birthing center.

(a) A certificate of birth for each live birth shall be filed with the Department's Center for Health Statistics, or as otherwise directed by the State Registrar, within 5 days after the birth, in accordance with Code of Ala. 1975, § 22-9A-7 and Ala. Admin. Code r. 420-7-1-.03.

(b) A report of fetal death shall be filed with the Center for Health Statistics, or as otherwise directed by the State Registrar, within 5 days after the occurrence is known if the fetus has advanced to, or beyond, the 20th week of uterogestation, in accordance with Code of Ala. 1975, § 22-9A-13 and Ala. Admin. Code r. 420-7-1-.03.

(c) A certificate of death shall be filed with the Center for Health Statistics, or as otherwise directed by the State Registrar, within 5 days of the death, in accordance with Code of Ala. 1975, § 22-9A-14 and Ala. Admin. Code r. 420-7-1-.03 and -.10.

(d) If a record of death or fetal death has not been created in the state's electronic registration system, the administrator or his/her designee must report to the Center for Health Statistics, or as otherwise directed by the State Registrar, any dead body or fetal death no later than the fifth day of the following month of which the body was handled by the birthing center.

(e) All records and reports registered by the birthing center with the Center for Health Statistics shall be in a format prescribed by the State Registrar.

(11) Disposition of Records. When a birthing center ceases to operate either voluntarily or by revocation of its license, the governing body shall develop a proposed plan for the disposition of its medical records. Such plan shall be submitted to the State Board of Health and shall contain provisions for the proper storage, safeguarding, and confidential transfer and/or disposal of patient medical records and x-ray files. Any birthing center that fails to develop a plan for disposition of its records acceptable to the State Board of Health shall dispose of its records as directed by a court of appropriate jurisdiction.

(12) System of Periodic Review. There shall be a system for periodic record review and documentation of issues and outcomes.

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420-5-13-.12 Rights and Responsibilities of the Patient and Family.

(1) The rights and responsibilities of the patient and family, however defined, shall be clearly delineated in the birthing center's policies and procedures and communicated on the patient's admission for care. All patients have a right to:

(a) Be treated with respect, dignity, and consideration.

(b) Be assured of confidentiality.

(c) Be informed of the benefits, risks, and eligibility requirements for care in the birthing center.

(d) Be informed of the services provided by the birthing center and those provided by contract, consultation, and referral.

(e) Be informed of the identity and qualifications of care providers, consultants, and related services and institutions.

(f) Have access to their medical records and all results of screening or diagnostic studies.

(g) Be informed of all diagnostic procedures and reports, recommendations, and treatments.

(h) Participate in decisions relating to the plan for management of the patient's care and all changes in that plan, once established, including referral or transfer to other practitioners or other levels of care.

(i) Receive a written statement of fees for services and responsibilities for payment.

(j) Be informed of the birthing center's plan for the provision of emergency and nonemergency care in the event of complications to mother or newborn.

(k) Receive a written statement of the birthing center's plan and the family's responsibility to ensure adequate supportive home care and follow-up health supervision of the mother and infant.

(l) Be informed of, and reserve the right to refuse, participation in research or student education programs.

(m) Be informed of the birthing center's policy for hearing grievances. The telephone number to register complaints with the Alabama Department of Public Health, Division of

Health Care Facilities, shall be posted in a prominent location and shall be included in the written material given to the patient upon discharge. A grievance log, including the nature of the complaint and its resolution, shall be maintained by the birthing center and made available for inspection by the Department on its request.

(n) Be informed of the liability insurance status of the birthing center and medical staff.

(2) The birthing center shall provide or demonstrate its availability to provide a range of services to meet the physical, emotional, socio-economic, informational, and medical needs of the individual patient while under care, including, but not limited to:

(a) An orientation to the facility fees and services of the birthing center.

(b) Written information, including a glossary of terms, on the established criteria for admission to, and continuation in, the birthing center's program of care.

(c) Prenatal care (may be provided at a related practitioner or clinic site).

(d) A program of education for pregnancy, labor, breastfeeding, infant care, early discharge, parenting, self-care/self-help, and sibling preparation.

(e) Laboratory services.

(f) Twenty-four (24) hour telephone consultation services.

(g) Intrapartum care.

(h) Light nourishment during labor and postpartum.

1. When patients remain in the birthing center for 24 hours, food must be provided to meet the dietary needs of those patients. If meals are prepared in the birthing center, the facility shall meet the requirements of Alabama Administrative Code, Chapter 420-5-7-.16 Hospitals, with the following exceptions:

§420-5-7-.16(3)(a) - Number of Meals
§420-5-7-.16(3)(b) - Timing of Meals
§420-5-7-.16(5)(a) - Dining Room

In addition to meeting the requirements of §420-5-7-.16(1)(a) - Direction and Supervision, the birthing center must provide a qualified food service manager and consultation by a licensed registered dietitian as required to meet the dietary needs of the patients.

2. Food prepared outside the facility shall be performed only by facilities which meet the requirements of Alabama Administrative Code, Chapter 420-3-14, Food Service Sanitation. In addition, the birthing center must provide a food preparation area with:

- Double sink, if disposables are not utilized at all times.
- Microwave oven.
- Refrigerator.
- Hand-washing sink.
- Counter space.
- Towel cabinet.
- Soap dispenser.
- Garbage cans with cover.
- Coffee maker.
- Storage area for silverware and cutlery, if disposables are not utilized at all times.

(i) Immediate postpartum care.

(j) Home or office follow-up for mother and newborn.

(k) Additional options:

1. Exercise programs.
2. Parent support groups.
3. Postpartum classes.
4. Family planning.
5. Well baby care.
6. Circumcision.
7. Nursing mother support programs.
8. Well woman gynecologic care.
9. Public education.
10. Professional education.

11. Clinical investigation and/or research.

(3) The birthing center shall inform patients that drugs for induction or augmentation of labor, vacuum extractors, and forceps are not necessary during normal labor and are not appropriate for use in birthing centers. Patients must be provided with and consent to this policy.

(4) The birthing center's policy and procedure manual shall include all aspects of birthing center practice and care and shall be made available to practitioners and support staff at all times.

(5) The birthing center's practice protocols must be approved by the staff physician or consultant physician and made available to the hospital receiving transfers upon request.

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420-5-13-.13 Quality Assurance.

(1) There shall be a written quality assurance program consisting of an interdisciplinary committee which shall perform quality assurance reviews for maternal and newborn care provided in the birthing center, including, but not limited to:

(a) At least annual review of protocols, policies, and procedures relating to the maternal and newborn care provided during the prenatal, intrapartum, and postpartum periods.

(b) The appropriateness of the criteria for determining eligibility for admission to and continuation in the birthing center's program of care.

(c) The appropriateness of diagnostic and screening procedures, including laboratory studies, sonography, and nonstress tests, and their impact on quality of care and patient cost.

(d) The appropriateness of medications prescribed, dispensed, or administered in the birthing center.

(e) Performance evaluations of medical and support staff employed by the birthing center (peer review - self evaluation).

(f) Quarterly meetings of medical staff to review the management of care of individual patients (medical chart reviews) and make recommendations for improving the plan for care.

(g) Quarterly review of all transfers of mothers and neonates to hospital care, to determine the appropriateness and quality of the transfer.

(h) Immediate review and evaluation of all complications of pregnancy, labor, and postpartum periods arising in the birthing center and the appropriateness of medical staff's consultation and treatment of the same.

(i) Evaluation of staff's ability to manage emergency situations via unannounced periodic drills for fire, maternal/newborn emergencies, power failures, etc.

(j) The birthing center's responses to patient grievances and feedback.

(2) Patient records shall be audited by the medical staff at least every 3 months and a sample audited by the quality assurance committee at least every 6 months. The audit shall evaluate the following for accuracy and completeness:

(a) Initial history, physical examination, risk assessments, and laboratory tests.

(b) Documentation of clinical observations, examinations, and treatments.

(c) Evidence that appropriate actions have been taken in response to clinical findings.

(d) Counseling, education, consultation, and referral activities are recorded.

(e) Consent forms are signed.

(f) All entries are legible, dated, and signed in ink or typed.

(3) The quality assurance committee shall analyze the incidence of maternal and perinatal morbidity and mortality, obstetrical risk assessments, pre-term labor risk assessments, consultant referrals and outcomes, and transfers of care and outcomes.

(4) The quality assurance program ensures quality of care to patients and the community through an effective system for collection and analysis of data, which includes, but is not limited to, utilization of information obtained through the following:

(a) Orientation sessions.

(b) Patient registrations.

(c) Women attending educational programs at the birthing center.

(d) Total number of encounters/visits antepartum.

(e) Number of and reasons for antepartum transfers.

(f) Intrapartum care admissions.

(g) Number of and reasons for intrapartum transfers.

(h) Time in the birthing center before delivery.

(i) Births occurring in the birthing center.

(j) Births occurring en route to the birthing center.

(k) Time in birthing center after delivery.

(l) Number of and reasons for maternal postpartum transfers.

(m) Number of and reasons for newborn transfers.

(n) Postpartum home visits.

(o) Follow-up maternal postpartum office visits.

(p) Follow-up newborn office visits.

(q) Total classes conducted antepartum.

(r) Total classes conducted postpartum.

(s) Outcomes of care provided.

1. Loss of pregnancy before 20 weeks gestation.

2. Type of anesthesia/analgesia used.

3. Type of delivery.

4. Place of delivery.

5. Complications of delivery, including postpartum hemorrhages of more than 1,000 cc.

6. Episiotomies, lacerations.

7. Infants with birth weight below 2,500 grams or over 4,000 grams.

8. Apgar scores.

9. Neonatal morbidity/mortality.

10. Maternal morbidity/mortality.

11. Maternal or newborn admissions from home to hospital in a 4-week postpartum period.

(t) Deviations from written protocols.

(5) The birthing center's quality assurance plan should, at a minimum, address any issues related to the following:

(a) Administrative or supervisory action.

(b) Continuing education or simulation.

(c) Modification of policies and procedures.

(d) Revision of risk criteria.

(e) Revision of health record or other forms.

(f) Utilization of outside consultation and expertise.

(g) Changes to facility, equipment, or supplies.

(6) Professional Accreditation. The birthing center must apply for, obtain, and maintain accreditation from a nationally recognized accrediting organization as a condition of receiving a license.

(7) Yearly Evaluation. The birthing center shall assess the needs of the childbearing community and continue to develop services and programs to address the following:

(a) The general geographical area to be served.

(b) Demographic data and vital statistics of the community to be served.

(c) Availability of and access to maternal and newborn services, including practitioners, hospital obstetrical and newborn services, home birth services, family-centered maternity care programs, birthing rooms/suites, clinics for disadvantaged families, laboratory services, supplementary social and welfare services, childbirth education, and parental support programs.

(d) Periodic market surveys to determine the impact of the birthing center on the community and to assess the needs of childbearing families in the population served, for purposes of program planning and development.

(e) Changes in population, environment, regulations, legislation, reimbursement, and access to and availability of maternal and newborn services in the community.

(8) Reports of the quality assurance committee shall be given to the governing body.

(9) The governing body shall examine the reports of the quality assurance committee and shall make such reports available for inspection by the licensing authorities for the facility and the providers.

Authors: Dana Billingsley, Denise Milledge
Statutory Authority: Code of Ala. 1975, §22-2-2(6), et seq.; §22-21-20, et seq.
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420-5-13-.14 Reports.

(1) An annual report shall be created by the birthing center no later than the 30th day of the month following the end of the calendar year and kept on file by the facility. At a minimum, the report shall contain the following information and shall be made available for inspection by the Department upon its request:

(a) Name and address of the birthing center.

(b) Number of patients accepted for care during the reporting year.

(c) Number of deliveries and number of deliveries of newborns less than 2,500 grams.

(d) Number of transfers to hospitals, the reasons for transfer, and outcomes.

(e) Number of maternal and newborn deaths and stillborns associated with birthing center patients.

(f) Range and average length of stay in hours.

(g) Range and average length of stay after birth in hours.

(h) The nature and number of surgical procedures performed in the birthing center.

(i) Any other additional information the Department may require.

Authors: Dana Billingsley, Denise Milledge
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420-5-13-.15 Pharmaceutical Services.

(1) The birthing center shall develop, implement, and enforce written policies and procedures governing the provision of pharmaceutical services.

(2) Administering Drugs and Medicines.

(a) Drugs and medicines shall not be administered to patients unless ordered by a physician duly licensed to prescribe such drugs, or, by a licensed CNM, as authorized by the CNM's collaborative practice protocol or formulary pursuant to the rules of the Alabama Board of Nursing and the Alabama State Board of Medical Examiners, as applicable, and approved protocols. Such orders shall be in writing and signed personally by the prescriber.

(b) All verbal or telephone orders for medication shall be received by an RN, LPN, CNM, physician, or registered pharmacist and shall be placed in writing into the patient's permanent medical record. The order shall include the name of the prescribing physician or CNM, accompanied by the time, date, name, and title of the person making the entry into the record. All verbal or telephone orders shall be countersigned by the prescriber within 48 hours of the order.

(c) All treatments and medications provided to patients shall be recorded in the medical record by the nurse administering the treatment or medication. CPMs may not administer drugs and medicines to patients or handle drugs or medicines for administration to patients, other than anti-hemorrhagic medication and oxygen in an emergency.

(d) Preparation and administration of medications shall be under the supervision of a physician or CNM. Pain control should depend primarily on close emotional support and adequate preparation for the birth experience.

(e) The birthing center shall not dispense any medications to outpatients. The birthing center may procure medications for its patients from community pharmacists through contractual agreements with those pharmacies. Individual medication containers shall be properly stored in individual patient bins/trays within a lockable area, room or cabinet; or the birthing center may procure medications via the staff physician's or CNM's registration. Medical staff shall administer or order medications to be administered to patients solely while in the birthing center. Medications for patients to take home shall be provided only via written prescription by the attending physician or CNM.

(f) An individual qualified by licensure and experience to meet the requirements of subsections (d) and (g) of this section shall be responsible for the overall supervision of the handling, administration, storage, record-keeping, and final disposition of medications and controlled substances stocked within the birthing center.

(g) Prescribing, dispensing, and administration of medications shall meet all standards required by law and by regulations of the Alabama State Board of Medical Examiners, the Alabama State Board of Pharmacy, and the Alabama Board of Nursing.

(3) Medicine Storage.

(a) Medicines and drugs maintained in the birthing center shall be stored in a drug room of sufficient size for orderly storage and accurate identification. The room shall be adequately illuminated and maintained at a temperature for safe storage of drugs.

(b) Safety. Drug rooms shall be provided with safeguards to prevent entrance of unauthorized persons, including bars on accessible windows and locks on doors. Controlled drugs and ethyl alcohol, if stocked, shall be stored under double locks and in accordance with applicable federal and state laws.

(c) Only authorized personnel shall have access to the drug/medicine room, as defined by the birthing center.

(d) The drug/medicine room shall be provided with a counter and sink.

(4) Emergency Kit. The birthing center, upon the written advice and written approval of its staff physician or consultant physician, shall provide an emergency kit or stock supply of drugs and medicines for the exclusive use of the physician or CNM in treating the emergency needs of patients.

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420-5-13-.16 Laboratory Services.

(1) The birthing center may provide a clinical laboratory or make contractual arrangements with a certified laboratory to perform services commensurate with the needs of the birthing center and the laboratory's level of certification.

(a) Outside Laboratory.

1. Qualifications. An approved outside laboratory may be a state licensed hospital laboratory or state licensed independent clinical laboratory and must have all necessary current federal CLIA numbers and waivers.

2. A contractual arrangement shall be deemed as meeting the requirements of this rule so long as the arrangement includes written policies, procedures, and individual chart documentation evidencing that the policies of the birthing center are met and the needs of the patients are being provided, including the processing of specimens and reporting of test results to the birthing center on a 24/7 basis, as the demands of labor and delivery require.

(b) In-House Laboratory.

1. In-house laboratory services shall be licensed by the state as required and have all necessary federal CLIA certificates and waivers. The laboratory shall be under the direction and supervision of an individual meeting the qualifications set forth in the Department's Rules and Regulations for Independent Clinical Laboratories and CLIA regulations, based on the level of laboratory testing performed.

2. The laboratory must be of sufficient size and adequately equipped to perform the necessary services of the birthing center.

3. Provisions shall be made for a preventive maintenance and an acceptable quality control program covering all types of analyses performed by the laboratory. Documentation must be maintained for both programs.

4. Written policies and procedures shall be developed and approved for all services provided by the laboratory.

5. Documentation of patient laboratory values shall be recorded on appropriate laboratory report forms and duplicate copies of these reports retained for a minimum of 2 years in the laboratory. A record must be maintained to reflect the apparent condition of the specimen collected, time and date collected, and name of the patient. All personnel collecting specimens shall be adequately and appropriately trained and, where otherwise required by law shall be licensed, and their personnel files shall reflect such training and licensure.

6. Contractual arrangements for referral laboratory testing shall be made in accordance with subsection (1)(a) above for laboratory testing procedures not provided by the in-house laboratory.

7. If medical laboratory technologists are employed on the staff of the birthing center, such technologists must meet one of the following requirements:

(i) Successful completion of 2 years of academic study (a minimum of 60 semester hours or equivalent) in an accredited college or university, with an associate degree as a medical laboratory technologist; or

(ii) Graduation from high school, and subsequent to graduation, 2 years of documented, hands-on experience as a technician trainee in a clinical laboratory of a hospital, health department, university, or medical research institution, or in a clinical laboratory providing equivalent hands-on training accepted by the Alabama Department of Public Health; or

(iii) Graduation from high school and successful completion of an official military laboratory procedures course of at least 12 calendar months of study, with at least 1 year of hands-on experience as a technician trainee in a clinical laboratory of a hospital, health department, university, or medical research institution, or in a clinical laboratory providing equivalent hands-on training accepted by the Alabama Department of Public Health.

Authors: Dana Billingsley, Denise Milledge
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420-5-13-.17 Physical Environment.

(1) Safety. The governing authority shall develop written policies and procedures designed to safeguard patients, staff, and visitors while in the birthing center and on its grounds. The policies and procedures shall include the following:

(a) Safety rules and practices pertaining to personnel, equipment, liquids, and drugs, with particular attention to hazards of children, such as uncovered electrical outlets, unsafe toys, unprotected stairs, and unlocked storage cabinets, as well as walkways, parking lots, and outside play areas.

(b) Provisions for reporting and investigation of accidental events regarding patients, visitors, and personnel (incidents), and corrective actions taken.

(c) Provision for dissemination of safety-related information to employees and users of the facility.

(d) Provision for syringe and needle storage, handling, and disposal.

(e) Provide a security alarm and camera service to ensure controlled/limited access to the facility; activate protocols to screen family members and visitors; restrict public entry to the birthing center during certain hours and all general access to patient areas; provide panic buttons for staff and alarm bracelets for mothers and infants; and develop Code Pink plans to be approved by the Department.

(2) Housekeeping/Sanitation. The birthing center shall provide a safe and sanitary environment, properly constructed and maintained to protect the health of patients.

(a) The birthing center shall be maintained in a clean condition and have written policies and procedures for housekeeping and sanitation. The birthing rooms shall be appropriately cleaned after each birth, using appropriate disinfectants to assure asepsis between each use, as approved by the Infection Control Committee.

(b) The premises and equipment shall be kept clean and free of insects, rodents, litter, and rubbish.

(c) There shall be strict adherence to regulations of OSHA for handling of medical waste, regulations of the Alabama Department of Environmental Management (ADEM), and other applicable federal regulations for disposal of medical waste (medical waste includes, but is not limited to, disposable gowns, soiled dressings, sponges, surgical gloves, bacteriological

cultures, blood and blood products, excretions, secretions, other bodily fluids, catheters, needles, IV tubing with needles attached, scalpel blades, glassware, and syringes that have been removed from their original sterile containers).

(d) Adequate arrangements for housekeeping staff shall be made, or housekeeping staff shall be employed to fulfill the above requirements. Primary patient care personnel shall not perform routine decontamination and housekeeping duties during periods in which they are caring for patients.

(3) Linen and Laundry.

(a) An adequate supply of clean linen or disposable materials shall be available at all times for the proper care and comfort of patients.

(b) Provisions for proper laundering of linen and washable goods shall be made. Linens used for draping must be sterilized. All reusable linens, including those used as sterilizing wrappers, must be laundered before reuse. Linens shall be handled, stored, processed, and transported in such a manner as to prevent the spread of infection. Soiled and clean linen must be handled and stored separately.

(c) A sufficient supply of cloth or disposable towels shall be available so that a fresh towel can be used after each hand washing. Towels shall not be shared.

(4) Disaster Preparedness.

(a) The birthing center shall have a posted plan for evacuation of patients, staff, and visitors in case of fire, severe weather, natural disasters or other emergencies, or threats to the personal safety of patients or staff.

(b) Disaster Drills.

1. At least one fire or emergency drill shall be held every 3 months to familiarize employees with the drill procedure. Reports of the drills shall be maintained with records of attendance.

2. Records shall show that action has been taken to correct any identified problems with fire drills.

(c) The birthing center shall develop a plan or methods to communicate with patients in the event of a disaster-related temporary closure of the facility. The birthing center shall advise the Department in writing of any such closure within 24 hours thereof.

(5) Infection Control.

(a) An Infection Control Committee, or comparable group, comprised of the staff physician or consultant physician and members of the nurse-midwifery staff, nursing staff,

administration, and other services of the birthing center, shall be established and shall be responsible for investigating, controlling, and preventing infections in the birthing center. The Infection Control Committee shall meet quarterly and maintain written documentation and an attendance roster for all such meetings.

(b) There shall be written procedures to govern the use of aseptic techniques and procedures in all areas of the birthing center.

(c) To keep infections at a minimum, such procedures and techniques shall be reviewed on an annual basis by the Infection Control Committee.

(d) Continuing education shall be provided on an annual basis to all birthing center personnel on the causes, effects, transmission, prevention, and elimination of infection.

(e) Reports of infections observed during any follow-up or return visit of the patient shall be made and kept as a part of the patient's medical record. The birthing center shall maintain a surveillance logbook recording all follow-up visits and telephone inquiries in which infections or other complaints are reported or observed. This logbook shall be reviewed at least once quarterly by the birthing center's staff physician or consultant physician.

(f) Efforts shall be made to determine the origin of any infection, and if the birthing process was found to be related to acquiring the infection, remedial action shall be taken to prevent recurrence.

1. In the event of sustained numbers of infections (three or more patients in 1 week), the Department shall be immediately notified. Upon order of the Department, operation of the birthing center shall be discontinued until approval for continuation of operation is granted by the Department.

2. If the birthing center wishes to contest such closure, the Department shall provide an opportunity for a hearing under the contested case provisions of the Alabama Administrative Procedure Act. Such hearing shall be held not more than 2 working days after notice of appeal is given to the Department, unless the birthing center agrees otherwise. The birthing center shall be entitled to full rights of appeal from any adverse decision rendered as a result of the hearing, in accordance with state law.

(g) Written policies and procedures shall be developed to ensure that employees with any communicable disease in an infectious stage shall not be on duty in the birthing center.

(h) Call Records. In addition to the infection control record required by these rules, a facility must keep a record of all calls taken by the RN, CNM, CPM, or physician. The call record should include the patient's name, time and date of call, a brief description of the reason for the call, date of the procedure, location of any emergency department the patient is presenting to, if known and applicable, and any action taken in response. A full description of any adverse conditions and the instructions or treatment given in response must be noted in the patient's medical record.

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420-5-13-.18 Service Facilities, Equipment, and Supplies.

(1) The birthing center shall establish and maintain a safe environment for healthy women anticipating an uncomplicated labor and birth, with adequate space for furnishings, equipment, and supplies necessary to ensure comfortable and private accommodations for the mother and family, and adequate space for personnel, including but not limited to:

(a) Admissions Office. There shall be a room designated as the admissions office, where patients may discuss personal matters in private. The admissions office may be combined with the business office and medical record room if privacy can be maintained when confidential matters are being discussed. This space shall be separated from the treatment area by walls.

(b) Business Office. This space shall be adequate for the number of birthing center personnel.

(c) Reception and Waiting Area. A waiting room shall be provided with sufficient seating for the maximum number of persons that may be waiting at any time. Public toilets, telephones, and drinking fountains, accessible to the handicapped, shall be available.

(d) Staff/Employee Locker Rooms and Toilets. The birthing center shall provide male and female toilet and locker rooms, which are centrally located.

(e) Family Room and Play Area for Children. The size and number of family rooms shall be adequate for the patient caseload. A couch, chairs, end table, reading lights, and toy storage area shall be included. Sufficient precautions for child safety shall be observed. Depending on the size of the caseload, the family area may double as a conference room and/or classroom. Toilet facilities shall be available.

(f) Conference/Educational Facilities/Library Area. These areas may be one room or separate rooms; however, each area shall be of sufficient size for the number of personnel in the birthing center and the patient caseload. The conference area may be used for childbirth classes, staff inservice education, meetings, etc.

(g) Clean Utility. A clean workroom for storage and assembly of supplies shall contain storage cabinets or storage carts, a work counter, and a sink.

(h) Soiled Utility. The soiled utility room shall contain a deep sink, work counter, waste receptacle, and soiled linen receptacle.

(i) Medicine Room. The medicine room shall include a sink, small refrigerator, locked storage, narcotic locker, and work counter. The medicine area may be combined with the clean utility room.

(j) Clean Linen Storage. The clean linen storage shall contain a closet large enough to hold an adequate supply of clean linen. This can be combined with the clean utility room.

(k) Kitchen Facilities. The kitchen/nourishment centers shall have sufficient storage for patients' prepared food and beverages. A centralized kitchen/nourishment center may be shared or individual nourishment centers may be present in each birthing room.

(l) Janitor's closet.

(m) Laundry. A laundry room with a residential washer and dryer shall be provided if an outside laundry contract is not used.

(n) Laboratory. The laboratory area shall contain a counter, sink, and storage area for supplies.

(o) Emergency cart storage.

(p) Examination Rooms. The number of examination rooms shall be adequate for the patient caseload. When used for prenatal care, the examination rooms shall be situated away from the birthing rooms. Each examination room shall contain at least 100 square feet. At least one examination room shall be provided for admission evaluation, containing an examining table with stirrups, stool, goose neck light, equipment table, sink, and supply storage area.

(q) Central Sterile Supply. Written policies and procedures shall be maintained for the sterilization of supplies and water and reprocessing of sterile supplies at specific time periods. The following areas shall be separated:

1. The receiving and clean-up area shall include a two-compartment sink with two drainboards.

2. The area for instrument pack assembly shall have a sterilizer or approved alternate source of sterilization, work counter, and a lavatory or sink. A sterile storage area shall also be provided.

3. When sterilization services are provided via contract outside of the birthing center, there shall be a separately designated area in the facility for dirty, clean, and sterile supplies.

(r) Birthing Rooms.

1. Birthing rooms shall have sufficient space for a double bed, cradle, nightstand, rocking chair, cabinet for supplies, and a sink, with a minimum of 120 square feet. A counter

area for infant resuscitation should be lighted in such a manner as to provide at least 100 foot candles at the infant's body surface, and should include an overhead source of radiant heat, a heating pad overlying a thin mattress on which the neonate is placed, and a large wall clock with a clearly visible second hand.

2. Ceiling height of the birthing rooms shall be a minimum of 8 feet.

3. Each birthing room will have immediate access to a bathroom. Tubs are recommended.

4. Birthing rooms shall be designed to provide privacy for the mother and family.

5. All walls and floors shall be suitable for washing.

6. A nurse call outlet or emergency call system shall exist, with control switches in all birthing rooms that can be activated during an emergency.

7. Portable oxygen and suction shall be available. All outlets shall be grounded.

(2) Equipment.

(a) The birthing center shall have properly maintained equipment for routine care of women and neonates, including, but not limited to:

1. A radiant heat source for newborn examination.

2. Transfer incubator or isolette.

3. Sterilizer or an approved alternate source of sterilization.

4. Blood pressure equipment, thermometers, fetoscope/doptone.

5. Intravenous equipment.

6. Oxygen equipment for mother and newborn.

7. Instruments for delivery, episiotomy, and repair.

(b) Testing and Diagnostic Equipment. All testing and diagnostic equipment, including equipment that is readily available to perform ongoing assessments of the mother and fetus/infant, shall be maintained in good working order at all times and tested on a routine basis.

1. If equipment is obsolete or permanently unusable because of irreparable damage, malfunction, or any other condition that renders its use detrimental to patient care, it shall be immediately separated from the equipment currently in use, clearly tagged as permanently unusable, and properly disposed of as soon as possible.

2. If equipment is temporarily unusable, it shall be immediately separated from equipment currently in use and clearly tagged as being temporarily unusable until it is repaired or otherwise made fit for use. Equipment is temporarily unusable if in need of repair or if not maintained in accordance with manufacturer standards, regardless of whether there is an apparent defect. Tagged equipment shall not be returned to use until repaired and tested to ensure proper operation.

(a) Preventive Maintenance. There shall be a schedule of preventive maintenance developed for all equipment in the birthing center integral to patient care to assure satisfactory operation thereof. This schedule shall cover at least the following equipment and shall be retained by the birthing center for a minimum of 2 years:

1. Ultrasound. All ultrasound machines must be tested and calibrated by a trained, qualified technician in accordance with the manufacturer's recommendations. In no event shall testing and calibration be done less than annually.

2. Autoclave. All autoclaves must be tested and maintained at least annually by a trained, qualified technician in accordance with the manufacturer's recommendations, except that necessary routine weekly cleaning, maintenance, and inspection may be performed by properly trained clinic staff or a trained, qualified technician in accordance with the manufacturer's recommendations. Dated chemical indicators shall be used with every load to ensure sterilization. Biological indicator testing must be performed every 40 service-hours, and the results of the biological indicator testing must be logged.

3. A readily accessible emergency cart or tray for the mother shall be equipped to carry out the birthing center's written emergency procedures. A written log of routine equipment maintenance shall be maintained for the emergency cart. The emergency cart or tray for the mother shall contain mechanical ventilating assistance equipment, airways, manual breathing bag, laryngoscope and endotracheal tubes, suction equipment, emergency drugs and supplies, intravenous equipment, an automatic external defibrillator (AED), blood expanders, and postpartum hemorrhagic equipment.

4. A readily accessible emergency cart or tray for the newborn shall be equipped to carry out the birthing center's written emergency procedures and shall be securely placed with a written log of routine maintenance. The emergency cart or tray for the newborn shall contain mechanical ventilating assistance equipment, airways, manual breathing bag, laryngoscope and endotracheal tubes, suction equipment, emergency drugs and supplies, and intravenous equipment and shall be available in each birthing room.

(b) The birthing center must maintain a record for all equipment containing the following information:

1. Manufacturer, make, and model of the equipment.

2. Date of purchase.

3. Any dates on which the equipment was removed from service for repair or maintenance and, if applicable, date equipment was returned to service.

4. Date and description of all tests, maintenance, or repairs performed on the equipment, including all routine inspection and maintenance performed by medical staff.

5. Names and qualifications of the company and technician performing the tests, maintenance, or repairs.

6. Results of any tests, maintenance, or repairs.

7. All manufacturer literature and information. Any missing information shall be noted in the equipment record, and if there is no record of proper maintenance in the last year, the equipment must be immediately tested and, if necessary, calibrated or repaired.

(c) The birthing center shall have properly maintained accessory equipment, which includes, but is not limited to:

1. A conveniently placed telephone and emergency call system.

2. Portable lighting, including an emergency light source.

3. Kitchen equipment usually found in home for light refreshment.

4. Laundry area for residential washer and dryer if an outside laundry contract is not used.

(3) Supplies.

(a) The inventory of supplies shall be sufficient to care for the number of childbearing women and families registered for care.

(b) Shelf life of all medications and intravenous fluids shall be monitored. Medications and supplies which have deteriorated or reached their expiration dates shall not be used for any reason. All expired or deteriorated items shall be disposed of promptly and properly. The birthing center shall examine all stored medications and supplies no less frequently than once each month and shall remove from its inventory all deteriorated items and all items for which the expiration date has been reached. The birthing center shall maintain a log recording each such examination with its date, time, the person conducting the examination, and a description of each item or group of items removed from inventory and the reason for removal.

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420-5-13-.19 Physical Plant.

(1) General.

(a) Location. The birthing center shall be in a location that is free from undue noise, smoke, dust, or foul odors and shall have sufficient parking spaces to accommodate patients and their families.

(b) Local Requirements. The birthing center shall comply with all local zoning, building, and fire ordinances. A birthing center may not be operated in a private residence.

(c) Accessibility. The birthing center shall be located on streets or roads which can be kept passable at all times.

(d) Communication. The birthing center shall have telephones to summon help in case of fire or other emergency.

(e) Occupancy. No part of the birthing center may be rented, leased, or used for any commercial purpose or for any purpose not necessary or in conjunction with the operation of the birthing center. Food and drink machines may be maintained or a diet kitchen provided for prepared foods.

(2) Submission of Plans and Specifications.

(a) Scope. A facility constructed or renovated after the effective date of these rules shall be classified as Business Occupancy and shall comply with the codes and standards adopted by the State Board of Health and in effect at the time of plan submission, including, but not limited to, the specific requirements for freestanding birth centers set forth in the Guidelines for Design and Construction of Hospitals and Outpatient Facilities, applicable Life Safety Codes, and the National Fire Protection Association (NFPA) International Building Code (IBC).

(b) New Construction, Additions, and Major Alterations. When construction is contemplated for new buildings, conversions, or additions to existing buildings coming within the scope of these rules, plans and specifications shall be submitted for review by the Department in accordance with Alabama Administrative Code Rule 420-5-22, "Submission of Plans and Specifications for Health Care Facilities."

(c) Minor Alterations and Remodeling. Minor alterations and remodeling which do not affect the structural integrity of the building, change functional operation, affect fire safety, and add services to those for which the birthing center is licensed need not be submitted for review.

(d) Water Supply, Plumbing, and Drainage. No system of water supply, plumbing, sewage, garbage, or refuse disposal shall be installed, nor shall any such existing system be

materially altered or extended until complete plans and specifications for the installation, alteration, or extension have been submitted to the Department for review.

(e) Inspections. The State Board of Health and its authorized representatives shall have access to the work for inspection wherever it is in preparation or progress.

(3) Building Requirements.

(a) Structural Soundness. The building shall be structurally sound, free from leaks and excessive moisture, in good repair, and painted at intervals to be reasonably attractive inside and out.

(b) Temperature to be Maintained. The mechanical system shall be capable of maintaining a temperature of 70° F to 75° F throughout the birthing center.

(c) Lighting. There shall be general lighting and provision for adequate examination lights in the birthing room.

(d) Screens. All screen doors and non-stationary windows (except in air-conditioned areas) shall be equipped with tight fitting, full length 16 mesh screens. Screen doors shall swing out and shall be equipped with self-closing devices.

(e) Emergency Lighting System. Emergency lighting systems shall be provided to adequately light corridors, exit signs, stairways, and lights at the exterior of each exit in case of electrical power failure.

(f) Emergency Power. An emergency generator shall be provided to operate the emergency lighting system and make life sustaining equipment operable in case of power failure. Emergency outlets shall be provided in all patient care areas.

(g) Floors. All floors in birthing rooms shall be smooth resilient tile, free from cracks, and finished for easy cleaning. All other floors shall be covered with hard tile, resilient tile, carpet, or the equivalent. Carpeting is prohibited as a floor covering in birthing rooms.

(h) Interior Finish and Decorative Materials. All combustible decorative and acoustical material, to include wall paneling, shall be as follows:

1. Materials on wall and ceiling in corridors and rooms occupied by four or more persons shall carry a flame spread rating of 25 or less and a smoke density rating of 450 or less in accordance with ASIM E-84.

2. Rooms occupied by less than four persons shall have a flame spread rating of 75 or less and a smoke density rating of 450 or less in accordance with ASIM E-84.

(i) Ramps. Ramps shall not be steeper than 1 foot of rise in 12 feet of run, shall be finished with a nonslip surface, and shall be provided with handrails on both sides. Exterior ramps, where installed, shall be provided with handrails on open sides.

(j) Doors.

1. The minimum width of doors to all rooms needing access for stretchers shall be 3 feet 8 inches.

2. Hardware on all toilet and bathroom doors shall be operable from outside the room.

3. Birthing doors shall not be equipped with hardware that will permit a patient to lock herself within the room.

(k) Floor Levels. All differences in floor levels or step-downs within the building shall be accomplished by stairs of not less than three 6-inch risers or ramps and shall be equipped with handrails on both sides.

(1) Ventilation. The building shall be well ventilated at all times. Birthing rooms shall be ventilated in such a manner as to supply fresh air and to prevent accumulation of objectionable odors. Kitchens, laundries, service rooms, toilets, bathrooms, and all inside rooms shall be ventilated by louvers, wall vents, or undercut in doors and by windows, gravity vents, or mechanical means so as to prevent offensive odors from entering other parts of the building.

(m) Fire Extinguisher. An all purpose fire extinguisher shall be provided at each exit and special hazard area and located so a person would not have to travel more than 75 feet to reach an extinguisher. Fire extinguishers shall be of a type approved by the local fire department or State Fire Marshal and shall be inspected at least annually. An attached tag shall bear the initials or name of the inspector and the date inspected.

(n) Elevators. Multi-story facilities shall be equipped with at least one automatic elevator of a size sufficient to carry a patient on a stretcher.

(o) Multi-Story Buildings. All multi-story buildings shall be of fire resistive construction in accordance with NFPA 220, Standard Types of Building Construction.

(p) Exits. Each floor of a facility shall have two or more exit ways remote from each other, leading directly to the outside or to a 2-hour fire resistive passage to the outside. Exits shall be so located that the maximum distance from any point in a floor area, room, or space to an exit doorway shall not exceed 100 feet, except that when a sprinkler system is installed, the distance of travel shall not exceed 150 feet.

(q) Exit Doors. Exit doors shall meet the following criteria:

1. Shall be no less than 44 inches wide.

2. Shall swing in the direction of the exit and shall not obstruct the travel along any required fire exit route.

3. One exit door shall be easily accessible to ambulances in the event of an emergency transport.

(r) Exit Signs. Exits shall be equipped with approved illuminated signs bearing the word "Exit" in letters at least 4 1/2 inches high. Exit signs shall be placed in corridors and passageways to indicate the direction of exit.

(s) Carpet. All carpet or pad shall carry a flame spread rating of 75 or less or a radiant flux greater than 0.45 watts per square centimeter and a smoke density rating of 450 or less.

(t) Curtains. All draperies shall be rendered and maintained flame retardant.

(u) Handicapped Facilities. The facility shall be accessible to the physically handicapped and shall comply with ANSI 117.1, "Making Buildings and Facilities Accessible and Useable by the Physically Handicapped."

(v) Garbage Disposal. Space and facilities shall be provided for the sanitary storage and disposal of waste by incineration, containerization, removal, or by a combination of these techniques. Infectious waste materials shall be rendered noninfectious on the premises by appropriate measures.

(w) Corridors. Corridors shall comply with the following:

1. All rooms shall open onto a corridor leading to an exit.

2. Corridors used by patients shall be a minimum of 6 feet wide.

3. Service corridors may be a minimum of 4 feet wide.

(x) Water Temperature. Water temperature shall be as follows:

1. Hot water at handwashing facilities shall not exceed 120° F.

2. Hot water at bathing facilities shall not exceed 110° F.

Authors: Dana Billingsley, Denise Milledge
Statutory Authority: Code of Ala. 1975, §22-2-2(6), et seq.; §22-2 1-20, et seq.
History: Filed November 19, 1987. **Amended:** Filed February 20, 1997; effective March 27, 1997. **Amended:** Filed June 18, 2002; effective July 23, 2002. **Repealed:** Filed April 16, 2010; effective May 21, 2010. **New Rule filed** XX-XX-XXXX; **effective** XX-XX-XXXX.

