

STATE OF NORTH CAROLINA  
COUNTY OF WAKE

IN THE GENERAL COURT OF JUSTICE  
SUPERIOR COURT DIVISION

**PLANNED PARENTHOOD SOUTH ATLANTIC, A WOMAN'S CHOICE OF CHARLOTTE, INC., A WOMAN'S CHOICE OF GREENSBORO, INC., and A WOMAN'S CHOICE OF RALEIGH, INC.**, on behalf of themselves, their physicians and staff, and their patients; **KATHERINE FARRIS, M.D., ANNE LOGAN BASS, F.N.P., SISTERSONG WOMEN OF COLOR REPRODUCTIVE JUSTICE COLLECTIVE**, on behalf of its members; **ELIZABETH DEANS, M.D., and JONAS SWARTZ, M.D.**, on behalf of themselves and their patients,

*Plaintiffs,*

v.

**TIMOTHY K. MOORE**, as Speaker of the North Carolina House of Representatives, in his official capacity; **PHILIP E. BERGER**, as President Pro Tempore of the North Carolina Senate, in his official capacity; **JOSH STEIN**, as Attorney General of North Carolina, in his official capacity; **SATANA DEBERRY**, as District Attorney ("DA") for Prosecutorial District ("PD") 16, in her official capacity; **BENJAMIN R. DAVID**, as DA for PD 6, in his official capacity; **LORRIN FREEMAN**, as DA for PD 10, in her official capacity; **WILLIAM R. WEST**, as DA for PD 14, in his official capacity; **JAMES R. WOODALL**, as DA for PD 18, in his official capacity; **AVERY M. CRUMP**, as DA for PD 24, in her official capacity; **SPENCER B. MERRIWEATHER III**, as DA for PD 26, in his official capacity; **JAMES R. O'NEILL**, as DA for PD 31, in his official capacity; **TODD M. WILLIAMS**, as DA for PD 40, in his official capacity; **MANDY K. COHEN, M.D., M.P.H.**, as Secretary of the North Carolina Department of Health and Human Services, in her official capacity; **BRYANT A. MURPHY, M.D., M.B.A.**, as President of the North Carolina Medical Board, in his official capacity, on behalf of himself, the board, and its members; **MARTHA ANN HARRELL**, as Chair of the North Carolina Board of Nursing, in her official capacity, on behalf of herself, the Board, and its members,

*Defendants.*

## COMPLAINT

(Three-Judge Court Pursuant to  
N.C. Gen. Stat. § 1-267.1)

Plaintiffs Planned Parenthood South Atlantic (“PPSAT”); A Woman’s Choice (“AWC”) of Charlotte, Inc.; AWC of Greensboro, Inc.; AWC of Raleigh Inc. (collectively, the “AWC Clinics”); Katherine Farris, M.D.; Anne Logan Bass, F.N.P.; SisterSong Women of Color Reproductive Justice Collective (“SisterSong”); Elizabeth Deans, M.D.; and Jonas Swartz, M.D. (collectively “Plaintiffs”<sup>1</sup>), by and through their undersigned attorneys, bring this action against the above-named Defendants, their employees, agents, and successors (“Defendants”). In support thereof, Plaintiffs allege the following:

### INTRODUCTORY STATEMENT

1. This action for declaratory and injunctive relief challenges the constitutionality of several North Carolina laws that violate the fundamental rights of North Carolinians, as guaranteed by the North Carolina Constitution.

2. The North Carolina Constitution’s Declaration of Rights grants robust protections to its citizens. In particular, Article I, Section 1 protects North Carolinians’ rights to equality and to “life, liberty, the enjoyment of the fruits of their own labor,” and Article I, Section 19 provides procedural and substantive due process protections.<sup>2</sup>

3. The North Carolina Supreme Court has emphasized that the fundamental principles set forth in Article I’s Declaration of Rights are “broad in scope”<sup>3</sup> and “interpreted as evolving

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<sup>1</sup> In this Complaint, Plaintiffs PPSAT, the AWC Clinics, Farris, Bass, Deans, and Swartz are referred to collectively as the “Plaintiff Providers.”

<sup>2</sup> See, e.g., *Tully v. City of Wilmington*, 370 N.C. 527, 538, 810 S.E.2d 208, 216–17 (2018); *In re Moore's Sterilization*, 289 N.C. 95, 97–98, 221 S.E.2d 307, 309 (1976); *State v. Ballance*, 229 N.C. 764, 769, 51 S.E.2d 731, 734 (1949).

<sup>3</sup> *Ballance*, 229 N.C. at 769, 51 S.E.2d at 734.

responsively to the felt needs of the times.”<sup>4</sup> Indeed, the Court has explained that the North Carolina Constitution is not simply a reflection of the federal constitution, and that the state judiciary has an independent “responsibility to protect the state constitutional rights of the citizens,” which requires “a liberal interpretation in favor of its citizens with respect to those provisions which were designed to safeguard the liberty and security of the citizens in regard to both person and property.”<sup>5</sup>

4. Plaintiffs challenge five laws that burden, restrict, and discriminate against Plaintiffs and their patients or their members in violation of their and their patients’ or members’ constitutional rights.

5. The challenged laws create a web of medically unnecessary restrictions on abortion care that serve no legitimate, let alone compelling, government interest. Instead, these laws impede patients’ abilities to maintain personal bodily autonomy; endanger patients’ and their families’ health and well-being; burden North Carolinians’ fundamental right to decide whether and when to bear a child; single out patients seeking abortion and their health care providers for discriminatory treatment; and restrict the rights of health care providers to pursue their livelihoods.

6. Specifically, Plaintiffs challenge the following abortion restrictions: (1) the **Advanced Practice Clinician (“APC”) Ban**, (2) the **Telemedicine Ban**, (3) the **Targeted Regulation of Abortion Providers (“TRAP”) Scheme**, (4) the **72-Hour Mandatory Delay**, and (5) the **Biased Counseling Requirement** (collectively, the “**Abortion Restrictions**”).

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<sup>4</sup> *Kiser v. Kiser*, 325 N.C. 502, 510, 385 S.E.2d 487, 491 (1989) (citing *State v. Harris*, 216 N.C. 746, 6 S.E.2d 854 (1940)).

<sup>5</sup> *Corum v. Univ. of N.C. Through Bd. of Governors*, 330 N.C. 761, 783, 413 S.E.2d 276, 290 (1992); see also *Meads v. N.C. Dep’t of Agric., Food & Drug Prot. Div.*, 349 N.C. 656, 671, 509 S.E.2d 165, 175 (1998) (noting that North Carolina has “reserved the right to grant Section 19 relief against unreasonable and arbitrary state statutes in circumstances where relief might not be obtainable under the Fourteenth Amendment to the United States Constitution”).

7. The **APC Ban** (N.C. Gen. Stat. § 14-45.1(a), (g)) exempts abortions provided by licensed physicians, but not other qualified advanced clinicians, from North Carolina’s general criminalization of abortion. Providing abortion care in violation of this law is a felony, punishable by imprisonment. Because of these restrictions, APCs do not provide abortion care in North Carolina, regardless of their education, training and experience. Yet, as discussed further below, under North Carolina law, it is within the scope of practice for qualified APCs—who are trained clinical professionals such as Physician Assistants (“PAs”), Certified Nurse-Midwives (“CNMs”), and Nurse Practitioners (“NPs”)—to perform virtually identical procedures as are used for abortion, and to prescribe medications used for abortion, in other contexts. Thus, the **APC Ban** unnecessarily restricts who may provide abortion care without any logical justification, let alone a justification related to patient health or safety. *See infra* ¶¶ 106–40.

8. By preventing qualified APCs from providing abortion care, the **APC Ban** unjustifiably reduces the number of abortion providers throughout North Carolina, which in turn delays and restricts abortion access throughout the State. This violates the constitutional rights of North Carolinians who seek access to abortion, and also violates the constitutional rights of APCs to pursue their livelihoods and to enjoy the fruits of their own labor. *See infra* ¶¶ 141–61.

9. These barriers to care are exacerbated by the **Telemedicine Ban** (N.C. Gen. Stat. § 90-21.82(1)(a)). Telemedicine is routinely used throughout North Carolina and is not categorically banned in any context other than medication abortion. As reaffirmed most recently during the COVID-19 pandemic, telemedicine is a safe, effective, and crucial way for patients to access health care. *See infra* ¶¶ 162–71.

10. By unnecessarily requiring the prescribing clinician to be physically before the patient when the first of the pills necessary for a medication abortion is administered,<sup>6</sup> North Carolina law singles out and prevents abortion providers and patients from utilizing telemedicine, without any health or safety justification for doing so. *See infra* ¶¶ 172–79.

11. By singling out and categorically prohibiting the use of telemedicine in only the context of abortion, the **Telemedicine Ban** arbitrarily violates the constitutional rights of North Carolinians who seek access to abortion and violates the constitutional rights of the Plaintiff Providers to conduct their business and enjoy the fruits of their own labor.

12. These unjustified restrictions on abortion are compounded by North Carolina’s **TRAP Scheme**. *See* N.C. Gen. Stat. § 14-45.1(a). The **TRAP Scheme** unconstitutionally and arbitrarily singles out non-hospital-affiliated abortion providers, such as PPSAT and the AWC Clinics and their staff, subjecting them to onerous and medically unjustified requirements that no other providers of office-based medical care must meet, thus interfering with—and in some cases outright preventing—the provision of abortion services. For example, PPSAT cannot dispense the medications required for a medication abortion at its Greensboro, Raleigh, and Durham health centers because those facilities cannot meet various unnecessary requirements, *see infra* ¶¶ 198–208, including 60-inch wide hallways, elevators that can accommodate a stretcher, and specific ventilation and air supply standards, *see* 10A N.C. Admin. Code 14E.0203–.0204, .0206. But these health centers are permitted to dispense the very same medications required for a medication abortion for miscarriage management—and also perform a variety of medical procedures including

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<sup>6</sup> As explained in further detail below, *see infra* ¶ 75 and note 25, medication abortion typically involves a combination of two pills: mifepristone and misoprostol. The patient takes the mifepristone first and then generally takes the misoprostol 24 to 48 hours after that.

intrauterine device (“IUD”) insertions, Pap tests, and cervical cancer screenings—without needing to meet any such medically unnecessary requirements.

13. Moreover, PPSAT and the AWC Clinics that provide abortion care must continue to comply with the onerous, expensive, and unnecessary requirements regarding the clinics’ physical facilities, operations, recordkeeping, and staffing in order to maintain licensure. If these health centers do not comply, they are subject to harsh penalties, including loss of licensure.

14. Thus, the **TRAP Scheme** discriminates against and limits the availability of abortion care in North Carolina, violating the constitutional rights and compromising the health and safety of patients seeking abortion care and violating the constitutional rights of PPSAT, the AWC Clinics, and their staff to conduct their business and enjoy the fruits of their own labor.

15. Similarly, the **72-Hour Mandatory Delay** (N.C. Gen. Stat. § 90-21.82(1)–(2)) unconstitutionally burdens, stigmatizes, and interferes with the constitutionally protected decision to have an abortion, and inflicts harm on abortion patients.

16. Except in the case of a medical emergency, the **72-Hour Mandatory Delay** requires abortion patients to wait a minimum of 72 hours after receiving state-mandated counseling before they can obtain an abortion.

17. This so-called “waiting period” is one of the most extreme in the country and is premised on the unsupported belief that patients are unable to make a reasoned, informed decision about their own health without state intervention.

18. The relevant evidence shows that, far from benefiting patients, the **72-Hour Mandatory Delay** pushes patients seeking abortion care to obtain that care later in pregnancy. While abortion is extremely safe, delay can increase both the risks and the expenses related to the

procedure. This prevents some patients from accessing their preferred abortion method and others from obtaining an abortion altogether.