EXHIBIT C

M E M O R A N D U M

TO: State Committee of Public Health

THROUGH: Scott Harris, M.D., M.P.H.
State Health Officer

Karen M. Landers, M.D., F.A.A.P.
Chief Medical Officer

Amber Clark-Brown, M.D., F.A.A.P.M.R.
Medical Officer, Bureau of Health Provider Standards

FROM: Denise Milledge, M.B.A., B.S.N.
Director, Bureau of Health Provider Standards

DATE: August 8, 2023

SUBJECT: Proposed Rules for Birthing Centers, Chapter 420-5-13

The Bureau of Health Provider Standards requests final adoption on the above-referenced Rules for Birthing Centers. The Birthing Center Rules previously included in this Chapter were repealed on May 21, 2010, because there were no active birthing centers in Alabama; however, the department proposes the adoption of new rules regulating such facilities due to the recently expressed interest of several health care providers in establishing new birthing centers in various locations in the state.

The proposed rules were approved on June 15, 2023, for publication for public comment, and the comment period ended August 4, 2023. Numerous comments were received, and staff responses are enclosed. In light of these comments, several changes are proposed to the rules as published, including updating of various medical terms and criteria; clarification of timeframes related to newborn screening requirements; and updated food service and dietary provisions.

Your consideration of this request is appreciated.

DM/PK
Attachment

PUBLIC COMMENTS AND RESPONSES TO PROPOSED RULES FOR BIRTHING CENTERS IN CHAPTER 420-5-13

The department has afforded all interested parties an opportunity to submit views or arguments, orally and in writing, concerning the proposed rules for the regulation of birthing centers in Chapter 420-5-13. All written and oral submissions have been fully considered by the department. A summary of all comments, including conflicting views, received during the public comment period are reflected below, followed by the department's response.

Approximately 73 members of the public participated in the administrative hearing held on July 13, 2023, to receive comments on the proposed rules. Participants included public citizens who spoke in favor of and/or have received midwifery services, Doulas, Certified Professional Midwives (CPMs), Certified Nurse Midwives (CNMs), two Alabama licensed OB-GYNs, and representatives from the Alabama Hospital Association, the Alabama State Board of Midwifery (ASBM), the Alabama State Board of Medical Examiners (ASBME), the American Association of Birthing Centers, and various women's health groups. Over 116 general comments were received from members of the public, including a substantial number of non-residents, by the Bureau of Health Provider Standards staff and the Office of General Counsel both preceding and following the public hearing, in addition to the formal comments summarized below.

Comment 1 Summary:

Following the hearing, a letter of support regarding the proposed rules was submitted on behalf of the ASBME. In particular, the letter stated that "the Board of Medical Examiners proclaimed its support for these proposed regulations as being the appropriate *minimum standards* for any physician, or any other licensed healthcare personnel, to attend the birth of a child in an out of hospital healthcare facility."

Response:

No further revisions to the rules, as published for public comment, are proposed to the State Committee of Public Health in response to these comments.

Comment 2 Summary:

Following the hearing, a letter of support regarding the proposed rules was submitted on behalf of the Alabama Board of Nursing (ABN). In particular, the letter stated that the ABN is generally supportive of the proposed rules because they "establish additional opportunities for the care of patients during childbirth and recognize the capability of CNMs to provide safe, competent care for patients during childbirth in a setting other than a hospital." However, the ABN expressed concern regarding "the requirement that the physician 'be available to be physically present at the birthing center within 30 minutes to provide needed hands-on care to patients at the birthing center when

called.' Proposed Rules 420-5-1 3- 01(2)(f) and 420-5-13-.03(2)(a)." Specifically, the letter stated that the requirement is unnecessary and requests reconsideration of the same because:

- Only low risk patients are permitted to receive services in a birthing center (proposed Rule 420-5-13-.01(p));
- The proposed rules do not permit operative obstetrics, Cesarean sections, or the use of vacuum extractors or forceps to occur at the birthing center; thus, a patient requiring such interventions would have to be transferred to the hospital to receive that care (proposed Rule 420-5-13-.01(v)); and
- Medical consultation can be achieved through telecommunication. Patients whose conditions warrant a higher level of care must be transferred to the hospital with which the birthing center has a Transfer Agreement. Such hospital must be "located no more than 30 minutes driving time by emergency transport vehicle from the birthing center." Moreover, the Transfer Agreement itself must include "phone consultations as needed to address emergency situations." (proposed Rule 420-5-13-.01(x)).

Response:

No further revisions to the rules, as published for public comment, are proposed to the State Committee of Public Health in response to these comments. While the department acknowledges that the proposed regulations make every effort to prepare for any contingency and limit the possibility of poor outcomes for mothers and their newborns in a birthing facility, the requirement for physician availability within 30 minutes is consistent with the requirement for supervision and oversight on the part of the staff or consulting physician. However, the department is amenable to reconsideration of this requirement upon receipt of data concerning birthing outcomes in this new facility type.

Comment 3 Summary:

Following the public hearing, a letter in opposition to the proposed rules was submitted by the ASBM. In particular, the letter stated that the department's promulgation of new rules was violative of Governor Ivey's Executive Order Number 735, and the ASBM requested that the department withdraw the proposed rules and "form a new committee composed of experts in out of hospital birth to draft rules that would affect women who chose the out of hospital setting." Specifically, the letter states that the rules would:

- Effectively prohibit licensed midwives from starting or practicing independently in any birth center in Alabama. "This proposal drastically reduces the ability of Licensed Midwives to care safely for women and babies in Alabama, especially in rural areas."
- The absence of the proposed rule does not "significantly harm or endanger the public health, welfare or safety." "The safety of mothers and infants in planned,

low-risk, non-emergency births outside of a hospital setting, is already protected by The Child Birth Freedom Act in 2017 (Act 2017-383, §2.), its standards provided in law, and in the ASBM rules and regulations.

- "This rule does not allow a mother to choose her setting of birth with a licensed midwife, and women in rural Alabama and other settings will see their birth options decrease."
- There is another, less restrictive method of regulation available that could adequately protect the public, modeled after Texas freestanding birth centers, run primarily by licensed midwives.
- The rules are in direct opposition to the ability of licensed midwives to care for women in out-of-hospital settings under Ala. Code § 34-19-16(a).
- Building codes and numerous medical personnel are not required to run an efficient and safe facility.
- The requirement to obtain transfer agreements with hospitals will be opposed by the hospitals, who are the birthing centers' direct competitors.
- There have been many studies to prove that out of hospital birth is as safe, or even safer than, a hospital birth.
- The proposed rules are effectively establishing a "mini-hospital."
- The department is stretching the definition of a "hospital" to include freestanding birth centers. "The ASBM does not agree with the Attorney General's opinion that a free-standing birth center qualifies as a hospital in order for ADPH to regulate it. And therefore, we believe that ADPH's proposed definition of 'birthing center' is beyond their statutory authority to regulate 'hospitals' as defined in section 22-21-20, and as a result, improperly limits the settings in which licensed midwives can provide midwifery care."
- The language used to define a "birthing center" in Ala. Admin. Code r. 420-5-13-.02(2)(b) is "vague and ambiguous."
- CPMs should have a direct role in births, not merely assistive roles.
- "The ADPH Public Health Committee has no legal authority to propose rules which will change or limit the scope of independent practice of licensed midwives in the state of Alabama or where they may practice."
- "We feel it would be wise, safe, and more economical, and would address the needs in Alabama's maternal care deserts, if ADPH would follow the rules and guidelines already in place in Texas."

Response:

No further revisions to the rules, as published for public comment, are proposed to the State Committee of Public Health in response to these comments. In light of the comments received, the proposed rules have undergone careful review by the department's administration, staff, and legal counsel, and the inclusion of each requirement is considered necessary to ensure the health and safety of families seeking the services of a birthing center in this state. The department is acting in accordance with the opinion of the Alabama Attorney General in Op. No. 2023-2 (Dec. 15, 2022), which held that "[i]f the [State Board of Health] determines that a freestanding birth center is primarily engaged in offering obstetrical care, then the freestanding birth center is a

'hospital' as defined by section 22-21-20(1) of the Code and must be licensed by the Board." Ala. Act 2017-383 merely amends the midwifery provisions under Alabama law.

Supervision requirements for CNMs under the proposed rules are consistent with the rules of the ASBME and the ABN governing collaborative practice agreements between CNMs and physicians. The department's regulations applicable to health care facility licensing routinely include staffing and building requirements, as well as the requirement for a medical director (i.e., in the department's rules for ambulatory surgery centers, freestanding emergency departments, hospices, skilled nursing facilities, and independent laboratories). In the proposed rules for a health care facility setting, CPMs take an "assistive" role in births, since they cannot perform medical interventions in the same manner as physicians or CNMs. This does not affect their scope of practice in the home setting, where CPMs are permitted to have a direct role in births. Neither do the proposed staffing requirements alter the CPMs' scope of practice any more so than any other discipline. In particular, the department has added restrictions, even requiring additional certifications, training, etc., to physicians in the Freestanding Emergency Department (FED) setting because those restrictions were determined to best promote patient health and safety. Facilities offering care to the public are rightly subject to requirements not applicable in arrangements between CPMs and expecting mothers in private settings.

The department's rules for other health care facility types include requirements for written transfer agreements in the event medically appropriate care for a patient is not available at the treating facility and must be sought from another health care facility. In particular, transfer agreements are required under the department's licensure rules for home care hospice services (Ala. Admin. Code r. 420-5-17-.22), ambulatory surgery centers (Ala. Admin. Code r. 420-5-2-.02), rehabilitation centers (Ala. Admin. Code r. 420-5-11-.02), and skilled nursing facilities (Ala. Admin. Code r. 420-5-10-.03(38)). While ambulatory surgery centers may be viewed as direct competitors to hospitals when independently owned, they are still required to obtain transfer agreements with hospitals as a condition of licensure. Other states whose regulations for birthing centers include requirements for transfer agreements include Alaska, Delaware, Georgia, Illinois, Louisiana, Massachusetts, Mississippi, Montana, New Jersey, New York, Ohio, Oklahoma, and Pennsylvania.

Birthing centers do not otherwise appear to offer a solution to access to care in "maternity deserts." CPMs are currently authorized to provide care in private settings of a mother's choice, including any county identified as a maternity desert. Despite this, data available to the department reflects that CPMs have not done so. Based on data reported to the department's Center for Health Statistics (CHS) by CPMs for the years 2019 to date, as required by Alabama law, CPMs have assisted Alabama births in the traditional Black Belt counties of Barbour, Bullock, Butler, Choctaw, Crenshaw, Dallas, Greene, Hale, Lowndes, Macon. Marengo, Montgomery, Perry, Pickens, Pike, Russell, Sumter, and Wilcox in the following numbers/percentages:

2019 - 3/86 deliveries (3.5 percent)
2020 - 12/175 deliveries (6.9 percent)
2021 - 13/284 deliveries (4.6 percent)
2022 - 17/309 deliveries (5.5 percent)
2023 (to 7/19) - 7/167 deliveries (4.2 percent)

CPM services and the costs associated with home births may not always be covered by private insurers. When a patient is accepted for monthly services under the Alabama Medicaid program, a CNM's care must include plans for a delivery to be accomplished in a licensed hospital, except in an emergency. All CNM services must be rendered under appropriate physician supervision. Ala. Admin. Code r. 560-X-21-.06(1), (2). The department has been unable to locate any provisions under the Alabama Medicaid rules permitting services to be rendered by a CPM.

Comment 4 Summary:

Following the hearing, a letter of comment regarding the proposed rules was submitted on behalf of the Alabama Hospital Association (AlaHA). In particular, the letter questioned the need for the proposed rules and suggested that the department consider withdrawing them as being unnecessary. Should the department elect to proceed with the rules, the letter:

- Asks that the rules be clarified to make clear that ADPH must be provided evidence that need has been shown through a Certificate of Need (CON), as occurs when other healthcare facilities submit plans for review.
- Suggests that birthing centers located on a hospital campus should be owned by the hospital to assure continuity of care.
- States that there are at least three situations requiring transfers to a hospital that should be addressed in separate protocols: 1) the mother has not delivered, and the mother and/or baby are in distress and need a higher level of care; 2) delivery has occurred, and the baby is in distress and requires a higher level of care; and 3) delivery has occurred, and the mother is in distress and requires a higher level of care. AlaHA suggests that language should be added to require a birthing center to develop written protocols for each such scenario and that, when a transfer is initiated, the Medical Director of each birthing center shall be responsible for communicating with the receiving hospital *and* the appropriate medical staff at the receiving hospital to arrange for the continuance of care.

Response:

No further revisions to the rules, as published for public comment, are proposed to the State Committee of Public Health in response to these comments. In light of the comments received, the proposed rules have undergone careful review by the department's administration, staff, and legal counsel, and the inclusion of each requirement is considered necessary to ensure the health and safety of families seeking the services of a birthing center in this state.

The Alabama State Health Planning and Development Agency (SHPDA) has not yet determined whether a CON or Letter of Non-Reviewability (LNR) will be required for birthing centers, preferring to postpone that determination until final licensure rules, if any, are approved by the State Committee of Public Health. The department notes that documentation of CON approval is included in the requirements for other health care

facilities as a condition of licensure. However, as proposed, Ala. Admin. Code r. 420-5-13-.01(6)(b) provides, in pertinent part, "The birthing center shall comply with laws relating to fire and life safety, sanitation, communicable and reportable diseases, Certificate of Need review and approval, reporting of health care acquired infections, adverse event reporting, and other relevant health and safety requirements."

The department declines to impose a higher restriction on ownership of any birthing center under the proposed rules. AlaHA's proposal would limit the ability of qualified OB-GYNs to establish and maintain a birthing center on a campus for a hospital where they enjoy privileges to practice and from whom consent to establish a birthing center on campus has been obtained.

The proposed rules require the birthing center to have a written protocol for emergency situations, which shall include the criteria and protocols for transfer, consistent with professionally recognized standards of practice. A complete copy of the health record of both the mother and newborn, maintained up to and including the time of transfer, shall be provided to the referred provider or facility upon transfer. The Transfer Agreement itself must include "phone consultations as needed to address emergency situations."

Comment 5 Summary:

At the public hearing, a letter in opposition to the proposed rules was submitted by Chloe Raum, LM, CPM-TN. In particular, the letter stated that the proposed rules present a barrier to the successful operation of birthing centers in Alabama because they are "contrary to evidence-based care and industry best practices." Specifically:

- Licensed midwives with the CPM credential are restricted from serving as a primary care provider.
- Unnecessary physical facility requirements increase costs.
- Physician supervision and RN staffing requirements increase costs and create staffing bottlenecks.
- A written transfer agreement requirement allows a hospital to block the opening of a birthing center, which is its economic competitor.
- The "Low Risk Patient" qualifications are overly restrictive, thus limiting the number of women who qualify for birthing center care.

Response:

No further revisions to the rules, as published for public comment, are proposed to the State Committee of Public Health in response to these comments. In light of the comments received, the proposed rules have undergone careful review by the department's administration, staff, and legal counsel, and the inclusion of each requirement is considered necessary to ensure the health and safety of families seeking the services of a birthing center in this state. The department's rules for other health care facility types include requirements for written transfer agreements in the event medically appropriate care for a patient is not available at the treating facility and must be sought from another health care facility. In particular, transfer agreements are required under the

department's licensure rules for home care hospice services (Ala. Admin. Code r. 420-5-17-.22), ambulatory surgery centers (Ala. Admin. Code r. 420-5-2-.02), rehabilitation centers (Ala. Admin. Code r. 420-5-11-.02), and skilled nursing facilities (Ala. Admin. Code r. 420-5-10-.03(38)). While ambulatory surgery centers may be viewed as direct competitors to hospitals when independently owned, they are still required to obtain transfer agreements with hospitals as a condition of licensure. Other states whose regulations for birthing centers include requirements for transfer agreements include Alaska, Delaware, Georgia, Illinois, Louisiana, Massachusetts, Mississippi, Montana, New Jersey, New York, Ohio, Oklahoma, and Pennsylvania.

Supervision requirements for CNMs under the proposed rules are consistent with the rules of the ASBME and the ABN governing collaborative practice agreements between CNMs and physicians. The department's regulations applicable to health care facility licensing routinely include building and staffing requirements.

Comment 6 Summary:

At the public hearing, a letter in opposition to the proposed rules was submitted by Safer Birth in Bama, a 501c3 organization dedicated to the education of citizens and professionals, with the goal of improving maternal and infant mortality in Alabama. In particular, the letter stated that the proposed rules do not convey the department's core values and:

- The proposed regulations are not consistent with national standards put forth by the American Association of Birth Centers.
- The regulations are not evidence based.
- The regulations would prevent birthing centers from being able to open or operate sustainably due to unrealistic requirements.
- The regulations would place additional burdens on CNMs, CPMs, and RNs that are not present in their respective code/rules.
- The regulations discriminate against Family Practice physicians with OB/GYN specialty training and prevent them from collaborating with birth centers.
- The regulations were not formed with a collaborative meeting of all licensed care providers and seek control and not collaboration with the members of the midwifery profession.

Response:

No further revisions to the rules, as published for public comment, are proposed to the State Committee of Public Health in response to these comments. In light of the comments received, the proposed rules have undergone careful review by the department's administration, staff, and legal counsel, and the inclusion of each requirement is considered necessary to ensure the health and safety of families seeking the services of a birthing center in this state. The rules as drafted permit a medical doctor qualified as family practice physician with an obstetrical emphasis or fellowship to serve as a staff or consultant physician for a birthing center. Supervision requirements for CNMs under the proposed rules are consistent with the rules of the ASBME and the ABN

governing collaborative practice agreements between CNMs and physicians. The department's regulations applicable to health care facility licensing routinely include staffing requirements.

Comment 7 Summary:

At the public hearing, a letter in opposition to the proposed rules was submitted by Nancy Megginson, RN, CPM. The letter stated that the department has not sought the opinion of Alabama licensed midwives, who are "expert in out-of-hospital birth," when drafting these rules; that the rules go against the department's core values; and that they alter the scope of practice of Alabama licensed midwives. In particular, the letter states:

- Licensed midwives are not "assistive" personnel and do not work under an RN or any other practitioner per statute.
- Initial newborn screenings are to be performed at 24-48 hours, not at 72 hours.
- There are 11 misused terminologies, such as toxemia and intrauterine growth retardation, currently known as preeclampsia and intrauterine growth restriction.

The letter agrees that the regulations belong under ADPH facilities, but that passing them now is in violation of the Governor's Executive Order imposing a moratorium on new rules.

Response:

In light of the comments received, the proposed rules have undergone careful review by the department's administration, staff, and legal counsel. The rules include some changes to medical terminology and criteria as published, including preeclampsia and fetal growth restriction.

The proposed rules require newborn screening monitoring to be performed as recommended by the American Academy of Pediatrics and American College of Obstetricians and Gynecologists (ACOG) Guidelines for Perinatal Care and the rules and regulations of the department. While a blood sample for metabolic screening is generally taken from a newborn between 24 and 48 hours of age, the department recognizes that births may occur in birthing centers lacking their own laboratory facilities on days (such as Fridays) for which the earliest available testing would occur at 72 hours. Accordingly, the timeframe for testing was extended to 72 hours for that sole purpose.

The promulgation of these rules does not violate the Governor's Executive Order Number 735, which provides an exception for the protection of the public health, safety, or welfare. The department's regulations applicable to health care facility licensing routinely include staffing requirements. In the proposed rules for a health care facility setting, CPMs take an "assistive" role in births, since they cannot perform medical interventions in the same manner as physicians or CNMs. This does not affect their scope of practice in the home setting, where CPMs are permitted to have a direct role in births. The proposed rules' staffing requirements do not alter CPMs' scope of practice any more so than any other discipline. In particular, the department has added restrictions, even

requiring additional certifications, training, etc., to physicians in the FED setting because those restrictions were determined to best promote patient health and safety.

Comment 8 Summary:

At the public hearing, a letter in opposition to the proposed rules was submitted by the American College of Nurse-Midwives, on behalf of its Alabama affiliate. In particular, the letter stated that:

- The proposed rules impact the ability of CPMs and CNMs to practice their professions, and their input on the proposed rules was not solicited.
- The regulations will hinder the operation of a birthing center.
- It is well documented that midwifery care in a birth center setting is safe and often superior in outcomes to hospital birth.
- "In the National Birth Center study II, researchers found significantly lower rates of cesarean section birth, extremely low rates of adverse events, and no maternal deaths, all while improving cost savings to the system. These findings were replicated by Jolles et al, showing that families cared for within this model of care achieved high-quality outcomes, both in rural and urban settings, meeting or exceeding national benchmarks. The findings of the Strong Start initiative clearly demonstrated that birth centers and the midwifery model provide better outcomes for mothers and babies and reduce costs compared with typical care, and that women are highly satisfied with birth center care."
- Physicians are not experts in out-of-hospital births or the midwifery model of care that is central to birth centers. Physicians are not needed for the autonomous practice of experienced CNMs or CPMs. This is supported in the Joint Statement of Practice Relations Between Obstetricians-Gynecologists and Certified Nurse-Midwives:

  "Ob-Gyns and CNMs/CMs are educated, trained, and licensed independent clinicians who are experts in their respective fields of practice and work in mutual collaboration to optimize care for individuals they serve. Practicing to the full extent of their education, training, experience, and licensure, Ob-Gyns and CNMs/CMs support team-based care. ACOG and ACNM advocate for health care policies that ensure access to appropriate levels of care for all individuals seeking obstetric, midwifery, gynecological, and primary health care. Quality of care is enhanced by collegial relationships characterized by mutual respect and trust; professional responsibility and accountability; and national uniformity in full practice authority and licensure across all states."

- Physician response to a birthing center emergency is not needed because hospital transfer would be most appropriate. The requirement for a written transfer agreement is another unnecessary barrier. If the written agreement requirement is to remain, there should be a "good faith clause," as there is in the regulations for skilled nursing facilities (Chapter 420-5-10) to allow a birthing center to open if

they are unable to secure a written agreement after making good faith attempts to secure such an agreement.

- Requiring documentation to ADPH for every transfer feels punitive. This is not required for ambulatory surgery centers or skilled nursing facilities.
- Closure for "sustained infections' is arbitrarily defined as "three cases in one week" for birthing centers, while it remains ambiguous for surgery centers (Chapter 420-5-2) and does not exist in regulations for hospitals. Another example of increased regulation on birth centers is the mandated monthly "in-services" for staff, that are not required for nursing homes, ambulatory surgery centers, or hospitals.
- The requirement for a Pap smear within the previous 6 months prior to birthing center care "is outrageously out of date with current cervical cancer screening guidelines."
- Among the outdated requirements that do not reflect modern standards of care are calling preeclampsia "toxemia;" the use of the word "fetal wastage;" routine urine dips for protein, glucose, and ketones; mandated pelvic exams; and umbilical cord care.
- The mandated staffing requirements are a financial barrier to a sustainable birth center. It is not reasonable to require two RNs at each birth, as their salaries are cost prohibitive, in addition to the requirement for administrative personnel, staff physician(s), CNMs or CPMs, a food service manager, a licensed dietician, an infection control committee, a quality committee, and a board of directors.

Response:

In light of the comments received, the proposed rules have undergone careful review by the department's administration, staff, and legal counsel. The rules include some changes to medical terminology and criteria as published, including preeclampsia and miscarriage or spontaneous abortion. The department also recommends a change in the requirement for a Pap smear within the last 6 months, in favor of the recommendation of the American Society of Colposcopy and Cervical Pathology (ASCCP) for Pap smears every 3 years (age 21-30) and every 5 years with co-testing (age 31-64), which may not fall within the 6 months prior to pregnancy.

The department recommends a change in the proposed food and dietary service provisions to correct outdated rule references and clarify that birthing centers shall have organized dietary services that are directed and staffed by adequate qualified personnel when meals are prepared in the facility. However, a birthing center that has a contract with an outside food management company may meet the requirements of this rule if the company has a dietitian who serves the birthing center on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this rule and provides for constant liaison with the birthing center medical staff for recommendations on dietetic policies affecting patient treatment.

Ala. Admin. Code r. 420-5-10-.03(39) provides for skilled nursing facilities that "The facility is considered to have a transfer agreement in effect if the facility has attempted in good faith to enter into an agreement with a hospital sufficiently close to the facility to make transfer feasible." However, the services offerings and patient

populations of a birthing center and a skilled nursing facility are not comparable, and a lessening of this requirement does not serve the best interests of the public's health and safety. Notwithstanding the same, the department's rules governing waivers or variances may provide relief from such regulatory requirements in instances where there is a true impossibility to obtain such an agreement.

The department's rules for other health care facility types include requirements for written transfer agreements in the event medically appropriate care for a patient is not available at the treating facility and must be sought from another health care facility. In particular, transfer agreements are required under the department's licensure rules for home care hospice services (Ala. Admin. Code r. 420-5-17-.22), ambulatory surgery centers (Ala. Admin. Code r. 420-5-2-.02), rehabilitation centers (Ala. Admin. Code r. 420-5-11-.02), and skilled nursing facilities (Ala. Admin. Code r. 420-5-10-.03(38)). While ambulatory surgery centers may be viewed as direct competitors to hospitals when independently owned, they are still required to obtain transfer agreements with hospitals as a condition of licensure. Other states whose regulations for birthing centers include requirements for transfer agreements include Alaska, Delaware, Georgia, Illinois, Louisiana, Massachusetts, Mississippi, Montana, New Jersey, New York, Ohio, Oklahoma, and Pennsylvania.

Documentation required from other health care facility types may not be comparable to the documentation requirements for birthing centers, since other facility types have federal requirements on documentation imposed through their conditions of participation in the Medicare and Medicaid Programs.

Further, supervision requirements for CNMs under the proposed rules are consistent with the rules of the ASBME and the ABN governing collaborative practice agreements between CNMs and physicians. The department's regulations applicable to health care facility licensing routinely include staffing requirements. The proposed rules merely require 24-hour availability of qualified RNs unless the patient is in labor, during birth, and throughout the postpartum period, while in the center.

In the proposed rules for a health care facility setting, CPMs take an "assistive" role in births, since they cannot perform medical interventions in the same manner as physicians or CNMs. This does not affect their scope of practice in the home setting, where CPMs are permitted to have a direct role in births. Neither do the proposed staffing requirements alter the CPMs' scope of practice any more so than any other discipline. In particular, the department has added restrictions, even requiring additional certifications, training, etc., to physicians in the FED setting because those restrictions were determined to best promote patient health and safety.

Comment 9 Summary:

At the public hearing, a letter in opposition to the proposed rules was submitted by Grow Midwives, LLC, a national consulting firm engaged in the establishment of free-standing birthing centers around the country. In particular, the letter stated:

- Grow Midwives support state initiatives to implement and regulate birth centers using standards that align with the Commission for the Accreditation of Birth Centers (CABC).

- The regulations as currently proposed will hinder operating a birthing center using the midwifery-led model of care. "The midwifery-led model, as defined in two funded CMS studies, demonstrated improved outcomes and cost of care when compared to routine care. And all study participants were covered by Medicaid insurance."
- A multistakeholder, non-biased team of public health officials and diverse healthcare providers should be brought together to work on modernized, evidence-based regulations.
- "If the Alabama Dept of Health wants to improve the overall health of childbearing families, it is imperative that Alabama's Birth Center regulations are prioritized and moved forward with the requirement to implement evidence-based, national standards and criterion designed by CABC."

Response:

No further revisions to the rules, as published for public comment, are proposed to the State Committee of Public Health in response to these comments. In light of the comments received, the proposed rules have undergone careful review by the department's administration, medical staff, and legal counsel. As proposed, the rules require a birthing center to apply for, obtain, and maintain accreditation from a nationally recognized accrediting organization as a condition of receiving a license. In its comments, the CABC stated that "The proposed regulations overall are quite duplicative of the quality measures/Indicators used by CABC to evaluate birth centers for accreditation."

Comment 10 Summary:

Following the public hearing, a letter in opposition to the proposed rules was submitted by the CABC. In particular, the letter stated that:

- CABC reviews all aspects of the birth center, including:
  o business operations and financial stability
  o compliance with applicable local, state, and federal regulations and guidelines
  o facility design and compliance with applicable architectural standards
  o staff training and ongoing education and competency assessment
  o safety, quality, and appropriateness of clinical care
  o collaboration with medical, hospital, and EMS personnel
  o continuous quality improvement program
  o data collection to allow evaluation of perinatal outcomes and client experience.

- CABC requires sentinel event review by CABC-accredited birth centers and provides a formal complaint process for consumers and other stakeholders.
- CABC strongly recommends that the Alabama birth center regulations state clearly that CABC accreditation is required for licensure and that a birth center that is accredited by the CABC will be deemed as licensed in the state.

- CABC recommends that a provision be made for those birth centers operating when Alabama regulations are promulgated to allow them to continue to operate until they can achieve CABC accreditation and licensure. CABC makes provision for a 6-month temporary license, with the option of a 6-month extension. The average time for completion of the CABC accreditation process is 6-12 months.
- Requirements for formal transfer agreements create insurmountable barriers to opening a birthing center. CABC requires accredited birth centers to have a detailed plan for providing smooth access to hospital and obstetric and neonatal care specialists when needed, which is achievable without formal agreements. The Emergency Medical Treatment and Labor Act (EMTALA) requires hospitals to accept transfers of people in labor, and hospitals perceive birthing centers as competitors, making agreements difficult to obtain.
- Failure to allow CPMs to practice midwifery in birth centers is inconsistent with Ala. Code § 34-19-16. The persons appropriate for birthing center care are no different from those appropriate for home birth, considered within the scope of practice for CPMs in Alabama.
- The requirement for the staff physician to have overall responsibility for the quality of all clinical care provided to birthing center patients is inconsistent with the positions of the ACOG and the American College of Nurse-Midwives (ACNM), who recognize CNMs/CMs as independent clinicians. Licensed midwives are not required to have physician supervision or a formal practice agreement with a physician under Alabama law.
- "Requirements for formal collaborative agreements do not ensure physician availability when needed, and there is no evidence that they improve the safety or quality of care. They create an unfair economic disadvantage for birth centers and midwives."
- The requirement that the collaborative physician "oversee at least one prenatal visit in the second trimester" is not supported by any professional organization nor CABC Indicators and places an unnecessary burden on any physician considering working with the birthing center.
- The requirement that the "consultant physician must be available to be physically present at the birth center within 30 minutes to provide hands-on care to patients at the birthing center" is inappropriate. "*If the patient needs a physician, then they also need a hospital*."
- Requiring two RNs in addition to the provider (CNM, CPM, or physician) presents a significant barrier to operating a birthing center. CABC requires that two staff trained in NRP and certified in adult CPR be present for every birth, one of which is the provider (CNM/CM or CPM). Requiring 1-year's experience in obstetrics is not supported by evidence and makes RN recruitment even more difficult.
- The regulations include multiple risk criteria that are not evidence-based, not consistent with national standards, or use outdated or unclear terminology that is no longer supported or used in medical literature. Examples include:
  o Age restrictions (<16/>40)
  o Parity >5 (without physician approval)
  o "Fetal wastage"

o Intrauterine growth retardation
o Toxemia
o Pyelonephritis (if resolved?)
o History of premature delivery
o Labor "progressing normally"
o Prolonged ruptured membranes
o Required use of anticonvulsant drug
o "Drug addiction" – history of substance abuse but currently not using illegal drugs vs current use

- "**The proposed regulations overall are quite duplicative of the quality measures/Indicators used by CABC to evaluate birth centers for accreditation.** Duplicating these requirements in regulations that are less easily updated risks holding Alabama birth centers to practices and operations that are outdated and unsupported by evolving evidence. They also can serve to restrict access for childbearing individuals for whom birth center care has been shown to provide improved perinatal outcomes." Emphasis added.
- "CABC strongly advises that the proposed regulations be discarded, and that experts and stakeholders be actively involved in drafting new regulations. These experts and stakeholders include both local experts and stakeholders, including owners of all current and proposed birth centers, the Alabama Midwifery Board, the Alabama Birth Coalition, and the Alabama Midwives Alliance. The national experts include the American Association of Birth Centers, the Commission for the Accreditation of Birth Centers, the National Association of Certified Professional Midwives, and the American College of Nurse-Midwives."

Response:

In light of the comments received, the proposed rules have undergone careful review by the department's administration, medical staff, and legal counsel. The rules include some changes to medical terminology and criteria as published, including preeclampsia, fetal growth restriction, miscarriage or spontaneous abortion, and substance misuse and abuse.

As proposed, the rules require a birthing center to apply for, obtain, and maintain accreditation from a nationally recognized accrediting organization as a condition of licensure.

Supervision requirements for CNMs under the proposed rules are consistent with the rules of the ASBME and the ABN governing collaborative practice agreements between CNMs and physicians. The department's regulations applicable to health care facility licensing routinely include staffing requirements. The proposed rules merely require 24-hour availability of qualified RNs unless the patient is in labor, during birth, and throughout the postpartum period while in the center.

In the proposed rules for a health care facility setting, CPMs take an "assistive" role in births, since they cannot perform medical interventions in the same manner as physicians or CNMs. This does not affect their scope of practice in the home setting, where CPMs are permitted to have a direct role in births. Neither do the proposed staffing

requirements alter the CPMs' scope of practice any more so than any other discipline. In particular, the department has added restrictions, even requiring additional certifications, training, etc., to physicians in the FED setting because those restrictions were determined to best promote patient health and safety.

The department's rules for other health care facility types include requirements for written transfer agreements in the event medically appropriate care for a patient is not available at the treating facility and must be sought from another health care facility. In particular, transfer agreements are required under the department's licensure rules for home care hospice services (Ala. Admin. Code r. 420-5-17-.22), ambulatory surgery centers (Ala. Admin. Code r. 420-5-2-.02), rehabilitation centers (Ala. Admin. Code r. 420-5-11-.02), and skilled nursing facilities (Ala. Admin. Code r. 420-5-10-.03(38)). While ambulatory surgery centers may be viewed as direct competitors to hospitals when independently owned, they are still required to obtain transfer agreements with hospitals as a condition of licensure. Other states whose regulations for birthing centers include requirements for transfer agreements include Alaska, Delaware, Georgia, Illinois, Louisiana, Massachusetts, Mississippi, Montana, New Jersey, New York, Ohio, Oklahoma, and Pennsylvania.

While the department acknowledges that the proposed regulations make every effort to prepare for any contingency and limit the possibility of poor outcomes for mothers and their newborns in a birthing facility, the requirement for physician availability within 30 minutes is consistent with the requirement for supervision and oversight on the part of the staff or consulting physician. However, the department is amenable to reconsideration of this requirement upon receipt of data concerning birthing outcomes in this new facility type.

Comment 11 Summary:

During the public hearing, Dr. Yashica Robinson, an Alabama licensed OB-GYN in North Alabama, provided comment in opposition to the proposed rules. In particular, Dr. Robinson stated as follows:

- "Alabama is placing nearly insurmountable obstacles to opening birth centers under the premise of making births safer."
- "Right now in Alabama regulations are limiting people being able to choose the setting of their birth. I am a willing OB provider, willing and desiring to open a birth center in North Alabama. I want to provide additional low intervention options for appropriate candidates."
- "The current proposed ADPH regulations would make it difficult, if not impossible for me to do so and for it to be sustainable."
- The proposed regulations are not evidence-based, do not take into account patient values, fashion birthing centers into miniature hospitals, "exclude CPMs, the experts in out-of-hospital care from practicing as independent providers within their scope in Alabama birth centers," and push facility restrictions that do not enhance patient safety.

- "The restrictions will not make birth safer. They will just make it harder for people to obtain the care that aligns with their values, or these people may opt out of care altogether."
- Over thirty-seven percent of Alabama counties are maternity deserts without providers of maternity care. "We need to work to take affordable care to the people who need it."
- During the pandemic, Dr. Robinson stated that she cared for a patient who wanted a birth center option because she was afraid to give birth in a hospital, **but "could not afford the out-of-pocket expense of a home birth with a private midwife."** Emphasis added.

Response:

No further revisions to the rules, as published for public comment, are proposed to the State Committee of Public Health in response to these comments. In light of the comments received, the proposed rules have undergone careful review by the department's administration, staff, and legal counsel, and the inclusion of each requirement is considered necessary to ensure the health and safety of families seeking the services of a birthing center in this state.

Supervision requirements for CNMs under the proposed rules are consistent with the rules of the ASBME and the ABN governing collaborative practice agreements between CNMs and physicians. The department's regulations applicable to health care facility licensing routinely include staffing and building requirements. In the proposed rules for a health care facility setting, CPMs take an "assistive" role in births, since they cannot perform medical interventions in the same manner as physicians or CNMs. This does not affect their scope of practice in the home setting, where CPMs are permitted to have a direct role in births. Neither do the proposed staffing requirements alter the CPMs' scope of practice any more so than any other discipline. In particular, the department has added restrictions, even requiring additional certifications, training, etc., to physicians in the FED setting because those restrictions were determined to best promote patient health and safety. Facilities offering care to the public are rightly subject to requirements not applicable in arrangements between CPMs and expecting mothers in private settings.

In its comments, the CABC stated, "The proposed regulations overall are quite duplicative of the quality measures/Indicators used by CABC to evaluate birth centers for accreditation."

Birthing centers do not otherwise appear to offer a solution to access to care in "maternity deserts." CPMs are currently authorized to provide care in private settings of a mother's choice, including any county identified as a maternity desert. Despite this, data available to the department reflects that CPMs have not done so. Based on data reported to CHS by CPMs for the years 2019 to date, as required by Alabama law, CPMs have assisted Alabama births in the traditional Black Belt counties of Barbour, Bullock, Butler, Choctaw, Crenshaw, Dallas, Greene, Hale, Lowndes, Macon. Marengo, Montgomery, Perry, Pickens, Pike, Russell, Sumter, and Wilcox in the following numbers/percentages:

2019 - 3/86 deliveries (3.5 percent)
2020 - 12/175 deliveries (6.9 percent)

2021 - 13/284 deliveries (4.6 percent)
2022 - 17/309 deliveries (5.5 percent)
2023 (to 7/19) - 7/167 deliveries (4.2 percent)

CPM services and the costs associated with home births may not always be covered by private insurers. When a patient is accepted for monthly services under the Alabama Medicaid Program, a CNM's care must include plans for a delivery to be accomplished in a licensed hospital, except in an emergency. All CNM services must be rendered under appropriate physician supervision. Ala. Admin. Code r. 560-X-21-.06(1), (2). The department has been unable to locate any provisions under the Alabama Medicaid rules permitting services to be rendered by a CPM.

Comment 12 Summary:

During the public hearing, Dr. Heather Skanes, an Alabama licensed OB-GYN in the Birmingham area, on behalf of the Oasis Family Birthing Center, provided comments in opposition to the proposed rules. In particular, Dr. Skanes stated as follows:

- "Oasis Family Birthing Center began serving families and doing births in the fall of 2022. Since opening, we have served approximately two dozen families. Of those families served, the majority used our facility for births. And I can report that we had zero maternal deaths, zero infant deaths, zero birth injuries and zero transfers to the hospital. This demonstrates that we can regulate ourselves and we have safe outcomes without the assistance of ADPH."
- "Our success is due to the utilization of national standards created by clinical experts such as the American Association of Birth Centers. These proposed regulations ignore these recommendations of clinical experts and serve only the political interest of Alabama hospitals."
- "Birth centers, like Oasis Family Birth Center, and expanded access to midwifery care are a critical tool and part of the solution for responding to the maternal and infant health crisis in Alabama."

Response:

No further revisions to the rules, as published for public comment, are proposed to the State Committee of Public Health in response to these comments. In light of the comments received, the proposed rules have undergone careful review by the department's administration, staff, and legal counsel, and the inclusion of each requirement is considered necessary to ensure the health and safety of families seeking the services of a birthing center in this state. Dr. Skanes has cooperated with a cease and desist request from the department concerning the operation of the Oasis Family Birthing Center, effective April 2023.

Comment 13 Summary:

Following the hearing, a letter in opposition to the proposed rules was submitted by Dr. Heather Skanes, an Alabama licensed OB-GYN in the Birmingham area, on behalf of the Oasis Family Birthing Center. In particular, the letter stated that the development of birth centers and implementation of midwifery care will expand access to quality health care and improve outcomes in maternal care deserts, especially in rural areas where care options are limited. Specifically, the proposed rules should be revised to:

- Eliminate the requirement for written hospital and ambulance transfer agreements, which are not necessary due to EMTALA and are unethical to impose.
- Include CPMs as eligible attendants for births in birth centers and allow them to work within their full scope of practice, without supervision by physicians or CNMs as they currently do for home births.
- Remove the requirement for RNs. Nurses are in short supply and not needed in birthing centers.
- Remove distance requirements. Requiring licensed birth centers to be within 30 minutes of a hospital that provides OB services makes it impossible for providers to meet the needs of rural communities that have the greatest need.
- Remove language such as “fetal growth retardation,” which is inappropriate terminology. This should be replaced with “fetal growth restriction.”
- Remove criteria requiring women to have less than five children.
- Remove age restrictions.
- Remove requirement of a Pap smear within the last 6 months. Recommendation by the American Society of Colposcopy and Cervical Pathology (ASCCP) is for Pap smears every 3 years (age 21-30) and every 5 years with co-testing (age 31-64), which may not fall within the 6 months prior to pregnancy.
- Remove requirement of urinalysis with each prenatal visit. ACOG states, “In the absence of both risk factors and symptoms for preeclampsia, there has not been shown to be a benefit in routine urine dipstick testing for women of low risk.”
- Remove requirement for pelvic examination and hemoglobin prior to discharge from birthing center. ACOG recommends women have pelvic exams only when they have symptoms or have a medical history that requires it.
- Remove definition of premature rupture of membranes (PROM), which recommends consultation or transfer for rupture >12 hours before active labor. ACOG guidelines on management of PROM consider expectant management for PROM up to 24 hours acceptable management and does not exclude patients from birth center or midwifery scope of practice.
- Correct hemorrhage definition to >1000 cc to be consistent with ACOG definition.
- Correct fetal bradycardia definition to be <110 bpm for greater than 10 minutes to be consistent with ACOG definitions.
- Remove clinically unnecessary structural requirements, like 6-ft corridors and sprinkler systems. Many qualified providers renovate homes to convert to a birth center. This is cost effective and safe. Unnecessary structural requirements

increase cost without any true benefit. This will have the undesired effect of limiting the opening of birth centers in areas with great need.

- Remove the requirement for each center to have an isolet for infant transfer. The neonatal transport team will come with an isolet if needed.
- Remove the requirement for a CON.
- Remove requirements for annual certifications as most certifications are good for 2 years.
- Staff physicians in birthing centers should not have overall responsibility for the quality of clinical care provided to patients and for the ethical conduct and professional practices of the center's staff members.
- **Birthing centers should not be required to be accredited by the American Association of Birthing Centers (AABC)**. The accreditation process takes a significant amount of time and would delay provision of services and business revenue while awaiting status. While many birth centers can and do meet AABC standards for accreditation, they may opt out, as the yearly accreditation fees may be cost prohibitive to smaller birthing centers. Emphasis added.
- The requirements to provide a security alarm and camera service to ensure controlled limited access to the facility, separate locker rooms for males and females, and nurse or emergency call systems are expensive and unnecessary.
- The requirement for a written agreement with a consultant physician will inhibit the development of midwifery owned and led birthing centers.
- The timing of in-services should be determined by the facility.

Response:

In light of the comments received, the proposed rules have undergone careful review by the department's administration, staff, and legal counsel, and the inclusion of each requirement is considered necessary to ensure the health and safety of families seeking the services of a birthing center in this state. The rules include some changes to medical terminology and criteria as published, including fetal growth restriction and fetal bradycardia. The department also recommends a change in the requirement for a Pap smear within the last 6 months, in favor of the recommendation of the American Society of Colposcopy and Cervical Pathology (ASCCP) for a Pap smear every 3 years (age 21-30) and every 5 years with co-testing (age 31-64), which may not fall within the 6 months prior to pregnancy.

Supervision requirements for CNMs under the proposed rules are consistent with the rules of the ASBME and the ABN governing collaborative practice agreements between CNMs and physicians. The department's regulations applicable to health care facility licensing routinely include staffing, security, and building requirements, as well as the requirement for a medical director (i.e., in the department's rules for ambulatory surgery centers, freestanding emergency departments, hospices, skilled nursing facilities, and independent laboratories). The proposed rules merely require 24-hour availability of qualified RNs unless the patient is in labor, during birth, and throughout the postpartum period, while in the center.

In the proposed rules for a health care facility setting, CPMs take an "assistive" role in births, since they cannot perform medical interventions in the same manner as

physicians or CNMs. This does not affect their scope of practice in the home setting, where CPMs are permitted to have a direct role in births. Neither do the proposed staffing requirements alter the CPMs' scope of practice any more so than any other discipline. In particular, the department has added restrictions, even requiring additional certifications, training, etc., to physicians in the FED setting because those restrictions were determined to best promote patient health and safety. Facilities offering care to the public are rightly subject to requirements not applicable in arrangements between CPMs and expecting mothers in private settings.

The department's rules for other health care facility types include requirements for written transfer agreements in the event medically appropriate care for a patient is not available at the treating facility and must be sought from another health care facility. In particular, transfer agreements are required under the department's licensure rules for home care hospice services (Ala. Admin. Code r. 420-5-17-.22), ambulatory surgery centers (Ala. Admin. Code r. 420-5-2-.02), rehabilitation centers (Ala. Admin. Code r. 420-5-11-.02), and skilled nursing facilities (Ala. Admin. Code r. 420-5-10-.03(38)). While ambulatory surgery centers may be viewed as direct competitors to hospitals when independently owned, they are still required to obtain transfer agreements with hospitals as a condition of licensure. Other states whose regulations for birthing centers include requirements for transfer agreements include Alaska, Delaware, Georgia, Illinois, Louisiana, Massachusetts, Mississippi, Montana, New Jersey, New York, Ohio, Oklahoma, and Pennsylvania.

Documentation of CON approval is included in the requirements for other health care facilities as a condition of licensure and must be provided for birthing centers, as applicable. SHPDA has not yet determined whether a CON or LNR will be required for birthing centers, preferring to postpone that determination until final licensure rules, if any, are approved by the State Committee of Public Health.

Birthing centers do not otherwise appear to offer a solution to access to care in "maternity deserts." CPMs are currently authorized to provide care in private settings of a mother's choice, including any county identified as a maternity desert. Despite this, data available to the department reflects that CPMs have not done so. Based on data reported to CHS by CPMs for the years 2019 to date, as required by Alabama law, CPMs have assisted Alabama births in the traditional Black Belt counties of Barbour, Bullock, Butler, Choctaw, Crenshaw, Dallas, Greene, Hale, Lowndes, Macon. Marengo, Montgomery, Perry, Pickens, Pike, Russell, Sumter, and Wilcox in the following numbers/percentages:

2019 - 3/86 deliveries (3.5 percent)
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2022 - 17/309 deliveries (5.5 percent)
2023 (to 7/19) - 7/167 deliveries (4.2 percent)

CPM services and the costs associated with home births may not always be covered by private insurers. When a patient is accepted for monthly services under the Alabama Medicaid Program, a CNM's care must include plans for a delivery to be accomplished in a licensed hospital, except in an emergency. All certified nurse midwife services must be rendered under appropriate physician supervision. Ala. Admin. Code r. 560-X-21-.06(1),

(2). The department has been unable to locate any provisions under the Alabama Medicaid rules permitting services to be rendered by a CPM.

Comment 14 Summary:

During the public hearing, Aubre Tompkins, President of the AABC, provided comments in opposition to the proposed rules. In particular, the AABC stated as follows:

- The proposed regulations are outdated, nonevidence-based and actually represent clear danger and harm if they are followed as written. They would effectively prevent birthing centers from opening.
- Birth centers led by midwives decrease maternal mortality, decrease infant mortality, and decrease the rate of caesarean birth while increasing all of the positive outcomes associated with them.
- These regulations should be completely disregarded and redrafted with the assistance of experts in birth center and midwifery care.

Response:

No further revisions to the rules, as published for public comment, are proposed to the State Committee of Public Health in response to these comments. In light of the comments received, the proposed rules have undergone careful review by the department's administration, staff, and legal counsel, and the inclusion of each requirement is considered necessary to ensure the health and safety of families seeking the services of a birthing center in this state.

Comment 15 Summary:

Following the public hearing, a letter in opposition to the proposed rules was submitted by the AABC. In particular, AABC recommends that the regulations clearly state that an Alabama birthing center will be deemed licensed when accredited by the CABC. Specifically, the letter states that:

- Many of the provisions outlined in the proposed regulations do not align with current evidence based national standards or CABC accreditation. Since CABC accreditation will be required for all licensed birth centers in the state, CABC indicators should be used for licensure.
- The requirement for a medical director or supervising physician in the facility should be eliminated and is not associated with better outcomes. In the event of a clinical situation requiring physician involvement, the safest course of action is to transfer the patient to a hospital where a physician is ready and able to intervene as needed.
- CPMs are the only perinatal care provider type with an educational pathway that requires training and demonstrated expertise in the out of hospital setting. Over half the birth centers in the country are owned and/or staffed by CPMs. This designation as "assistive personnel" is out of alignment with AABC Standards.

Current studies that show improved outcomes with birth center care include birth centers led by CPMs, CNMs, and certified midwives.

- The requirement for RNs in the birthing center is in direct contradiction to AABC and CABC standards and indicators. While RNs are valuable care givers and highly regarded professionals in their own right, they are not required staff for birth centers. Birth assistants may be paramedics, midwifery students, or other personnel who are trained to provide assistance at a birth outside the hospital setting, such as those who've completed AABC's Community Birth Assistant Training. There is no need to have two RNs present if there is only one laboring patient in the building, as may often be the case in a low volume birth center.
- The requirement for a written transfer agreement with a hospital constitutes a barrier for birthing centers within the state and is not necessary due to EMTALA requirements. Thirty-seven percent of Alabama counties are maternity care deserts where there are no midwifery or obstetric services. Freestanding birth centers can fill vital gaps in the state's perinatal care infrastructure, especially in the context of rural labor and delivery unit closures. Where birthing centers are not yet integrated into the health care system, hospitals may refuse to enter into signed transfer agreements. Thus, the AABC standards and CABC accreditation require the birthing center to have written policies and procedures for collaboration and safe transfer of care.
- The criteria for a "low risk patient" should not include the following:
    - Toxemia should be changed to pre-eclampsia.
    - Fetal wastage is offensive and is properly miscarriage and spontaneous abortion.
    - National standards permit birthing centers to care for those with five or more term pregnancies if they have a low risk medical and obstetrical history.
    - CABC accreditation does not prevent birthing centers from providing vaginal birth after a previous cesarean if other risk factors do not complicate the pregnancy or birth.
    - Birthing centers may also care for a nullipara over 40 years of age and will use clinical judgment on this risk factor for appropriateness for birth center admission in labor.
    - For a pregnancy impacted by congenital anomalies, there may be cases where a condition is not compatible with extrauterine life. In these cases, the birthing center should be an option as a place for birth of that fetus if the family chooses.
- The AABC recommends the formation of a committee or taskforce of local and national birth center experts, perinatal care providers, and other stakeholders to draft new regulations for review, including Alabama State Board of Midwifery, Alabama Midwives Alliance, Alabama Chapter of the American College of Nurse Midwives, AABC, CABC, National Association of Certified Professional Midwives, Alabama Birth Coalition, Safer Birth in Bama, and consumer representation through the inclusion of Alabama residents of childbearing age.

Response:

In light of the comments received, the proposed rules have undergone careful review by the department's administration, medical staff, and legal counsel. The rules include some changes to medical terminology and criteria as published, including preeclampsia and miscarriage or spontaneous abortion.

As proposed, the rules require a birthing center to apply for, obtain, and maintain accreditation from a nationally recognized accrediting organization as a condition of receiving a license. In its comments, the CABC stated, "The proposed regulations overall are quite duplicative of the quality measures/Indicators used by CABC to evaluate birth centers for accreditation."

Supervision requirements for CNMs under the proposed rules are consistent with the rules of the ASBME and the ABN governing collaborative practice agreements between CNMs and physicians. The department's regulations applicable to health care facility licensing routinely include staffing requirements, as well as the requirement for a medical director (i.e., in the department's rules for ambulatory surgery centers, FEDs, hospices, skilled nursing facilities, and independent laboratories). The proposed rules merely require 24-hour availability of qualified RNs unless the patient is in labor, during birth, and throughout the postpartum period, while in the center, with a staffing ratio of one licensed RN for every two patients.

In the proposed rules for a health care facility setting, CPMs take an "assistive" role in births, since they cannot perform medical interventions in the same manner as physicians or CNMs. This does not affect their scope of practice in the home setting, where CPMs are permitted to have a direct role in births. Neither do the proposed staffing requirements alter the CPMs' scope of practice any more so than any other discipline. In particular, the department has added restrictions, even requiring additional certifications, training, etc., to physicians in the FED setting because those restrictions were determined to best promote patient health and safety.

The department's rules for other health care facility types include requirements for written transfer agreements in the event medically appropriate care for a patient is not available at the treating facility and must be sought from another health care facility. In particular, transfer agreements are required under the department's licensure rules for home care hospice services (Ala. Admin. Code r. 420-5-17-.22), ambulatory surgery centers (Ala. Admin. Code r. 420-5-2-.02), rehabilitation centers (Ala. Admin. Code r. 420-5-11-.02), and skilled nursing facilities (Ala. Admin. Code r. 420-5-10-.03(38)). Other states whose regulations for birthing centers include requirements for transfer agreements include Alaska, Delaware, Georgia, Illinois, Louisiana, Massachusetts, Mississippi, Montana, New Jersey, New York, Ohio, Oklahoma, and Pennsylvania.

Birthing centers do not otherwise appear to offer a solution to access to care in "maternity deserts." CPMs are currently authorized to provide care in private settings of a mother's choice, including any county identified as a maternity desert. Despite this, data available to the department reflects that CPMs have not done so. Based on data reported to CHS by CPMs for the years 2019 to date, as required by Alabama law, CPMs have assisted Alabama births in the traditional Black Belt counties of Barbour, Bullock, Butler, Choctaw, Crenshaw, Dallas, Greene, Hale, Lowndes, Macon. Marengo, Montgomery, Perry, Pickens, Pike, Russell, Sumter, and Wilcox in the following numbers/percentages:

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CPM services and the costs associated with home births may not always be covered by private insurers. When a patient is accepted for monthly services under the Alabama Medicaid Program, a CNM's care must include plans for a delivery to be accomplished in a licensed hospital, except in an emergency. All CNM services must be rendered under appropriate physician supervision. Ala. Admin. Code r. 560-X-21-.06(1), (2). The department has been unable to locate any provisions under the Alabama Medicaid rules permitting services to be rendered by a CPM.

Comment 16 Summary:

Following the hearing, a letter in opposition to the proposed rules was submitted on behalf of the Alabama Affiliate of the American College of Nurse-Midwives, the Alabama Birth Center, Alabama Midwives Alliance, Alabama State Board of Midwifery, AABC, American College of Nurse-Midwives, Birth Sanctuary Gainesville, CABC, National Association of Certified Professional Midwives, Oasis Family Birthing Center, and the Policy Institute for Community Birth and Midwifery. In particular, the letter restates the same objections to the proposed regulations set forth in the letter submitted by the AABC, and demands that the rules as promulgated be discarded and a taskforce including the following be convened to draft new rules: the Alabama State Board of Midwifery, Alabama Birth Center owners including Heather Skanes, Yashica Robinson, and Stephanie Mitchell, AABC, CABC, American College of Nurse-Midwives, Alabama Affiliate, National Association of Certified Professional Midwives, and Alabama Midwives Alliance.

Response:

No further revisions to the rules, as published for public comment, are proposed to the State Committee of Public Health in response to these comments. In light of the comments received, the proposed rules have undergone careful review by the department's administration, medical staff, and legal counsel. As proposed, the rules require a birthing center to apply for, obtain, and maintain accreditation from a nationally recognized accrediting organization as a condition of receiving a license. In its comments, the CABC stated, "The proposed regulations overall are quite duplicative of the quality measures/Indicators used by CABC to evaluate birth centers for accreditation."

Supervision requirements for CNMs under the proposed rules are consistent with the rules of the ASBME and the ABN governing collaborative practice agreements between CNMs and physicians. The department's regulations applicable to health care facility licensing routinely include staffing requirements. In the proposed rules for a health care facility setting, CPMs take an "assistive" role in births, since they cannot

perform medical interventions in the same manner as physicians or CNMs. This does not affect their scope of practice in the home setting, where CPMs are permitted to have a direct role in births. Neither do the proposed staffing requirements alter the CPMs' scope of practice any more so than any other discipline. In particular, the department has added restrictions, even requiring additional certifications, training, etc., to physicians in the FED setting because those restrictions were determined to best promote patient health and safety.

The department's rules for other health care facility types include requirements for written transfer agreements in the event medically appropriate care for a patient is not available at the treating facility and must be sought from another health care facility. In particular, transfer agreements are required under the department's licensure rules for home care hospice services (Ala. Admin. Code r. 420-5-17-.22), ambulatory surgery centers (Ala. Admin. Code r. 420-5-2-.02), rehabilitation centers (Ala. Admin. Code r. 420-5-11-.02), and skilled nursing facilities (Ala. Admin. Code r. 420-5-10-.03(38)). Other states whose regulations for birthing centers include requirements for transfer agreements include Alaska, Delaware, Georgia, Illinois, Louisiana, Massachusetts, Mississippi, Montana, New Jersey, New York, Ohio, Oklahoma, and Pennsylvania.

Birthing centers do not otherwise appear to offer a solution to access to care in "maternity deserts." CPMs are currently authorized to provide care in private settings of a mother's choice, including any county identified as a maternity desert. Despite this, data available to the department reflects that CPMs have not done so. Based on data reported to CHS by CPMs for the years 2019 to date, as required by Alabama law, CPMs have assisted Alabama births in the traditional Black Belt counties of Barbour, Bullock, Butler, Choctaw, Crenshaw, Dallas, Greene, Hale, Lowndes, Macon. Marengo, Montgomery, Perry, Pickens, Pike, Russell, Sumter, and Wilcox in the following numbers/percentages:

2019 - 3/86 deliveries (3.5 percent)
2020 - 12/175 deliveries (6.9 percent)
2021 - 13/284 deliveries (4.6 percent)
2022 - 17/309 deliveries (5.5 percent)
2023 (to 7/19) - 7/167 deliveries (4.2 percent)

CPM services and the costs associated with home births may not always be covered by private insurers. When a patient is accepted for monthly services under the Alabama Medicaid Program, a CNM's care must include plans for a delivery to be accomplished in a licensed hospital, except in an emergency. All CNM services must be rendered under appropriate physician supervision. Ala. Admin. Code r. 560-X-21-.06(1), (2). The department has been unable to locate any provisions under the Alabama Medicaid rules permitting services to be rendered by a CPM.

Comment 17 Summary:

Following the hearing, a letter in opposition to the proposed rules was submitted on behalf of the International Cesarean Awareness Network (ICAN), "a nonprofit organization whose mission is to improve maternal-child health by reducing preventable cesareans through education, supporting cesarean recovery, and advocating for vaginal birth after cesarean (VBAC)." In particular, the letter stated that the proposed regulations

will restrict access of midwives in Alabama, unjustly limit the scope of practice for CPMs, and make it nearly impossible to open and sustain birth centers. Specifically:

- The AABC reported that under the Strong Start for Mothers and Newborns Initiative funded by the Center for Medicare and Medicaid Innovation as part of the Affordable Care Act, birthing centers delivered improved health outcomes at a lower cost, averaging 21 percent lower cost of birth and 15 percent lower cost for care for women and infants for the first year after birth.
- Midwives could be used to solve shortages of maternity care that disproportionately affect rural and low-income mothers.
- Issues with the regulations include CPM restrictions, eligibility criteria that are not evidence based, physician role, transfer agreements, and RN staffing requirements.

Response:

No further revisions to the rules, as published for public comment, are proposed to the State Committee of Public Health in response to these comments. In light of these comments, the proposed rules have undergone careful review by the department's administration, staff, and legal counsel, and the inclusion of each requirement is considered necessary to ensure the health and safety of families seeking the services of a birthing center in this state.

Supervision requirements for CNMs under the proposed rules are consistent with the rules of the ASBME and the ABN governing collaborative practice agreements between CNMs and physicians. The department's regulations applicable to health care facility licensing routinely include staffing requirements. In the proposed rules for a health care facility setting, CPMs take an "assistive" role in births, since they cannot perform medical interventions in the same manner as physicians or CNMs. This does not affect their scope of practice in the home setting, where CPMs are permitted to have a direct role in births. Neither do the proposed staffing requirements alter the CPMs' scope of practice any more so than any other discipline. In particular, the department has added restrictions, even requiring additional certifications, training, etc., to physicians in the FED setting because those restrictions were determined to best promote patient health and safety.

The department's rules for other health care facility types include requirements for written transfer agreements in the event medically appropriate care for a patient is not available at the treating facility and must be sought from another health care facility. In particular, transfer agreements are required under the department's licensure rules for home care hospice services (Ala. Admin. Code r. 420-5-17-.22), ambulatory surgery centers (Ala. Admin. Code r. 420-5-2-.02), rehabilitation centers (Ala. Admin. Code r. 420-5-11-.02), and skilled nursing facilities (Ala. Admin. Code r. 420-5-10-.03(38)). Other states whose regulations for birthing centers include requirements for transfer agreements include Alaska, Delaware, Georgia, Illinois, Louisiana, Massachusetts, Mississippi, Montana, New Jersey, New York, Ohio, Oklahoma, and Pennsylvania.

Birthing centers do not otherwise appear to offer a solution to access to care in "maternity deserts." CPMs are currently authorized to provide care in private settings of a

mother's choice, including any county identified as a maternity desert. Despite this, data available to the department reflects that CPMs have not done so. Based on data reported to the department's CHS by CPMs for the years 2019 to date, as required by Alabama law, CPMs have assisted Alabama births in the traditional Black Belt counties of Barbour, Bullock, Butler, Choctaw, Crenshaw, Dallas, Greene, Hale, Lowndes, Macon. Marengo, Montgomery, Perry, Pickens, Pike, Russell, Sumter, and Wilcox in the following numbers/percentages:

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CPM services and the costs associated with home births may not always be covered by private insurers. When a patient is accepted for monthly services under the Alabama Medicaid program, a CNM's care must include plans for a delivery to be accomplished in a licensed hospital, except in an emergency. All CNM services must be rendered under appropriate physician supervision. Ala. Admin. Code r. 560-X-21-.06(1), (2). The department has been unable to locate any provisions under the Alabama Medicaid rules permitting services to be rendered by a CPM.

Comment 18 Summary:

Following the hearing, a letter in opposition to the proposed rules was submitted on behalf of individuals associated with Case Western Reserve University and other private citizens, who utilized these comments as a form letter. In particular, the letter stated that the proposed regulations create significant barriers and hardship for Alabama families and are restrictive and unsafe. Specifically:

- Requiring physician oversight of birthing centers. Alabama's Black Belt counties do not have any licensed OB-GYNs available for oversight or any who are competent in overseeing midwifery practices.
- Excluding CPMs in a state where midwives have historically assisted black communities.
- Requiring written contracts for transfer of care between birth centers and a hospital are "unethical" in light of EMTALA.
- Limiting CPMs to assistance personnel required to work under MDs or CNMs is in opposition to the CPM scope of practice under Alabama law. Requiring two nurses to be present for births is not standard care in hospital-based births, and obstetric nurses are not educated or trained in midwifery models of care.
- The regulations are not aligned with National Birth Center standards or accreditation requirements. They are also at odds with regulations in other states whose maternal morbidity and mortality rates are significantly better than Alabama's. "With this context, it is clear these regulations are racist and medically neglectful to the health and welfare of the public of Alabama."

- Restricting midwifery practice additionally conflicts with ADPH's own strategic plan to reduce and eliminate cervical cancer.
- The proposed regulations conflict with Alabama Perinatal Excellence Collaborative's (APEC) mission statement:
  To lower infant mortality and improve maternal and infant health in Alabama through:
  Implementation and utilization of evidence-based obstetric care guidelines (ACOG supports and recommends midwifery care for low risk individuals);
  Assessment of meaningful quality benchmarks (midwives are capable of contributing to community health assessment and quality improvement initiatives);
  Enhanced communication and collaboration with providers, both primary and sub-specialty, and patients.

Response:

No further revisions to the rules, as published for public comment, are proposed to the State Committee of Public Health in response to these comments. In light of these comments, the proposed rules have undergone careful review by the department's administration, staff, and legal counsel, and the inclusion of each requirement is considered necessary to ensure the health and safety of families seeking the services of a birthing center in this state.

Supervision requirements for CNMs under the proposed rules are consistent with the rules of the ASBME and the ABN governing collaborative practice agreements between CNMs and physicians. The department's regulations applicable to health care facility licensing routinely include staffing requirements. In the proposed rules for a health care facility setting, CPMs take an "assistive" role in births, since they cannot perform medical interventions in the same manner as physicians or CNMs. This does not affect their scope of practice in the home setting, where CPMs are permitted to have a direct role in births. Neither do the proposed staffing requirements alter the CPMs' scope of practice any more so than any other discipline. In particular, the department has added restrictions, even requiring additional certifications, training, etc., to physicians in the FED setting because those restrictions were determined to best promote patient health and safety.

In its comments, the CABC stated, "The proposed regulations overall are quite duplicative of the quality measures/Indicators used by CABC to evaluate birth centers for accreditation."

The department's rules for other health care facility types include requirements for written transfer agreements in the event medically appropriate care for a patient is not available at the treating facility and must be sought from another health care facility. In particular, transfer agreements are required under the department's licensure rules for home care hospice services (Ala. Admin. Code r. 420-5-17-.22), ambulatory surgery centers (Ala. Admin. Code r. 420-5-2-.02), rehabilitation centers (Ala. Admin. Code r. 420-5-11-.02), and skilled nursing facilities (Ala. Admin. Code r. 420-5-10-.03(38)). Other states whose regulations for birthing centers include requirements for transfer

agreements include Alaska, Delaware, Georgia, Illinois, Louisiana, Massachusetts, Mississippi, Montana, New Jersey, New York, Ohio, Oklahoma, and Pennsylvania.

Birthing centers do not otherwise appear to offer a solution to access to care in "maternity deserts." CPMs are currently authorized to provide care in private settings of a mother's choice, including any county identified as a maternity desert. Despite this, data available to the department reflects that CPMs have not done so. Based on data reported to CHS by CPMs for the years 2019 to date, as required by Alabama law, CPMs have assisted Alabama births in the traditional Black Belt counties of Barbour, Bullock, Butler, Choctaw, Crenshaw, Dallas, Greene, Hale, Lowndes, Macon. Marengo, Montgomery, Perry, Pickens, Pike, Russell, Sumter, and Wilcox in the following numbers/percentages:

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CPM services and the costs associated with home births may not always be covered by private insurers. When a patient is accepted for monthly services under the Alabama Medicaid Program, a CNM's care must include plans for a delivery to be accomplished in a licensed hospital, except in an emergency. All CNM services must be rendered under appropriate physician supervision. Ala. Admin. Code r. 560-X-21-.06(1), (2). The department has been unable to locate any provisions under the Alabama Medicaid rules permitting services to be rendered by a CPM.

Comment 19 Summary:

Following the hearing, a letter in opposition to the proposed rules was submitted on behalf of the National Association of Certified Professional Midwives (NACPM). In particular, the letter stated that the proposed rules "will restrict access to care and make opening, operating, and staffing a freestanding birth center almost impossible." Specifically:

- The practice of CPMs is restricted under the proposed rules, limiting them to an assistive birth role. CPMs should be treated as full scope providers consistent with Act 2017-383, §2 and the Alabama State Board of Midwifery rules and regulations.
- CPMs attend births in out of hospital community settings without physician supervision and with responsibility for their patients' care.
- CPMs are especially qualified to work to full scope in freestanding birth centers as they are experts in out of hospital births.
- CPMs licensed in Alabama are trained according to the standards set forth by the Midwifery Education Accreditation Council (MEAC), and CPMs hold the only birth provider credential that requires knowledge, training, and experience in out-of-hospital settings.

- ACOG recognizes CPMs as one of the types of providers who are qualified to attend birth at the "birth center" level of care.
- CPMs are an essential part of the birth center workforce. More than half of the birth centers in the U.S. are owned or staffed by CPMs.
- "The current Alabama Department of Public Health Licensure Advisory Board does not currently have representatives which have the needed expertise to write the rules for freestanding birth centers. … We urge the Alabama Department of Public Health to reform or add to the current advisory or decision-making board. We encourage the Governor to appoint representatives to the advisory board from the following expert organizations in the field of out of hospital birth care: American Association of Birth Centers, Commission of the Accreditation of Birth Centers, American College of Nurse-Midwives Alabama State Affiliate, and the Alabama Midwives Alliance (who represent CPMs in Alabama).We also encourage the Governor to appoint a consumer representative from the Alabama Birth Coalition that has experienced a freestanding birth center or home birth in Alabama. We also urge the owners or representatives of birth centers in development in Alabama: Dr Stephanie Mitchell DNP, CNM, CPM, Birth Sanctuary Gainesville, Dr. Heather Skanes, OBGYN, Oasis Family Birth Center, and Dr. Yashica Robinson, Alabama Birth Center to be included as well."
- These rules should be consistent with national best practice standards.

Response:

No further revisions to the rules, as published for public comment, are proposed to the State Committee of Public Health in response to these comments. In light of these comments, the proposed rules have undergone careful review by the department's administration, staff, and legal counsel, and the inclusion of each requirement is considered necessary to ensure the health and safety of families seeking the services of a birthing center in this state.

Supervision requirements for CNMs under the proposed rules are consistent with the rules of the ASBME and the ABN governing collaborative practice agreements between CNMs and physicians. In the proposed rules for a health care facility setting, CPMs take an "assistive" role in births, since they cannot perform medical interventions in the same manner as physicians or CNMs. This does not affect their scope of practice in the home setting, where CPMs are permitted to have a direct role in births. Neither do the proposed staffing requirements alter the CPMs' scope of practice any more so than any other discipline. In particular, the department has added restrictions, even requiring additional certifications, training, etc., to physicians in the FED setting because those restrictions were determined to best promote patient health and safety.

In its comments, the CABC stated, "The proposed regulations overall are quite duplicative of the quality measures/Indicators used by CABC to evaluate birth centers for accreditation."

The composition of the Licensure Advisory Board is statutory, as provided in Ala. Code § 22-21-27, and is not subject to amendment by the department. Statutory changes may be made solely by the Alabama Legislature. The law provides, in pertinent part, for an advisory board of 17 members "to assist in the establishment of rules, regulations, and

standards necessary to carry out this article and to serve as consultants to the State Health Officer." The composition of the board under Ala. Code § 22-21-27 is as follows:

- 4 hospital members appointed by AlaHA
- 3 physicians appointed by the Board of Censors of the Medical Association of the State of Alabama
- 1 RN appointed by the Executive Board of the Alabama State Nurses Association
- 1 member representing and appointed by the State Board of Human Resources
- 1 registered pharmacist appointed by the Executive Committee of the Alabama Pharmacy Association
- 3 nursing home operators appointed by the Executive Committee of the Alabama Nursing Home Association
- 1 member appointed by the Alabama Hospice Association
- 2 members appointed by the Assisted Living Association of Alabama
- 1 consumer member appointed by the Governor who is at least 65 years of age, with no financial interest in any Alabama licensed health care facility

General Comments:

The general comments were highly duplicative of the issues raised in the formal comments described herein. The major themes included the following:

The proposed birth center regulations will make it nearly impossible for birthing centers to open and operate in Alabama. In a state where 37 percent of counties are maternity care deserts, we need more skilled providers serving the communities.

ADPH should throw out these regulations and consult experts and stakeholders for the next draft.

According to ADPH, only 16 of Alabama's 54 rural counties have hospitals providing obstetric services. Seven counties have no hospitals at all. As of 2020, 40 percent of the state was considered a "maternity care desert" with virtually no access to services in 25 counties and low access in another 21.

The barriers created for birthing centers under these regulations leave many patients with no options within a reasonable driving distance.

The proposed regulations are "racist" and "medically neglectful."

The regulations are not aligned with national birth center or accreditation standards.

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CIRCUIT COURT OF
MONTGOMERY COUNTY, ALABAMA
GINA J. ISHMAN, CLERK

EXHIBIT D

ALABAMA STATE BOARD OF HEALTH
ALABAMA DEPARTMENT OF PUBLIC HEALTH
ADMINISTRATIVE CODE

CHAPTER 420-5-13
BIRTHING CENTERS

TABLE OF CONTENTS

420-5-13-.01 General.

(1) Legal Authority for Adoption of Rules. The following rules for Birthing Centers are adopted by the Alabama State Board of Health pursuant to §22-21-20, et seq., Code of Ala. 1975.

(2) Definitions

(a) "Administrator" means a natural person who is the governing authority of a health care facility or a natural

person who is designated by the governing authority of a health care facility. Such person must have sufficient authority to interpret and implement all policies of the owner or proprietor and must be qualified to perform those tasks. The administrator shall be the addressee of all correspondence and inquiries from the State Board of Health.

(b) "Birthing Center" means a publicly or privately owned health care facility, place, or institution, constructed, renovated, leased, or otherwise established, where nonemergency births are planned to occur away from the mother's usual residence following a documented period of prenatal care for a low risk patient, as defined herein. Such facility, place, or institution must be a freestanding unit, not part of a hospital or other facility licensed for other purposes by the State Board of Health, and hold itself out to the public as a birthing center by advertising by some public means, such as a newspaper, directory, a website, the Internet, etc. The offices of private physicians assisting births strictly on an emergency basis does not constitute birthing centers for the purposes of this rule. Care provided in a birthing center shall be provided by a licensed physician, or by a duly licensed certified nurse midwife and a licensed registered nurse. Certified professional midwives may also provide care as assistive personnel to staff certified nurse midwives and registered nurses in a birthing center, provided that the staffing requirements of these rules are met when patients are present, laboring, and delivering in the birthing center. Nothing in this rule shall be construed to expand the existing scope of practice for a certified professional midwife.

(c) "Board" or "State Board of Health" means the Alabama State Board of Health.

(d) "Certified Nurse Midwife" (CNM) means an advanced practice nurse who is in an active collaborative practice agreement with the licensed physician who is serving as the staff physician or consultant physician for the birthing center, which includes the birthing center as an approved practice site, and who meets the requirements of and is approved by the Alabama Board of Nursing. CNMs in birthing centers shall have at least 1 year of experience in labor and delivery and/or newborn intensive care, be trained and annually certified in adult and infant cardiopulmonary resuscitation (CPR), and possess a Neonatal Resuscitation Program (NRP) certificate or the equivalent thereof.

(e) "Certified Professional Midwife" (CPM) means a person who holds an active license with the Alabama Board of Midwifery. A CPM in a birthing center shall have at least 1 year of documented experience in providing all phases of prenatal, delivery, and postnatal care, be trained and annually

certified in adult and infant CPR, and possess an NRP certificate or the equivalent thereof.

(f) "Consultant Physician" means a person currently licensed by and in good standing with the Medical Licensure Commission of Alabama to practice medicine and/or osteopathy in this state and who has a valid agreement to serve as a consultant to the birthing center. In the absence of a staff physician, the consultant physician must also have an approved collaborative practice agreement with the CNM employed by or working at the birthing center. The services of a consultant physician are required for any birthing center which does not have a physician on the medical staff who is currently licensed by and in good standing with the Medical Licensure Commission of Alabama. Consultant physicians must be either (1) certified by the American Board of Obstetrics and Gynecology or the American Board of Osteopathic Obstetricians and Gynecologists or (2) qualified as family practice physicians with an obstetrical emphasis or fellowship. The consultant physician must be trained and annually certified in adult CPR, equivalent to the American Heart Association's Class C basic life support, infant CPR, and neonatal resuscitation endorsed by the American Academy of Pediatrics/ American Heart Association. The consultant physician must have hospital obstetrical privileges with the hospital that is a party to the birthing center's Transfer Agreement and must be available to be physically present at the birthing center within 30 minutes to provide needed hands-on care to patients at the birthing center when called. A facility is ineligible for licensure as a birthing center unless it has an Alabama licensed physician on the medical staff or a valid agreement with a consultant physician to provide consulting and hands-on services as needed.

(g) "Department" means the Alabama Department of Public Health.

(h) "Documented Period of Prenatal Care" means prenatal evaluation and care initiated by an appropriate care provider prior to the third trimester, until 37-42 weeks of gestation.

(i) "Family Centered Care" means a philosophy of care that allows family and significant others to participate in the pregnancy, birth, and postpartum period in a homelike environment.

(j) "Freestanding" means a separate and distinct health care facility, place, or institution, constructed, renovated, leased, or otherwise established, for purposes of these rules, to provide the services of a birthing center. Each freestanding birthing center must obtain its own license and comply with all applicable licensing standards promulgated by the State Board of Health and these rules; provided, however,

that a hospital affiliated birthing center located on the hospital's campus does not constitute a freestanding birthing center and is not required to be separately licensed.

(k) "Governing Authority" means the owner or proprietor of the birthing center, or the body, such as a board of directors, which maintains and controls the operation of the birthing center and who is legally responsible for its operation.

(l) "Hospital" means a health care facility duly licensed by the State Board of Health as a general acute care or specialty hospital with an organized obstetrical service, as defined herein, and operating in compliance with the Department's rules in Chapter 420-5-7. The usual service provided in the obstetric gynecology service of an acute care hospital does not constitute or qualify as a birthing center.

(m) "Hospital Affiliated Birthing Center" means a separate and distinct unit of a hospital or a building owned, leased, rented, or utilized by a hospital for the purpose of providing the services of a birthing center. A hospital affiliated birthing center located on the hospital campus may operate under the general acute care or specialty license issued to the hospital. A hospital affiliated birthing center that is not located on the hospital campus is required to be separately licensed and may not operate under the general acute care or specialty license issued to the hospital.

(n) "License" means the legal authority to operate a birthing center, as defined above, to admit patients, and to offer and provide care as permitted under these rules. A license may only be granted by the Board through the actions of its authorized agents.

(o) "Licensed Practical Nurse" (LPN) means a person who holds an active license with the Alabama Board of Nursing or a multistate nursing license which includes a privilege to practice nursing in Alabama. An LPN in a birthing center shall have at least 1 year of experience in obstetrics, be trained and annually certified in adult and infant CPR and infant resuscitation, and possess an NRP certificate or the equivalent thereof.

(p) "Low Risk Patient" means an individual who does not have any of the listed risk factors for an adverse pregnancy outcome and who is eligible to receive services in a birthing center because the individual:

1. Is in general good health with an uncomplicated prenatal course.

2. Is participating in an ongoing prenatal care and education program that addresses, at a minimum, anticipated changes during pregnancy, the need for prenatal care, nutritional needs during pregnancy, the effects of smoking and substance abuse, the danger signs of preterm labor, what to expect during labor and delivery, and care and feeding of the newborn, including instruction on lactation (breast feeding).

3. Has no major medical problems, including, but not limited to chronic hypertension, heart disease, pulmonary embolus or congenital heart defects; severe renal disease; medication-controlled diabetes; required use of anticonvulsant drugs; bleeding disorder or hemolytic disease; pyelonephritis; or thrombophlebitis.

4. Has no signs or significant symptoms of preeclampsia, hydramnios, abruptio placenta, chorioamnionitis, malformed fetus, multiple gestation, fetal growth restriction, fetal meconium, fetal distress, alcoholism, substance abuse or misuse, Rh or other blood group antigen sensitization.

5. Has no history of miscarriage or spontaneous abortion or premature delivery.

6. Has no previous significant obstetrical complications likely to recur, nor previous uterine wall surgery or Caesarean section.

7. Has given birth to fewer than five children, unless a justification for a variation is approved in writing by the staff physician or consultant physician.

8. If between 36 and 40 years of age and has never before given birth, has been cleared medically by the staff physician or consultant physician, and has both a normal comprehensive sonogram and normal chromosomal testing.

9. Is not less than 16 years of age at the onset of pregnancy.

10. Is appropriate for a setting where anesthesia is limited to local infiltration of the perineum, or a pudendal block, and analgesia is limited.