19. North Carolina does not categorically subject patients seeking access to any other type of medical care, let alone constitutionally protected care, to such a delay. The **72-Hour Mandatory Delay** violates the constitutional rights and compromises the health and safety of patients seeking abortion care while serving no legitimate, let alone compelling, purpose.

20. Finally, the **Biased Counseling Requirement** (N.C. Gen. Stat. § 90-21.82(1)–(2)) undermines the core principles of informed consent by requiring the same state-scripted counseling for every abortion patient, regardless of circumstance.

21. North Carolina law already requires health care professionals to obtain informed consent prior to undergoing a medical procedure. *See id.* § 90-21.13. However, the one-size-fits-all **Biased Counseling Requirement** singles out abortion for additional requirements that have no parallel in North Carolina law or medical practice.

22. For example, Plaintiff Providers and their staff are forced to tell all patients, including patients with wanted pregnancies who decide to terminate after a diagnosis of a lethal fetal condition, of the existence of social welfare programs that would assist them in raising children who will not survive, *id.* § 90-21.82(2)(a)–(b), and to explain to all patients, including minor patients who have become pregnant as a result of incest, that they can seek “support of the child” from the “father,” *id.* § 90-21.82(2)(c).

23. This law subverts rather than advances informed consent and ultimately harms patients by undermining the clinician-patient relationship and preventing patients from receiving compassionate, patient-centered care. The **Biased Counseling Requirement** thus violates the constitutional rights and compromises the health and safety of patients seeking abortion care.

24. By manufacturing unnecessary delay and imposing artificial limits on the availability and location of abortion providers, the **Abortion Restrictions** not only interfere with North Carolinians’ exercise of guaranteed constitutional protections, but also utilize the power of the state to place unnecessary, expensive, and time-consuming obligations on patients and providers that make abortion care more difficult to obtain; force patients to delay care; require pregnant people to travel significant distances to access care, a serious hardship for many; increase the risks to patients’ lives and health; and prevent some from obtaining abortions altogether.

25. And by forcing some patients to continue a pregnancy after they have already decided to terminate, these laws also force patients to suffer the psychological, financial, logistical, emotional, and dignitary harms of maintaining an unwanted pregnancy. These harms include increased risks to pregnant people of intimate partner violence and other forms of abuse, and heightened risks of some patients using unsafe means to attempt to end their pregnancies without the involvement of a medical provider. *See infra* ¶¶ 85–95.

26. While the impact of these unlawful restrictions is felt by all North Carolinians who seek to exercise their constitutional right to abortion, the impact falls disproportionately on North Carolinians of color—who suffer from higher rates of poverty,<sup>7</sup> higher rates of maternal mortality,<sup>8</sup>

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<sup>7</sup> Brian Kennedy, *North Carolina’s Poverty Rate Remains 15th Highest in the Nation*, N.C. Just. Ctr. (Sept. 30, 2019), <https://www.ncjustice.org/publications/north-carolinas-poverty-rate-remains-15th-highest-in-the-nation/#:~:text=In%202018%2C%2019.7%20percent%2C%20or, North%20Carolina%2C%20lived%20in%20poverty.&text=Last%20year%2C%2021.1%20percent%20of ,Asian%20Americans%20live%20in%20poverty.>

<sup>8</sup> *See* DHHS, *Pregnancy-Related Mortality per 100,000 Live Births for Blacks and Whites, North Carolina Residents 1999-2013*, (May 11, 2016), [https://schs.dph.ncdhhs.gov/data/maternal/Table4\\_MMReport2013.pdf](https://schs.dph.ncdhhs.gov/data/maternal/Table4_MMReport2013.pdf) [hereinafter “DHHS Pregnancy-Related Mortality Report”]; *see also* United Health Found., *Maternal Mortality, America’s Health Rankings*, [https://www.americashealthrankings.org/explore/health-of-women-and-children/measure/maternal\\_mortality\\_a/state/NC](https://www.americashealthrankings.org/explore/health-of-women-and-children/measure/maternal_mortality_a/state/NC). This mirrors national data, which similarly reports wide gaps between Black women (37.3 deaths per 100,000 live births) and white women (14.9 deaths per 100,000 live births). Donna L. Hoyert &



and higher rates of preterm term birth (the largest contributor to infant death)<sup>9</sup> when they choose (or are forced) to carry their pregnancies to term—and on North Carolinians with limited financial means. *See infra* ¶¶ 83–84.

27. In sum, each of these **Abortion Restrictions** violates the rights guaranteed to each citizen in the North Carolina Constitution. Not only are they medically unnecessary, but these laws serve only to prevent North Carolinians from exercising their constitutional right to abortion; discriminate against and stereotype abortion patients and deny them the right to their bodily autonomy; undermine the clinician-patient relationship and discriminate against abortion providers; and impede health care providers’ ability to pursue their livelihoods and enjoy the fruits of their labors.

28. To prevent these medically unjustified and unconstitutional restrictions from inflicting ongoing harm, Plaintiffs ask this Court to declare that the **Abortion Restrictions** are unconstitutional and to permanently enjoin their enforcement.

### **JURISDICTION AND VENUE**

29. This Court has jurisdiction of this action pursuant to Articles 26 and 26A of Chapter 1 of the General Statutes.

30. Under N.C. Gen. Stat. § 1-81.1(a1), the exclusive venue for this action is the Wake County Superior Court.

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Arialdi M. Miniño, *Maternal Mortality in the United States: Changes in Coding, Publication, and Data Release, 2018*, 69 Nat’l Vital Stat. Reps. 1, 5 (2020).

<sup>9</sup> March of Dimes, *2019 Report Card for North Carolina*, <https://www.marchofdimes.org/peristats/tools/reportcard.aspx?reg=37> (last visited Sept. 2, 2020).

31. Under N.C. Gen. Stat. § 1-267.1(a1), a three-judge court must be convened because this action challenges the facial validity of numerous acts of the General Assembly.