11. While in active labor:

(i) Demonstrates no significant signs or symptoms or evidence of anemia, significant hypertension, placenta previa, fetal distress, malformed fetus or breech.

(ii) Is progressing normally.

(iii) Is without prolonged ruptured membranes.

(iv) Is not in premature labor.

12. Is no more than 40 years of age at the outset of pregnancy.

(q) "Nonemergency Births" means those births that are planned to occur away from the mother's usual residence and have been determined to be low risk through an ongoing risk assessment from the first prenatal visit throughout admission in labor, and the labor, birth, and postpartum period.

(r) "Organized Obstetrical Service" means a hospital which has an obstetrician (or family practitioner with training and experience in obstetric medicine) and a pediatrician (or family practitioner with training and experience in pediatric medicine) on the active staff, a 24-hour emergency room and Cesarean section capability, and which provides skilled nursing care, facilities, and equipment appropriate for the patient being transferred from the birthing center. The organized obstetrical service must be located no more than 30 minutes driving time by emergency transport vehicle from the birthing center.

(s) "Pediatrician" means a physician who is currently licensed by and in good standing with the Medical Licensure Commission of Alabama, and who is certified in general pediatrics or a pediatric subspecialty by the American Board of Pediatrics. The pediatrician must be trained and annua1ly certified in infant CPR and neonatal resuscitation endorsed by the American Academy of Pediatrics/American Heart Association and possess an NRP certificate or the equivalent thereof.

(t) "Registered Nurse" (RN) means a person who holds an active license as such with the Alabama Board of Nursing or a multistate nursing license which includes a privilege to practice nursing in Alabama. An RN in a birthing center shall have at least 1 year of experience in obstetrics, be trained and annually certified in adult and infant CPR and infant resuscitation, and possess an NRP certificate or the equivalent thereof.

(u) "Risk Criteria" means:

1. Birthing center patients are limited to those women who are initially determined to be at low maternity risk and who are evaluated regularly throughout pregnancy to assure that they remain at low risk for an adverse pregnancy outcome.

2. Each birthing center shall establish a written risk assessment system which shall be developed by the staff physician or consultant physician in accordance with the parameters set forth herein for low-risk patients and all applicable standards of good medical practice, to be included in the birthing center's policy and procedure manual. Ongoing written risk assessments from the first prenatal visit throughout admission in labor, and the labor, birth, and postpartum period shall form part of each patient's clinical record.

3. The general health status and risk assessment shall be conducted by the staff physician or consultant physician, CNM, or CPM by obtaining a detailed medical history, performing a physical examination, and considering family circumstances and other social and psychological factors. The patient's health status and risk assessment shall be reviewed by the staff physician or consultant physician or CNM and initially approved as suitable for delivery in the birthing center.

4. The criteria upon which the risk status of patients is determined under the birthing center's written risk assessment system shall be applied to all patients prior to acceptance for birthing center services and throughout the pregnancy for continuation of services. Patients presenting with or later developing any of the risk factors listed under the definition of a low-risk patient in these rules shall be ineligible to receive services **in a** birthing center and shall be referred to another qualified physician for continuing maternity care and hospital delivery.

5. Acceptance for and continuation of care throughout pregnancy and labor is limited to those women for whom it is appropriate to give birth in a setting where anesthesia is limited to local infiltration of the perineum or a pudendal block and where analgesia is limited.

(v) "Services Provided in a Birthing Center" shall be defined and limited as follows:

1. Surgical services shall be limited to those normally performed during uncomplicated childbirth, such as episiotomy and repair, and shall not include operative obstetrics or Cesarean sections. Surgical repairs of fourth degree lacerations may only be performed in a birthing center by the staff physician or consultant physician. Circumcisions of male infants may be performed in a birthing center by the staff physician or consultant physician or by a CNM who has been approved to perform circumcision of male infants through a collaborative

practice agreement approved by the Alabama State Board of Medical Examiners and the Alabama Board of Nursing.

2. Labor shall not be inhibited, stimulated, or augmented with chemical agents during the first or second stage of labor (i.e., up to and including vaginal delivery). CPMs are permitted to administer anti-hemorrhagic medication and oxygen in an emergency circumstance.

3. Systemic analgesia may be administered and local anesthesia for pudenda) block and episiotomy repair may be performed; however, general and conduction anesthesia shall not be administered. CPMs may not order or administer narcotic analgesia.

4. Vacuum extractors and forceps shall not be used in the birthing center.

5. Patients and their newborns shall not routinely remain in the birthing center in excess of24 hours. Exceptional circumstances justifying a stay in excess of24 hours are set forth in Ala. Admin. Coder. 420-5-13-.09(8).

(w) "Staff Physician" means a person currently licensed by and in good standing with the Medical Licensure Commission of Alabama to practice medicine and/or osteopathy in this state and who is (l) certified by the American Board of Obstetrics and Gynecology or the American Board of Osteopathic Obstetricians and Gynecologists or (2) qualified as a family practice physician with an obstetrical emphasis or fellowship. The staff physician must be trained and annually certified in adult CPR, equivalent to the American Heart Association's Class C basic life support, infant CPR, and neonatal resuscitation endorsed by the American Academy of Pediatrics/American Heart Association. The staff physician must have hospital obstetrical privileges with the hospital that is a party to the birthing center's Transfer Agreement and must be available to be physically present at the birthing center within 30 minutes to provide needed hands-on care to patients at the birthing center when called. A birthing center is ineligible for licensure unless it has an Alabama licensed physician on the medical staff or a valid agreement with a consultant physician.

(x) "Transfer Agreement" means a birthing center's written agreement with a hospital located no more than 30 minutes driving time by emergency transport vehicle from the birthing center, which has an organized obstetrical service, as defined in these rules. The Transfer Agreement shall provide for the hospital's acceptance of referrals from the birthing center and phone consultations as needed to address emergency situations; the agreement shall address financial responsibility for services rendered. A birthing center is

ineligible for licensure unless it has a Transfer Agreement with a licensed, qualified hospital. A written agreement with at least one currently licensed emergency medical service (EMS) is also required for the rapid response and transport of a patient or infant to the hospital named in the Transfer Agreement.

(3) Type of License.

(a) Regular License. A regular license may be issued by the State Board of Health after the Board has determined that the birthing center is in substantial compliance with these rules.

(b) Probational License. At its discretion, the Board may grant a probational license when it determines that both of the following conditions exist:

1. The birthing center has engaged in one or more deficient practices which are serious in nature, chronic in nature, or which the birthing center has failed to correct.

2. The birthing center's current governing authority has demonstrated the capability and willingness to correct cited problems and to maintain compliance.

(c) A probational license shall be granted for a specific period which may be extended, but which shall in no case exceed 1 year.

(4) Licensing.

(a) Application. Application for an initial license or renewal of a license shall be made on forms provided by the State Board of Health, including all information required by law, these rules, and the policies and procedures of the Department. An applicant shall submit such additional information as shall be required by the Department in its discretion to demonstrate that the applicant has the ability and the willingness to comply with these rules. Each application shall be signed by a person authorized to bind the applicant to the representations in the application and shall include any supporting documentation with the application.

(b) Fee. An initial license application, an application for license renewal, or an application for a change in ownership shall be accompanied by the application fee specified in §22-21-24, Code of Ala. 1975. An application for a name change is not subject to a license application fee. An application fee is non-refundable. Any application fee submitted in the incorrect amount shall nevertheless be

deposited. If the fee submitted is too large, a refund for the difference shall be processed using the Department's usual procedures. If the fee submitted is too small, the applicant shall be notified, and the application shall not be considered until the difference is received. Any application submitted without any fee shall be returned to the applicant. If an incomplete application is submitted, the application fee shall be deposited, and the applicant shall be notified in writing of the defects in the application. If the applicant fails to submit all required additional information within IO working days of the date of the notice, the application shall be denied. The Department may, in its discretion, extend the deadline for submitting additional information. Denial of an application as incomplete shall not prejudice the applicant from submitting a new application, accompanied by the requisite fee, at a future date.

(c) Renewal. A license, unless suspended or revoked, shall be renewable annually as a matter of course upon submission of a completed renewal application and payment of the required fee. When the Department has served written notice on a birthing center of its intent to revoke or downgrade the license, a renewal application shall be filed, but does not affect the proposed adverse licensure action.

(d) Name. Every birthing center shall be designated by a permanent and distinctive name which shall be used in applying for a license, which shall include the words "birthing center." No birthing center shall change its name without first applying for a change of name approval, nor shall it change its name until such approval is granted. The Department may, in its discretion, deny an initial birthing center application or an application for a change of name if the Department determines that the proposed name is misleading to the public or that the name is overly similar to the name of an already licensed birthing center. Separately licensed birthing centers owned by the same governing authority may have names that are similar to one another and distinguished from one another in some other manner, such as a geographic description. If an initial birthing center application is denied under this rule, the applicant shall be provided a reasonable period of time to submit a revised application with a different name. No freestanding birthing center shall include the word "hospital" in its name.

(e) Issuance of License. All licenses issued by the State Board of Health shall set forth the name of the birthing center, the physical address, the name of the licensee, and the license number.

(f) Separate License. A hospital-affiliated birthing center or facility that is not located on the hospital campus is

required to be licensed separately and may not operate under the license issued to the hospital.

(g) Posting of License. Licenses shall be posted in a conspicuous place on the licensed premises.

(h) License Not Transferable. The license shall not be transferable or assignable and shall be issued for the premises named in the application.

(i) Expiration of License. Each license shall expire on December 31 following the date of issuance.

(j) Condition of Licensure. It is a condition of licensure that the licensee must continuously occupy the licensed premises, remain open to the public as a birthing center, fully staffed, and otherwise capable of admitting and treating patients. If a birthing center fails to remain open and staffed as required for 30 days, its license shall become void. If a licensee abandons the licensed premises, the license shall immediately become void. If the facility subsequently wishes to reopen as a birthing center, it shall be required to file an initial licensure application, to include plan review and building inspection, and obtain a certificate of completion before the application can be processed by the Department.

(k) The following changes in the status of the birthing center will require issuance of a new license.

1. Change in facility ownership or operating entity (application fee required).

2. Change in facility name (no application fee required).

3. Relocation.

The governing authority shall file with the State Board of Health an application for license and application fee (if applicable) 30 days before any proposed change requiring a new license in order to permit processing of the application and issuance of the license prior to the desired effective date of the change.

(l) The Department shall be notified in writing within 30 days prior to the effective date of any change in the birthing center's administrator or staff physician and of the birthing center's intent to cease operation.

(m) Denial and Revocation of a License.

1. The Board may deny a license to any applicant or suspend or revoke the license to operate a birthing center in any case in which it finds that there has been

a substantial failure to comply with the requirements established under these rules or on grounds of insufficient evidence of the willingness or ability to comply with §§22-21-20 through 22-21-34, Code of Ala. 1975, or these rules. Each license shall be returned to the Board immediately upon its revocation or after the birthing center voluntarily ceases operation.

2. Hearing procedures concerning the denial, suspension, or revocation of a license shall be governed by the provisions of the Alabama Administrative Procedure Act, §41-22-1, et seq., Code of Ala. 1975, and the Board's Rules for Hearing of Contested Cases, Chapter 420-1-3, Ala. Admin. Code.

(5) Failure to Renew a License. Any licensee who fails to renew a license on or before the close of business on the last business day in December shall be assessed a late fee equal to the amount of the original license fee. A license may only be renewed with the payment of a late fee before the close of business on the last business day in January of any calendar year. A license which has not been renewed by the end of January has expired and shall be void.

(6) Compliance with Federal, State, and Local Laws. The birthing center shall be in compliance with applicable federal, state, and local laws, including all applicable zoning ordinances. A birthing center may not be operated in a private residence.

(a) Licensing of Staff. Staff of the birthing center shall be currently licensed, certified, or registered in accordance with applicable laws.

(b) Compliance with Other Laws. The birthing center shall comply with laws relating to fire and life safety, sanitation, communicable and reportable diseases, Certificate of Need review and approval, reporting of health care acquired infections, adverse event reporting, and other relevant health and safety requirements. If a birthing center utilizes the services of a clinical laboratory located outside the state of Alabama, the birthing center shall ensure that, in connection with any work performed for the birthing center, the laboratory complies with the requirements for the reporting of notifiable diseases to the Department, as set forth in state law and the rules of the Board.

(7) A birthing center shall promptly notify the Department in writing when there is any change in its accrediting organization or its status with the accrediting organization.

(8) Waiver and Variance. At its discretion, the State Board of Health may grant an exception to, or modify the application of,

one or more provisions of these rules or reference codes for a period and under conditions, if any, determined by the Board. The exceptions or modifications shall be based on hardship, impracticality, or economic infeasibility in complying with the rules. The birthing center's request shall be in writing and meet the requirements of Rule 420-1-2-.09, including a statement regarding the specific provisions for which the exception or modification is requested and the reasons for each requested exception or modification.

(9) Disclosure of information. Official reports, such as statements of deficiencies generated by the State Board of Health as a result of on-site inspections and plans of correction submitted in response to those statements of deficiencies, are subject to public disclosure. Information received through other means and reports, other than statements of deficiencies, shall be deemed to be confidential and shall not be publicly disclosed except in response to a valid subpoena or court order or in proceedings involving the birthing center's license or proceedings involving the license of another facility operated by the same governing authority. Inspection reports will never contain the name or other identification of any patient or client in the inspected facility.

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420-5-13-.02 Administration.

(1) Governing Authority.

(a) Responsibility. The governing authority is the person or persons responsible for the management, maintenance, control, and operation of the birthing center, including the provision of personnel, facilities, equipment, supplies, and services to mothers and families, as well as appointment of persons to fill the minimum staffing requirements. The governing authority shall ensure that the birthing center is organized, equipped, staffed, and administered in a manner to provide adequate care for each patient.

(b) The governing body shall be formally organized in accordance with a written constitution, bylaws, rules, or regulations. In the event the governing authority consists of one person, this requirement shall still be met. The written constitution, bylaws, rules, or regulations of the birthing center shall:

1. Specify by name the person to whom responsibility for operation and maintenance of the birthing center is delegated and methods established by the governing authority for holding such individuals responsible.

2. Provide for at least annual meetings of the governing authority. Minutes shall be maintained of such meetings.

3. Require policies and procedures consistent with professionally recognized standards of practice to include provisions for administration and use of the birthing center, compliance, personnel, medical records, patient rights, emergency care/transfers, emergency preparedness, policy reviews, quality assurance, infection control, procurement of outside services and consultations, patient care policies, and services offered.

4. Provide for annual reviews and evaluations of the birthing center's policies and services offered.

(c) Contracted Services. The governing authority shall be responsible for services furnished in the birthing center, whether or not they are furnished under contracts. The governing authority shall ensure that a contractor of services furnishes services that permit the birthing center to maintain compliance with the requirements of these rules.

1. The governing authority shall ensure that the services performed under a contract are provided in a safe and effective manner.

2. The birthing center shall maintain a list of all contracted services, including the scope and nature of the services provided.

(d) The governing authority shall provide for the selection and appointment of the medical or nurse midwifery and nursing staff and the granting of clinical privileges and shall be responsible for the professional conduct of these persons.

(2) Administrator.

(a) Responsibility. The governing authority shall appoint a qualified person as administrator of the birthing center to represent the governing authority and shall define the administrator's authority and duties in writing. The administrator shall be responsible for the management of the birthing center, implementation of the policies of the governing authority, and shall be authorized and empowered to carry out the provisions of these rules. Appropriate procedures to enforce these policies, assure proper patient care and safety, and meet requirements of these rules shall

be developed in writing by an appropriate committee of professionals and shall be reviewed at least annually.

(b) The governing authority of the birthing center shall notify the Department in writing of any change in the birthing center's administrator within 30 days of the effective date of such change.

(3) Personnel Records. The birthing center shall maintain a personnel record of each employee. At a minimum, the personnel record shall include a copy of the application for employment that contains information regarding education, certification, experience, and if applicable, registration and/or licensure information of the applicant, a current job description, all physical examinations, and evidence of continuing education or in service training and education. Personnel records shall be confidential. Representatives of the Department conducting an inspection of the facility shall have the right to inspect personnel records.

Author: Dana Billingsley, Denise Milledge
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420-5-13-.03 Medical Staff.

(1) Organization. There shall be an organized medical staff consisting of a minimum of one staff physician or consultant physician, and CNMs and RNs. CPMs may also provide assistive care to the medical staff of a birthing center while a patient is laboring, during birth, and throughout the postpartum period when in the birthing center. The staff physician shall have overall responsibility for the quality of a11 clinical care provided to patients, and for the ethical conduct and professional practices of its staff members. In the event the birthing center does not have a qualified staff physician on the medical staff, the consultant physician shall have overall responsibility for the quality of all clinical care provided to patients, and for the ethical conduct and professional practices of its staff members. The staff physician and consultant physician shall maintain independent medical judgment related to the practice of medicine at all times.

(a) The medical staff shall be accountable to the governing authority and organized in a manner consistent with the birthing center's documented staff organization and bylaws, rules, and regulations, provided that only a physician may

conduct an annual appraisal or evaluation of another physician.

(b) The medical staff shall conduct annual appraisals of its members, examine the credentials of candidates for medical staff membership, and make recommendations to the governing authority on the appointment of the candidates.

(2) The staff physician shall develop written policies and protocols for clinical care identifying the roles and responsibilities of each staff member and consultant. In the event the birthing center does not have a qualified staff physician on the medical staff, the consultant physician shall develop written policies and protocols for clinical care identifying the roles and responsibilities of each staff member and consultant. Each policy and protocol shall be signed by the staff physician or consultant physician who is a member of the medical staff. The organization and policies and protocols of the medical staff shall be approved by the birthing center's governing authority. The policies and protocols shall require that patients are admitted to the birthing center only when they have been prescheduled to deliver there following a documented period of prenatal care for a patient who has been determined to be low risk, as defined herein, through an ongoing risk assessment from the first prenatal visit throughout admission in labor, and the labor, birth, and postpartum period, and upon immediate evaluation by the medical staff to be low risk.

(a) Consultant Physician.

1. Services of a consultant physician are required in those birthing centers which do not have an Alabama licensed physician on the medical staff who serves as the staff physician. The consultant physician must have hospital obstetrical privileges with the hospital that is a party to the birthing center's Transfer Agreement and must be available to be physically present at the birthing center within 30 minutes to provide needed hands-on care to patients at the birthing center when called.

2. The responsibilities and functions of the consultant physician shall be specifically described in the policy and procedure manual and the patient care protocols.

3. The governing body shall maintain a written agreement with each consultant physician who agrees to provide advice and services to the birthing center as requested.

4. If a birthing center does not have a staff physician and is unable to enter into an agreement with a consultant physician, the license of the birthing center shall be denied or suspended, and no patient services may

be rendered until an agreement with a consultant physician is formalized.

(b) The initial appointment and continued medical staff membership shall be dependent upon professional competence and ethical practice in keeping with the qualifications, standards, and requirements set forth in the medical staff policies and protocols and governing authority bylaws, rules, and regulations.

(c) Hospital Privileges. The staff physician and/or consultant physician shall have full active privileges in obstetrics at the hospital that is a party to the birthing center's Transfer Agreement.

(d) Staffing. There shall *be* a minimum of two licensed RNs at the birthing center at all times when patients are present, with a staffing ratio of one licensed RN for every two patients. There shall be a staff physician or consultant physician or CNM at the birthing center when a patient is laboring, during delivery, and for a minimum of 2 hours post-delivery. When the patient census exceeds the above, additional medical staff are to be called in or the patients are to be transferred to a hospital. There shall be an adequate number of medical and support staff on duty and on call to meet demands for services routinely provided and periods of high demand or emergency, to assure that no mother in active labor shall remain unattended.

(e) Licensure. All birthing center personnel shall be currently licensed to perform the services they render when such services require licensure under the laws of the state of Alabama.

(f) Health Examinations. At a minimum, each employee coming in contact with patients shall have a pre-employment health examination by a physician, certified registered nurse practitioner, or physician assistant. The examination is to be repeated annually and more frequently if indicated to ascertain freedom from communicable diseases. The extent of such examinations shall be determined by the governing authority in consultation with the staff physician and documentation made in the employee's personnel folder. The examination shall include a chest x-ray or a tuberculin test. Each employee must be offered a Hepatitis B vaccine and sign a written declination if the vaccination is refused. Documentation of immunization status for vaccine preventable diseases in pregnancy may be required.

(g) Staff Development. All medical staff will participate in an orientation and training program developed by the birthing center upon hire and at least annually in staff development, including, but not limited to, recertification of adult and

infant CPR training and education programs to maintain knowledge and skills used in birthing center practice.

(h) Nursing Service.

1. Staffing Pattern. There shall be 24-hour availability of qualified RNs and CNMs as defined in these rules. A minimum of two RNs shall be in the birthing center whenever a patient is in labor, during birth, and throughout the postpartum period while a patient is in the center.

2. Nursing Care Plan. An RN must plan, supervise, and evaluate the nursing care of each patient from admission to discharge. Prior to discharge, each patient shall be given a referral with a specific time, date, and place for postpartum, family planning, and infant care. A 2-week health status of the baby shall be documented on the patient's record following review of records evidencing the pediatric or neonatal care provided at the birthing center or other facility.

3. LPNs who are currently licensed to practice within the state may provide nursing care that does not require the skill and judgment of an RN, under the supervision of an RN. LPNs providing such care shall maintain current certification in both adult and infant CPR.

(i) Certified Nurse Midwifery and Physician Service.

1. A CNM or the staff physician or consultant physician shall be in the birthing center when a patient is in labor, during birth, and for a minimum of 2 hours postpartum, or longer if necessary. A physician obstetrician and pediatrician shall be available 24 hours a day for phone consultation pursuant to a written agreement with the birthing center.

2. There shall be a minimum of one CNM or physician for every two patients in the birthing center, to ensure that every patient in labor is attended.

3. Care policies and procedures shall be consistent with professionally recognized standards and shall be in accordance with the Nurse Practice Act and Medical Practice Act of the State of Alabama. Policies shall, at a minimum, include the following:

(i) Diagnostic and therapeutic orders.

(ii) Assignment of care of patients.

(iii) Medication orders.

(iv) Charting.

(v) Infection control.

(vi) Patient and personnel safety.

(vii) Family centered maternity care.

(j) Inservice and Continuing Education. An inservice education program shall be provided for all staff members of the birthing center to improve existing practices, obtain new knowledge and skills, keep personnel informed of changes in policies and procedures, and discuss problems in the birthing center.

1. The inservice program shall be planned, scheduled, documented, and held monthly.

2. All medical staff shall participate annually in appropriate training programs for the safe and effective use of diagnostic and therapeutic equipment, for CPR, and infant resuscitation and transport.

3. All personnel shall have training that meets state and federal guidelines, as applicable, including, but not limited to, regulations of the Occupational Safety and Health Administration (OSHA), the Health Insurance Portability and Accountability Act (HIPAA), and Clinical Laboratory Improvement Amendments (CLIA).

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420-5-13-.04 Informed Consent.

(1) Before admission to services, a patient shall be informed of:

(a) The qualifications of the birthing center medical staff

(b) The risks related to out-of-hospital childbirth.

(c) The possibility of referral or transfer if complications arise during pregnancy or labor, with additional costs for services rendered by any hospital to which the patient may be transferred.

(2) The birthing center medical staff shall obtain the patient's written consent for birthing center services using the form, "Consent to Deliver in a Birthing Center," as provided by the Department.

(3) The signed consent form shall be included with the patient's individual clinical record.

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Statutory Authority: Code of Ala. 1975, §22-2-2(6). et seq.; §22-21-20, et seq.
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420-5-13-.05 Patient Orientation And Preparation For Childbirth.

(1) Prior to admission for services, patients shall be fully informed of:

(a) The criteria adopted by the birthing center for the selection and admission of patients.

(b) The philosophy of the birthing center's governing body and medical staff regarding childbirth care and management, including the limited use of analgesics and anesthetics.

(c) The scope of services to be provided.

(d) Th expectation that the patient and family will be responsible for self-care to the extent and feasible and safe. Birthing centers shall not provide the level of care offered in an acute care hospital.

(e) The customary length of stay following delivery.

(f) The policies of the birthing center regarding transfer to hospitals with whom the birthing center has a written agreement.

(g) The qualifications of the medical staff.

(2) During the course of prenatal care, the patient and family, to the extent necessary, shall be counseled or instructed to prepare them for childbirth. At a minimum, the educational topics shall include:

(a) Anticipated changes during pregnancy.

(b) Need for prenatal care.

(c) Nutritional needs during pregnancy.

(d) Effects of smoking and substance abuse.

(e) Danger signs of preterm labor.

(f) What to expect during labor and delivery.

(g) Care and feeding of the newborn, including instruction on lactation (breast feeding).

Author: Dana Billingsley, Diane Milledge
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420-5-13-.06 Prenatal Visits.

(1) The birthing center's medical practitioners shall follow the guidelines set forth by the American College of Obstetricians and Gynecologists for testing pregnant women for sexually transmitted diseases.

(2) Initial Visit.

(a) The birthing center shall at a minimum conduct one prenatal visit in which a comprehensive health history of the patient shall be completed, which includes medical, emotional, dietary, and obstetrical data, including a preterm delivery risk assessment.

(b) A physical examination of the patient shall be completed by qualified staff, within their scope of practice, including height and weight measurements; vital signs, including blood pressure; and examination of the skin, head and neck, heart and lungs, breasts, abdomen, pelvis, and neurologic reactions.

(c) The following tests are also required to be performed by a staff member or by other of the birthing center's qualified personnel:

1. Hemoglobin and hematocrit.

2. Urinalysis by dipstick for protein, sugar, and ketones.

3. Cervical cytology. Recommendation by The American Society of Colposcopy and Cervical Pathology (ASCCP) is for pap smears every 3 years (age 21-30) and every 5 years with co-testing (age 31-64).

4. Rh determination and blood type.

5. Prenatal screening recommended by the American Academy of Pediatrics and American College of Obstetricians and Gynecologists Guidelines for Perinatal Care and the rules and regulations of the Department, to include, but not be limited to, HIV, syphilis, and Hepatitis B surface antigen screening.

(2) At a minimum, return visits to the birthing center shall include the following measurements and testing:

(a) Weight, blood pressure, fundal height, and fetal heart rate, as applicable.

(b) Urinalysis by dipstick for protein and sugar.

(c) Hemoglobin and hematocrit should be repeated at least twice and more often if indicated during the course of the pregnancy.

(d) Review of signs and symptoms of complications of pregnancy and risk status.

(e) Examination to determine the estimated weeks of gestation, fetal position, and presentation.

(3) If prenatal visits subsequent to an initial visit are offered at the birthing center, they should be scheduled at least every 4 weeks until the 28th week, every 2 weeks until the 36th week, and then every week until delivery, unless more frequent monitoring is required. Patients must be evaluated by qualified medical staff at the birthing center at their initial prenatal visit and regularly throughout their pregnancy, with a copy of each performed risk assessment retained in their file, to assure that they remain at low risk for an adverse pregnancy outcome. If prenatal visits subsequent to the initial visit are conducted at a location other than the birthing center, visit summaries must be obtained by the birthing center and reviewed as part of the continuing risk assessment for that patient. Prenatal visits conducted by a provider other than the birthing center must be scheduled and conducted with the same frequency as the visits conducted by the birthing center under these rules and must meet the same evaluation and risk assessment requirements for each visit in order for the patient to remain eligible for delivery in the birthing center.

(4) All patients shall receive specific instruction regarding preterm labor, including the potential hazards, preventive measures, symptoms, detection and timing of contractions, and the need for prompt notification of the health provider.

(5) At least one prenatal visit in the second trimester of pregnancy shall be overseen by the staff physician or consultant physician, to certify that the patient remains eligible for delivery in the birthing center. All patients found to be at obstetrical risk pursuant to the criteria set forth in these rules shall be referred to a qualified local physician, certified by the American Board of Obstetrics and Gynecology or the American Board of Osteopathic Obstetricians and Gynecologists, for continued care.

Author: Dana Billingsley, Diane Milledge
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420-5-13-.07 Intrapartum Care.

(1) A member of the medical staff shall be present or available to the patient at all times throughout her stay in the birthing center.

(2) The medical staff shall monitor the progress oflabor and condition of the mother and fetus at sufficiently frequent intervals to identify abnormalities or complications as soon as possible.

(3) The patient shall be transferred to a hospital if complications requiring medical or surgical intervention occur, as set forth in the criteria established in these rules.

(4) The birthing center shall be able to respond to medical emergencies that may arise during the provision of services to patients, including adult basic life support, neonatal resuscitation, and initial management of postpartum complications.

(5) The patient's family or persons offering her support shall be instructed as needed to assist the patient during labor and delivery.

(6) Labor shall not be inhibited, stimulated, or augmented with drugs administered in the birthing center except when the patient is to be transported immediately to the hospital and the drug is prescribed by the medical consultant or physician who will

receive the patient and manage her continued care. All such drugs shall be administered solely by appropriate, qualified staff within each staff member's permissible scope of practice.
Author: Dana Billingsley, Diane Milledge
Statutory Authority: Code of Ala. 1975, §22-2-2(6), et seq.; §22-21-20, et seq.
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420-5-13-.08 Surgical Services And Use Of Analgesics And Anesthetics.

(1) No surgical procedures shall be performed in the birthing center except episiotomy, repair of episiotomy or laceration, or circumcision. Surgical repairs of fourth degree lacerations may only be performed in a birthing center by the staff physician or consultant physician. Circumcisions of male infants may be performed in a birthing center by the staff physician or consultant physician or by a CNM who has been approved to perform circumcision of male infants through a collaborative practice agreement approved by the Alabama State Board of Medical Examiners and the Alabama Board of Nursing.

(2) Systemic analgesics and local anesthetics may be administered under the following conditions:

(a) The medical staff member who administers the systemic analgesic is legally authorized to do so and shall be present in the birthing center during the use of intravenous analgesics. CPMs may not order or administer narcotic analgesia.

(b) The dosage and drugs are specifically noted in the protocols for clinical services.

(c) The use of such drugs is in conformance with the policies and procedures of the birthing center.

(3) General and conduction anesthesia shall not be administered at birthing centers.
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420-5-13-.09 Postpartum Care.

(1) Immediate postpartum care shall be provided to the mother at the birthing center by qualified members of the medical staff.

(2) The condition of the mother shall be monitored frequently to detect signs of hemorrhage or other complications requiring prompt transfer to a hospital.

(3) Adequate nutrition must be provided to the mother during her stay at the birthing center, as evidenced by written dietary requirements on file at the birthing center.

(4) Qualified members of the birthing center's staff shall perform a postpartum examination on the mother, as permitted within the staff member's legal scope of practice, prior to discharge and within 72 hours after delivery, and an additional examination of the mother shall be performed at approximately 4 to 6 weeks after delivery by the birthing center, a referral facility, or a qualified medical professional.

(a) The patient examination prior to discharge and within 72 hours shall include, at a minimum:

1. Interval history.

2. Blood pressure measurement.

3. Observation of the breasts, perineum, and abdomen.

(b) The patient examination at 4 t o6 weeks shall include all of the above and:

1. Weight.

2. Hemoglobin and hematocrit.

3. Bi-manual pelvic examination.

(5) Immediate postpartum care shall be provided to the newborn at the birthing center by qualified members of the medical staff as permitted within the staff member's legal scope of practice.

(a) A prophylaxis shall be instilled into each eye of the newborn.

(b) A cord blood sample shall be secured for laboratory testing for type, Rh determination, and direct Coombs test when the mother is Rh negative. The newborn shall also receive umbilical cord care.

(c) Newborn screening monitoring as recommended by the American Academy of Pediatrics and American College of

Obstetricians and Gynecologists Guidelines for Perinatal Care and the rules and regulations of the Department, to include, but not be limited to, testing for Group B Streptococcal infection, HIV, syphilis, and metabolic screening, to include newborn hearing screening and congenital cardiac screening, as required by state law.

(d) The newborn shall be weighed, measured, and examined for abnormalities and complications, and an Apgar score shall be obtained and recorded at 1 and 5 minutes. An identification tape shall be placed on all newborns.

(e) One-half milligram of Vitamin K shall be administered to the newborn within 24 hours after birth.

(f) The newborn must be examined by a qualified medical staff member, pursuant to each one's scope of practice, prior to discharge and shall be immediately referred to a qualified physician or hospital care if any of the following conditions occur:

1. Low birth weight (under 2,500 grams).

2. Apgar score of 7 or less at 5 minutes.

3. Signs of pre- or post-maturity.

4. Jaundice.

5. Persistent hypothermia consisting of a body temperature of less than 97°F for more than 2 hours after birth.

6. Respiratory difficulties.

7. Major congenital anomalies.

8. Exaggerated tremors.

9. Any other condition requiring medical care.

(6) Discharge Criteria.

(a) Prior to discharge of the newborn, recommendations and care consistent with the American Academy of Pediatrics and American College of Obstetricians and Gynecologists Guidelines for Perinatal Care and the rules and regulations of the Department must be followed, to include, but not be limited to, any required treatment for congenital syphilis, post-exposure prophylaxis for HIV, Hepatitis B immune globulin, and Hepatitis B vaccination. The newborn should also be evaluated for the risk for hyperbilirubinemia by

either blood or transcutaneous measurement, with a written plan for medical follow up.

(b) The mother and newborn shall be discharged from the birthing center within 24 hours after the birth occurs, except under the following conditions:

1. The mother is in a deep sleep when the 24-hour period is completed. In this case, the mother shall be discharged as soon after waking as is feasible; or

2. The 24-hour period is completed between the hours of 10 p.m. and 6 a.m.

(7) If the mother or newborn is retained at the birthing center longer than 24 hours after the birth, a report shall be filed with the Department's Division of Licensure and Certification within 48 hours after the birth, describing the circumstances and reasons for retention.

(8) The mother shall be counseled and receive written information regarding breastfeeding, perineal care, family planning, signs of common complications, activities and exercises, sex relations, care and feeding of the newborn, and changing family relationships prior to discharge from the birthing center.

(9) Prior to discharge, the parents shall be instructed by the birthing center in the importance of immunization and a 2-week screening for the newborn in accordance with the American Academy of Pediatrics schedule of visits. Parents shall also be instructed in the importance of repeat metabolic screening starting at several weeks of age. The parents shall be referred to providers of pediatric care if not provided on site.

(10) Observation of the Newborn at 72 Hours and 4 to 6 Weeks. A metabolic screening test shall be performed on the newborn by the birthing center, a referral facility, or a qualified medical professional between 24-72 hours and shall include, at a minimum, hypothyroidism and phenylketonuria. Sickle cell testing should be included if indicated. An examination of the newborn should also be made at 4 to 6 weeks by qualified members of the birthing center's medical staff, pursuant to each staff member's legal scope of practice, or a licensed pediatrician, family medicine practitioner, or pediatric nurse practitioner.

(11) If complications in the mother or newborn occur during the postpartum period, a consultation or referral shall be made to the appropriate source of secondary or tertiary care.

(12) If the mother refuses to permit eye prophylaxis, Vitamin K injections, or a metabolic screening test prophylaxis for the newborn due to religious beliefs, a waiver indicating this

decision shall be signed by the mother, witnessed by a medical staff member, and filed with the clinical record.
Author: Dana Billingsley, Diane Milledge
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420-5-13-.10 Management Of Emergencies.

(1) When necessary, patients shall be transferred from the birthing center to a hospital with which a written Transfer Agreement is in effect. A complete copy of the health record of both the mother and newborn, maintained up to and including the time of transfer, shall be provided to the referred provider or facility upon transfer.

If the mother is unable to ride in an upright position, or the mother's condition is such that she needs observation or treatment by EMS personnel, or the mother requires transportation on a stretcher, gurney, or cot, the birthing center shall arrange or request transportation services only from providers who are ambulance service operators licensed by the Alabama State Board of Health and with whom the birthing center has a written agreement for the transport of a patient to the hospital named in the Transfer Agreement. For the purposes of this rule, an upright position means no more than 20° from vertical.

(2) The birthing center shall have a written protocol for emergency situations, which shall include:

(a) The name, address, telephone numbers, and contact persons of the licensed ambulance service; identify the hospital under written agreement with the birthing center to provide emergency obstetrical and neonatal services; and list other hospitals in the vicinity.

(b) The conditions specified in the arrangements between the birthing center, the ambulance service, and the hospital, including financial responsibility for services rendered.

(c) The criteria requiring medical consultation with a qualified physician who is (1) certified by the American Board of Obstetrics and Gynecology or the American Board of Osteopathic Obstetricians and Gynecologists or (2) qualified as a family practice physician with an obstetrical emphasis or fellowship, or transfer to the hospital under written agreement with the birthing center, including, but not limited to:

1. Premature labor, meaning labor occurring at less than 37 weeks gestation.

2. Estimated fetal weight less than 2,500 grams. Newborns weighing more than 4,000 grams may require referral in the clinical judgment of the staff physician or consultant physician.

3. Hypertension.

4. Preeclampsia.

5. Failure to progress in labor.

6. Evidence of an infectious process.

7. Premature rupture of the membranes, meaning rupture occurring more than 24 hours before onset of active labor, provided there is no evidence of infection.

8. Suspected placenta previa or abruption.

9. Non-vertex presentation.

10. Hemorrhage of greater than 500 cc of blood.

11. Anemia, consisting of less than 10 grams of hemoglobin per 100 milliliters of blooc or 30 percent hematocrit.

12. Persistent fetal tachycardia (heart rate more than 160 beats per minute), repetitive fetal bradycardia (heartbeat less than 110 beats per minute for more than 10 minutes), or undiagnosed abnormalities of the fetal heart tones.

13. Persistent hypothermia in the newborn.

(d) Criteria to determine risk status which requires immediate emergency transfer include, but are not limited to:

1. Prolapsed cord.

2. Uncontrolled hemorrhage.

3. Placental abruption.

4. Convulsions.

5. Major anomaly of the newborn.

6. Apgar score of 7 or less at 5 minutes.

7. Fetal heart rate of 90 or less beats each minute for 3 minutes.

8. Thick meconium staining at the time of membrane rupture.

9. Respiratory distress in the newborn.

10. Weight less than 2,500 grams.

(e) The criteria and protocols for transfer shall be readily accessible to medical staff members at all times.

(3) The name and telephone numbers of the licensed ambulance services providing transport for the birthing center, the Children's Hospital Critical Care Transport Team, and the hospital accepting transfer shall be clearly posted at each telephone in the birthing center.

(4) A written report of the transfer shall be provided and retained for quality assurance review and Departmental inspection. The report shall include:

(a) The Patient's name.

(b) The date of the event.

(c) The reason for transfer.

(d) The provider and mode of transportation to the hospital.

(e) The exact time of the initial call and of any subsequent calls.

(f) Time of arrival of the emergency personnel.

(g) Time of the patient's departure from the birthing center.

(h) Time of arrival at the hospital.

(i) Name of the receiving hospital.

(j) Details concerning the initiation of EMS.

(k) The condition of the patient at the time of transfer.

(l) Any information regarding the medical care of the patient and outcome.

(5) The medical staff, consultants, and governing authority shall review and evaluate the criteria, protocols, and emergency transfer reports on a monthly basis. The results of the evaluation shall be documented.

Author: Dana Billingsley, Diane Milledge
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420-5-13-.11 Patient Records.

(1) Medical Records to be Kept. A birthing center shall keep comprehensive, organized, and readily accessible records for each patient (mother and newborn), including, but not limited to, admission and discharge notes, histories, physical examinations, nurses notes, procedure schedules, anesthesia/analgesic records, informed consent, follow-up care, and records of tests performed. The patients' records shall be current and kept with sufficient detail, consistent with good medical and professional practice, based on the services provided to each patient.

(2) Authentication of Records. All records shall be written, dated, and signed in an indelible manner, with the identity of the writer indicated, and made part of the patient's permanent record.

(3) Indexes. All health records should be indexed according to the patient's name.

(4) Facilities. A room or area shall be designated for maintaining paper copies of patient health records within the birthing center if a paper record is prepared. The area shall be sufficiently large and adequately equipped to permit the proper processing and storing of records and to protect them from fire or water damage. Access to electronic health records shall be properly secured and restricted to the birthing center's medical staff. All health records must be easily retrievable and readily accessible to the medical staff.

(5) Ownership. Health records shall be property of the facility and must be protected against loss, destruction, and unauthorized use; responsibility for the control of all such records shall rest with the administrator and the governing authority.

(6) Preservation of Records. Health records shall be preserved either in the original form, by microfilm, or in electronic form for a period of not less than 6 years following the most recent discharge of the patient. In the case of a minor, records shall be kept for 6 years after obtaining legal age. Mother and newborn records shall be kept together.

(7) Records are Confidential. Records and information regarding patients shall be confidential; however, patients may access and request copies of their own and their newborn's medical records, consistent with the provisions of HIPAA. The clinical record shall not be released without the written consent of the patient except under the following conditions:

(a) When the patient is transferred to another source of care. A complete patient record shall accompany the mother or newborn in the event of an emergent or non-emergent transfer of care.

(b) For audit by the Department during licensure inspection.

(c) In response to a lawfully issued subpoena or court order.

(d) As otherwise provided or required by HIPAA or other applicable state of federal law.

(8) Individual Patient Records. Each patient's health record shall include, but is not limited to, at least the following information:

(a) Demographic information and patient identification.

(b) Orientation to program and informed consent.

(c) Complete social, family, medical, reproductive, nutrition, and behavioral history.

(d) Initial physical examination, laboratory tests, and evaluation of risk status.

(e) Appropriate referral of at risk patients with report of findings on risk assessment.

(f) Development of a plan for care.

(g) Continuous periodic prenatal examination and evaluation of risk factors including documentation of prenatal care provided outside the center at related practitioner or clinic sites.

(h) Instruction and education including nutritional counseling, changes in pregnancy, self-care in pregnancy, orientation to health record and understanding of findings on examinations and laboratory tests, preparation for labor, sibling preparation, preparation for early discharge, newborn assessment and care, and feeding and medical evaluation.

(i) History, physical examination, and risk assessment on admission to the birthing center in labor (labor graph).

(j) Ongoing assessment of maternal and fetal status after admission to care and during the intrapartum period.

(k) Evaluation of progress in labor with ongoing assessment of maternal and newborn reaction to the process of labor.

(l) Consultation, referral, and transfer for maternal or neonatal problems that elevate risk status.

(m) Physical assessment of newborn, including apgar scores, gestational age, maternal newborn interaction, feeding, prophylactic procedures, postpartum monitoring of vital signs, and accommodation to extrauterine life. The birthing center must perform an ongoing postpartum assessment of both mother and newborn.

(n) Labor summary.

(o) Discharge summary for mother and newborn.

(p) Plan for newborn health supervision and required screening tests.

(q) Plan for newborn health supervision and required screening tests.

(r) Late postpartum evaluation of mother, counseling for family planning and other services, and evaluation of mother-child relationships.

(s) Eye care, vitamin K.

(t) All entries shall be dated and signed by the attending professional staff members.

(9) Completion of records. All health records shall be completed promptly. Reports of laboratory tests, treatments, and consultations shall be entered promptly on the health record.

(10) Vital Statistics Report. A record shall be kept of all births, deaths, and stillbirths that occur within the birthing center.

(a) A certificate of birth for each live birth shall be filed with the Department's Center for Health Statistics, or as otherwise directed by the State Registrar, within 5 days after the birth, in accordance with Code of Ala. 1975, §22-9A-7 and Ala. Admin. Code r. 420-7-1-.03.

(b) A report of fetal death shall be filed with the Center for Health Statistics, or as otherwise directed by the State Registrar, within 5 days after the occurrence is known if the fetus has advanced to, or beyond, the 20th week of

uterogestation, in accordance with Code of Ala. 1975, § 22-9A-13 and Ala. Admin. Coder. 420-7-1-.03.

(c) A certificate of death shall be filed with the Center for Health Statistics, or as otherwise directed by the State Registrar, within 5 days of the death, in accordance with Code of Ala. 1975 § 22-9A-14 and Ala. Admin. Coder. 420-7-1-.03 and -.10.

(d) If a record of death or fetal death has not been created in the state's electronic registration system, the administrator or his/her designee must report to the Center for Health Statistics, or as otherwise directed by the State Registrar, any dead body or fetal death no later than the fifth day of the following month of which the body was handled by the birthing center.

(e) All records and reports registered by the birthing center with the Center for Health Statistics shall be in a format prescribed by the State Registrar.

(11) Disposition of Records. When a birthing center ceases to operate either voluntarily or by revocation of its license, the governing body shall develop a proposed plan for the disposition of its medical records. Such plan shall be submitted to the State Board of Health and shall contain provisions for the proper storage, safeguarding, and confidential transfer and/or disposal of patient medical records and x-ray files. Any birthing center that fails to develop a plan for disposition of its records acceptable to the State Board of Health shall dispose of its records as directed by a court of appropriate jurisdiction.

(12) System of Periodic Review. There shall be a system for periodic record review and documentation of issues and outcomes.

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420-5-13-.12 Rights And Responsibility Of The Patient And Family.

(1) The rights and responsibilities of the patient and family, however defined, shall be clearly delineated in the birthing center's policies and procedures and communicated on the patient's admission for care. All patients have a right to:

(a) Be treated with respect, dignity, and consideration.

(b) Be assured of confidentiality.

(c) Be informed of the benefits, risks, and eligibility requirements for care in the birthing center.

(d) Be informed of the services provided by the birthing center and those provided by contract, consultation, and referral.

(e) Be informed of the identity and qualifications of care providers, consultants, and related services and institutions.

(f) Have access to their medical records and all results of screening or diagnostic studies.

(g) Be informed of all diagnostic procedures and reports, recommendations, and treatments.

(h) Participate in decisions relating to the plan for management of the patient's care and all changes in that plan, once established, including referral or transfer to other practitioners or other levels of care.

(i) Receive a written statement of fees for services and responsibilities for payment.

(j) Be informed of the birthing center's plan for the provision of emergency and nonemergency care in the event of complications to mother or newborn.

(k) Receive a written statement of the birthing center's plan and the family's responsibility to ensure adequate supportive home care and follow-up health supervision of the mother and infant.

(l) Be informed of, and reserve the right to refuse, participation in research or student education programs.

(m) Be informed of the birthing center's policy for hearing grievances. The telephone number to register complaints with the Alabama Department of Public Health, Division of Health Care Facilities, shall be posted in a prominent location and shall be included in the written material given to the patient upon discharge. A grievance log, including the nature of the complaint and its resolution, shall be maintained by the birthing center and made available for inspection by the Department on its request.

(n) Be informed of the liability insurance status of the birthing center and medical staff.

(2) The birthing center shall provide or demonstrate its availability to provide a range of services to meet the physical, emotional, socio-economic, informational, and medical needs of the individual patient while under care, including, but not limited to:

(a) An orientation to the facility fees and services of the birthing center.

(b) Written information, including a glossary of terms, on the established criteria for admission to, and continuation in, the birthing center's program of care.

(c) Prenatal care (may be provided at a related practitioner or clinic site).

(d) A program of education for pregnancy, labor, breastfeeding, infant care, early discharge, parenting, self-care/self-help, and sibling preparation.

(e) Laboratory services.

(f) Twenty-four (34) hour telephone consultation services.

(g) Intrapartum care.

(h) Light nourishment during labor and postpartum.

1. When patients remain in the birthing center for 24 hours, food must be provided to meet the dietary needs of those patients. If meals are prepared in the birthing center, the facility shall have organized dietary services that are directed and staffed by adequate qualified personnel, including a qualified food service manager and consultation by a licensed registered dietician as required to meet the dietary needs of the patients. However, a birthing center that has a contract with an outside food management company may meet the requirements of this rule if the company has a dietitian who serves the birthing center on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this rule and provides for constant liaison with the birthing center medical staff for recommendations on dietetic policies affecting patient treatment.

2. Food prepared outside the facility shall be performed only by facilities which meet the requirements of Alabama Administrative Code, Chapter 420-3-14, Food Service Sanitation. In addition, the birthing center must provide a food preparation area with:

• Double sink, if disposable are not utilized at all times.

• Microwave oven.

• Refrigerator.

• Hand-washing sink.

• Counter space.

• Towel cabinet.

• Soap dispenser.

• Garbage cans with cover.

• Coffee maker.

• Storage area for silverware and cutlery, if disposables are not utilized at all times.

(i) Immediate post partum care.

(j) Home or office follow-up for mother and newborn.

(k) Additional options:

1. Exercise p0rograms.

2. Parent support groups.

3. Postpartum classes.

4. Family planning.

5. Well baby care.

6. Circumcision.

7. Nursing mother support programs.

8. Well woman gynecologic care.

9. Public education.

10. Professional education.

11. Clinical investigation and/or research.

(3) The birthing center shall inform patients that drugs for induction or augmentation of labor, vacuum extractors, and forceps are not necessary during normal labor and are not

appropriate for use in birthing centers. Patients must be provided with and consent to this policy.

(4) The birthing center's policy and procedure manual shall include all aspects of birthing center practice and care and shall be made available to practitioners and support staff at all times.

(5) The birthing center's practice protocols must be approved by the staff physician or consultant physician and made available to the hospital receiving transfers upon request.

Author: Dana Billingsley, Denise Milledge
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420-5-13-.13 Quality Assurance.

(1) There shall be a written quality assurance program consisting of an interdisciplinary committee which shall perform quality assurance reviews for maternal and newborn care provided in the birthing center, including, but not limited to:

(a) At least annual review of protocols, policies, and procedures relating to the maternal and newborn care provided during the prenatal, intrapartum, and postpartum periods.

(b) The appropriateness of the criteria for determining eligibility for admission to and continuation in the birthing center's program of care.

(c) The appropriateness of diagnostic and screening procedures, including laboratory studies, sonography, and nonstress tests, and their impact on quality of care and patient cost.

(d) The appropriateness of medications prescribed, dispensed, or administered in the birthing center.

(e) Performance evaluations of medical and support staff employed by the birthing center (peer review - self evaluation).

(f) Quarterly meetings of medical staff to review the management of care of individual patients (medical chart reviews) and make recommendations for improving the plan for care.

(g) Quarterly review of all transfers of mothers and neonates to hospital care, to determine the appropriateness and quality of the transfer.

(h) Immediate review and evaluation of all complications of pregnancy, labor, and postpartum periods arising in the birthing center and the appropriateness of medical staffs consultation and treatment of the same.

(i) Evaluation of staff's ability to manage emergency situations via unannounced periodic drills for fire, maternal/newborn emergencies, power failures, etc.

(j) The birthing center's responses to patient grievances and feedback.

(2) Patient records shall be audited by the medical staff at least every 3 months and a sample audited by the quality assurance committee at least every 6 months. The audit shall evaluate the following for accuracy and completeness:

(a) Initial history, physical examination, risk assessments, and laboratory tests.

(b) Documentation of clinical observations, examinations, and treatments.

(c) Evidence that appropriate actions have been taken in response to clinical findings.

(d) Counseling, education, consultation, and referral activities are recorded.

(e) Consent forms are signed.

(f) All entries are legible, dated, and signed in ink or typed.

(3) The quality assurance committee shall analyze the incidence of maternal and perinatal morbidity and mortality, obstetrical risk assessments, pre-term labor risk assessments, consultant referrals and outcomes, and transfers of care and outcomes.

(4) The quality assurance program ensures quality of care to patients and the community through an effective system for collection and analysis of data, which includes, but is not limited to, utilization of information obtained through the following:

(a) Orientation sessions.

(b) Patient registrations.

(c) Women attending educational programs at the birthing center.

(d) Total number of encounters/visits antepartum.

(e) Number of and reasons for antepartum transfers.

(f) Intrapartum care admissions.

(g) Number of and reasons for intrapartum transfers.

(h) Time in the birthing center before delivery.

(i) Births occurring in the birthing center.

(j) Births occurring en route to the birthing center.

(k) Time in birthing center after delivery.

(l) Number of and reasons for maternal postpartum transfers.

(m) Number of and reasons for newborn transfers

(n) Postpartum home visits.

(o) Follow-up maternal postpartum office visits.

(p) Follow-up newborn office visits.

(q) Total classes conducted antepartum.

(r) Total classes conducted postpartum.

(s) Outcomes of care provided.

1. Loss of pregnancy before 20 weeks gestation.

2. Type of anesthesia/analgesia used.

3. Type of delivery.

4. Place of delivery.

5. Complications of delivery, including postpartum hemorrhages of more than 1,000 cc.

6. Episiotomies, lacerations.

7. Infants with birth weight below 2,500 grams or over 4,000 grams.

8. Apgar scores.

9. Neonatal morbidity/mortality.

10. Maternal morbidity/mortality.

11. Maternal or newborn admissions from home to hospital in a 4-week postpartum period.

(t) Deviations from written protocols.

(5) The birthing center's quality assurance plan should, at a minimum, address any issues related to the following:

(a) Administrative or supervisory action.

(b) Continuing education or simulation.

(c) Modification of policies and procedures.

(d) Revision of risk criteria.

(e) Revision of health record or other forms.

(f) Utilization of outside consultation and expertise.

(g) Changes to facility, equipment, or supplies.

(6) Professional Accreditation. The birthing center must apply for, obtain, and maintain accreditation from a nationally recognized accrediting organization as a condition of receiving a license.

(7) Yearly Evaluation. The birthing center shall assess the needs of the childbearing community and continue to develop services and programs to address the following:

(a) The general geographical area to be served.

(b) Demographic data and vital statistics of the community to be served.

(c) Availability of and access to maternal and newborn services, including practitioners, hospital obstetrical and newborn services, home birth services, family-centered maternity care programs, birthing rooms/suites, clinics for disadvantaged families, laboratory services, supplementary social and welfare services, childbirth education, and parental support programs.

(d) Periodic market surveys to determine the impact of the birthing center on the community and to assess the needs of childbearing families in the population served, for purposes of program planning and development.

(e) Changes in population, environment, regulations, legislation, reimbursement, and access to and availability of maternal and newborn services in the community.

(8) Reports of the quality assurance committee shall be given to the governing body.

(9) The governing body shall examine the reports of the quality assurance committee and shall make such reports available for inspection by the licensing authorities for the facility and the providers.

Author: Dana Billingsley, Denise Milledge
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420-5-13-.14 Reports.

(1) An annual report shall be created by the birthing center no later than the 30th day of the month following the end of the calendar year and kept on file by the facility. At a minimum, the report shall contain the following information and shall be made available for inspection by the Department upon its request:

(a) Name and address of the birthing center.
(b) Number of patients accepted for care during the reporting year.
(c) Number of deliveries and number of deliveries of newborns less than 2, 500 grams.
(d) Number of transfers to hospitals, the reasons for transfer, and outcomes.
(e) Number of maternal and newborn deaths and stillborns associated with birthing center patients.
(f) Range and average length of stay in hours.
(g) Range and average length of stay after birth in hours.
(h) The nature and number of surgical procedures performed in the birthing center.
(i) Any other additional information the Department may require.

Author: Dana Billingsley, Diane Milledge
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420-5-13-.15 Pharmaceutical Services.

(1) The birthing center shall develop, implement, and enforce written policies and procedures governing the provision of pharmaceutical services.

(2) Administering Drugs and Medicines.

(a) Drugs and medicines shall not be administered to patients unless ordered by a physician duly licensed to prescribe such drugs, or, by a licensed CNM, as authorized by the CNM's collaborative practice protocol or formulary pursuant to the rules of the Alabama Board of Nursing and the Alabama State Board of Medical Examiners, as applicable, and approved protocols. Such orders shall be in writing and signed personally by the prescriber.

(b) All verbal or telephone orders for medication shall be received by an RN, LPN, CNM, physician, or registered pharmacist and shall be placed in writing into the patient's permanent medical record. The order shall include the name of the prescribing physician or CNM, accompanied by the time, date, name, and title of the person making the entry into the record. All verbal or telephone orders shall be countersigned by the prescriber within 48 hours of the order.

(c) All treatments and medications provided to patients shall be recorded in the medical record by the nurse administering the treatment or medication. CPMs may not administer drugs and medicines to patients or handle drugs or medicines for administration to patients, other than anti-hemorrhagic medication and oxygen in an emergency.

(d) Preparation and administration of medications shall be under the supervision of a physician or CNM. Pain control should depend primarily on close emotional support and adequate preparation for the birth experience.

(e) The birthing center shall not dispense any medications to outpatients. The birthing center may procure medications for its patients from community pharmacists through contractual agreements with those pharmacies. Individual medication containers shall be properly stored in individual patient bins/trays within a lockable area, room or cabinet; or the birthing center may procure medications via the staff physician's or CNM's registration. Medical staff shall administer or order medications to be administered to patients solely while in the birthing center. Medications for patients to take home shall be provided only via written prescription by the attending physician or CNM.

(f) An individual qualified by licensure and experience to meet the requirements of subsections (d) and (g) of this

section shall be responsible for the overall supervision of the handling, administration, storage, record-keeping, and final disposition of medications and controlled substances stocked within the birthing center.

(g) Prescribing, dispensing, and administration of medications shall meet all standards required by law and by regulations of the Alabama State Board of Medical Examiners, the Alabama State Board of Pharmacy, and the Alabama Board of Nursing.

(3) Medical Storage.

(a) Medicines and drugs maintained in the birthing center shall be stored in a drug room of sufficient size for orderly storage and accurate identification. The room shall be adequately illuminated and maintained at a temperature for safe storage of drugs.

(b) Safety. Drug rooms shall be provided with safeguards to prevent entrance of unauthorized persons, including bars on accessible windows and locks on doors. Controlled drugs and ethyl alcohol, if stocked, shall be stored under double locks and in accordance with applicable federal and state laws.

(c) Only authorized personnel shall have access to the drug/ medicine room, as defined by the birthing center.

(d) The drug/medicine room shall be provided with a counter and sink.

(4) Emergency Kit. The birthing center, upon the written advice and written approval of its staff physician or consultant physician, shall provide an emergency kit or stock supply of drugs and medicines for the exclusive use of the physician or CNM in treating the emergency needs of patients.
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History: Filed November 19, 1987. **Repealed:** Filed April 16, 2010; effective May 21, 2010. **New Rule:** Published August 31, 2023; effective October 15, 2023.

420-5-13-.16 Laboratory Services.

(1) The birthing center may provide a clinical laboratory or make contractual arrangements with a certified laboratory to perform services commensurate with the needs of the birthing center and the laboratory's level of certification.

(a) Outside Laboratory.

1. Qualifications. An approved outside laboratory may be a state licensed hospital laboratory or state licensed independent clinical laboratory and must have all necessary current federal CLIA numbers and waivers.

2. A contractual arrangement shall be deemed as meeting the requirements of this rule so long as the arrangement includes written policies, procedures, and individual chart documentation evidencing that the policies of the birthing center are met and the needs of the patients are being provided, including the processing of specimens and reporting of test results to the birthing center on a 24/7 basis, as the demands of labor and delivery require.

(b) In-House Laboratory.

1. In-house laboratory services shall be licensed by the state as required and have all necessary federal CLIA certificates and waivers. The laboratory shall be under the direction and supervision of an individual meeting the qualifications set forth in the Department's Rules and Regulations for Independent Clinical Laboratories and CLIA regulations, based on the level of laboratory testing performed.

2. The laboratory must be of sufficient size and adequately equipped to perform the necessary services of the birthing center.

3. Provisions shall be made for a preventive maintenance and an acceptable quality control program covering all types of analyses performed by the laboratory. Documentation must be maintained for both programs.

4. Written policies and procedures shall be developed and approved for all services provided by the laboratory.

5. Documentation of patient laboratory values shall be recorded on appropriate laboratory report forms and duplicate copies of these reports retained for a minimum of2 years in the laboratory. A record must be maintained to reflect the apparent condition of the specimen collected, time and date collected, and name of the patient. All personnel collecting specimens shall be adequately and appropriately trained and, where otherwise required by law shall be licensed, and their personnel files shall reflect such training and licensure.

6. Contractual arrangements for referral laboratory testing shall be made in accordance with subsection (l)

(a) above for laboratory testing procedures not provided by the in house laboratory.

7. If medical laboratory technologists are employed on the staff of the birthing center, such technologists must meet one of the following requirements.

(i) Successful completion of2 years of academic study (a minimum of 60 semester hours or equivalent) in an accredited college or university, with an associate degree as a medical laboratory technologist; or

(ii) Graduation from high school, and subsequent to graduation, 2 years of documented, hands-on experience as a technician trainee in a clinical laboratory of a hospital, health department, university, or medical research institution, or in a clinical laboratory providing equivalent hands-on training accepted by the Alabama Department of Public Health; or

(iii) Graduation from high school and successful completion of an official military laboratory procedures course of at least 12 calendar months of study, with at least 1 year of hands-on experience as a technician trainee in a clinical laboratory of a hospital, health department, university, or medical research institution, or in a clinical laboratory providing equivalent hands-on training accepted by the Alabama Department of Public Health.

Author: Dana Billingsley, Diane Milledge
Statutory Authority: Code of Alabama, 1975, §22-2-2(6), et seq. §22 21-20, et seq.
History: Filed November 19, 1987. **Repealed:** Filed April 16, 2010; effective May 21, 2010. **New Rule:** Published August 31, 2023; effective October 15, 2023.

420-5-13-.17 Physical Environment.

(1) Safety. The governing authority shall develop written policies and procedures designed to safeguard patients, staff, and visitors while in the birthing center and on its grounds. The policies and procedures shall include the following:

(a) Safety rules and practices pertaining to personnel, equipment, liquids, and drugs, with particular attention to hazards of children, such as uncovered electrical outlets, unsafe toys, unprotected stairs, and unlocked storage cabinets, as well as walkways, parking lots, and outside play areas.

(b) Provisions for reporting and investigation of accidental events regarding patients, visitors, and personnel (incidents), and corrective actions taken.

(c) Provision for dissemination of safety-related information to employees and users of the facility.

(d) Provision for syringe and needle storage, handling, and disposal.

(e) Provide a security alarm and camera service to ensure controlled/limited access to the facility; activate protocols to screen family members and visitors; restrict public entry to the birthing center during certain hours and all general access to patient areas; provide panic buttons for staff and alarm bracelets for mothers and infants; and develop Code Pink plans to be approved by the Department.

(2) Housekeeping/Sanitation. The birthing center shall provide a safe and sanitary environment, properly constructed and maintained to protect the health of patients.

(a) The birthing center shall be maintained in a clean condition and have written policies and procedures for housekeeping and sanitation. The birthing rooms shall be appropriately cleaned after each birth, using appropriate disinfectants to assure asepsis between each use, as approved by the Infection Control Committee.

(b) The premises and equipment shall be kept clean and free of insects, rodents, litter, and rubbish.

(c) There shall be strict adherence to regulations of OSHA for handling of medical waste, regulations of the Alabama Department of Environmental Management (ADEM), and other applicable federal regulations for disposal of medical waste (medical waste includes, but is not limited to, disposable gowns, soiled dressings, sponges, surgical gloves, bacteriological cultures, blood and blood products, excretions, secretions, other bodily fluids, catheters, needles, IV tubing with needles attached, scalpel blades, glassware, and syringes that have been removed from their original sterile containers).

(d) Adequate arrangements for housekeeping staff shall be made, or housekeeping staff shall be employed to fulfill the above requirements. Primary patient care personnel shall not perform routine decontamination and housekeeping duties during periods in which they are caring for patients.

(3) Linen and Laundry.

(a) An adequate supply of clean linen or disposable materials shall be available at all times for the proper care and comfort of patients.

(b) Provisions for proper laundering oflinen and washable goods shall be made. Linens used for draping must be sterilized. All reusable linens, including those used as sterilizing wrappers, must be laundered before reuse. Linens shall be handled, stored, processed, and transported in such a manner as to prevent the spread of infection. Soiled and clean linen must be handled and stored separately.

(c) A sufficient supply of cloth or disposable towels shall be available so that a fresh towel can be used after each hand washing. Towels shall not be shared.

(4) Disaster Preparedness.

(a) The birthing center shall have a posted plan for evacuation of patients, staff, and visitors in case of fire, severe weather, natural disasters or other emergencies, or threats to the personal safety of patients or staff.

(b) Disaster Drills.

1. At least one fire or emergency drill shall be held every 3 months to familiarize employees with the drill procedure. Reports of the drills shall be maintained with records of attendance.

2. Records shall show that action has been taken to correct any identified problems with fire drills.

(c) The birthing center shall develop a plan or methods to communicate with patients in the event of a disaster-related temporary closure of the facility. The birthing center shall advise the Department in writing of any such closure within 24 hours thereof.

(5) Infection Control.

(a) An Infection Control Committee, or comparable group, comprised of the staff physician or consultant physician and members of the nurse-midwifery staff, nursing staff, administration, and other services of the birthing center, shall be established and shall be responsible for investigating, controlling, and preventing infections in the birthing center. The Infection Control Committee shall meet quarterly and maintain written documentation and an attendance roster for all such meetings.

(b) There shall be written procedures to govern the use of aseptic techniques and procedures in all areas of the birthing center.

(c) To keep infections at a minimum, such procedures and techniques shall be reviewed on an annual basis by the Infection Control Committee.

(d) Continuing education shall be provided on an annual basis to all birthing center personnel on the causes, effects, transmission, prevention, and elimination of infection.

(e) Reports of infections observed during any follow-up or return visit of the patient shall be made and kept as a part of the patient's medical record. The birthing center shall maintain a surveillance logbook recording all follow-up visits and telephone inquiries in which infections or other complaints are reported or observed. This logbook shall be reviewed at least once quarterly by the birthing center's staff physician or consultant physician.

(f) Efforts shall be made to determine the origin of any infection, and if the birthing process was found to be related to acquiring the infection, remedial action shall be taken to prevent recurrence.

1. In the event of sustained numbers of infections (three or more patients in l week), the Department shall be immediately notified. Upon order of the Department, operation of the birthing center shall be discontinued until approval for continuation of operation is granted by the Department.

2. If the birthing center wishes to contest such closure, the Department shall provide an opportunity for a hearing under the contested case provisions of the Alabama Administrative Procedure Act. Such hearing shall be held not more than 2 working days after notice of appeal is given to the Department, unless the birthing center agrees otherwise. The birthing center shall be entitled to full rights of appeal from any adverse decision rendered as a result of the hearing, in accordance with state law.

(g) Written policies and procedures shall be developed to ensure that employees with any communicable disease in an infectious stage shall not be on duty in the birthing center.

(h) Call Records. In addition to the infection control record required by these rules, a facility must keep a record of all calls taken by the RN, CNM, CPM, or physician. The call record should include the patient's name, time and date of call, a brief description of the reason for the call, date of

the procedure, location of any emergency department the patient is presenting to, if known and applicable, and any action taken in response. A full description of any adverse conditions and the instructions or treatment given in response must be noted in the patient's medical record.

Author: Dana Billingsley, Diane Milledge
Statutory Authority: Code of Ala. 1975, §22-2-2(6), et seq.; §22-21-20, et seq.
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420-5-13-.18 Service Facilities, Equipment And Supplies.

(1) The birthing center shall establish and maintain a safe environment for healthy women anticipating an uncomplicated labor and birth, with adequate space for furnishings, equipment, and supplies necessary to ensure comfortable and private accommodations for the mother and family, and adequate space for personnel, including but not limited to:

(a) Admissions Office. There shall be a room designated as the admissions office, where patients may discuss personal matters in private. The admissions office may be combined with the business office and medical record room if privacy can be maintained when confidential matters are being discussed. This space shall be separated from the treatment area by walls.

(b) Business Office. This space shall be adequate for the number of birthing center personnel.

(c) Reception and Waiting Area. A waiting room shall be provided with sufficient seating for the maximum number of persons that may be waiting at any time. Public toilets, telephones, and drinking fountains, accessible to the handicapped, shall be available.

(d) Staff/Employee Locker Rooms and Toilets. The birthing center shall provide male and female toilet and locker rooms, which are centrally located.

(e) Family Room and Play Area for Children. The size and number of family rooms shall be adequate for the patient caseload. A couch, chairs, end table, reading lights, and toy storage area shall be included. Sufficient precautions for child safety shall be observed. Depending on the size of the caseload, the family area may double as a conference room and/or classroom. Toilet facilities shall be available.

(f) Conference/Educational Facilities/Library Area. These areas may be one room or separate rooms; however, each area shall be of sufficient size for the number of personnel in the birthing center and the patient caseload. The conference area may be used for childbirth classes, staff inservice education, meetings, etc.

(g) Clean Utility. A clean workroom for storage and assembly of supplies shall contain storage cabinets or storage carts, a work counter, and a sink.

(h) Soiled Utility. The soiled utility room shall contain a deep sink, work counter, waste receptacle, and soiled linen receptacle.

(i) Medicine Room. The medicine room shall include a sink, small refrigerator, locked storage, narcotic locker, and work counter. The medicine area may be combined with the clean utility room.

(j) Clean Linen Storage. The clean linen storage shall contain a closet large enough to hold an adequate supply of clean linen. This can be combined with the clean utility room.

(k) Kitchen Facilities. The kitchen/nourishment centers shall have sufficient storage for patients' prepared food and beverages. A centralized kitchen/nourishment center may be shared or individual nourishment centers may be present in each birthing room.

(l) Janitor's closet.

(m) Laundry. A laundry room with a residential washer and dryer shall be provided if an outside laundry contract is not used.

(n) Laboratory. The laboratory area shall contain a counter, sink, and storage area for supplies.

(o) Emergency cart storage.

(p) Examination Rooms. The number of examination rooms shall be adequate for the patient caseload. When used for prenatal care, the examination rooms shall be situated away from the birthing rooms. Each examination room shall contain at least I 00 square feet. At least one examination room shall be provided for admission evaluation, containing an examining table with stirrups, stool, goose neck light, equipment table, sink, and supply storage area.

(q) Central Sterile Supply. Written policies and procedures shall be maintained for the sterilization of supplies and

water and reprocessing of sterile supplies at specific time periods. The following areas shall be separated:

1. The receiving and clean-up area shall include a two-compartment sink with two drainboards.

2. The area for instrument pack assembly shall have a sterilizer or approved alternate source of sterilization, work counter, and a lavatory or sink. A sterile storage area shall also be provided.

3. When sterilization services are provided via contract outside of the birthing center, there shall be a separately designated area in the facility for dirty, clean, and sterile supplies.

(r) Birthing Rooms.

1. Birthing rooms shall have sufficient space for a double bed, cradle, nightstand, rocking chair, cabinet for supplies, and a sink, with a minimum of 120 square feet. A counter area for infant resuscitation should be lighted in such a manner as to provide at least 100 foot candles at the infant's body surface, and should include an overhead source of radiant heat, a heating pad overlying a thin mattress on which the neonate is placed, and a large wall clock with a clearly visible second hand.

2. Ceiling height of the birthing rooms shall be a minimum of 8 feet.

3. Each birthing room will have immediate access to a bathroom. Tubs are recommended.

4. Birthing rooms shall be designed to provide privacy for the mother and family.

5. All walls and floors shall be suitable for washing.

6. A nurse call outlet or emergency call system shall exist with control switches in all birthing rooms that can be activated during an emergency.

7. Portable oxygen and suction shall be available. All outlets shall be grounded.

(2) Equipment.

(a) The birthing center shall have properly maintained equipment for routine care of women and neonates, including, but not limited to:

1. A readiant heat source for newborn examination.

2. Transfer incubator or isolete.

3. Sterilizer or an approved alternate source of sterilization.

4. Blood pressure equipment, thermometers, fetoscope/ doptone.

5. Intravenous equipment.

6. Oxygen equipment for mother and newborn.

7. Instruments for delivery, episiotomy, and repair.

(b) Testing and Diagnostic Equipment. All testing and diagnostic equipment, including equipment that is readily available to perform ongoing assessments of the mother and fetus/infant, shall be maintained in good working order at all times and tested on a routine basis.

1. If equipment is obsolete or permanently unusable because of irreparable damage, malfunction, or any other condition that renders its use detrimental to patient care, it shall be immediately separated from the equipment currently in use, clearly tagged as permanently unusable, and properly disposed of as soon as possible.

2. If equipment is temporarily unusable, it shall be immediately separated from equipment currently in use and clearly tagged as being temporarily unusable until it is repaired or otherwise made fit for use. Equipment is temporarily unusable if in need of repair or if not maintained in accordance with manufacturer standards, regardless of whether there is an apparent defect. Tagged equipment shall not be returned to use until repaired and tested to ensure proper operation.

(c) Preventive Maintenance. There shall be a schedule of preventive maintenance developed for all equipment in the birthing center integral to patient care to assure satisfactory operation thereof. This schedule shall cover at least the following equipment and shall be retained by the birthing center for a minimum of 2 years:

1. Ultrasound. All ultrasound machines must be tested and calibrated by a trained, qualified technician in accordance with the manufacturer's recommendations. In no event shall testing and calibration be done less than annually.

2. Autoclave. All autoclaves must be tested and maintained at least annually by a trained, qualified technician in accordance with the manufacturer's recommendations, except that necessary routine weekly cleaning, maintenance, and inspection may be performed by properly trained clinic staff or a trained, qualified technician in accordance with the manufacturer's recommendations. Dated chemical indicators shall be used with every load to ensure sterilization. Biological indicator testing must be performed every 40 service-hours, and the results of the biological indicator testing must be logged.

3. A readily accessible emergency cart or tray for the mother shall be equipped to carry out the birthing center's written emergency procedures. A written log of routine equipment maintenance shall be maintained for the emergency cart. The emergency cart or tray for the mother shall contain mechanical ventilating assistance equipment, airways, manual breathing bag, laryngoscope and endotracheal tubes, suction equipment, emergency drugs and supplies, intravenous equipment, an automatic external defibrillator (AED), blood expanders, and postpartum hemorrhagic equipment.

4. A readily accessible emergency cart or tray for the newborn shall be equipped to carry out the birthing center's written emergency procedures and shall be securely placed with a written log of routine maintenance. The emergency cart or tray for the newborn shall contain mechanical ventilating assistance equipment, airways, manual breathing bag, laryngoscope and endotracheal tubes, suction equipment, emergency drugs and supplies, and intravenous equipment and shall be available in each birthing room.

(d) The birthing center must maintain a record for all equipment containing the following information:

1. Manufacturer, make, and model of the equipment.

2. Date of purchase.

3. Any dates on which the equipment was removed from service for repair or maintenance and, if applicable, date equipment was returned to service.

4. Date and description of all tests, maintenance, or repairs performed on the equipment, including all routine inspection and maintenance performed by medical staff.

5. Names and qualifications of the company and technician performing the tests, maintenance, or repairs.

6. Results of any tests, maintenance, or repairs.

7. All manufacturer literature and information. Any missing information shall be noted in the equipment record, and if there is no record of proper maintenance in the last year, the equipment must be immediately tested and, if necessary, calibrated or repaired.

(e) The birthing center shall have properly maintained accessory equipment, which incudes, but is not limited to:

1. A conveniently placed telephone and emergency call system.

2. Portable lighting, including an emergency light source.

3. Kitchen equipment usually found in home for light refreshment.

4. Laundry area for residential washer and dryer if an outside laundry contract ids not used.

(3) Supplies.

(a) The inventory of supplies shall be sufficient to care for the number of childbearing women and families registered for care.

(b) Shelf life of all medications and intravenous fluids shall be monitored. Medications and supplies which have deteriorated or reached their expiration dates shall not be used for any reason. All expired or deteriorated items shall be disposed of promptly and properly. The birthing center shall examine all stored medications and supplies no less frequently than once each month and shall remove from its inventory all deteriorated items and all items for which the expiration date has been reached. The birthing center shall maintain a log recording each such examination with its date, time, the person conducting the examination, and a description of each item or group of items removed from inventory and the reason for removal.

Author: Dana Billingsley, Diane Milledge
Statutory Authority: Code of Ala. 1975, §22-2-2(6), et seq.; §22-21-20, et seq.

History: Filed November 19, 1987. **Repealed:** Filed April 16, 2010; effective May 21, 2010. **New Rule:** Published August 31, 2023; effective October 15, 2023.

420-5-13-.19 Physical Plant.

(1) General.

(a) Location. The birthing center shall be in a location that is free from undue noise, smoke, dust, or foul odors and shall have sufficient parking spaces to accommodate patients and their families.

(b) Local Requirements. The birthing center shall comply with all local zoning, building, and fire ordinances. A birthing center may not be operated in a private residence.

(c) Accessibility. The birthing center shall be located on streets or roads which can be kept passable at all times.

(d) Communication. The birthing center shall have telephones to summon help in case of fire or other emergency.

(e) Occupancy. No part of the birthing center may be rented, leased, or used for any commercial purpose or for any purpose not necessary or in conjunction with the operation of the birthing center. Food and drink machines may be maintained or a diet kitchen provided for prepared foods.

(2) Submission of Plans and Specifications.

(a) Scope. A facility constructed or renovated after the effective date of these rules shall be classified as Business Occupancy and shall comply with the codes and standards adopted by the State Board of Health and in effect at the time of plan submission, including, but not limited to, the specific requirements for freestanding birth centers set forth in the Guidelines for Design and Construction of Hospitals and Outpatient Facilities, applicable Life Safety Codes, and the National Fire Protection Association (NFPA) International Building Code (IBC).

(b) New Construction, Additions, and Major Alterations. When construction is contemplated for new buildings, conversions, or additions to existing buildings coming within the scope of these rules, plans and specifications shall be submitted for review by the Department in accordance with Alabama Administrative Code Rule 420-5-22, "Submission of Plans and Specifications for Health Care Facilities)".

(c) Minor Alterations and Remodeling. Minor alterations and remodeling which do not affect the structural integrity of the building, change functional operation, affect fire safety, and add services to those for which the birthing center is licensed need not be submitted for review.

(d) Water Supply, Plumbing, and Drainage. No system of water supply, plumbing, sewage, garbage, or refuse disposal shall be installed, nor shall any such existing system be materially altered or extended until complete plans and specifications for the installation, alteration, or extension have been submitted to the Department for review.

(e) Inspections. The State Board of Health and its authorized representatives shall have access to the work for inspection wherever it is in preparation or progress.

(3) Building Requirements.

(a) Structural Soundness. The building shall be structurally sound, free from leaks and excessive moisture, in good repair, and painted at intervals to be reasonably attractive inside and out.

(b) Temperature to be Maintained. The mechanical system shall be capable of maintaining a temperature of 70° F to 75° F throughout the birthing center.

(c) Lighting. There shall be general lighting and provision for adequate examination lights in the birthing room.

(d) Screens. All screen doors and non-stationary windows (except in air-conditioned areas) shall be equipped with tight fitting, full length 16 mesh screens. Screen doors shall swing out and shall be equipped with self-closing devices.

(e) Emergency Lighting System. Emergency lighting systems shall be provided to adequately light corridors, exit signs, stairways, and lights at the exterior of each exit in case of electrical power failure.

(f) Emergency Power. An emergency generator shall be provided to operate the emergency lighting system and make life sustaining equipment operable in case of power failure. Emergency outlets shall be provided in all patient care areas.

(g) Floors. All floors in birthing rooms shall be smooth resilient tile, free from cracks, and finished for easy cleaning. All other floors shall be covered with hard tile, resilient tile, carpet, or the equivalent. Carpeting is prohibited as a floor covering in birthing rooms.

(h) Interior Finish and Decorative Materials. All combustible decorative and acoustical material, to include wall paneling, shall be as follows:

1. Materials on wall and ceiling in corridors and rooms occupied by four or more persons shall carry a flame spread rating of 25 or less and a smoke density rating of 450 or less in accordance with ASIM E-84.

2. Rooms occupied by less than four persons shal1 have a flame spread rating of 75 or less and a smoke density rating of 450 or less in accordance with ASIM E-84.

(i) Ramps. Ramps shall not be steeper than 1 foot of rise in 12 feet of run, shall be finished with a nonslip surface, and shall be provided with handrails on both sides. Exterior ramps, where installed, shall be provided with handrails on open sides.

(j) Doors.