## **PARTIES**

### **I. Plaintiffs**

32. Plaintiff **PPSAT** is a not-for-profit corporation organized under the laws of North Carolina, operating nine health centers throughout the state, as well as in South Carolina, Virginia, and West Virginia.<sup>10</sup> Depending on the location, PPSAT health centers provide a broad range of reproductive and sexual health services, including cervical cancer screenings; breast and annual gynecological exams; family planning counseling; pregnancy testing and counseling; reproductive health education; testing and treatment for sexually transmitted infections (“STIs”); contraception; procedural and medication abortion services and related care; prenatal consultation and care; primary care; gender affirming hormone therapy; and health care related to miscarriage. In the 2019 calendar year, PPSAT served 23,488 patients in North Carolina.

33. Currently, only six of PPSAT’s nine North Carolina health centers are able to offer abortion care,<sup>11</sup> and only on limited days per month when physicians are available. But for the **Abortion Restrictions**, PPSAT would expand abortion services to all its North Carolina health centers, offer medication abortion as part of all clinics through telemedicine, offer training to all its qualified staff to provide aspiration abortions, expand the days abortion services are provided, and

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<sup>10</sup> PPSAT’s North Carolina health centers are located in Asheville, Chapel Hill, Charlotte, Durham, Fayetteville, Greensboro, Raleigh, Wilmington, and Winston-Salem.

<sup>11</sup> PPSAT’s Durham, Greensboro, and Raleigh locations do not provide abortions.

see more patients without unnecessary delay, thereby greatly increasing the number of patients served. PPSAT sues on behalf of itself, its staff, and its patients.

34. Plaintiff **Katherine Farris, M.D.**, is a physician licensed to practice medicine in North Carolina, South Carolina, West Virginia, and Virginia, is board-certified in family medicine. Since July 2013, she has been PPSAT's Interim Affiliate Medical Director, then Affiliate Medical Director, then Chief Medical Officer. Dr. Farris provides managerial and supervisory services and a full range of family planning and reproductive health care to her patients, including abortion care, at PPSAT's North Carolina health centers in Winston-Salem, Charlotte, and Asheville (and periodically in Fayetteville, Wilmington, and Chapel Hill), as well as in the other states in which she is licensed. But for the **Telemedicine Ban** and the **TRAP Scheme**, Dr. Farris would immediately provide medication abortion through telemedicine to patients at all the PPSAT health centers. Because of the **72-Hour Mandatory Delay**, Dr. Farris is forced to unnecessarily delay abortion care, which subjects her patients to increased risks and costs. Further, because of the **Biased Counseling Requirement**, Dr. Farris is unable to ensure that her abortion patients receive patient-centered counseling, subjecting some to unnecessary trauma. Dr. Farris challenges all the **Abortion Restrictions** on behalf of herself and her patients.

35. Plaintiff **Anne Logan Bass, F.N.P.**, is PPSAT's Clinical Director of Family Planning and a Family Nurse Practitioner who provides health care at PPSAT health centers in North Carolina, Virginia, and West Virginia. Plaintiff Bass began working at PPSAT in June 2008 and became Clinical Director of Family Planning in September 2019. In addition to her managerial and supervisory duties, Plaintiff Bass provides a full range of reproductive health care to her patients, including patient counseling, diagnosis and treatment of sexually transmitted infections, vulvar and endometrial biopsies, IUD insertion and removal, limited gynecological ultrasounds,

such as for intrauterine contraceptive (“IUC”) localization and gestational age measurements, early pregnancy care, and follow-up care for abortion patients. Based on her training and qualifications, Plaintiff Bass provides medication abortions through telemedicine in Virginia and will be qualified to provide aspiration abortions there in the near future. But for the **Abortion Restrictions**, Plaintiff Bass would immediately be able to provide medication abortion through telemedicine to patients at various PPSAT health centers and, when her training is complete, provide aspiration abortions at various health centers as well. Plaintiff Bass sues on behalf of herself and her patients.

36. Plaintiff **SisterSong** is a nationwide non-profit membership organization, headquartered in Atlanta, Georgia. SisterSong was formed in 1997 by 16 organizations led by and representing Indigenous, Black, Latinx, and Asian American women and transgender people who recognized their right and responsibility to represent themselves in advancing their needs. By asserting the human right to reproductive justice—the ability to maintain personal bodily autonomy, have children, not have children, and parent one’s children in safe and sustainable communities—SisterSong works to build an effective network of individuals and organizations addressing institutional policies, systems, and cultural practices that limit the reproductive lives of marginalized people.

37. SisterSong’s membership in North Carolina includes people of reproductive age whose fundamental constitutional rights and bodily autonomy, along with their health and safety, are threatened by the **Abortion Restrictions**. SisterSong sues on behalf of its members.

38. Plaintiff **Elizabeth Deans, M.D., M.P.H.**, is a physician licensed to practice medicine in the State of North Carolina and is board-certified in obstetrics and gynecology. She currently provides a range of obstetric and gynecological services, including abortion care, in Durham, and provides contraceptive and gynecological care, including abortion care, in Chapel Hill

and Fayetteville. Because of the **72-Hour Mandatory Delay**, Dr. Deans is forced to unnecessarily delay abortion care, which subjects some of her patients to increased risks and costs, and forces some to undergo more invasive procedures. Further, because of the **Biased Counseling Requirement**, Dr. Deans is unable to ensure that her abortion patients receive patient-centered counseling, subjecting some to unnecessary trauma. Dr. Deans brings this action in her individual capacity, and she sues on behalf of herself and her patients.

39. Plaintiff **Jonas Swartz, M.D., M.P.H.** is a physician licensed to practice medicine in the State of North Carolina and is board-certified in obstetrics and gynecology. He currently provides a range of obstetric and gynecological services, including abortion care, in Durham and provides contraceptive and gynecological care, including abortion care, in Chapel Hill and Fayetteville. Because of the **72-Hour Mandatory Delay**, Dr. Swartz is forced to unnecessarily delay abortion care, which subjects some of his patients to increased risks and costs, and forces some to undergo more invasive procedures. Further, because of the mandatory **Biased Counseling Requirement**, Dr. Swartz is unable to ensure his abortion patients receive patient-centered counseling, subjecting some to unnecessary trauma. Dr. Swartz brings this action in his individual capacity, and he sues on behalf of himself and his patients.