1. The minimum width of doors to all rooms needing access for stretchers shall be 3 feet 8 inches.

2. Hardware on all toilet and bathroom doors shall be operable from outside the room.

3. Birthing doors shall not be equipped with hardware that will permit a patient to lock herself within the room.

(k) Floor Levels. All differences in floor levels or step-downs within the building shall be accomplished by stairs of not less than three 6-inch risers or ramps and shall be equipped with handrails on both sides.

(l) Ventilation. The building shall be well ventilated at all times. Birthing rooms shall be ventilated in such a manner as to supply fresh air and to prevent accumulation of objectionable odors. Kitchens, laundries, service rooms, toilets, bathrooms, and all inside rooms shall be ventilated by louvers, wall vents, or undercut in doors and by windows, gravity vents, or mechanical means so as to prevent offensive odors from entering other parts of the building.

(m) Fire Extinguisher. An all purpose fire extinguisher shall be provided at each exit and special hazard area and located so a person would not have to travel more than 75 feet to reach an extinguisher. Fire extinguishers shall be of a type approved by the local fire department or State Fire Marshal and shall be inspected at least annually. An attached tag shall bear the initials or name of the inspector and the date inspected.

(n) Elevators. Multi-story facilities shall be equipped with at least one automatic elevator of a size sufficient to carry a patient on a stretcher.

(o) Multi-Story Buildings. All multi-story buildings shall be of fire resistive construction in accordance with NFPA 220, Standard Types of Building Construction.

(p) Exits. Each floor of a facility shall have two or more exit ways remote from each other, leading directly to the outside or to a 2-hour fire resistive passage to the outside. Exits shall be so located that the maximum distance from any point in a floor area, room, or space to an exit doorway shall not exceed 100 feet, except that when a sprinkler system is installed, the distance of travel shall not exceed 150 feet.

(q) Exit Door. Exit doors shall meet the following criteria:

1. Shall be no less than 44 inches wide.

2. Shall swing in the direction of the exit and shall not obstruct the travel along any required fire exit route.

3. One exit door shall be easily accessible to ambulances in the event of an emergency transport.

(r) Exit Signs. Exits shall be equipped with approved illuminated signs bearing the word "Exit" in letters at least 4 1/2 inches high. Exit signs shall be placed in corridors and passageways to indicate the direction of exit.

(s) Carpet. All carpet or pad shall carry a flame spread rating of 75 or less or a radiant flux greater than 0.45 watts per square centimeter and a smoke density rating of 450 or less.

(t) Curtains. All draperies shall be rendered and maintained flame retardant.

(u) Handicapped Facilities. The facility shall be accessible to the physically handicapped and shall comply with ANSI 117.1, "Making Buildings and Facilities Accessible and Useable by the Physically Handicapped."

(v) Garbage Disposal. Space and facilities shall be provided for the sanitary storage and disposal of waste by incineration, containerization, removal, or by a combination of these techniques. Infectious waste materials shall be rendered noninfectious on the premises by appropriate measures.

(w) Corridors. Corridors shall comply with the following:

1. All rooms shall open onto a corridor leading to an exit.

2. Corridors used by patients shall be a minimum of 6 feet wide.

3. Service corridors may be a minimum of 4 feet wide.

(x) Water Temperature. Water temperature shall be as follows:

1. Hot water at handwashing facilities shall not exceed 120° F.

2. Hot water at bathing facilities shall not exceed 110° F.

Author: Dana Billingsley, Diane Milledge
Statutory Authority: Code of Ala. 1975, §22-2-2(6), et seq.; §22-21-20, et seq.
History: Filed November 19, 1987. **Amended:** Filed February 20, 1997; effective March 27, 1997. **Amended:** Filed June 18, 2002; effective July 23, 2002. **Repealed:** Filed April 16, 2010; effective May 21, 2010. **New Rule:** Published August 31, 2023; effective October 15, 2023.

420-5-13-AA **Appendix A (Repealed 5/21/10).**
Author:
Statutory Authority:
History:

420-5-13-AB **Appendix B (Repealed 5/21/10).**

CODE OF ALA. 1975, SECTIONS 22-21-20, ET SEQ.
Author:
Statutory Authority:
History:

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CIRCUIT COURT OF
MONTGOMERY COUNTY, ALABAMA
GINA J. ISHMAN, CLERK

EXHIBIT E

IN THE CIRCUIT COURT OF MONTGOMERY COUNTY, ALABAMA
FIFTEENTH JUDICIAL CIRCUIT – CIVIL DIVISION

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OASIS FAMILY BIRTHING CENTER, LLC, on behalf of itself and its patients; HEATHER SKANES, M.D., on behalf of herself and her patients; ALABAMA BIRTH CENTER; YASHICA ROBINSON, M.D., on behalf of herself and her patients; ~~BIRTH SANCTUARY; STEPHANIE MITCHELL, DNP, CNM, CPM, on behalf of herself and her patients;~~ ALABAMA AFFILIATE OF THE AMERICAN COLLEGE OF NURSE-MIDWIVES, on behalf of its members; JO CRAWFORD, CPM, on behalf of herself and her patients; TRACIE STONE, CPM, on behalf of herself and her patients,

Plaintiffs,

v.

ALABAMA DEPARTMENT OF PUBLIC HEALTH; SCOTT HARRIS, in his official capacity as the State Health Officer at the Alabama Department of Public Health,

Defendants.

Civil Action No.

03-CV-2023-901109.00 - GOG

FIRST AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF[1]

INTRODUCTION

1. In the midst of one of the most severe maternal and infant health crises in the entire country, Defendants Alabama Department of Public Health and Scott Harris, State Health Officer, are prohibiting Plaintiffs from offering critically needed, high-quality prenatal, birthing, and postpartum care (also referred to herein as "pregnancy-related care") that is proven to offer

[1] A version of the First Amended Complaint showing track-changes is attached hereto as Ex. E.

substantial benefits to the health of pregnant people and their babies.

2. Plaintiffs are individual health care providers, health care centers, and a professional membership organization that offer or intend to offer midwifery-based care in freestanding (i.e., non-hospital-affiliated) birth centers. Freestanding birth centers provide low-risk pregnant patients with prenatal, birthing, postpartum, and early newborn care from licensed providers in a supportive, homelike environment outside the hospital setting and have been shown to achieve equivalent or better patient outcomes, at a fraction of the cost, when compared to hospital-based care.

3. Despite the proven benefits for maternal and infant health and the critical need for increased access to such care in Alabama—where nearly 40% of counties are classified as "maternity care deserts" [2] and existing hospital-based services are pushed past capacity—Defendants have refused to allow freestanding birth centers, including Plaintiffs, to operate in the state, even threatening Plaintiff Oasis Family Birthing Center with criminal and civil penalties, despite its perfect safety record, and forcing it to close its doors to patients.

4. Far from creating a timely, feasible path to licensure, Defendants' recent birth center regulations (2023 Final Regulations), which took effect October 15, 2023, continue to block freestanding birth centers from opening and operating in Alabama.

~~4.~~5. Defendants' de facto ban on freestanding birth centers, including through the adoption of the 2023 Final Regulations, is a dramatic about-face from their position—taken just

[2] A "maternity care desert" is a county that lacks access to maternity care providers, including having no hospitals offering obstetric services, no birth centers, and no obstetricians or certified nurse midwives. *See Maternity Care Deserts Report: Nowhere to Go: Maternity Care Deserts Across the U.S. (2022 Report),* March of Dimes, https://www.marchofdimes.org/maternity-care-deserts-report#divMaps (last visited ~~Aug. 3, 2023~~Jan. 17, 2024).

three years ago—that they did not regulate birth centers *at all*, and far exceeds their statutory authority under Alabama law to regulate and license "hospitals," as defined under section 22-21-20(1) of the Alabama Code, and violates the constitutional rights of Plaintiffs, their members, and their patients. Absent relief from this Court, the birth center ban will continue to inflict irreparable harm on Plaintiffs, their members, and their patients, and on the public health and welfare of Alabamians.

JURISDICTION AND VENUE

~~5.~~6. This Court has jurisdiction pursuant to the Alabama Administrative Procedure Act, Ala. Code § 41-22-10, the Alabama Declaratory Judgment Act, *id.* § 6-6-222, and the Due Process and Equal Protection Clauses of the Alabama Constitution, art. I, ~~§§~~§§ 1, 13, and the United States Constitution, amend. XIV, § 1.

~~6.~~7. Venue is proper in this Court under Alabama Code section 41-22-10, which provides that the validity or applicability of an agency rule may be determined in an action for a declaratory judgment or its enforcement stayed by injunctive relief in the circuit court of Montgomery County. Venue is also proper in this Court to hear Plaintiffs' constitutional challenges because the government entity and government official defendants officially reside and have their principal place of business in Montgomery County. *See Ex parte Bd. of Water & Sewer Comm'rs of City of Mobile*, 272 So. 3d 635, 639 (Ala. 2018).

PARTIES

A. Plaintiffs

~~7.~~8. Oasis Family Birthing Center, LLC (OFBC), is a freestanding birthing center[3] in Birmingham, Alabama, founded in June 2022, to provide women in the Birmingham area with

[3] Plaintiffs use the terms "birth center" and "birthing center" interchangeably.

high-quality, affordable, patient-centered care in an out-of-hospital setting, including prenatal, birthing (i.e., labor and delivery), postpartum, and newborn care. OFBC operates in the midwifery model of care[4] and is dedicated to creating an inclusive environment for Black women, women of color, gender-non-conforming people, low-income patients, religious families, and other communities who often lack access to affordable, patient-centered care. OFBC began seeing patients in September 2022 but was forced by Defendant Alabama Department of Public Health to cease providing care and stop taking new patients ~~earlier this year.~~in spring 2023. OFBC sues on behalf of itself and its patients.

~~8.~~9. Heather Skanes, M.D., is a Board-certified obstetrician and gynecologist (OB/GYN) who has provided comprehensive reproductive health care in Alabama for 4 years. She currently provides a broad range of health care to patients at her private practice, Oasis Women's Health in Birmingham, Alabama, including but not limited to general OB/GYN care; minimally invasive outpatient surgery; and management of infertility and menopause treatment. She is also the founder and Executive Director of Plaintiff OFBC. Dr. Skanes sues on her own behalf and on behalf of her patients who seek access to midwifery care and non-hospital birth in a birth center.

~~9.~~10. Alabama Birth Center (ABC) is a freestanding birth center in development and under construction in Huntsville, Alabama, which will provide high-quality, affordable, patient-centered care in an out-of-hospital setting, including prenatal, birthing, postpartum, and newborn care. ABC will operate in the midwifery model of care, with a focus on serving low-income populations who otherwise lack affordable options for out-of-hospital births.

~~10.~~11. Yashica Robinson, M.D., is a Board-certified OB/GYN who has provided

[4] The midwifery model of care is also referred to as the "midwives' model of care" and is further defined below.

comprehensive reproductive health care in Alabama for nearly twenty years. Dr. Robinson currently provides a broad range of health care in her private practice and as Medical Director of Alabama Women's Wellness Center, P.C., in Huntsville, Alabama, including but not limited to general OB/GYN care; major and minor gynecological surgeries; management of infertility; and primary care. She is also the founder and Medical Director of Plaintiff ABC. Dr. Robinson sues on her own behalf and on behalf of her patients who seek access to midwifery care and non-hospital birth in a birth center.

~~11. Birth Sanctuary was established in 2020 to provide high-quality, affordable, patient-centered, community-based midwifery care in Gainesville, Alabama, and the surrounding areas. Birth Sanctuary is in the process of constructing a freestanding birth center to expand access to prenatal, birthing, and postpartum care in Sumter County, a rural, underserved region of Alabama currently classified as a maternity care desert, with a focus on serving families at all income levels, including low-income individuals who otherwise lack affordable options for out-of-hospital births.~~

~~12. Stephanie Mitchell, DNP, CNM, CPM, is licensed as a certified professional midwife (CPM)[5] and registered nurse in Alabama and currently provides midwifery care and home birth services in Sumter County, Alabama, and the surrounding areas, including prenatal, birthing, and postpartum care. Dr. Mitchell is also Board-certified as a certified nurse-midwife and, prior to relocating to Alabama, provided the full scope of nurse-midwifery care in private collaborative~~

~~[5] Two kinds of midwives are licensed to practice in Alabama: certified nurse-midwives and certified professional midwives. Certified nurse-midwives are advanced practice registered nurses specializing in midwifery care and are licensed by the State Board of Nursing. Certified professional midwives are skilled practitioners holding a certification from an accredited organization and are licensed by the State Board of Midwifery. Both kinds of midwives provide care in the midwifery model but complete different educational and training requirements.~~

~~practice and teaching hospital settings as a certified nurse midwife in Massachusetts and Rhode Island for approximately four years. She also has an additional nine years' experience as a pediatric and labor and delivery nurse. She is the founder, Executive Director, and Clinical Midwifery Director of Birth Sanctuary. Dr. Mitchell sues on her own behalf and on behalf of her patients who seek access to midwifery care and non-hospital birth in a birth center.~~

~~13.~~12. The Alabama affiliate of the American College of Nurse-Midwives (ACNM-AL) is the local state affiliate in Alabama of ACNM, the nationwide professional association of certified nurse-midwives (CNMs).[6] ACNM sets the national standards for nurse-midwifery education and practice in the United States. The Alabama affiliate of ACNM is the primary organization representing CNMs in the state of Alabama. It provides professional support and liaises with the national organization on behalf of members with respect to questions about national standards, state laws, and regulations; engages in advocacy on behalf of the nurse-midwifery community in Alabama; and provides a forum for communication and relationship-building among CNMs practicing in the state. Its membership includes all Alabama-based members of ACNM, including members~~, like Dr. Mitchell,~~ who are dually certified as CNMs and certified professional midwives (CPMs~~.~~).

13. Jo Crawford is a nationally-certified, Alabama-licensed CPM currently providing midwifery care in Alabama at Plaintiff OFBC and through her home birth practice, Home Sweet Birth, LLC. She also previously provided midwifery care at Plaintiff OFBC when it first opened

[6] Two kinds of midwives are licensed to practice in Alabama: certified nurse midwives and certified professional midwives. Certified nurse midwives are advanced practice registered nurses specializing in midwifery care and are licensed by the State Board of Nursing. Certified professional midwives are skilled practitioners holding a certification from an accredited organization and are licensed by the State Board of Midwifery. Both kinds of midwives provide care in the midwifery model but complete different educational and training requirements.

in 2022, until it was forced to close by ADPH. She is licensed as a CPM in Virginia as well, and provides midwifery care there on a part-time basis in freestanding birth centers. She has over nine years of experience providing midwifery care as a CPM in both freestanding birth centers and home birth settings, in addition to more than fifteen years of experience as a certified doula and childbirth educator. She is also approved by the North American Registry of Midwives as a preceptor and has extensive experience training student midwives in that capacity. Crawford sues on her own behalf and on behalf of her patients who seek access to midwifery care and non-hospital birth in a birth center.

14. Tracie Stone, CPM, is a nationally-certified CPM who obtained a license in December 2023 to practice as a professional midwife in Utah and is in the process of seeking CPM licensure in Alabama. Once licensed in Alabama, she plans to provide midwifery care at Plaintiff ABC. She has spent the last four years completing an apprenticeship as a student midwife with a home birth practice in Alabama. She also has more than six years of experience as a doula and childbirth educator and is completing additional midwifery education through the Midwest Maternity Childbirth Institute. Stone sues on her own behalf and on behalf of her patients who seek access to midwifery care and non-hospital birth in a birth center.

B. Defendants

~~14.~~15. The Alabama Department of Public Health (ADPH) acts for the State Board of Health[7] under section 22-1-1 of the Alabama Code. *See Ex parte Torbert*, 224 So. 3d 598, 598 n.1

[7] "The terms State Board of Health, State Committee of Public Health, State Department of Public Health, and State Health Officer are used interchangeably except where the context prohibits." Ala. Admin. Code r. 420-1-5-.01. The State Board of Health is constituted of the Medical Association of the State of Alabama, *see* Ala. Code § 22-2-1, which is the professional organization for physicians practicing in Alabama and whose mission includes physician advocacy and education.

(Ala. 2016). ADPH promulgates rules and regulations through the State Board of Health and the State Committee of Public Health. Ala. Code §§ 22-1-1, -2-2, -21-28(a). ADPH's principal place of business is 201 Monroe Street, Montgomery, Alabama.

~~15.~~16. Under section 22-21-22 of the Alabama Code, ADPH has the authority to license and regulate "hospitals," which are defined for these purposes as follows:

> General and specialized hospitals, including ancillary services; independent clinical laboratories; rehabilitation centers; ambulatory surgical treatment facilities for patients not requiring hospitalization; end stage renal disease treatment and transplant centers, including free-standing hemodialysis units; abortion or reproductive health centers; hospices; health maintenance organizations; and other related health care institutions when such institution is primarily engaged in offering to the public generally, facilities and services for the diagnosis and/or treatment of injury, deformity, disease, surgical or obstetrical care. Also included within the term are long term care facilities such as, but not limited to, skilled nursing facilities, intermediate care facilities, assisted living facilities, and specialty care assisted living facilities rising to the level of intermediate care. The term "hospitals" relates to health care institutions and shall not include the private offices of physicians or dentists, whether in individual, group, professional corporation or professional association practice. This section shall not apply to county or district health departments.

§ 22-21-20(1); *see also* Ala. Admin. Code r. 420-5-7-.02(3)(a) (ADPH may grant license to hospitals as "agent" for the State Board of Health).

~~16.~~17. ADPH may issue a license for covered facilities based on compliance with either "the minimum standards provided in [article 2 of title 22, chapter 21] or by regulations issued under its authority." Ala. Code § 22-21-23; *see also id.* § 22-21-25(a). ~~As such,~~ ADPH ~~is responsible for adopting~~ has adopted a policy of general applicability that freestanding birth centers require a hospital license and ~~for the failure~~has failed to provide any timely, feasible path to such licensure, ~~resulting~~including by adopting burdensome regulations that make it extremely difficult if not impossible to work in, "establish[]," "construct[]," "maint[ain]," or "operat[e]"

freestanding birth centers in Alabama. *See* Ala. Code § 22-21-21. ADPH's actions have resulted in a de facto ban on birth centers in Alabama.

~~17.~~18. Scott Harris, M.D., MPH, is the State Health Officer for ADPH. The State Health Officer is, *inter alia*, the executive officer of the ADPH. *Id.* § 22-2-8. As State Health Officer, Harris is responsible, *inter alia*, for supervising and directing the licensing of hospitals, as defined under Alabama law. *See id.* § 22-2-2 *et seq.*; Ala. Admin. Code r. 420-5-7-.01 *et seq.* As such, Defendant Harris is responsible for ADPH's policy of general applicability that freestanding birth centers require a hospital license and for its failure to provide any timely, feasible path to such licensure, resulting in a de facto ban on birth centers in Alabama. Defendant Harris is sued in his official capacity.

FACTUAL STATEMENT

A. Establishment of Plaintiffs' Birth Centers

~~18.~~19. Recognizing the lack of access to midwifery and out-of-hospital birthing care in Alabama, as well as the high demand for these services among pregnant Alabamians, the birth center and individual Plaintiffs took various steps over the last several years to establish freestanding birth centers and expand access to this critically needed care.

~~19.~~20. ~~As of the filing of this Complaint, there are no freestanding birth centers operating in Alabama. Therefore, as set forth further below.~~As of the filing of this First Amended Complaint, the only freestanding birth centers that can operate in Alabama are those that receive a temporary license pursuant to this Court's preliminary injunction orders, *see* Order Granting Pls.' Mot. Prelim. Inj., Doc. 110 (Sept. 30, 2023) [hereinafter "Prelim. Inj. Order"], *supplemented by* Suppl. Prelim. Inj. Order, Doc. 119 (Oct. 3, 2023) [hereinafter "Suppl. Prelim. Inj. Order"], *reconsideration denied*, Order Defs.' Mot. Recons., Doc. 131 (Oct. 16, 2023). As of the filing of

this First Amended Complaint, one birth center has received a temporary license, effective January 1, 2024, pursuant to the injunction and reopened. Therefore, as set forth further below, but for the temporary relief granted by this Court during the pendency of this lawsuit, the only options for birthing care in Alabama are hospitals, which many areas lack and which are frequently pushed past capacity where they do exist, or home births, which are not accessible to all patients because of lack of access to a suitable or comfortable home space, affordability, or other access challenges.

Oasis Family Birthing Center

~~20.~~21. Dr. Skanes began taking steps to open OFBC in 2021. Over the next year, she spent considerable time and resources getting the birth center ready to operate. This included scouting out and eventually leasing a suitable property; applying for and obtaining numerous grants, including a first-place prize from Magic City Match, a grant program for Black-owned businesses in Birmingham, and a scholarship prize from the American Association of Birth Centers, among others, and completing fellowship programs to fund the birth center; recruiting staff; and sourcing and acquiring equipment.

~~21.~~22. OFBC was officially founded in June 2022. Between June and September 2022, Dr. Skanes completed physical improvements on the property that would become the birth center.

~~22.~~23. Throughout the process of establishing OFBC, Dr. Skanes relied on national standards from the American Association of Birth Centers (AABC),[8] the leading nationwide source for best practices and standards for freestanding birth centers, to ensure that OFBC adhered

[8] *See Birth Center Standards*, Am. Ass'n ~~of~~ Birth Ctrs., https://www.birthcenters.org/birth-center-standards (last visited ~~July 28, 2023~~Jan. 17, 2024). These standards are relied on by the Commission for the Accreditation of Birth Centers (CABC), a non-profit organization and the only nationwide accrediting organization for birth centers, as the basis for accrediting birth centers nationwide. *See About the CABC*, Comm'n ~~for the~~ Accreditation ~~of~~ Birth ~~Centers,~~Ctrs., https://birthcenteraccreditation.org/about-commission-accreditation-birth-centers/ (last visited ~~July 28, 2023~~Jan. 17, 2024).

to evidence-based guidelines for safe, high-quality birthing centers.

~~23.~~24. OFBC opened to patients in September 2022. OFBC provided comprehensive midwifery services for pregnancy-related care, including births, and neonatal care through six weeks after birth, utilizing the midwifery model of care, as defined *infra* Part C. OFBC also provided extensive patient education and counseling, including education on breastfeeding, preparing for childbirth, and newborn care.

~~24.~~25. OFBC's services were primarily provided by CPMs, including Plaintiff Crawford, and student midwives training under the supervision of the CPMs and Dr. Skanes. The CPMs conducted the majority of prenatal and postpartum visits and attended births in the birthing center, with assistance from the student midwives, who are also trained as doulas, certified lactation consultants, and birth assistants with training in basic life support and neonatal resuscitation. Dr. Skanes was available for consultation and patient referrals whenever the midwifery staff determined such consultation or referral was necessary or beneficial for the patient. Dr. Skanes also conducted initial patient intakes and provided limited prenatal care to birth center patients throughout their pregnancies. OFBC also intended to employ CNMs in the future. In addition, OFBC collaborated with other birth and pregnancy workers—including educators, nutritionists, prenatal yoga specialists, and additional doulas and lactation consultants—who periodically offered classes or services at OFBC or to whom OFBC made referrals for particular patients.

~~25.~~26. As part of the midwifery care model, all patients received continuous risk assessment to ensure that they remained eligible for birthing care in the birth center. Patients who developed risk factors were either referred for consultation with Dr. Skanes or, for serious risks, transferred to her care for the remainder of their pregnancies and hospital-based births.

~~26.~~27. Between opening and when ADPH forced OFBC to stop offering care to patients

at the birth center, twenty-two patients received care at OFBC. Of these, six patients were identified during their pregnancies through OFBC's risk assessment process as having risk factors rendering them ineligible to give birth in the birthing center, and two others elected to deliver in the hospital but received prenatal care in the birth center. These eight patients were referred to Dr. Skanes and delivered with her successfully in the hospital.

~~27.~~28. The remaining fourteen patients delivered successfully and without complication at OFBC, attended by a CPM and with assistance from student midwives. No patients were transferred to hospital-based care during labor, delivery, or the postpartum period. All mothers and babies treated by OFBC to date are healthy and doing well. One infant's initial screening for sickle cell disease came back positive following a routine newborn screening by OFBC; they were promptly referred to a pediatrician for further care.

~~28.~~29. As set forth below, due to ADPH's actions, OFBC ~~is no longer able~~was unable to offer birthing services or other patient care~~.~~ for approximately six months. During that time, OFBC ~~has~~ had to tell at least ten established patients that they could no longer continue their care with or give birth at OFBC, and ~~it has~~, between March and August 2023 alone, as a result of ADPH's action, OFBC had to turn away more than a dozen prospective patients who ~~have~~ inquired about care at OFBC. In the meantime, Dr. Skanes ~~continues~~continued to incur significant costs, including monthly rental payments, for a space she ~~is no longer using~~was unable to use and may never ~~be~~have been able to resume or continue using absent relief from this Court. While the preliminary injunction entered by this Court provides temporary relief from some of these harms, absent full and final relief from this Court, ADPH's actions will continue to cause irreparable harm to OFBC, Dr. Skanes, and her patients.

30. As further set forth below, it would not be feasible for OFBC to operate under the

2023 Final Regulations.

Alabama Birth Center

~~29.~~31. As early as 2019, Dr. Robinson began exploring opportunities to expand her private OB/GYN practice to include a freestanding birth center, including searching for suitable locations in Huntsville for ABC.

~~30.~~32. In early 2020, she made an initial offer on a property for the birth center and eventually secured a property in December of 2020. Over the next year, she retained and consulted with architects and commenced construction on the planned clinical and educational areas of the facility, intending to start construction on office space and birthing suites in 2022. When completed, she intends for the birth center to be consistent with AABC standards. Throughout this time, Dr. Robinson also sought grants, engaged in fundraising efforts, hired staff to manage patient inquiries, and took other steps to establish and publicize ABC and the care ABC intended to offer.

~~31.~~33. Because of ADPH's actions, as discussed below, Dr. Robinson ~~has~~ halted construction on the birth center because she ~~has~~had no way of knowing whether the property, as planned, would ultimately satisfy ADPH's licensing criteria, and she ~~cannot~~could not afford to continue to invest money into a business she ~~may~~might never ~~be~~have been permitted to operate. At the time of filing the Original Complaint, Dr. Robinson and the future of the ABC ~~have~~had already been left in a state of arrested development for more than a year, impeding fundraising, necessitating renegotiation of repayment terms for a loan she had taken to help fund ABC, and requiring her to pay a mortgage on an unused space while she ~~waits~~waited to see if she ~~will~~would ever be able to open. ~~Since this time~~Between June 2022, when Dr. Robinson was forced to halt construction, and January 2024, ABC ~~has~~ received more than ~~a~~two hundred inquiries about services at the birth center. While the preliminary injunction entered by this Court provides

temporary relief from some of these harms, absent full and final relief from this Court, ADPH's actions will continue to cause irreparable harm to ABC, Dr. Robinson, and her patients.

~~*Birth Sanctuary*~~

~~32. Dr. Mitchell founded Birth Sanctuary and began planning to open a birth center in 2020, after relocating with her family from Massachusetts, where she had practiced as a CNM for many years, to Sumter County.~~

~~33. Sumter County and the majority of the surrounding counties are classified as maternity care deserts because they lack any hospitals providing obstetric care, birth centers, obstetricians, or licensed CNMs.[9] Currently, the nearest hospital-based labor and delivery services to Sumter County are in Tuscaloosa or Demopolis, Alabama, or Meridian, Mississippi, which are approximately 75-100 miles away round-trip, limiting access to care for patients in the region. The only other option for pregnant patients in Sumter County who do not want to or cannot make that trip is a home birth. Dr. Mitchell is currently the only CPM based in the area.~~

34. ~~Recognizing the immense need for more high-quality, patient-centered pregnancy and birthing care in her community, and the lack of access to midwifery care generally in Alabama,~~ As set forth below, as of the time of the filing of this First Amended Complaint, ABC is preparing to submit its application for temporary licensure from ADPH pursuant to this Court's preliminary injunction, and to open as soon as possible thereafter once that process is complete. Plaintiff Stone plans to provide midwifery care at ABC once it obtains a temporary license.

35. As further set forth below, it would not be feasible for ABC to operate under the 2023 Final Regulations.

~~34. Dr. Mitchell always planned to open a freestanding birth center as part of Birth~~

[9] ~~*Maternity Care Deserts Report*, March of Dimes, *supra* note 1.~~

Sanctuary in order to provide patients with an alternative to home birth and to serve as a resource for training the next generation of midwives in Alabama in providing out-of-hospital birth care. She plans to include on-site and virtual patient education resources as part of the birth center and to create space for other services for pregnant women, such as prenatal massage.

35. Dr. Mitchell acquired property in Gainesville, Alabama, for the birth center in late summer 2020 and began renovations shortly thereafter. When completed, she intends for the birth center to be consistent with AABC standards. She has subsequently engaged in considerable fundraising and other planning efforts to establish the birth center. But for the state of limbo imposed by ADPH's actions, set forth below, Dr. Mitchell would open the birth center in January 2024.

36. Because Alabama, unlike Massachusetts, does not permit CNMs to practice independently from a supervising physician, Dr. Mitchell became licensed as a CPM in Alabama instead (CPMs in Alabama are not subject to any physician supervision requirement). Becoming nationally certified as a CPM required Dr. Mitchell to obtain additional formalized training attending out-of-hospital births. Dr. Mitchell had to seek training in Arizona because of the limited opportunities in Alabama for such hands-on training for CPMs. She obtained her CPM license in December 2021 and, in the spring of 2022, began offering pregnancy-related care and home birth services in the Sumter County area through Birth Sanctuary while she continued work on the birth center.

37. Because of ADPH's actions, as described below, Dr. Mitchell has no way of knowing whether Birth Sanctuary, as planned, will ultimately satisfy ADPH's licensing criteria for a birth center and whether she will ever be able to operate the birth center she has dedicated significant time and resources to building over the past three years.

B. Maternal and Infant Health in Alabama

~~38.~~36. The United States has the highest maternal mortality rate of any high-income country in the world, reporting 23.8 deaths per 100,000 live births in 2020.[10]

~~39.~~37. According to Defendant ADPH, Alabama's maternal mortality rate is even higher than the national average, reporting in 2020 a rate of 36.4 deaths per 100,000 live births, the third highest in the country.[11]

38. An analysis of more recent data from the U.S. Centers for Disease Control and Prevention's National Center for Health Statistics shows that Alabama has the worst maternal mortality rate in the country, reporting a rate of 64.6 deaths per 100,000 live births, nearly double the national rate.[12]

~~40.~~39. According to investigations conducted by ADPH, the majority of maternal deaths in Alabama are preventable.[13]

~~41.~~40. Alabama also has the ~~sixth~~third-highest infant mortality rate in the country.[14]

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[10] Donna L. Hoyert, ~~Div. of Vital Stat.,~~ Nat'l Ctr. ~~for~~ Health Stat., Ctrs. ~~for~~ Disease Control & Prevention, *Maternal Mortality Rates in the United States, 2020*~~,~~ at 1 (2022), https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/E-stat-Maternal-Mortality-Rates-2022.pdf [hereinafter *U.S. Maternal Mortality Rates 2020*]. The CDC defines maternal ~~morality~~mortality as a maternal death occurring during pregnancy or within 42 days after pregnancy. *Id.* Other sources define maternal mortality to include deaths up to one year after pregnancy.

[11] Bur. ~~of~~ Family Health Servs., Ala. Dep't of Pub. Health, *2020 Maternal Mortality Review* 6 (2022), https://www.alabamapublichealth.gov/perinatal/assets/2020_final_annual_mmr.pdf.

[12] Katherine Sacks, Lawson Mansell & Brooke Shearon, Milken Inst., Maternal Mortality Among Vulnerable US Communities 3–4 (Aug. 2023), https://milkeninstitute.org/sites/default/files/2023-07/MaternalMortalityamongVulnerableUSCommunities.pdf.

[13] ~~*Id.*~~ADPH, *2020 Maternal Mortality Review*, *supra* note 9, at 10.

[14] *Infant Mortality Rates by State*, Nat'l Ctr. for Health Stat., Ctrs. for Disease Control & Prevention,

According to Defendant ADPH, in 2021, the infant death rate was 7.6 deaths per 1,000 live births, an increase of 8.6% compared to 2020.[15] Alabamians also suffer high rates of preterm birth (13.1%) and low birth weight (10.5%), significant risk factors for infant mortality.[16]

~~42.~~41. Nationwide, Black women are nearly three times more likely to die from pregnancy-associated causes than their white counterparts and twice as likely to suffer severe maternal morbidity.[17] Black women also experience higher rates of fetal death after 20 weeks of pregnancy and stillbirth compared to white women.

~~43.~~42. According to Defendant ADPH, Black Alabamians are likewise disproportionately harmed by the maternal and infant health crisis. Black Alabamians suffer a disproportionate share of maternal deaths in the state,[18] and Black infants die at more than twice the rate of white infants (12.1 vs. 5.8 deaths per 1,000 live births), accounting for almost half of all infant deaths in the

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https://www.cdc.gov/nchs/pressroom/sosmap/infant_mortality_rates/infant_mortality.htm (sort by death rate) (last visited ~~July 28, 2023~~Jan. 17, 2024).

[15] Ala. Dep't~~.~~ of Pub. Health, *Alabama's infant mortality rate for 2021 announced*, Alabama's Health (Nov. 17, 2022), https://www.alabamapublichealth.gov/blog/2022/11/nr-17.html ~~(last visited Aug. 7, 2023);~~; *see also* Ctr. for Health Statistics, Ala. Dep't of Pub. Health, *Infant Mortality: Alabama 2021*~~,~~ at 2, 5 (2022), https://www.alabamapublichealth.gov/healthstats/assets/infantmortality2021.pdf.

[16] *Infant Mortality: Alabama 2021*, *supra* note ~~12~~13, at 10–14, 24, 26.

[17] *U.S. Maternal Mortality Rates 2020*, *supra* note 8, at 1; Eugene Declercq & Laurie Zephyrin, Commonwealth Fund, *Severe Maternal Morbidity in the United States: A Primer* 8 (Oct. 2021), https://www.commonwealthfund.org/sites/default/files/2021-10/Declercq_severe_maternal_morbidity_in_US_primer_db.pdf.

[18] *See* ADPH, *2020 Maternal Mortality Review*, *supra* note 9, at 17 (reporting that Black patients make up 36.3% of maternal deaths in Alabama but only 30.6% of all births). Data from the CDC show a maternal mortality rate for Black women in Alabama of 100.07 per 100,000 live births. Ctrs. Disease Control & Prevention, Nat'l Ctr. Health Stat., *Underlying Cause of Death, 2018-2021*, CDC WONDER Online Database (search with parameters Alabama, race Black or African American, and ICD-10 Codes limited to those used in Sacks et al., *supra* note 10, at 3, yields a result of 71 deaths); Ctrs. Disease Control & Prevention, Nat'l Ctr. Health Stat., *Natality*, CDC WONDER Online Database (search with parameters Alabama, years 2018–2021, and mother's race Black or African American yields a result of 70,948 births).

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state.[19]

~~44.~~43. One significant factor contributing to the maternal and infant health crisis in Alabama is lack of access to pregnancy-related care.

~~45.~~44. More than two-thirds of Alabama counties have inadequate access to such care: 37.3% of counties are classified as "maternity care deserts," defined as areas without any hospitals, birthing centers, obstetricians, or nurse-midwives; and an additional 31.3% have only low or moderate access to care.[20]

~~46.~~45. Moreover, hospital-based services in Alabama are insufficient to meet the need for pregnancy-related care in the state.

~~47.~~46. Hospital-based labor and delivery units, especially in rural hospitals, are closing at an alarming rate in Alabama. As Defendant ADPH reports, the majority of rural counties in the state have lost access to hospital-based obstetrical care in recent decades, and only a third of rural hospitals in Alabama currently offer labor and delivery care.[21] Many of those remaining are losing money and at risk of closure.

~~48.~~47. Hospitals in urban areas, meanwhile, are frequently over-taxed and often lack the staff resources or capacity to meet the high need for care.

48. Three additional hospitals—one in Birmingham, located in a predominantly Black

[19] *Infant Mortality: Alabama 2021*, *supra* note ~~12~~13, at 3, 5.

[20] *Maternity Care Desert: Alabama*, March of Dimes: PeriStats (Oct. 2022), https://www.marchofdimes.org/peristats/data?reg=99&top=23&stop=641&lev=1&slev=4&obj=18&sreg=01~~ (last visited Aug. 7, 2023).~~.

[21] *Rural Health: At a Glance*, Ala. Pub. Health, https://www.alabamapublichealth.gov/ruralhealth/at-a-glance.html (last visited ~~July 28, 2023~~Jan. 17, 2024); Off. of Primary Care & Rural Health, Ala. Pub. Health, *A Picture of the Loss of Rural Obstetrical Service in Alabama 1980 to 2019* (2019), https://www.alabamapublichealth.gov/healthrankings/assets/a_picture_of_the_loss_of_rural_obstetrical_service.pdf.

community, another in Shelby County, and one in Monroe County—closed their labor and delivery units in October and November 2023, leaving those communities and counties with either reduced options or no options for hospitals providing birthing care.

49. Ensuring maternal and infant health is not solely about access to care during labor and delivery. As Defendant ADPH acknowledges, inadequate access to pregnancy-related care, especially prenatal care, is a significant driver of maternal and infant mortality, increasing the risk of preterm birth and low birthweight.[22] In fact, the vast majority of maternal deaths occur either during pregnancy or within six weeks after birth,[23] not during labor and delivery.

50. According to Defendant ADPH, more than one in four pregnant Alabamians receives inadequate prenatal care during pregnancy.[24]

51. As Defendant Harris has stated, health inequities are frequently driven by race-based disparities in social determinants of health.[25] Research also shows that social and economic factors disproportionately affecting Black communities and other communities of color, such as racism and chronic stress, contribute to poor outcomes for birthing people and their babies. Published research shows that people of color are significantly more likely to report mistreatment

[22] ADPH, *2020 Maternal Mortality Review*, *supra* note 9, at 10; Latoya Hill et al., *Racial Disparities in Maternal and Infant Health: Current Status and Efforts to Address Them*, KFF (Nov. 1, 2022), https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-disparities-in-maternal-and-infant-health-current-status-and-efforts-to-address-them; -*Prenatal Care: Why Do I Need Prenatal Care?*, Off. on Women's Health, U.S. Dep't of Health & Hum. Servs., https://www.womenshealth.gov/a-z-topics/prenatal-care (last updated Feb. 22, 2021).

[23] Emily E. Petersen et al., *Vital Signs: Pregnancy-Related Deaths, United States, 2011-2015, and Strategies for Prevention, 13 States, 2013-17*, 68 CDC Morbidity & Mortality Wkly. Rep. 423, 425–26 (2019), https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6818e1-H.pdf.

[24] *Infant Mortality: Alabama 2021*, *supra* note ~~12~~13, at 20.

[25] *Member Spotlight: Scott Harris*, Assoc. of State & Territorial Health Officials: Blog (Feb. 1, 2018), https://www.astho.org/communications/blog/member-spotlight-scott-harris-alabama~~/(last visited Aug. 7, 2023).~~.

during pregnancy and to experience a lower quality of care. Ensuring access to patient-centered and culturally competent care (i.e., care that is tailored to the patient's social and cultural needs) can improve patient experiences and patient outcomes.

C. Birth Centers and the Midwifery Model of Care

52. A freestanding birth center provides pregnancy, birthing, postpartum, and newborn care in a homelike environment, utilizing a midwifery model of care, to patients anticipating a low-risk pregnancy and birth. Freestanding birth centers are independent, autonomous health care centers and are not attached to or organized as part of a hospital or other acute care facility.[26]

53. Many patients prefer out-of-hospital births based on their values, beliefs, health needs, or past experiences, or because they live far distances from hospital-based care. For patients seeking an out-of-hospital birth, birth centers provide an alternative to a home birth. While home births are legal in Alabama, birth centers provide an additional option for out-of-hospital care for patients who do not feel safe or comfortable birthing in their own home. Birth centers can also provide important access to high-quality prenatal and postpartum care, even for patients who plan to give birth in a hospital or who, for medical reasons, end up doing so.

54. While the practice of midwifery is part of a centuries-long tradition, the modern midwifery model of care melds that tradition with an evidence-based, patient-centered health care model for pregnancy-related care and newborn care, with a focus on shared-decision making, patient education, and physiological birth[27] with minimal technological interventions. The

[26] *What Is a Birth Center?*, Am. Ass'n of Birth Ctrs., https://www.birthcenters.org/what-is-a-bc (last visited ~~July 28, 2023~~Jan. 17, 2024).

[27] Physiological birth means labor and delivery that relies on the innate capacities of the human body for the birthing process, as opposed to the use of medical interventions to initiate, augment, or manage the birth process.

midwifery model of care centers the physical, psychological, and social wellbeing of birthing people, according to their values, beliefs, and autonomous choices.[28]

55. Midwifery is a distinct health care specialty from obstetrics. It is practiced by trained midwives with a different skill set, education, and training background than obstetricians, and, where appropriate for the patient, prioritizes physiological birth over medical and technological interventions in the birthing process. Obstetrics, by contrast, emphasizes a medicalized model of care with a focus on identifying and treating pathology or abnormality in pregnancy. Compared to the medicalized model of care, midwifery care also places increased attention on providing patients with access to non-medical support, education, and resources to help address patients' socio-economic and psychological needs and promote overall health and wellbeing.

56. Two kinds of midwives are licensed to practice in Alabama: certified nurse midwives and certified professional midwives. Both provide care in the midwifery model of care.

57. CNMs are advanced practice registered nurses who are certified by the State Board of Nursing to engage in advanced nursing practice as a nurse midwife. CNMs must complete a nursing program qualifying them as a registered nurse, in addition to specialized training and certification in nurse midwifery. Ala. Code § 34-21-81(1), (2)(b).

58. According to national standards, a CNM's scope of practice encompasses "independent provision of care during pregnancy, childbirth, and the postpartum period; sexual and reproductive health; gynecologic health; . . . family planning services, including preconception care," and "primary care for individuals from adolescence throughout the lifespan as well as care

[28] *See* Am. Ass'n of Birth Ctrs., *supra* note ~~23~~24.

for the healthy newborn during the first 28 days of life."[29] A CNM's scope of practice includes conducting patient examinations; prescribing medication independently; making decisions about patient admission, management, and discharge; and ordering and interpreting lab results. They practice in diverse settings, including hospitals, ambulatory surgical centers, private offices, birth centers, patients' homes, and via telehealth.[30]

59. In accordance with national standards, in the majority of states, CNMs practice autonomously and independently, meaning they do not need to enter into a formal agreement or supervisory relationship with a physician to provide care within their scope of practice.

60. In Alabama, unlike in the majority of states, CNMs are not permitted to practice fully independently and must enter into a collaborative practice agreement (CPA) with a physician. Ala. Code § 34-21-81(1). CPAs are formal agreements between CNMs and physicians setting out prior-approved written protocols under which a CNM may practice. *Id.* § 34-21-81(5).

61. It can be difficult to identify physicians in Alabama willing to enter into such agreements and, if no physician agrees to do so, a CNM may not be licensed in Alabama at all, despite satisfying all other educational, training, and qualification requirements. While the settings in which CNMs may practice are not formally restricted by Alabama law, in practice, CPAs and the need for a physician willing to enter into a formal, supervisory relationship involving that practice setting mean that the vast majority of CNMs in Alabama only attend births in hospital settings.

[29] Am. Coll. of Nurse-Midwives, *Definition of Midwifery and Scope of Practice of Certified Nurse-Midwives and Certified Midwives* 1 (2021), https://www.midwife.org/acnm/files/acnmlibrarydata/uploadfilename/000000000266/Definition%20Midwifery%20Scope%20of%20Practice_2021.pdf.

[30] *Id.*

62. CPMs [31] are skilled practitioners holding a certification from an accredited organization and licensed by the State Board of Midwifery to provide primary maternity care during the pregnancy, birth, and postpartum periods in an out-of-hospital setting. Ala. Code § 34-19-11.[32]

63. CPMs must obtain national certification from the North American Registry of Midwives based on a combination of education, training, and a minimum of two years' direct, hands-on clinical experience or apprenticeship with an experienced CPM.[33] The CPM credential is the only national credential requiring training and experience in out-of-hospital birth settings.

64. According to national standards, a CPM's scope of practice encompasses independent provision of care, counseling, and education throughout pregnancy, birth, and the postpartum period, including conducting comprehensive assessments; making diagnoses and treating patients; recognizing conditions requiring consultation or referral to other healthcare providers; administering medications; ordering and interpreting lab and diagnostic tests; providing continuous, hands-on care during labor and delivery; and providing maternal and well-baby care through 6–8 weeks postpartum.

65. In Alabama, CPMs currently provide community-based pregnancy and birthing care. CPMs in Alabama are not subject to any CPA requirement; they practice independently of physicians or CNMs and can attend out-of-hospital births without any formal relationship with, supervision by, or assistance from a physician or CNM. CPMs in Alabama are authorized by law to practice "in the setting of the client's choice, except a hospital." Ala. Code § 34-19-16(a).

[31] CPMs are also sometimes referred to as "Licensed Midwives" under Alabama law.

[32] *Who Are CPMs?*, Nat'l Ass'n of Certified Pro. Midwives, https://www.nacpm.org/new-page-2 (last visited ~~July 28, 2023~~Jan. 17, 2024).

[33] For individuals also certified as CNMs, requirements differ but still include hands-on apprenticeship in out-of-hospital births.

However, because of the lack of options in Alabama for out-of-hospital births, CPMs in the state primarily provide home birth care.

66. The Board of Midwifery, which has licensing and regulatory authority over the practice of CPMs in Alabama, *id*. §§ 34-19-12, -14, regulates all care provided by CPMs, including home births. Such care is not subject to the vast majority of requirements, discussed further below, that ADPH seeks to impose on out-of-hospital care in birth centers.

~~66.~~67. The practice of midwifery—by both CNMs and CPMs—involves continuous assessment of patients throughout pregnancy, birth, and the postpartum period to proactively identify circumstances when risk factors or complications arise in a low-risk pregnancy that may warrant consultation with or referral to an obstetrician or other skilled provider and to ensure continuity of care in those circumstances.

~~67.~~68. There is extensive evidence showing that midwifery care and birth centers can play an important role in expanding access to pregnancy- and birthing-related care. This is especially critical in places, like many parts of Alabama, where access to skilled providers is limited and maternity care deserts are prevalent.

~~68.~~69. There is also extensive evidence showing that midwifery care and birth centers are as safe as hospitals, reporting similar maternal and infant mortality rates, and, on many factors, reporting better health outcomes, especially for Black, brown and other marginalized communities who are disproportionately affected by inequities in health care access and outcomes.

~~69.~~70. For example, patients giving birth in freestanding birth centers report fewer infant hospitalizations, as well as significantly lower rates of preterm births and low birthweight infants—significant risk factors for poor maternal and infant health outcomes.

~~70.~~71. Research also shows that freestanding birth centers and midwifery-led care achieve

significantly lower rates of deliveries by cesarean sections than hospital settings. Cesarean sections are major abdominal surgeries that carry a host of short- and long-term risks for patients, including infection; internal injury to nearby organs; and a risk of complications or repeat cesarean sections in future pregnancies.

~~71.~~72. According to ADPH, Alabama has a statewide rate of cesarean deliveries over 35% (with some hospitals reporting even higher rates),[34] significantly exceeding the 10–15% rate recognized by the World Health Organization as the maximum associated with medical necessity and improved maternal and infant health outcomes.[35] When patients are subjected to medically unnecessary cesarean sections, they are likewise exposed to unnecessary increased risk of short- and long-term health complications.

~~72.~~73. Midwifery care and birth centers are also associated with significant cost-savings compared to hospital births.

~~73.~~74. Research also shows that patients who receive prenatal and postpartum care in midwife-led birth centers also experience improved maternal and infant health outcomes even if patients end up giving birth in a hospital (either as planned or because of medical necessity).

~~74.~~75. Patients cared for by midwives, including in birth center settings, during pregnancy and birth also report greater satisfaction and a more positive birthing experience, compared to obstetrician-led, hospital-based care.

~~75.~~76. Midwives typically spend more time with patients, both during prenatal and postpartum visits and during labor and delivery, than what obstetricians' schedules typically allow

[34] Ala. Ctr. for Health Stat., Ala. Dep't Pub. Health, *Alabama Vital Statistics* 7–8 (2020), https://www.alabamapublichealth.gov/healthstats/assets/avs2020.pdf.

[35] World Health Org., *WHO Statement on Caesarean Section Rates* (2015), https://www.who.int/publications/i/item/WHO-RHR-15.02.

them to provide. Midwives also typically place an increased emphasis on individualized patient education and on addressing non-medical, psychosocial needs that affect health and wellbeing. Patients cared for by midwives report being less rushed, feeling more educated about their experience, and feeling more empowered throughout the birthing process.

~~76.~~77. Evidence demonstrates that states with greater integration of midwifery care into their health systems—including a higher density of practicing midwives and greater access to the midwifery model of care—achieve better maternal and infant health outcomes. These include significantly lower rates of neonatal death, preterm birth, low birthweight infants, and cesarean section, and significantly higher rates of breastfeeding, spontaneous vaginal birth, and vaginal births after a prior cesarean section.[36]

~~77.~~78. The level of integration of midwifery into the health system in Alabama ranks second-worst out of all fifty states and the District of Columbia.[37]

D. History of Midwifery in Alabama

~~78.~~79. Alabama has a long and rich history of midwifery. Early in the twentieth century, there was a significant community of traditional midwives (also known as lay midwives) practicing in Alabama, the vast majority of whom were Black and Indigenous. Midwives played critical roles within their communities as caregivers, educators, and spiritual leaders.

~~79.~~80. In the 1910s and 1920s, states including Alabama began requiring traditional midwives to be registered with the state and enroll in certain educational programs in order to practice. These formal requirements imposed barriers to some traditional midwives, as a result of

[36] Saraswathi Vedam et al., *Mapping Integration of Midwives Across the United States: Impact on Access, Equity, and Outcomes*, PLOS ONE, Feb. 2018, at 1–2 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5821332/pdf/pone.0192523.pdf.

[37] *Id.* at 8.

geography, literacy, and the impacts of segregation and discrimination in the Jim Crow South. Nonetheless, thousands of traditional midwives completed state requirements and, as a result, began practicing within the state health system.

~~80.~~81. In the decades after state registration, these midwives often played a critical role in expanding access within their communities to health and hygiene education, to vaccinations, and to the formal health system—a system that was otherwise frequently closed to rural and majority-Black communities as a result of geography, racial segregation, and distrust of the predominantly white medical establishment, given the history of forced sterilization and experimentation on Black women by early practitioners of obstetrics.

~~81.~~82. Despite the success and positive outcomes achieved by many traditional midwives in this system, midwives continued to face ongoing discrimination and bias from physicians and the formal medical system, who often devalued the specific skills of traditional midwives and stereotyped the practice of midwifery as primitive and contrary to science. These biases were linked to and compounded by race, gender, and class differences between the predominantly Black women practicing as traditional midwives in low-income and rural communities and the middle-class, white, male physicians who dominated the early practice of obstetrics.

~~82.~~83. Over the course of the twentieth century, restrictive regulation of midwifery, the increasing medicalization of birth under the obstetric model of care, lack of institutional support for traditional midwifery, and ongoing stigma and discrimination against traditional midwives—and Black midwives in particular—decreased the prevalence of midwife-assisted births and the number of known traditional midwives practicing across the South.

~~83.~~84. While traditional midwifery practices were waning during this time, the profession of nurse-midwifery was established. As nurse midwives became more integrated into public health

programs in the South, including in Alabama, they were often placed in a supervisory role with respect to traditional midwives.

~~84.~~85. Black women, who for generations had provided the bulk of midwifery care in their communities, encountered serious barriers in attempting to access this newly established profession. Very few accredited nursing programs in the South accepted Black students. When a nurse-midwifery program for Black students opened at the Tuskegee Institute in 1941, it closed after only 5 years due to lack of institutional support. As a result, nurse-midwifery became a predominantly white profession.

~~85.~~86. In 1976, Alabama passed a law outlawing the practice of all non-nurse midwifery, with the exception of a narrow subset of traditional midwives who held valid permits under the old rules "until such at time as [the midwife's] permit may be revoked." 1976 Ala. Acts 499 (codified at Ala. Code § 34-19-3(a)-(b)). Within five years, the legal practice of non-nurse midwifery effectively ended within Alabama, as state officials revoked or refused to renew or grant any more permits. These regulatory changes disproportionately affected Black midwives practicing in the state, rendering the majority of their practices illegal.

~~86.~~87. For nearly fifty years, the practice of traditional midwifery remained illegal in Alabama, a rule enforced by state prosecution of traditional midwives who attempted to continue practicing. *See, e.g.*, *State v. Kimpel*, 665 So. 2d 990 (Ala. Crim. App. 1995).

88. In 2017, after prolonged advocacy from the midwifery community, the Alabama Legislature passed a law providing a path for non-nurse midwives to practice in the state, with the creation of licensure for certified professional midwives and the creation of a State Board of Midwifery to oversee their practice. 2017 Ala. Laws 383 (effective Aug. 1, 2017) (codified, *inter alia*, at Ala. Code §§ 34-19-11 to -20) (repealing Ala. Code §§ 34-1-1 to -10). In doing so, the

Legislature authorized CPMs to provide care in out-of-hospital settings, such as birth centers, and delegated authority to the Board of Midwifery to exercise regulatory oversight of such care. *See* Ala. Code § 34-19-16(a) (licensed CPMs "may provide midwifery care in the setting of the client's choice, except a hospital"); *id.* §§ 34-19-12(a), -14; *see also* Ala. Att'y Gen. Op. No. 2023-12, at 4–5 (Dec. 15, 2022) [hereinafter "Att'y Gen. Op~~Acts 383 (effective Aug. 1, 2017) (codified at Ala. Code §§ 34-19-11–20) (repealing §§ 34-1-1–10).~~ ."] (concluding that freestanding birth centers are not hospitals for the purposes of section 34-19-16), https://opinions.alabamaag.gov/Documents/opin/2023-012.pdf.

~~87.~~89. In January of 2019, Alabama granted the first state licenses to Alabama CPMs.

E. Access to Midwifery Care and Birth Centers in Alabama Today

~~88.~~90. Both CNMs and CPMs remain marginalized within the health care system in Alabama today.

~~89.~~91. As noted above, under Alabama law, CNMs are restricted from practicing independently, and both CPMs and CNMs are restricted from practicing to their full scope of practice as set out in national standards and compared to the practice in the majority of states.

~~90.~~92. The lack of freestanding birth centers in Alabama ~~contributes~~has contributed to this marginalization, as it represents one less practice setting where CNMs and CPMs could see patients and offer much-needed care.

~~91.~~93. ~~As~~According to data from the Alabama Boards of ~~July~~Midwifery and Nursing, as of December 2023, there are only ~~29~~31 licensed CNMs[38] and ~~22~~23 licensed CPMs[39] in the entire

[38] Ala. Bd. of Nursing, Licensee Roster, *available for download at* https://abn.alabama.gov/applications/LicenseLookup.aspx~~#~~ (last visited ~~July 31, 2023~~Jan. 17, 2024).

[39] *Midwives*, Ala. State Bd. of Midwifery, https://alsbm.org/midwives~~/~~ (last visited ~~July 31, 2023~~Jan. 17, 2024) (search by State: Alabama).

state.

~~92.~~94. As a result of the limited number of midwives practicing in the state, resistance from the medical establishment, and cost-barriers, access to midwifery-based care remains inaccessible to many Alabamians.

~~93.~~95. ~~Access~~Until the events described in this First Amended Complaint, access to freestanding birth centers in Alabama has also been virtually non-existent. While Alabama had regulations in place to license freestanding birth centers between 1987 and 2010, they were eventually repealed because there were no freestanding birth centers operating in the state.

~~94.~~96. Prior to the establishment of OFBC in 2022, there were no known freestanding birth centers operating in the state of Alabama.

~~95.~~97. ~~Currently~~But for any freestanding birth centers that may be able to obtain temporary licensure pursuant to this Court's preliminary injunction, the only option for patients seeking out-of-hospital births in Alabama is a home birth.

~~96.~~98. While planned home births attended by CPMs can be a safe and appropriate option for certain patients, this option is not accessible to everyone. There are a limited number of CPMs in Alabama offering home birth services, and many patients do not feel that their home environments are suitable for a home birth~~,~~ because of space constraints, needs of other family members, lack of privacy, or location.

F. ADPH's Policies Restricting Birth Centers

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ADPH's Attempts to Regulate Freestanding Birth Centers in Alabama between 1987 and 2022.

~~97.~~99. In 1987, ADPH promulgated regulations for the operation of freestanding birth centers in Alabama. Ala. Admin. Code r. 420-5-13 (1987) (repealed 2010).

~~98.~~100. Upon information and belief, few, if any, freestanding birth centers were

ever licensed in Alabama under these regulations.

~~99.~~101. In 2010, ADPH repealed the 1987 regulations in full.

102. In 2017, the Alabama legislature explicitly authorized out-of-hospital births and created the Board of Midwifery to oversee these practices. 2017 Ala. Laws 383 (codified, *inter alia*, at Ala. Code §§ 34-19-11 to -20).

~~100.~~103. In 2020, ADPH informed members of Plaintiff ACNM-AL that it did not regulate birth centers.

~~101.~~104. In July 2022, more than two years after Plaintiffs started work on their birth centers—by, e.g., raising funds, securing property, beginning construction, and publicizing their services—ADPH reversed course and announced proposed state regulations for freestanding birth centers. *See* Birthing Center Rules, (proposed July 18, 2022), attached hereto as Ex. A [hereinafter "2022 Proposed Regulations"].

~~102.~~105. The proposed regulations were met with uniform opposition from national and state-based leaders in midwifery, freestanding birth centers, and pregnancy and birth worker communities, including AABC, the State Board of Midwifery, Plaintiff ACNM-AL members, the Alabama Midwives Association (ALMA),[40] and many individual licensed midwives.

~~103.~~106. Groups and individuals opposing the proposed regulations, including Plaintiffs, pointed out in public comments, both in writing and at the public hearing on August 18, 2022, that the proposed restrictions were not evidence-based, contradicted national standards for birth centers and midwifery care, and would be incredibly burdensome to comply with, making it onerous, if not impossible, for many proposed birth centers to operate.

[40] ALMA is the professional organization, similar to ACNM-AL, for Alabama-based CPMs. ~~-~~*See Home*, Ala. Midwives All., http://www.alabamamidwivesalliance.org (last visited ~~July 31, 2023~~Jan. 17, 2024).

~~104.~~107. Upon information and belief, ADPH did not consult with the State Board of Midwifery, the State Board of Nursing, ACNM or ACNM-AL, ALMA, AABC, the CNM program at University of Alabama at Birmingham (UAB), or any individual midwives before promulgating the 2022 Proposed Regulations.

~~105.~~108. Upon information and belief, many of these requirements were carried over wholesale from the 1987 regulations, despite those rules being considerably out of step with the best evidence currently available and the prevailing standards of care for midwifery and birth centers.

~~106.~~109. Among the provisions in the proposed regulations that were out of step with evidence-based standards were:

- the exclusion of CPMs from working in freestanding birth centers at all, *see* 2022 Proposed Regulations at 420-5-13.03(1), Ex. A at 10, despite their statutory authority under Alabama law to work in any setting of a client's choosing except a hospital and despite their experience and expertise providing out-of-hospital births;

- distance restrictions, preventing any freestanding birth center from operating more than a set distance from an established hospital with a labor and delivery unit, *see id.* at 420.5.13-.01(2)(q), (v), Ex. A at 3, 5, meaning that no freestanding birth centers could operate in the most underserved areas of the state that lack access to hospital-based care and where the need for improved access to pregnancy-related care is greatest;

- onerous requirements for formalized physician supervision and staffing arrangements, *see id.* at 420-5-13-.03, Ex. A at 10–13, which would prevent midwives from operating birth centers independently, despite being qualified to do so by their scope of practice and expertise in the midwifery model of care in which birth centers operate;

- requirements for written transfer agreements with hospitals and emergency medical services (EMS), *see id.* at 420-5-13-.01(2)(v), Ex. A at 5, which essentially give hospitals and EMS providers veto power over the ability of birth centers to operate, and are not necessary to ensure pregnant and laboring patients are safely transferred to hospital-based care when emergencies arise—as evidenced by the fact that hospitals and EMS services are legally obligated to transfer and accept patients in emergent circumstances without any such agreement in place, *see, e.g.*, 42 U.S.C. § 1395dd, and by the fact that CPMs currently conduct home births throughout the

state, transferring patients to hospital care when necessary, without any such transfer agreement requirements;

- overly rigid and outdated patient-eligibility criteria, *see* 2022 Proposed Regulations at Appendix A, Ex. A at 47–48, which would exclude many pregnant women with low-risk pregnancies from care in a birthing center, such as those over a particular age and those with more than a set number of prior births, all of whom can be—and are—safely cared for in out-of-hospital settings in other states; and

- cumbersome physical plant requirements, *see id.* at 420-5-.17 to -.19, Ex. A at 35–46, that would drastically increase the cost of operating a birth center and that are unnecessary to provide safe care to low-risk pregnant patients and are inappropriate for birth centers, which are designed to be homelike environments.

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~~107.~~110. The proposed regulations not only diverged from modern standards of care, but many of the requirements would have been extremely difficult, if not impossible, for Plaintiffs' birth centers to comply with.

~~108. For example, Dr. Mitchell, as a licensed CPM in Alabama, would have been barred from providing care in her birth center entirely and, in any event, would not have been able to operate a birth center in her acquired location, which was twelve miles farther from the closest hospital-based labor and delivery care than permitted under the proposed regulations. The strict distance requirement in the proposed regulations would have severely hampered the ability to open birth centers in maternity care deserts like Sumter County, where the need for increased access to skilled providers is greatest.~~

~~109.~~111. OFBC would not have been able to continue operating with ~~the CPMs~~CPMs, including Plaintiff Crawford, and student midwives, who together provided the vast majority of care and attended births~~,~~; would have had to hire additional CNMs and registered nurses~~,~~; and would have had to undertake costly renovations to retrofit the OFBC property to the regulations' requirements.

~~110.~~112. Dr. Robinson likewise would have had to undertake such extensive and

costly physical changes to the property she had acquired for ABC that, as a result of the proposed regulations, she ceased all construction indefinitely and began considering alternative locations for the birth center that would be less prohibitively expensive to retrofit according to the proposed standards. She also would have been prohibited from operating ABC with both CNMs and CPMs independently attending to patients, as she intended and as she felt was most appropriate for the needs of the patient population ABC intended to serve.

~~111.~~113. By state law, ADPH had 90 days from the close of public comment to finalize the regulations. Ala. Code § 41-22-6(b). The state took no action to finalize the flawed proposed regulations within the statutory time frame, thereby allowing them to lapse.

114. ADPH never publicly addressed the many concerns with the proposed regulations raised during the public comment period in 2022.

OFBC Operations After Opening in September 2022

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~~112.~~115. With no regulatory barriers in place, OFBC opened and began seeing patients in September 2022. The first birth in the birthing center occurred in October 2022.

~~113.~~116. Shortly thereafter, OFBC staff reached out to ADPH's Center for Health Statistics to inquire about granting OFBC access to the state's centralized system for registering births and deaths. OFBC staff were informed by agency staff that ADPH would work on setting up access for OFBC and that individual midwives should use their existing credentials to register births in the meantime.

~~114.~~117. Over the next several months, OFBC staff repeatedly reached out to ADPH to inquire about the status of OFBC's account and were assured repeatedly that an account for the facility was in process and would be provided soon.

~~115.~~118. In late February 2023, ADPH reversed course and informed OFBC staff that

facility access to the state's birth registry system had been halted. This information was later confirmed in an email by Nicole Henderson Rushing, Director of ADPH's Center for Health Statistics.

Attorney General's December 2022 Opinion and ADPH Actions Against OFBC

~~116.~~119. In December 2022, Alabama Attorney General Steve Marshall issued an Attorney General Opinion, pursuant to Alabama Code section 36-15-1(a), relating to birth centers.

~~117.~~120. The opinion was issued in response to two questions from ADPH: (1) whether birth centers could be considered "hospitals" under section 22-21-20(1) of the Alabama Code, thereby falling within ADPH's regulatory and licensing authority; and (2) whether CPMs were prohibited from practicing in birth centers under section 34-19-16 of the Alabama Code, which allows CPMs to practice "in any setting of the client's choice, except a hospital." ~~Ala.~~ Att'y Gen. Op. at 1–2.~~Att'y Gen. Op. No. 2023-12, at 1–2 (Dec. 15, 2022) [hereinafter "Att'y Gen. Op."], *available at* https://opinions.alabamaag.gov/Documents/opin/2023-012.pdf.~~

~~118.~~121. In response to ADPH's first question, the Attorney General's opinion did not categorically determine whether all freestanding birth centers fell within ADPH's regulatory and licensing authority. Instead, the AG Opinion concluded that, under Alabama law, whether any such facility fell within ADPH's regulatory and licensing authority was a factual determination. *Id.* at 3.

~~119.~~122. Under section 22-21-22 of the Alabama Code, ADPH must require a license for any facility deemed a "hospital" under the licensing statute. "Hospitals," for licensing purposes, are defined to include, *inter alia*, "health care institutions when such institution is primarily engaged in offering to the public generally, facilities and services for . . . obstetrical care." Ala. Code § 22-21-20(1).

~~120.~~123. Therefore, the Attorney General concluded that freestanding birth centers were "hospitals" requiring an ADPH license to operate *only if* ADPH determined, as a factual matter, that a birth center was "primarily engaged in offering obstetrical care to the public." Att'y Gen. Op. at 5.

~~121.~~124. In response to ADPH's second question, the Attorney General concluded that there was no statutory basis for prohibiting CPMs from working in birth centers because birth centers were *not* "hospitals" as that term is used in section 34-19-16. *Id.* at 4–5. Therefore, under the statute stating that CPMs could practice in any setting "except a hospital," CPMs could lawfully practice in freestanding birth centers.

~~122.~~125. In March 2023, Amber N. Clark-Brown, Medical Director for ADPH's Bureau of Health Provider Standards and Home and Community Services, contacted Dr. Skanes and informed her that ADPH considered her to be operating an "unlicensed hospital." Penalties for operating an unlicensed hospital include criminal misdemeanor penalties and civil liability. Ala. Code § 22-21-33(a)(1)–(3).

~~123.~~126. Dr. Skanes requested that OFBC be permitted to apply for a license, but ADPH refused, saying no such application was available. Dr. Clark-Brown informed Dr. Skanes that she would need to arrange for her existing patients to give birth elsewhere and to cease accepting new patients.

~~124.~~127. Dr. Skanes's counsel at the time met with ADPH's Assistant General Counsel, Dana H. Billingsley, on March 27, 2023. During that meeting, Ms. Billingsley re-confirmed ADPH's position that freestanding birth centers—even those exclusively offering a midwifery model of care—constitute "hospitals" for licensing purposes under Alabama law. Ms. Billingsley further confirmed that ADPH would not permit OFBC to operate without a license,

that no mechanism to seek such a license existed at that time, and that ADPH could not guarantee any particular timeline in which regulations for seeking such a license would be finalized.

~~125.~~128. On April 5, 2023, Dr. Skanes's counsel sent a letter proposing a pathway for OFBC to continue operating based on compliance with national standards for birth centers.

~~126.~~129. On April 7, 2023, Ms. Billingsley sent a letter on behalf of ADPH rejecting Dr. Skanes's proposal, reiterating its position that OFBC could not operate without a license, that no regulatory process for obtaining licensure existed, and that OFBC would need to cease providing birthing services immediately.

~~127.~~130. After additional communications between Dr. Skanes's counsel and ADPH in April 2023, ADPH agreed to let OFBC's existing patients who were already in their third trimester give birth at the birth center but continued to require all other existing patients to arrange to deliver elsewhere. The last patient permitted to give birth at OFBC under this agreement delivered in June 2023.

~~128.~~131. Based on these interactions with ADPH, Dr. Skanes understood that ADPH would not permit OFBC to resume providing birthing services at OFBC unless and until ADPH adopted regulations for freestanding birth centers and OFBC successfully obtained a license pursuant to those regulations.

~~129.~~132. At no point during the interactions with Dr. Skanes did ADPH explain how and on what basis it determined that, by providing midwifery care, OFBC was "primarily engaged in offering obstetrical care to the public." *See* Att'y Gen. Op. at 5. No ADPH employee ever visited OFBC or spoke to any of OFBC's midwifery team about the type of care they provided at OFBC.

~~130.~~133. As of the date of filing of this ~~complaint~~First Amended Complaint, and except as ordered by this Court, ADPH has not provided any timely, feasible path to licensure—

whether under existing statutory criteria or through their regulatory authority—for freestanding birth centers in Alabama.

134. Currently, the only timely, feasible path to licensure of freestanding birth centers in Alabama is through temporary licensure pursuant to the Preliminary Injunction issued in this case. Prelim. Inj. Order. The injunction prohibits ADPH from refusing to timely license freestanding birth centers, pursuant to its statutory licensing authority, that can demonstrate compliance with nationally-recognized, evidence-based standards set by the American Association of Birth Centers and remaining statutory requirements. *Id.*

ADPH's Proposed 2023 Regulations

~~131.~~135. In late June 2023, ADPH released a new set of proposed regulations, with a public comment period running from July 1 to August 4, 2023. Birthing Centers (proposed June 20, 2023) (to be codified at Ala. Admin. Code r. 420-5-13-.01 to -.19), https://www.alabamapublichealth.gov/about/assets/420-5-13.pdf, attached hereto as Ex. B [hereinafter "2023 Proposed Regulations"]. These ~~regulations~~2023 Proposed Regulations not only ~~retain~~retained many of the problematic, burdensome, and non-evidence-based requirements as the former proposed regulations but ~~are~~were, in many respects, even more restrictive.

~~132.~~136. For example, the ~~regulations retain~~2023 Proposed Regulations retained or ~~increase~~increased restrictions on the degree of physician supervision required, thereby restraining midwives from practicing to the full extent of their training and qualifications. 2023 Proposed Regulations at 420-5-13-.03, Ex. B at 13–16. While ADPH no longer has a legal basis to bar CPMs from practicing in birth centers, *see* Att'y Gen. Op. at 5, the proposed regulations nevertheless ~~restrict~~restricted CPMs' scope of practice to providing "assistive care" under the supervision of physicians and CNMs, 2023 Proposed Regulations at 420-5-13-.03(1), Ex. B at 13—even though

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the Alabama Legislature did not impose any such restriction on CPMs' scope of practice when they enacted the law authorizing CPMs to practice in Alabama in 2017, and even though CPMs currently provide care to home birth patients throughout Alabama without any such restrictions.

~~133.~~137. Other burdensome and irrational requirements—such as written transfer agreements, strict distance limitations to hospital-based obstetric care, and onerous and costly physical plant requirements—also ~~remain~~remained. *See* 2023 Proposed Regulations at 420-5-13-.10(1), -.01(v)(5)(x), -.19, Ex. B at 24, 7, 49–52.

~~134.~~138. These requirements would either prevent Plaintiffs from operating their birthing centers entirely or would condition the ability to operate them on significant and potentially cost-prohibitive changes to their facilities and staffing.

~~135. Upon information and belief, prior to issuing the 2023 proposed regulations, ADPH did not consult with the State Board of Midwifery, the State Board of Nursing, ACNM or ACNM-AL, ALMA, AABC, the CNM program at UAB, any of the plaintiffs in this case, or any individual midwives before promulgating the 2023 proposed regulations.~~

~~136. ADPH has never publicly addressed the many concerns raised during the public comment period in 2022.~~

~~137.~~139. On July 13, 2023, ADPH held a public hearing for comments on the proposed birth center regulations. Speakers at the public hearing—including AABC, the State Board of Midwifery, ALMA, and many of the plaintiffs in this case—expressed unanimous opposition to the proposed regulations, noting that they continued to contradict evidence-based standards and national guidelines and greatly ~~restrict~~restricted the ability of freestanding birth centers to operate in Alabama, including in the regions of the state most in need of improved access to pregnancy-related care.

~~138.~~140. No one spoke in favor of the proposed regulations.

Initiation of This Litigation

141. On August 8, 2023, Plaintiffs initiated the present litigation challenging ADPH's unlawful actions and de facto ban on birth centers as violating the Alabama Administrative Procedure Act and the Alabama and federal Constitutions. *See* Compl. Declaratory & Injunctive Relief, Doc. 002 (Aug. 8, 2023).

142. On August 9, 2023, Plaintiffs filed a motion for preliminary injunction, seeking an order enjoining ADPH from requiring freestanding birth centers operating in the midwifery model of care to seek and obtain a "hospital" license under section 22-21-22 of the Alabama Code or, in the alternative, from refusing to timely license, including through the issuance of temporary licenses, freestanding birth centers operating in the midwifery model of care that can demonstrate compliance with AABC standards and the remaining statutory requirements under ADPH's statutory licensing authority. *See* Pls.' Mot. Prelim. Inj., Doc. 008 (Aug. 9, 2023).

143. After hearing oral argument on September 28, 2023, the Court issued an oral ruling from the bench, followed by a written order the following day, denying Defendants' motion to dismiss and rejecting, *inter alia*, Defendants' argument that the 2023 Final Regulations would moot Plaintiffs' claims were the regulations to take effect. *See* Order, Doc. 104 (Sept. 29, 2023).

144. On September 28 and 29, 2023, the Court heard testimony from multiple witnesses and oral argument on Plaintiffs' motion for a preliminary injunction. *See* Scheduling Order Mot. Prelim. Inj., Doc. 018 (Aug. 10, 2023).

145. On September 30, 2023, the Court issued an order granting Plaintiffs' motion for a preliminary injunction and, on October 3, 2023, a supplemental preliminary injunction order, on Plaintiffs' alternative claims for relief and enjoined Defendants from "refusing to timely license

(including but not limited to refusing to timely issue temporary or interim licenses to) freestanding birth centers operating in the midwifery model of care (including [the named Plaintiffs], and/or any birth centers owned or operated by members of Plaintiff Alabama Affiliate of the American College of Nurse-Midwives) that can demonstrate substantial compliance with the standards set out by the American Association of Birth Centers and can satisfy the remaining statutory requirements, §§ 22-21-23, -24, -29(a), -31, pursuant to the Alabama Department of Public Health's statutory authority under Alabama Code Section 22-21-25(a)." Prelim. Inj. Order at 2; *see also* Suppl. Prelim. Inj. Order at 1–2.

146. On October 13, 2023, OFBC submitted an application for temporary licensure pursuant to this Court's injunction, and, at ADPH's request, supplemented that submission with additional information on November 1, 2023. ADPH conducted an entrance survey with respect to that application on December 1, 2023. On December 20, 2023, OFBC received its temporary license, effective January 1, 2024, and on January 1, it reopened and resumed patient services.

147. As of the filing of this First Amended Complaint, ABC is preparing to submit its application for temporary licensure from ADPH pursuant to this Court's preliminary injunction, and to open as soon as possible thereafter once that process is complete.

Adoption of the 2023 Final Regulations

148. On August 17, 2023, following the initiation of this litigation, ADPH approved the proposed regulations with minimal changes, and the final, approved regulations were published in the Alabama Administrative Monthly on August 31, 2023. A copy of the 2023 Final Regulations is attached hereto as Ex. C.

149. Upon information and belief, ADPH did not consult with the State Board of Midwifery, the State Board of Nursing, ACNM or ACNM-AL, ALMA, AABC, the CNM program

at UAB, any of the plaintiffs in this case, or any individual midwives before drafting and issuing the 2023 Proposed Regulations, nor did it consult with any such groups or individuals after receiving public comments in opposition to and prior to approving the 2023 Final Regulations.

150. The 2023 Final Regulations became effective on October 15, 2023, pursuant to Ala. Code § 41-22-6(c). *See* Ala. Admin. Code r. 420-5-13-.01 to -.19, Ex. C.

151. The extent of opposition to the 2023 Proposed Regulations was evident from an August memo issued by ADPH summarizing oral and written comments—almost all in opposition—received during the public comment period, including that the regulations were inconsistent with best practices, not evidence-based, and would prevent or severely impede the establishment, construction, maintenance, and operation of freestanding birth centers in Alabama. *See* Memorandum from Denise Milledge, MBA, BSN, Dir., ADPH Bureau of Health Provider Standards, to State Comm. of Pub. Health, *Proposed Rules for Birthing Centers, Chapter 420-5-13* (Aug. 8, 2023), attached hereto as Ex. D [hereinafter "Milledge Memo"].

152. However, as approved, the 2023 Final Regulations fail to address the vast majority of these concerns.

153. For example, despite numerous comments in opposition, the 2023 Final Regulations would continue to restrict CPMs, such as Plaintiffs Crawford and Stone, to providing only "assistive" care to a physician or CNM. *See* Ala. Admin. Code r. 420-5-13-.01(2)(b), -.03(1), -.15(2)(c), Ex. C at 2, 15, 43. These restrictions on CPMs prohibit them from providing independent patient care throughout pregnancy, birth, and the postpartum period, including attending deliveries, as CPMs are authorized by the legislature to perform in any out-of-hospital setting, *see* Ala. Code §§ 34-19-14(b)(1), -16(a), and as CPMs including Plaintiff Crawford currently do, and as Plaintiff Stone intends to do once licensed, in home birth settings across

Alabama. *See also* Milledge Memo at 2–3, 6–9, 13, 15, 18, 21–22, 26–28, 29–31 (summarizing comments in opposition).

154. This requirement would also prevent Plaintiffs OFBC and ABC from hiring qualified CPMs to provide independent patient care or from leveraging their birth centers to train CPM students, as intended. OFBC, for example, currently and previously employed CPMs, including Plaintiff Crawford, to train student midwives and to independently manage and attend all patient births in the birth center between October 2022 and June 2023, without additional physician or nurse-midwife supervision, and with a perfect safety record. ABC likewise intends to employ CPMs, such as Plaintiff Stone, to provide independent care to the full scope of their licensed practice within the birth center and to train CPM students.

155. The 2023 Final Regulations further restrict CPMs' and CNMs' ability to practice midwifery consistent with their statutorily-authorized scopes of practice. For example, the Final Regulations require all birth centers either to have a physician on staff or to have an agreement with a consulting physician and require such physicians to meet certain requirements, including but not limited to Board certification, admitting privileges, and physical presence and supervision requirements. Ala. Admin. Code r. 420-5-13-.01(2)(b), (2)(f), (2)(w), Ex. C at 2, 3, 8. Such requirements would prevent CPMs like Plaintiffs Crawford and Stone from engaging in independent practice in birth centers, as they are authorized to do by the legislature, separate and apart from the limitation to "assistive" care, *see* Ala. Code §§ 34-19-14(b)(1), -16(a), and would prevent CNMs, like Plaintiff ACNM-AL's members, from engaging in practice in a birth center pursuant to valid CPAs that satisfy all requirements imposed by the legislature and by the Boards of Medical Examiners and Nursing pursuant to their statutorily-delegated authority, Ala. Code §§ 34-21-83, -84, -85, -90. *See also* Milledge Memo at 1–3, 6–9, 13, 19, 21, 26–27, 29–30

(summarizing comments in opposition).

156. The 2023 Final Regulations also impose burdensome, clinically unnecessary requirements that would be difficult, if not impossible, for Plaintiffs OFBC and ABC to satisfy and that are not required for many other hospital and out-of-hospital settings in Alabama, including but not limited to certain staffing requirements, *see*, *e.g.*, Ala. Admin. Code r. 520-5-13-.01(2)(d)–(e), -.03(2)(d), Ex. C at 2–3, 17; *see also*, *e.g.*, Milledge Memo at 3, 6–7, 10, 13, 18, 22, 26, 27 (summarizing comments in opposition).