40. Plaintiff **AWC of Charlotte, Inc.** is a woman-owned and operated health care facility that provides high-quality reproductive health care in North Carolina, including cervical cancer screening, contraception services and counseling, STI testing and treatment, pregnancy testing and counseling, reproductive health education, care related to miscarriage, and abortion care.

41. Plaintiff **AWC of Greensboro, Inc.** is a woman-owned and operated health care facility that provides high-quality reproductive health care in North Carolina, including cervical

cancer screening, contraception services and counseling, STI testing and treatment, pregnancy testing and counseling, reproductive health education, care related to miscarriage, and abortion care.

42. Plaintiff **AWC of Raleigh, Inc.** is a woman-owned and operated health care facility that provides high-quality reproductive health care in North Carolina, including cervical cancer screening, contraception services and counseling, STI testing and treatment, pregnancy testing and counseling, reproductive health education, care related to miscarriage, and abortion care.

43. Together, AWC of Charlotte, Inc., Greensboro, Inc., and Raleigh, Inc. (collectively, the “AWC Clinics”) served 15,500 patients in calendar year 2019.

44. But for the **Abortion Restrictions**, the AWC Clinics would make their abortion care more accessible by, for instance, seeking qualified APCs to provide abortion care within the scope of their practice and training (now prevented by the **APC Ban**); incorporating telemedicine into their abortion care (now prevented by the **Telemedicine Ban**); ensuring patients receive patient-centered counseling (now prevented by the **Biased Counseling Requirement**); and scheduling care around patients’ schedules rather than the **72-Hour Mandatory Delay**. The AWC Clinics sue on behalf of themselves, their staff, and their patients.

## **II. Defendants**

45. Defendant **Timothy K. Moore** is the Speaker of the North Carolina House of Representatives. Defendant Moore is named in this suit pursuant to North Carolina Rule of Civil Procedure 19(d). Defendant Moore is sued in his official capacity.

46. Defendant **Philip E. Berger** is the President Pro Tempore of the North Carolina Senate. Defendant Berger is named in this suit pursuant to North Carolina Rule of Civil Procedure 19(d). Defendant Berger is sued in his official capacity.

47. Defendant **Josh Stein** is the Attorney General of North Carolina. Defendant Stein is authorized to seek injunctive relief against willful violations of the **Telemedicine Ban** (N.C. Gen. Stat. § 90-21.82(1)(a)) and the **72-Hour Mandatory Delay and Biased Counseling Requirement** (*id.* §§ 90-21.82(1)–(2)). *See id.* § 90-21.88(b). Defendant Stein is sued in his official capacity.

48. Defendant **Satana Deberry** is the District Attorney for Prosecutorial District 16, which includes the city of Durham. Defendant Deberry has the authority to prosecute violations of the **APC Ban** (N.C. Gen. Stat. §§ 14-44, 14-45, 14-45.1(a)) that occur in Prosecutorial District 16 and to prosecute the performance of abortions in a facility that is not certified by the North Carolina Department of Health and Human Services (“DHHS” or “the Department”) under the **TRAP Scheme** (*id.*) in Prosecutorial District 16. *See* N.C. Const. art. IV, § 18(1); N.C. Gen. Stat. §§ 7A-60, 7A-61. Defendant Deberry is sued in her official capacity.

49. Defendant **Benjamin R. David** is the District Attorney for Prosecutorial District 6, which includes the city of Wilmington. Defendant David has the authority to prosecute violations of the **APC Ban** (N.C. Gen. Stat. §§ 14-44, 14-45, 14-45.1(a)) that occur in Prosecutorial District 6 and to prosecute the performance of abortions in a facility that is not certified by DHHS under the **TRAP Scheme** (*id.*) in Prosecutorial District 6. *See* N.C. Const. art. IV, § 18(1); N.C. Gen. Stat. §§ 7A-60, 7A-61. Defendant David is sued in his official capacity.

50. Defendant **Lorrin Freeman** is the District Attorney for Prosecutorial District 10, which includes the city of Raleigh. Defendant Freeman has the authority to prosecute violations of the **APC Ban** (N.C. Gen. Stat. §§ 14-44, 14-45, 14-45.1(a)) that occur in Prosecutorial District 10 and to prosecute the performance of abortions in a facility that is not certified by DHHS under the **TRAP Scheme** (*id.*) in Prosecutorial District 10. *See* N.C. Const. art. IV, § 18(1); N.C. Gen. Stat. §§ 7A-60, 7A-61. Defendant Freeman is sued in her official capacity.

51. Defendant **William R. West** is the District Attorney for Prosecutorial District 14, which includes the city of Fayetteville. Defendant West has the authority to prosecute violations of the **APC Ban** (N.C. Gen. Stat. §§ 14-44, 14-45, 14-45.1(a)) that occur in Prosecutorial District 14 and to prosecute the performance of abortions in a facility that is not certified by DHHS under the **TRAP Scheme** (*id.*) in Prosecutorial District 14. *See* N.C. Const. art. IV, § 18(1); N.C. Gen. Stat. §§ 7A-60, 7A-61. Defendant West is sued in his official capacity.

52. Defendant **James R. Woodall** is the District Attorney for Prosecutorial District 18, which includes the city of Chapel Hill. Defendant Woodall has the authority to prosecute violations of the **APC Ban** (N.C. Gen. Stat. §§ 14-44, 14-45, 14-45.1(a)) that occur in Prosecutorial District 18 and to prosecute the performance of abortions in a facility that is not certified by DHHS under the **TRAP Scheme** (*id.*) in Prosecutorial District 18. *See* N.C. Const. art. IV, § 18(1); N.C. Gen. Stat. §§ 7A-60, 7A-61. Defendant Woodall is sued in his official capacity.

53. Defendant **Avery M. Crump** is the District Attorney for Prosecutorial District 24, which includes the city of Greensboro. Defendant Crump has the authority to prosecute violations of the **APC Ban** (N.C. Gen. Stat. §§ 14-44, 14-45, 14-45.1(a)) that occur in Prosecutorial District 24 and to prosecute the performance of abortions in a facility that is not certified by DHHS under the **TRAP Scheme** (*id.*) in Prosecutorial District 24. *See* N.C. Const. art. IV, § 18(1); N.C. Gen. Stat. §§ 7A-60, 7A-61. Defendant Crump is sued in her official capacity.

54. Defendant **Spencer B. Merriweather III** is the District Attorney for Prosecutorial District 26, which includes the city of Charlotte. Defendant Merriweather has the authority to prosecute violations of the **APC Ban** (N.C. Gen. Stat. §§ 14-44, 14-45, 14-45.1(a)) that occur in Prosecutorial District 26 and to prosecute the performance of abortions in a facility that is not certified by DHHS under the **TRAP Scheme** (*id.*) in Prosecutorial District 26. *See* N.C. Const. art.



IV, § 18(1); N.C. Gen. Stat. §§ 7A-60, 7A-61. Defendant Merriweather is sued in his official capacity.

55. Defendant **James R. O’Neill** is the District Attorney for Prosecutorial District 31, which includes the city of Winston-Salem. Defendant O’Neill has the authority to prosecute violations of the **APC Ban** (N.C. Gen. Stat. §§ 14-44, 14-45, 14-45.1(a)) that occur in Prosecutorial District 31 and to prosecute the performance of abortions in a facility that is not certified by DHHS under the **TRAP Scheme** (*id.*) in Prosecutorial District 31. *See* N.C. Const. art. IV, § 18(1); N.C. Gen. Stat. §§ 7A-60, 7A-61. Defendant O’Neill is sued in his official capacity.

56. Defendant **Todd M. Williams** is the District Attorney for Prosecutorial District 40, which includes the city of Asheville. Defendant Williams has the authority to prosecute violations of the **APC Ban** (N.C. Gen. Stat. §§ 14-44, 14-45, 14-45.1(a)) that occur in Prosecutorial District 40 and to prosecute the performance of abortions in a facility that is not certified by DHHS under the **TRAP Scheme** (*id.*) in Prosecutorial District 40. *See* N.C. Const. art. IV, § 18(1); N.C. Gen. Stat. §§ 7A-60, 7A-61. Defendant Williams is sued in his official capacity.

57. Defendant **Mandy K. Cohen, M.D., M.P.H.** is the Secretary of DHHS. The Department is statutorily charged with the licensure (“certification”) of abortion clinics in North Carolina. N.C. Gen. Stat. § 14-45.1(a1). The Department is also authorized to investigate complaints “relative to the care, treatment, or complications of any patient,” 10A N.C. Admin. Code 14E.0101, *et seq.*, and to “deny, suspend, or revoke a certificate” where the clinic does not comply with the regulations it issues under the **TRAP Scheme**, *id.* 14E.0110; *see also id.* 14E.0101–.0402. Defendant Cohen is sued in her official capacity.

58. Defendant **Bryant A. Murphy, M.D., M.B.A.**, is the President of the North Carolina Medical Board (the “Medical Board”). The Medical Board licenses physicians and PAs,

see N.C. Gen. Stat. §§ 90-9.1, 90-9.3, and, in conjunction with the North Carolina Board of Nursing (the “Nursing Board”), regulates NPs, *see id.* §§ 90-18(c)(14), 90-18.2. The Medical Board has the power to place physicians, PAs, and NPs on probation, impose other sanctions, or suspend or revoke their licenses for a variety of acts or conduct, including “[p]roducing or attempting to produce an abortion contrary to law.” *Id.* §§ 90-14(a)(2), 90-14(h), 90-14.5(c); 21 N.C. Admin. Code 32N.0111(b). Defendant Murphy is sued in his official capacity on behalf of himself, the Medical Board, and its members.

59. Defendant **Martha Ann Harrell** is the Chair of the Nursing Board. The Nursing Board has the power to place nurses on probation, impose other sanctions, or suspend or revoke their licenses for a broad range of activity that the Nursing Board may deem unethical. N.C. Gen. Stat. Ann. § 90-171.37. She is sued in her official capacity on behalf of herself, the Nursing Board, and its members.

## **BACKGROUND**

### **III. Abortion Safety and Methods**

60. Abortion is one of the safest and most common medical services performed or provided in the United States.<sup>12</sup>

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<sup>12</sup> Nat’l Acads. of Scis., Eng’g & Med., *The Safety & Quality of Abortion Care in the United States* 10 (2018) [hereinafter “National Academies Report”].

61. Nationwide, one in five pregnancies ends in abortion.<sup>13</sup> Approximately one out of every four women will have had an abortion by the time she reaches 45 years old.<sup>14</sup>

62. Abortion is significantly safer than carrying a pregnancy to term. The risk of death associated with childbirth is approximately 14 times higher than that associated with first-trimester abortion, and every pregnancy-related complication is more common among people having live births than among those having abortions.<sup>15</sup>

63. Even an uncomplicated pregnancy poses challenges to a person's entire physiology and stresses most major organs.<sup>16</sup> The heart and lungs must work harder during pregnancy,<sup>17</sup> and every organ in the abdomen—including the intestines, liver, and spleen—is increasingly compressed throughout pregnancy by the expanding uterus.<sup>18</sup>

64. Moreover, there is a 15–20% risk of miscarriage in every pregnancy. Complications from miscarriage can lead to infection, hemorrhage, surgery, and even death.

65. Furthermore, one-third of pregnancies result in a caesarean section (“C-section”) delivery. Even though C-section deliveries are relatively common, C-sections are major abdominal surgeries that carry risks of hemorrhage, infection, and injury to internal organs. And even vaginal

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<sup>13</sup> Rachel K. Jones et al., *Abortion Incidence and Service Availability in the United States, 2017*, at 3, Guttmacher Inst. (2019), [https://www.guttmacher.org/sites/default/files/report\\_pdf/abortion-incidence-service-availability-us-2017.pdf](https://www.guttmacher.org/sites/default/files/report_pdf/abortion-incidence-service-availability-us-2017.pdf).