157. The 2023 Final Regulations also continue to require birth centers to have written transfer agreements with a hospital within 30 minutes driving distance and with an EMS company, Ala. Admin. Code r. 420-5-13-.01(2)(r), (2)(x), Ex. C at 6, 8, and the staff or consultant physician to have admitting privileges at this hospital, *id.* r. 420-5-13-.01(2)(f), 2(w), Ex. C at 3, 8, thereby giving hospitals and EMS providers a veto power over whether birth centers can open at all—again, despite numerous comments opposing this requirement as unreasonable and unnecessary for patient safety, *see*, *e.g.*, Milledge Memo at 3, 6, 9–10, 13, 18, 22, 26–27 (summarizing comments in opposition), and despite the fact that CPMs in Alabama, such as Plaintiffs Crawford and Stone, attend home births without any such requirement, consistent with their licensed scope of practice, training, and expertise. Upon information and belief, it would be difficult, if not impossible, for OFBC or ABC to obtain and/or maintain such an agreement with a qualifying hospital or emergency medical service.

158. The distance limitation and other burdensome requirements, *see*, *e.g.*, Ala. Admin. Code r. 420-5-13-.01(2)(d)–(e), (2)(f), (2)(r), (2)w), (2)(x), Ex. C at 2–3, 6, 8–9, would further prevent birth centers from opening in many maternity care deserts and rural areas where the need for increased access to pregnancy-related care is greatest. *See* Milledge Memo at 2–3, 16, 18, 22,

27, 31 (summarizing comments in opposition).

159. The 2023 Final Regulations also include onerous physical and construction requirements that, as commenters informed ADPH, are not only clinically unjustified and inconsistent with the homelike environment that birth centers provide, but would also be extremely expensive, if not financially prohibitive, for OFBC or ABC to comply with. *See* Ala. Admin. Code r. 420-5-13-.18 to -.19, Ex. C at 50–60; *see also* Milledge Memo at 3, 6, 15, 18–19 (summarizing comments in opposition).

160. In addition, the 2023 Final Regulations impose requirements that are inconsistent with current standards of care, best practices, and patients' best interests. For example, the regulations exclude many low-risk patients who are otherwise appropriate for midwifery care in an out-of-hospital setting from eligibility based on clinically unjustified risk criteria, such as age, history of miscarriage, or prior number of births, Ala. Admin. Code r. 420-5-13-.01(2)(p), Ex. C at 4–5—restrictions that are not only counter to evidence-based practices but would also narrow the pool of patients that the Plaintiff birth centers could serve, prevent patients from exercising their statutory right to choose the out-of-hospital setting of their choice subject only to Board of Midwifery regulations, *see* Ala. Code § 34-19-16(a), and be inconsistent with midwives' training, expertise, and licensed scope of practice. *See also* Milledge Memo at 2–3, 6, 13–14, 18, 22, 26 (summarizing comments in opposition).

161. The 2023 Final Regulations also fail to provide *timely* access to licenses, creating a catch-22 that similarly makes it difficult, if not impossible, to establish, open, or operate a birth center. For example, the regulations require that birth centers obtain final accreditation from a national accrediting body, Ala. Admin. Code r. 420-5-13-.13(6), Ex. C at 41—despite ADPH's awareness that such a process can take six months to a year or more to complete and that, for this

reason, the national accrediting body recommends temporary or interim licensure while such a process is ongoing. *See* Milledge Memo at 13, 19, 21 (summarizing comments in opposition from CABC, among others). Without being able to open and operate while such a process is ongoing, it would be extremely difficult for birth centers to maintain a business (adequate staffing, property and equipment costs, etc.), while being unable to operate for such an extended period of time. The regulations, however, make no provision for temporary licensure while accreditation is underway. *See* Ala. Admin. Code r. 420-5-13-.13(6), Ex. C at 41.

162. As such, the 2023 Final Regulations not only diverge from modern standards of care, but also impose barriers that would make it extremely difficult, if not impossible, for Plaintiffs to open and operate freestanding birth centers.

G. Harmful Impact of ADPH's Actions on Birth Centers on Plaintiffs and their Patients

~~139.~~163. As a result of ADPH's policy that any and all freestanding birth centers are "hospitals" requiring an ADPH license and ADPH's ongoing failure to provide any ~~path to licensure~~timely, feasible path to licensure under either "the minimum standards provided in [article 2 of title 22, chapter 21] or by regulations issued under its authority," Ala. Code § 22-21-23, ADPH has imposed a de facto ban on freestanding birth centers in the state.

~~140.~~164. ADPH's actions are inflicting significant irreparable harm on Plaintiffs, their members, and their current and prospective patients, as detailed below.

~~141.~~165. Because of ADPH's threats and refusal to provide a timely, feasible path to licensure, and despite OFBC's compliance with the national standards for birth centers and perfect record of patient safety, as of the filing of this First Amended Complaint, OFBC ~~has been~~was forced to cease providing birthing care to patients in the Birmingham area entirely~~.~~ for six months. Because it ~~is~~was not practical for OFBC to continue providing only prenatal and postpartum care,

OFBC ~~has~~ lost midwifery personnel and ~~been~~was forced to stop providing *any* care through the birth center~~.~~ during that time.

~~142.~~166. ADPH's actions ~~are~~ also ~~forcing~~forced OFBC to turn away numerous patients seeking access to this critically needed care~~.~~ during the time that the birth center was forced to cease operations. For example, OFBC ~~has~~ had to turn away ten established patients who had selected OFBC for their pregnancy and birthing care, including two patients who were expecting to give birth at the birthing center in August and October 2023. OFBC ~~has~~ also had to turn away more than a dozen new patients who ~~have~~ inquired about care at OFBC between March and August 2023 alone.

~~143.~~167. By forcing Dr. Skanes and OFBC's midwifery staff, including Plaintiff Crawford, to stop providing care to their patients at OFBC consistent with their training, expertise, and professional judgment, ADPH's actions ~~are interfering~~interfere with their exercise of their professional judgment and their relationships with their patients, including patients with whom they had established provider-patient relationships and to whom they owed professional and ethical obligations.

~~144.~~168. ADPH's actions and forced cessation of OFBC's operations ~~places~~placed years of Dr. Skanes's work in limbo. During the time OFBC was unable to operate, Dr. Skanes ~~is also incurring~~incurred considerable financial costs—in addition to the investments she already made to establish OFBC—to maintain ~~a now~~ an unused space, without knowing if or when she might be able to resume operating her business.

~~145.~~169. Patients turned away from OFBC as a result of ADPH's actions ~~have been~~were left without any path to obtaining care in a freestanding birth center in Alabama, despite having previously determined, in consultation with their trusted health care providers, that such

care was the optimal care for them, based on their health, values, beliefs, needs, and financial situation. These patients ~~have been~~were forced to make other arrangements for either hospital-based care or a home birth, even though this is not the model of care they sought.

~~146.~~170. If OFBC could ~~operate~~have operated based on compliance with nationally recognized guidelines from AABC, it would ~~be able~~not have had to ~~resume services immediately, or as soon as practicable.~~cease providing patient care.

~~147.~~171. ADPH's actions are also harming Dr. Robinson~~, Dr. Mitchell,~~ and ~~their~~her birth ~~centers~~center, placing years of work and investment into limbo.

~~148.~~172. For example, because of ADPH's actions, Dr. Robinson ~~has~~ halted construction on ABC entirely and ~~is turning~~had to turn away interested patients. As a result, during the time that she halted construction, Dr. Robinson ~~is incurring~~incurred considerable financial costs—in addition to the considerable investments she already made in establishing ABC—to maintain ~~a now~~ an unused space, without knowing if or when she might be able to commence operating her business.

~~149.~~173. More than ~~one~~two hundred patients ~~have~~ inquired about care at ABC ~~since~~after Dr. Robinson was forced to halt construction in mid-2022.

~~150.~~ If ABC could operate based on compliance with nationally recognized guidelines from AABC, it would be able to begin providing patient care ~~within 90 days.~~

~~151. Because of ADPH's actions, Dr. Mitchell is continuing to make considerable financial and personal investments in establishing Birth Sanctuary's freestanding birth center without knowing if or when she will be able to open the center to patients.~~

~~152. If Birth Sanctuary is not able to operate as a freestanding birth center, Dr. Mitchell will be left with very few other options to practice her profession and offer the skilled care she is~~

~~trained to provide to her community. While she could continue practicing in home birth settings, because of the practical realities of working in a rural area in the state, Dr. Mitchell can take on fewer clients in a home birth practice than she would be able to see in the birth center, and she is unable to offer them many of the additional resources Birth Sanctuary plans to offer, such as group health education classes.~~

~~153. The additional patients Birth Sanctuary could serve are also left without other options for pregnancy-related or midwifery-based care in the area, which is classified as a maternity care desert.~~

~~154.~~174. ~~If Birth Sanctuary could operate based on compliance with nationally recognized guidelines from AABC, Dr. Mitchell estimates she would be able to open in January 2024.~~as soon as possible once ABC's application for temporary licensure from ADPH pursuant to this Court's preliminary injunction is submitted, and that process is complete.

~~155.~~175. Because of ADPH actions, ACNM-AL's members have been denied the opportunity to open and operate freestanding birth centers, to pursue employment in such birth centers, and to offer this out-of-hospital alternative to their patients, despite considerable interest from the membership and from members' patients in this model of care. This limits their ability to practice to their full scope of practice and to offer their patients the full scope of care they are trained to provide.

~~156.~~176. Because of ADPH's actions, ACNM-AL's members' patients have likewise been denied access to this model of care even if, in consultation with their CNM providers, they determine that such care would be the optimal care for them, based on their health, values, belief, needs, and financial situation.

177. Because of ADPH's actions, Plaintiff Crawford likewise was denied the

opportunity to pursue employment in birth centers during the time OFBC was forced to close. In order to meet her responsibilities to OFBC's patients, Crawford had reduced the volume of home birth patients she took on in her home birth practice. When OFBC was forced to close, this significantly impacted her income. OFBC's closure also denied her the opportunity to offer this out-of-hospital alternative to her patients, despite considerable interest from her patients in this model of care—and she can only do so today by virtue of the Court's injunction. This limits her ability to practice to her full scope of practice and to offer her patients the full scope of care she is trained to provide.

178. Plaintiff Crawford's patients have been denied access to this model of care—and, but for the injunction, would continue to be denied such access—even if, in consultation with her as their trusted provider, they determine that such care would be optimal for them, based on their health, values, beliefs, needs, and financial situation.

179. During her apprenticeship as a student midwife, Plaintiff Stone, like other CPM students in the state, was also denied the opportunity to seek training in birth centers as part of her clinical education, thereby delaying her ability to obtain and complete the necessary training experience within Alabama because of the more limited patient load in the home birth setting.

180. While these irreparable harms may be temporarily abated by this Court's preliminary injunction, that interim relief will only last during the pendency of this litigation. If applied to Plaintiffs, Plaintiffs' members, and their patients, the 2023 Final Regulations would only perpetuate and exacerbate these irreparable harms.

181. If applied to Plaintiffs, their members, and their patients, the 2023 Final Regulations would make it extremely burdensome, if not impossible, for the birth centers to open or continue to operate. The Final Regulations impose some requirements that, in some instances, would be

literally impossible for Plaintiffs to satisfy.

182. Other requirements in the 2023 Final Regulations would render operation of a birth center financially unsustainable, and, therefore, infeasible and impractical to operate.

183. The 2023 Final Regulations are also harming Dr. Skanes, Dr. Robinson, and their birth centers by continuing to place years of work and investment into limbo. They have spent years and made considerable personal and financial investments in establishing their birth centers, without knowing if they will be able to continue operating long term as a result of ADPH's actions and the burdensome and impractical requirements of the 2023 Final Regulations.

184. Plaintiffs, their staff, and their members are also harmed by unlawful and unconstitutional provisions in the 2023 Final Regulations that impose requirements for and limitations to patient care, including but not limited to clinically unjustified risk criteria excluding certain patients from eligibility for birth center care. These requirements are inconsistent with prevailing standards of care, patients' best interests, Plaintiffs' training, expertise, and clinical judgment, and, in some instances, Plaintiffs' ethical obligations to patients. By imposing such requirements, ADPH's actions interfere with Plaintiffs' exercise of professional judgment and disrupt their relationships with their patients, including patients with whom they have established provider-patient relationships and to whom they owe professional and ethical obligations.

185. Plaintiffs Crawford and Stone, the birth centers' other CPM staff, and ACNM-AL's CPM members are further harmed by the limitation in the 2023 Final Regulations restricting CPMs to providing "assistive" care in a birth center, which violates provisions of the Alabama Code authorizing licensed CPMs to practice independently "in the setting of a client's choice except a hospital," § 34-19-16(a); *see also* § 34-19-14(b)(2), and thereby prevents them from practicing their profession in Alabama.

186. Plaintiffs OFBC and ABC are likewise harmed by this limitation. It would be financially and practically unsustainable to employ CPMs in birth centers if limited to only providing "assistive" care under the supervision of a physician or CNM, thereby preventing the birth centers from employing or continuing to employ qualified CPMs to provide independent patient care in their birth centers and making it more expensive—and, in some cases, prohibitively expensive—to operate birth centers at all.

187. Due to the unsustainable and impractical costs, this limitation to "assistive" care for CPMs will likely prohibit CPMs, including Plaintiff Crawford, Plaintiff Stone, and ACNM-AL's CPM members, from practicing in a birth center entirely.

188. Moreover, as a newly-certified and soon-to-be-licensed CPM, Plaintiff Stone would be prohibited by the 2023 Final Regulations from working in a birth center in any capacity for at least a year, despite having fulfilled all qualifications required under Alabama statutory law and Board of Midwifery regulations to practice as a CPM in any setting of her patients' choice other than a hospital.

189. Plaintiffs' and their members' patients will also be harmed by the 2023 Final Regulations. To the extent that the Regulations make it impossible for birth centers to operate at all in Alabama, patients will be denied the option for out-of-hospital care in a birth center entirely, despite having previously determined, in consultation with their trusted health care providers, that such care was the optimal care for them, based on their health, values, beliefs, needs, and financial situation. These patients will be forced to make other arrangements for either hospital-based care or a home birth, even though this is not the model of care they sought.

190. Plaintiffs' and their members' patients will also be harmed by specific requirements in the 2023 Final Regulations—including but not limited to clinically unjustified risk criteria—

that will force birth centers to deny care to low-risk patients who are otherwise clinically appropriate for care in an out-of-hospital setting, despite having previously determined, in consultation with their trusted health care providers, that such care was the optimal care for them, based on their health, values, beliefs, needs, and financial situation. These patients will be forced to make other arrangements for either hospital-based care or a home birth, even though this is not the model of care they sought.

~~157.~~191. The public interest is also considerably harmed by ADPH's actions. Against the backdrop of a severe maternal and infant health crisis, especially for Black Alabamians, prevalent maternity care deserts, and inadequate access to pregnancy-related care in the state, ADPH's actions are preventing skilled providers of pregnancy-related care from offering their much-needed services to help expand access to quality care and improve patient outcomes.

~~158.~~192. Plaintiffs lack an adequate remedy at law.

CLAIMS

Primary Claim

Claim One: Alabama Administrative Procedure Act (AAPA)—Exceeds Statutory Authority

~~159.~~193. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through ~~158~~192.

~~160.~~194. Under Alabama law, a "hospital," for purposes of ADPH's regulatory and licensing authority, includes, *inter alia*, "institution[s] . . . primarily engaged in offering to the public generally . . . obstetrical care." Ala. Code § 22-21-20(1).

~~161.~~195. ADPH's determination that any and all freestanding birth centers are "hospitals" for purposes of its regulatory and licensing authority under section 22-21-20(1), including but not limited to ADPH's enforcement of that determination by threatening Dr. Skanes

with criminal and civil penalties for operating OFBC as an "unlicensed hospital~~,~~"" and adopting regulations for freestanding birth centers, Ala. Admin. Code r. 420-5-13-.01 to -.19, constitutes a rule under the AAPA because it is a "standard[] or statement of general applicability that implements, interprets, or prescribes law or policy." Ala. Code. § 41-22-3(9); *see also Ex parte Traylor Nursing Home, Inc.*, 543 So. 2d 1179, 1183–84 (Ala. 1988).

196. Because a freestanding birth center operating under the midwifery model of care is not engaged in offering obstetrical care to the public generally, it does not fall within ADPH's hospital regulatory and licensing authority.

~~162.~~197. Therefore, ADPH's adoption of the rule that any and all freestanding birth centers operating under the midwifery model of care are "hospitals" for purposes of its regulatory and licensing authority, ~~and~~including through the adoption of regulations for freestanding birth centers, and its application of that rule to Plaintiffs OFBC, ABC~~, Birth Sanctuary~~, and any other similarly situated birth centers that may be owned, operated, or staffed by the individual Plaintiffs or Plaintiff ACNM-AL's members, exceeds ADPH's statutory authority in violation of Alabama Code § 41-22-10.

Alternative Claims

Claim Two: AAPA—Exceeds Statutory Authority (De Facto Ban)

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~~163.~~198. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through ~~158~~192.

~~164.~~199. Plaintiffs bring this claim in the alternative to Claim One.

~~165.~~200. Even if ADPH is authorized to require a freestanding birth center operating in the midwifery model of care to obtain a license under its hospital regulatory and licensing authority, ADPH's adoption of a de facto ban on all freestanding birth centers by refusing to

provide any path to licensure constitutes a rule because it is a "standard[] or statement of general applicability that implements, interprets, or prescribes law or policy." Ala. Code. § 41-22-3(9); *see also Ex parte Traylor Nursing Home, Inc.*, 543 So. 2d at 1183–84.

~~166.~~201. ADPH's hospital regulatory and licensing authority is limited to the authority to "make and enforce . . . reasonable rules and regulations governing the operation and conduct of [regulated facilities]" and to "set uniform minimum standards applicable alike to all [regulated facilities] of like kind." Ala. Code § 22-21-28(a). ADPH lacks the authority under Alabama law to categorically prohibit a particular *type* of "hospital" covered under its regulatory and licensing authority from operating in Alabama entirely.

~~167.~~202. ADPH is authorized by statute to grant a license to operate a "hospital" under section 22-21-25(a) of the Alabama Code to any applicant who demonstrates compliance with minimum statutory criteria, without requiring the promulgation of additional regulations. *See also* Ala. Code § 22-21-23.

~~168.~~ Except as otherwise ordered by this Court, *see supra* paragraphs 145–47, ADPH has nonetheless categorically refused to consider applications for licensure by freestanding birth centers under the relevant statutory criteria, despite the proven safety record and benefits of freestanding birth centers, ~~including Plaintiff OFBC.~~

~~169.~~203. ~~ADPH has also failed to provide a regulatory path for licensure of freestanding birth centers,~~ and even though Plaintiffs OFBC~~,~~ and ABC~~, and Birth Sanctuary~~ have been engaged in public efforts to open freestanding birth centers in Alabama for over three years, and even though Plaintiff OFBC successfully provided prenatal, birthing, and postpartum care to over twenty patients before ADPH forced them to shut down on the grounds that they lacked a "hospital" license from ADPH.

204. Additionally, as discussed *infra* in Claims Three through Thirteen, the current birth center regulations are unlawful, unconstitutional, and make it difficult, if not impossible, to work in, establish, construct, maintain, or operate birth centers. Thus, ADPH has also failed to provide a regulatory path for licensure of freestanding birth centers, despite the proven safety record and benefits of freestanding birth centers, as described *supra* paragraphs 68–77.

~~170.~~205. ADPH's refusal to provide any statutory or regulatory path for licensure of freestanding birth centers therefore constitutes a de facto ban on freestanding birth centers in Alabama that exceeds ADPH's statutory authority in violation of Alabama Code § 41-22-10.

Claim Three: AAPA—Exceeds Statutory Authority (Unreasonable Regulatory Scheme)

206. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 192.

207. Plaintiffs bring this claim in the alternative to Claim One.

208. Even if ADPH is authorized to require a freestanding birth center operating in the midwifery model of care to obtain a license under its hospital regulatory and licensing authority, ADPH's adoption of the 2023 Final Regulations for freestanding birth centers, Ala. Admin. Code r. 420-5-13-.01 to -.19, exceeds its statutory authority in violation of the AAPA, Ala. Code § 41-22-10.

209. The purpose of ADPH's hospital regulatory and licensing authority is "to promote the public health, safety and welfare by providing for the development, establishment and enforcement of standards for the treatment and care of individuals in institutions within [its] purview . . . and the establishment, construction, maintenance and operation of such institutions which will promote safe and adequate treatment and care of individuals in such institutions." Ala. Code § 22-21-21.

210. ADPH's hospital regulatory and licensing authority is limited to "the power to make and enforce . . . *reasonable rules and regulations* governing the operation and conduct of hospitals as defined in Section 22-21-20." *Id.* § 22-21-28(a) (emphasis added). "All such regulations shall set uniform minimum standards applicable alike to all hospitals of like kind and purpose in view of the type of institutional care being offered there and shall be confined to setting minimum standards of sanitation and equipment found to be necessary and prohibiting conduct and practices inimical to the public interest and the public health." *Id.*

211. ADPH's regulatory scheme for freestanding birth centers imposes numerous unreasonable requirements on the Plaintiff birthing centers and their staff, including but not limited to burdensome and clinically unjustified limitations on midwives' scopes of practice, physician supervision and minimum staffing requirements, hospital and transport written transfer agreements, and physical plant prerequisites, that make it extremely burdensome, if not impossible to work in, establish, construct, maintain or operate a freestanding birth center in Alabama.

Claim Four: AAPA—Exceeds Statutory Authority
(Conflict with Childbirth Freedom Act, Act 2017-383)

212. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 192.

213. Plaintiffs bring this claim in the alternative to Claim One.

214. Even if ADPH is authorized to require a freestanding birth center operating in the midwifery model of care to obtain a license under its hospital regulatory and licensing authority, ADPH's adoption of the 2023 Final Regulations for freestanding birth centers, Ala. Admin. Code r. 420-5-13-.01 to -.19, exceeds its statutory authority in violation of the AAPA, Ala. Code § 41-22-10.

215. In exercising its hospital regulatory and licensing authority, ADPH "shall not have

power to promulgate any regulation in conflict with law." *Id.* § 22-21-28(a).

216. ADPH's 2023 Final Regulations for freestanding birth centers prohibit CPMs, including Plaintiffs Crawford and Stone, from practicing independently and to their full scope of practice in freestanding birth centers and prohibit the Plaintiff birth centers from employing CPMs to provide such independent patient care, thereby conflicting with Alabama law authorizing CPMs to practice midwifery independently in out-of-hospital settings, *e.g.*, *id.* §§ 34-19-11 to -21.

217. By statute, Alabama-licensed CPMs are authorized to "practice midwifery care in the setting of the client's choice, except a hospital," *id.* § 34-19-16(a), which includes freestanding birth centers, *see* Att'y Gen. Op. at 4–5 (concluding that freestanding birth centers are not hospitals for the purposes of section 34-19-16).

218. Moreover, when authorizing CPMs to practice in out-of-hospital settings such as birth centers, the Alabama Legislature specifically charged the State Board of Midwifery with licensing and regulating their practice, Ala. Code §§ 34-19-14 to -15, and required that any regulation of CPMs' practice must "ensure independent practice" and be implemented "in a manner consistent with the most current North American Registry of Midwives Job Analysis and with essential documents developed and published by the Midwives Alliance of North America," Ala. Code § 34-19-14(b)(1)–(2); *see also* Ala. Admin. Code r. 582-X-.01 to -.04.

219. Provisions of the 2023 Final Regulations conflict with these statutes including, but not limited to, because they restrict CPMs' scope of practice to only "assistive" care, Ala. Admin. Code r. 420-5-13-.01(2)(b), -.03(1), Ex. C at 2, 15, prohibit their independent practice, and otherwise restrict freestanding birth centers from employing CPMs in accordance with their statutorily-authorized scope of practice, *e.g.*, *id.* r. 420-5-13-.01(2)(b), (e), Ex. C at 2–3.

Claim Five: AAPA—Exceeds Statutory Authority
(Conflict with Certified Nurse Midwife Statutes)

220. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 192.

221. Plaintiffs bring this claim in the alternative to Claim One.

222. Even if ADPH is authorized to require a freestanding birth center operating in the midwifery model of care to obtain a license under its hospital regulatory and licensing authority, ADPH's adoption of the 2023 Final Regulations for freestanding birth centers, Ala. Admin. Code r. 420-5-13-.01 to -.19, exceeds its statutory authority in violation of the AAPA, Ala. Code § 41-22-10.

223. In exercising its hospital regulatory and licensing authority ADPH "shall not have power to promulgate any regulation in conflict with law." *Id.* § 22-21-28(a).

224. ADPH's 2023 Final Regulations for freestanding birth centers prevent CNMs who meet all statutory requirements for practice in Alabama, including Plaintiff ACNM-AL's members, from owning, operating, or practicing as authorized by Alabama statute in freestanding birth centers and prevent the Plaintiff birth centers from employing CNMs who otherwise meet all requirements for practice in Alabama, thereby conflicting with Alabama law governing the practice of CNMs, *e.g.*, *id.* §§ 34-21-80 to -93.1.

225. Per statute, the Board of Nursing is the "sole state authority designated to establish the qualifications necessary for a registered nurse to be certified to engage in advanced practice nursing," including nurse-midwifery, *id.* § 34-21-84, except to the extent that both the Board of Nursing and the Board of Medical Examiners shall approve protocols for "collaboration with a physician" pursuant to a Collaborative Practice Agreement (CPA), *id.* §§ 34-21-83, -84, -85, -90; *see also* Ala. Admin. Code r. 610-X-5-.14 to -.25.

226. ADPH's 2023 Final Regulations for freestanding birth centers prevent CNMs with

a valid CPA from owning, operating, or practicing as authorized by Alabama statute in birth centers and prevent birth centers from employing such CNMs by inappropriately imposing practice requirements beyond those established by the Alabama legislature and the Alabama Boards of Nursing and Medical Examiners pursuant to their statutorily-delegated responsibility, including but not limited to provisions requiring CNMs to enter into a CPA with the birth center's staff or consultant physician, even if they have another valid CPA already in place, *e.g.*, Ala. Admin. Code r. 420-5-13-.01(2)(d), Ex. C at 2, requiring a CNM's collaborating physician at the birth center to meet requirements not required for other remote practice sites under Alabama law, *e.g.*, *id.* r. 420-5-13-.01(2)(d), (f), (w), Ex. C at 2, 3, 8, and prohibiting CNMs from practicing in birth centers unless certain other qualifications and staffing requirements are met, *e.g.*, *id.* r. 420-5-13-.01(2)(b), (d), Ex. C at 2.

Claim Six: Due Process Right to Pursue Useful Activities under Alabama Constitution

~~171.~~227. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through ~~158~~192.

~~172.~~228. Plaintiffs bring this claim in the alternative to Claim One.

~~173.~~229. The right to due process under Article I, section 13 of the Alabama Constitution protects the right of individuals to "pursu[e] . . . useful activities" free from "restrictions that are unnecessary and unreasonable" and that "do not bear some substantial relation to the public health, safety, or morals, or to the general welfare, the public convenience, or the general prosperity." *Friday v. Ethanol Corp.*, 539 So. 2d 208, 216 (Ala. 1988).

~~174.~~230. ~~By preventing~~ADPH's actions, as set forth above—including but not limited to adopting the 2023 Final Regulations—do not bear any substantial relation to public health and thereby violate Plaintiffs' and their members' constitutional right to pursue useful

activities. Certain provisions of the 2023 Final Regulations, individually or collectively, will prevent Plaintiffs and Plaintiffs' members from owning, operating, and/or working at a freestanding birth center and providing critically necessary pregnancy-related care that is proven to improve health outcomes in the midst of one of the most severe maternal and infant health crises in the country, ~~ADPH's actions as set forth above violate Plaintiffs' constitutional right to pursue useful activities~~and others impose burdensome, costly, and clinically unjustified requirements on the operation of birth centers, without any substantial relation to public health.

Claim ~~Four~~Seven: AAPA—Violates Constitutional Provisions
(Due Process Right to Pursue Useful Activities under Alabama Constitution)

~~175.~~231. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through ~~158~~192.

~~176.~~232. Plaintiffs bring this claim in the alternative to Claim One.

~~177.~~233. For the same reasons stated in Claim ~~Three,~~Six ADPH's actions violate the AAPA because the agency's actions "violate[] constitutional provisions." Ala. Code § 41-22-10.

Claim ~~Five~~Eight: Right to Procreate under Alabama and U.S. Constitutions

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~~178.~~234. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through ~~158~~192.

~~179.~~235. Plaintiffs bring this claim in the alternative to Claim One.

~~180.~~236. The United States Constitution protects the fundamental right to procreate, one of the most "basic civil rights." *Skinner v. State of Oklahoma ex rel. Williamson*, 316 U.S. 535, 541 (1942). The Alabama Constitution protects such a right at least as strongly as its federal counterpart. *Gilbreath v. Wallace*, 292 So. 2d 651, 654–55 (Ala. 1974) ("While the Federal Constitution, as interpreted by the United States Supreme Court, establishes minimum standards, the states have the power and are free to provide greater safeguards and to extend this protection

through their own organic law—the State Constitutions.").

~~181.~~237. ADPH's actions, as set forth above~~,~~ —including but not limited to adopting the 2023 Final Regulations—are denying Plaintiffs' patients access to critically needed care that is proven to improve health outcomes in the midst of one of the most severe maternal and infant health crises in the country. By affirmatively preventing birth centers from operating and/or by imposing clinically unjustified requirements on patient care, amidst a statewide maternal health crisis—and despite ~~their~~birth centers' proven benefits and safety record—ADPH's actions subject Plaintiffs' patients to an increased risk of an unsafe pregnancy and birth and/or fetal or infant death and thereby violate Plaintiffs' patients' fundamental right to procreate under the United States and Alabama Constitutions.

Claim ~~Six~~Nine: AAPA—Violates Constitutional Provisions
(Right to Procreate under Alabama and U.S. Constitutions)

~~182.~~238. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through ~~158~~192.

~~183.~~239. Plaintiffs bring this claim in the alternative to Claim One.

240. For the same reasons stated in Claim Eight, ADPH's actions violate the AAPA because the agency's actions "violate[] constitutional provisions." Ala. Code § 41-22-10.

Claim Ten: Due Process—Unlawful Private Delegation
under Alabama and U.S. Constitutions

241. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 192.

242. Plaintiffs bring this claim in the alternative to Claim One.

243. The Due Process Clause of the U.S. Constitution protects against the unlawful delegation of state power that gives private parties the ultimate authority to determine the nature

of property rights in which others have a protectible property interest. *See*, *e.g.*, *Washington ex rel. Seattle Title Tr. Co. v. Roberge*, 278 U.S. 116 (1928). The Due Process Clause of the Alabama Constitution protects against such unlawful private delegations at least as strongly as its federal counterpart. *Gilbreath*, 292 So. 2d at 654–55.

244. Plaintiffs and Plaintiffs' members have a protectible property interest in practicing their professions and pursuing useful activities, including working at, opening, operating, and practicing to the full scope of their health care licenses at freestanding birth centers. *See Friday*, 539 So. 2d at 216; *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 577–78 (1972).

245. Several requirements in the 2023 Final Regulations for birth centers, including, but not limited to, those mandating written transfer agreements with hospitals within a certain geographic area, Ala. Admin. Code r. 420-5-13-.01(2)(r), (x), Ex. C at 6, 8–9, physician admitting privileges at such hospitals, *id.* r.420-5-13-.01(2)(f), (w), Ex. C at 3, 8, and written transfer agreements with emergency medical services, *id.* r. 420-5-13-.01(2)(x), Ex. C at 8–9, effectively delegate traditional licensing authority to private parties, including hospitals and emergency medical service companies, who are not bound by due process.

246. In the absence of any standards to govern the decision-making of these private entities regarding whether to enter into a written transfer agreement or to grant privileges, the 2023 Final Regulations unlawfully delegate to private parties—whose interests may be adverse to Plaintiffs'—the authority to deprive Plaintiffs of their protected property interests without due process of law. *See Roberge*, 278 U.S. at 121–22 (delegation must be "[]controlled by [a] standard or rule prescribed by legislative action"); *Eubank v. City of Richmond*, 226 U.S. 137, 143–44 (1912) (requiring a "standard by which the power . . . given is to be exercised").

Claim Eleven: AAPA—Violates Constitutional Provisions
(Unlawful Private Delegation under Alabama and U.S. Constitutions)

247. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 192.

248. Plaintiffs bring this claim in the alternative to Claim One.

249. For the same reasons stated in Claim Ten, ADPH's actions violate the AAPA because the agency's actions "violate[] constitutional provisions." Ala. Code § 41-22-10.

Claim Twelve: Due Process and Equal Protection under Alabama and U.S. Constitutions

250. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 192.

251. Plaintiffs bring this claim in the alternative to Claim One.

252. CNMs and CPMs, including Plaintiffs Crawford and Stone, and Plaintiff ACNM-AL's members, who work or intend to work in freestanding birth centers have a protectible due process property interest in practicing their profession. Ala. Const. art. 1, § 13; U.S. Const. amend. XIV; *see also Barnes v. State ex rel. Ferguson*, 151 So. 2d 619, 623 (Ala. 1963).

253. Dr. ~~Five~~Skanes and Dr. Robinson have a protectible due process property interest in operating and maintaining their businesses. Ala. Const. art. 1, § 13; U.S. Const. amend. XIV; *see also supra* paragraphs 244–246.

254. The 2023 Final Regulations deprive Plaintiffs of their protectible property interests by imposing provisions that prevent or impede licensed midwives from practicing their professions in birth centers and prevent or impede Plaintiffs from employing licensed midwives in their birth centers, or impose heightened costs on them for doing so, including, but not limited to, by imposing provisions limiting CPMs to providing only "assistive" care in birth centers, Ala. Admin. Code r. 420-5-13-.01(2)(b), -.03(1), Ex. C at 2, 15, requiring CNMs and physicians working in birth centers to enter into new or more burdensome collaborative practice agreements in order to work

in birth centers, *id.* r. 420-5-13-.01(2)(d), (f), Ex. C at 2–3, restricting CPMs' and CNMs' employment in birth centers, *id.* r. 420-5-13-.01(2)(d), (e), Ex. C at 2–3, and requiring CPMs and CNMs who seek to establish and operate birth centers to meet other irrational requirements, despite the fact that midwives safely provide effectively identical services to the same patient populations in a home birth setting without meeting such requirements, *e.g.*, *id.* r. 420-5-13-.01(2)(f), (r), (w), (x), -.03(2)(a), Ex. C at 3, 6, 7, 8–9, 16–17.

255. The 2023 Final Regulations also impose distinct and heightened requirements on individuals who own, operate, or work in freestanding birth centers—including but not limited to onerous staffing, personnel, and physical plant requirements, *e.g.*, *id.* r. 420-5-13-.01(2)(t), -.03(2)(d), (f), (h)(1), -.16(b)(7), -.19, Ex. C at 6, 17, 18, 46, 56–60—that are not imposed on individuals who establish, operate, or work in similarly situated health care facilities, and/or who provide effectively identical out-of-hospital birthing care, based merely on the location that midwives are providing such care, and without a rational basis for differential treatment.

256. Such differential treatment violates Plaintiffs' and their members' equal protection rights under Article I, section 13 of the Alabama Constitution and the Fourteenth Amendment of the U.S. Constitution. *See also Wallace v. Jones*, No. 2:10-CV-361-MEF, 2013 WL 5406799, at *12 n.11 (M.D. Ala. Sept. 25, 2013).

Claim Thirteen: AAPA—Violates Constitutional Provisions
(Due Process and Equal Protection under Alabama and U.S. Constitutions)

257. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 192.

258. Plaintiffs bring this claim in the alternative to Claim One.

~~184.~~259. For the same reasons stated in Claim Twelve, ADPH's actions violate the AAPA because the agency's actions "violate[] constitutional provisions." Ala. Code § 41-22-10.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court:

1. Issue:

    a. a declaratory judgment, pursuant to the Alabama Declaratory Judgment Act, Ala. Code § 6-6-222, and the AAPA, Ala. Code § 41-22-10, that freestanding birth centers operating in the midwifery model of care are not "hospitals" under section 22-21-20(1) of the Alabama Code and, therefore, ADPH has no authority to require such birth centers to obtain a license under section 22-21-22 of the Alabama Code or to otherwise regulate such birth centers, and that any such attempts to do so exceed statutory authority in violation of the AAPA;

    b. preliminary and permanent injunctive relief enjoining ADPH from requiring freestanding birth centers operating in the midwifery model of care to seek and obtain a "hospital" license under section 22-21-22 of the Alabama Code, and from taking any other adverse action against such entities, their owners, founders, or staff (including Plaintiffs and their members) for failing to seek or obtain such a license, including but not limited to threatening or seeking criminal or civil penalties under section 22-21-33 of the Alabama Code, as further detailed in Plaintiffs' ~~forthcoming~~ Motion for Preliminary Injunction;

2. Or, in the alternative to (1), issue:

    a. either

        ~~a.~~i. a declaratory judgment, pursuant to Alabama Declaratory

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Judgement Act, Ala. Code § 6-6-222, and the AAPA, Ala. Code § 41-22-10, that the failure to provide a timely, feasible path to licensure for freestanding birth centers operating in the midwifery model of care constitutes a de facto ban on freestanding birth centers that exceeds ADPH's statutory authority in violation of the AAPA and/or violates Plaintiffs', their members', and their patients' constitutional rights; and

~~b.~~ ii. preliminary and permanent injunctive relief enjoining ADPH from refusing to timely license freestanding birth centers operating in the midwifery model of care that can demonstrate compliance with AABC standards and can satisfy the remaining statutory requirements, *see* Ala. Code §§ 22-21-23, 24, 29(a), 31, including, but not limited to refusing to timely grant temporary or interim licenses based on such demonstrated compliance until at least such a time as ADPH adopts final regulations for birth centers and temporary- or interim-licensed facilities have had an opportunity to come into compliance with any such new regulations, as further detailed in Plaintiffs' ~~forthcoming~~ Motion for Preliminary Injunction.

b. or

i. a declaratory judgment, pursuant to Alabama Declaratory Judgement Act, Ala. Code § 6-6-222, and the AAPA, Ala. Code § 41-22-10, that the 2023 Final Regulations, in whole or in part,

exceed ADPH's statutory authority in violation of the AAPA and/or violate Plaintiffs', their members', and their patients' constitutional rights; and

ii. permanent injunctive relief enjoining ADPH from enforcing the 2023 Final Regulations in whole or in part, and from taking any other adverse action against such freestanding birth centers, their owners, founders, or staff (including Plaintiffs and their members) for failing to comply, in whole or in part, with unlawful provisions of the 2023 Final Regulations, including but not limited to denying a license on that basis or taking other adverse administrative, criminal or civil actions against the birth centers, their owners, founders, or staff (including Plaintiffs and their members).

3. Grant any such further relief as the court deems just and proper.

DATE: ~~August 8, 2023~~January 19, 2024

Respectfully submitted,

/s/ *Robert D. Segall*

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~~*Applications~~*Admitted pro hac vice*
***Application* for admission pro hac vice filed herewith.

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing has been served upon ~~Defendant Scott Harris, on behalf of himself and Defendant Alabama Department of Public Health, by sending the same through U.S. Certified Mail on August 7, 2023, to:~~counsel of record by electronic filing with the Clerk of Court through AlaFile, by e-mail, and/or by placing the same in the U.S. mail on this 19th day of January, 2024.

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~~Scott Harris~~
~~State Health Officer~~
~~Alabama Department of Public Health~~
~~RSA Tower~~
~~201 Monroe Street, Suite 1552~~
~~Montgomery, Alabama 36104~~

~~I hereby certify that, pursuant to Alabama Rule of Civil Procedure 4(c)(7), a copy of the foregoing has been served upon the Attorney General of the State of Alabama by sending the same through U.S. Certified Mail on August 7, 2023, to:~~

~~Steve Marshall~~
~~Attorney General of the State of Alabama~~
~~501 Washington Avenue~~
~~P.O. Box 300152~~
~~Montgomery, Alabama 36104~~

~~Additionally, copies of the foregoing have been served upon the following individuals by email:~~

~~Brian Hale~~
~~Alabama Department of Public Health~~
~~brian.hale@adph.state.al.us~~

~~Dana Billingsley~~
~~Assistant General Counsel~~
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~~General~~/s/ *Robert D. Segall*
Of Counsel

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