<sup>14</sup> Rachel K. Jones & Jenna Jerman, *Population Group Abortion Rates and Lifetime Incidence of Abortion: United States, 2008–2014*, 107 Am. J. Pub. Health 1904, 1907 (2017).

<sup>15</sup> Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 *Obstetrics & Gynecology* 215, 216 (2012).

<sup>16</sup> See generally Priya Soma-Pillay et al., *Physiological Changes in Pregnancy*, 27 *Cardiovascular J. Afr.* 89 (2016).

<sup>17</sup> See *id.* at 89–91.

<sup>18</sup> *Id.* at 92.

deliveries can lead to injury, such as pelvic floor damage, organ and muscle prolapse, vaginal tearing and scarring, and incontinence.

66. Even an uncomplicated pregnancy can suddenly become life-threatening during labor and delivery, when 20% of the pregnant person's blood flow is diverted to the uterus, placing a pregnant person at risk of hemorrhage and, in turn, death; indeed, hemorrhage is the leading cause of maternal mortality worldwide. To try to protect against hemorrhage, the body again produces more clotting factors, which increases the risk of blood clots or embolisms. This heightened risk extends past delivery into the postpartum period.

67. By contrast, complications from abortion are extremely rare, and when they occur, they are usually managed in an outpatient setting, either during the same visit as the abortion or in a follow-up visit.

68. Major complications—defined as complications requiring hospital admission, surgery, or blood transfusion—occur in less than one-quarter of one percent (0.23%) of all abortions.<sup>19</sup> Abortion-related emergency room visits constitute just 0.01% of all emergency room visits among women aged 15–49 in the United States.<sup>20</sup>

69. The risk of complications from an abortion in the first trimester of pregnancy—when the overwhelming majority of abortions occur—is even lower.<sup>21</sup>

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<sup>19</sup> Ushma Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 *Obstetrics & Gynecology* 175 (2015).

<sup>20</sup> Ushma Upadhyay et al., *Abortion-Related Emergency Room Visits in the United States: An Analysis of a National Emergency Room Sample*, 16 *BMC Med.* 1, 1 (2018).

<sup>21</sup> *Id.*

70. There is no difference in complication rates between first-trimester abortions provided by APCs and first-trimester abortions provided by physicians.<sup>22</sup>

71. People terminate pregnancies for a variety of deeply personal and often interconnected reasons. Some people have abortions because they conclude that it is not the right time in their lives to have a child or to add to their families; some do because they cannot afford to do so; some have abortions to preserve their life or health; some because they receive a fetal diagnosis; some because they have become pregnant as a result of rape or incest; and others because they are in an unstable or abusive relationship.<sup>23</sup>

72. Nationwide, approximately 60% of abortion patients already have at least one child, and most also plan to have children in the future—for many, when they are older, financially able to provide for them, and/or in a supportive relationship with a partner.<sup>24</sup>

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<sup>22</sup> Susan Yanow, *It Is Time to Integrate Abortion Into Primary Care*, 103 Am. J. Pub. Health 14, 15 (2013); Mary Anne Freedman et al., *Comparison of Complication Rates in First Trimester Abortions Performed by Physician Assistants and Physicians*, 76 Am. J. Pub. Health 550, 551 (1986); Marlene B. Goldman et al., *Physician Assistants as Providers of Surgically Induced Abortion Services*, 94 Am. J. Pub. Health 1352, 1355–56 (2004).

<sup>23</sup> See, e.g., M. Antonia Biggs et al., *Understanding Why Women Seek Abortions in the US*, 13 BMC Women's Health 29 (2013) [hereinafter “Biggs 2013”]; Sarah C.M. Roberts et al., *Alcohol, Tobacco and Drug Use as Reasons for Abortion*, 47 Alcohol & Alcoholism 640 (2012); Karuna S. Chibber et al., *The Role of Intimate Partners in Women's Reasons for Seeking Abortion*, 24 Women's Health Issues e131 (2014).

<sup>24</sup> Guttmacher Inst., *Induced Abortions in the United States* (2018), [https://www.guttmacher.org/sites/default/files/factsheet/fb\\_induced\\_abortion.pdf](https://www.guttmacher.org/sites/default/files/factsheet/fb_induced_abortion.pdf); see also Jenna Jerman et al., Guttmacher Inst., *Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2008*, at 6–7 (2016), [https://www.guttmacher.org/sites/default/files/report\\_pdf/characteristics-us-abortion-patients-2014.pdf](https://www.guttmacher.org/sites/default/files/report_pdf/characteristics-us-abortion-patients-2014.pdf); Biggs 2013, *supra* note 23.

73. Most people seeking an abortion in the United States are already certain of their decision when they first call the clinic to schedule an appointment,<sup>25</sup> and the evidence shows those who obtain abortions do not regret their decision years after the fact.<sup>26</sup>

74. There are two main methods of abortion: medication abortion and procedural abortion. Both methods are safe and effective.<sup>27</sup>

75. Medication abortion typically involves a combination of two pills: mifepristone and misoprostol.<sup>28</sup> Pursuant to North Carolina law, the prescribing physician must be physically present when the first medication (mifepristone) used for a medication abortion is administered. N.C. Gen. Stat. § 90-21.82(1)(a). The patient then typically takes the misoprostol 24 to 48 hours later at a location of their choosing, which causes them to expel the contents of the uterus in a manner similar to a miscarriage.

76. The minimal risks associated with medication abortion—infection and bleeding—do not typically arise until after the patient has begun to pass the pregnancy, which is one to two days after the patient has left the clinic. Accordingly, there is no reason for the patient to take the medication in the presence of a clinician.

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<sup>25</sup> See, e.g., Lauren J. Ralph et al., *Measuring Decisional Certainty Among Women Seeking Abortion*, 95 *Contraception* 269, 276 (2017); Sarah C.M. Roberts et al., *Do 72-Hour Waiting Periods and Two-Visit Requirements for Abortion Affect Women's Certainty? A Prospective Cohort Study*, 27 *Women's Health Issues* 400, 404 (2017).

<sup>26</sup> See, e.g., Corinne H. Rocca et al., *Decision Rightness and Emotional Responses to Abortion in the United States: A Longitudinal Study*, 10 *PLOS ONE* e0218832, e0218841 (2015); Corinne H. Rocca et al., *Women's Emotions One Week After Receiving or Being Denied an Abortion in the United States*, 45 *Persp. Sexual & Reprod. Health* 122, 127–28 (2013); Brenda Major, *Psychological Responses of Women After First-Trimester Abortion*, 57 *Archives Gen. Psychiatry* 777, 781 (2000).

<sup>27</sup> Luu Doan Ireland et al., *Medical Compared With Surgical Abortion for Effective Pregnancy Termination in the First Trimester*, 126 *Obstetrics & Gynecology* 22, 25 (2015); National Academies Report, *supra* note 12, at 10.

<sup>28</sup> National Academies Report, *supra* note 12, at 51.

77. When not restricted by state law, providers commonly permit the patient to take the mifepristone at a location of their choosing, consistent with American College of Obstetricians and Gynecologists (“ACOG”) and U.S. Food and Drug Administration (“FDA”) guidelines.

78. Medication abortion is available in North Carolina up to 77 days or 11 weeks of pregnancy, as measured from the first day of a patient’s last menstrual period (“LMP”).

79. Up to approximately 14 to 15 weeks LMP, procedural abortions typically involve the use of gentle suction to empty the contents of the uterus. This procedure, which is also referred to as an aspiration abortion, is the same procedure that is used to treat miscarriage. Aspiration abortion typically takes between five to ten minutes to complete. It can be done in a medical office under a local anesthetic—and indeed aspiration in cases of miscarriages are routinely done in medical offices.<sup>29</sup>

80. Starting around 14 to 15 weeks LMP, procedural abortions are generally performed using a method called dilation and evacuation (“D&E”), in which clinicians dilate the cervix and use a combination of suction and instruments to empty the uterus. Depending on the patient and method of cervical dilation, D&E can be performed as a one or two-day procedure. D&E abortions are routinely and safely provided in outpatient, office-based settings. D&E generally involves no more than moderate sedation, though clinicians use different levels of sedation depending on the setting and patient preference.

81. While sometimes referred to as “surgical” abortions, aspiration and D&E abortions are not what is commonly understood to be “surgery.” For example, they involve no incision, do

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<sup>29</sup> Courtney A. Schreiber et al., *Treatment Decisions at the Time of Miscarriage Diagnosis*, 128 *Obstetrics & Gynecology* 1347, 1347 (2016).

not require general anesthesia, and do not require a sterile field because the vagina naturally contains bacteria.

#### IV. The Impacts of Delay on Abortion Care

82. Patients generally seek abortion care as soon as they are able. Some patients, however, face logistical obstacles that can delay access to abortion care. Patients facing long travel distances typically must arrange and pay for transportation and arrange to take time off work. Many patients must also arrange and pay for childcare while they travel to their abortion appointment. For low-wage workers, who often have no paid time off or sick leave, these burdens are particularly acute: even if they are able to get time off work for an abortion appointment, they will likely have to forgo part of a paycheck.<sup>30</sup>

83. These barriers routinely delay abortion access for patients, particularly for the 75% of abortion patients nationwide who have limited financial means or struggle to make ends meet.<sup>31</sup> Indeed, 65–75% of the AWC Clinics' patients qualify for funding to help with the cost of an abortion.

84. A disproportionate percentage of the 1.4 million North Carolinians living in poverty are people of color.<sup>32</sup> Twenty-one percent of Black North Carolinians live below the official poverty

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<sup>30</sup> Jerman et al., *supra* note 24, at 6–7; Sarah E. Baum et al., *Women's Experience Obtaining Abortion Care in Texas After Implementation of Restrictive Abortion Laws: A Qualitative Study*, 11 PLOS ONE 1, 7–8, 11 (2016); Lawrence B. Finer et al., *Timing of Steps and Reasons for Delays in Obtaining Abortions in the United States*, 74 *Contraception* 334, 335 (2006).

<sup>31</sup> Guttmacher Inst., *supra* note 24.

<sup>32</sup> Kennedy, *supra* note 7.



line compared with 9.8% of white, 24.8% of Latinx, 20.1% of Native American, and 12.8% of Asian American North Carolinians.<sup>33</sup>

85. Delay inflicts physical, psychological, and financial harms on abortion patients.

86. Although abortion is extremely safe throughout pregnancy and significantly safer than continuing pregnancy through childbirth, delaying abortion care unnecessarily increases medical risk. A patient whose care is delayed—i.e., who must remain pregnant longer—will suffer both increased risks associated with remaining pregnant<sup>34</sup> and comparatively increased risks associated with the abortion procedure.

87. Delay also poses acute risks to the physical safety of people experiencing intimate partner violence. Intimate partner violence can manifest in sexual violence and reproductive control—with partners prohibiting their pregnant partners from obtaining an abortion, or threatening violence if they do.

88. As a result of the unnecessary delay, some patients are prevented from obtaining a medication abortion because they are pushed past the gestational age limit, or from obtaining an abortion altogether.

89. Medication abortion may be medically indicated for certain pregnant people (e.g., people with certain uterine anomalies), and strongly preferred by others (e.g., sexual assault survivors for whom the insertion of instruments into the vagina may cause emotional and psychological trauma,<sup>35</sup> or minors who have never had a pelvic exam). And for some pregnant

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<sup>33</sup> *Id.*

<sup>34</sup> Raymond & Grimes, *supra* note 15, at 216 (the mortality rate associated with term pregnancy in the United States is approximately 14 times higher than that associated with abortion).

<sup>35</sup> See, e.g., Katarina Swahnberg et al., *Strong Discomfort During Vaginal Examination: Why Consider a History of Abuse?*, 157 Eur. J. Obstetrics & Gynecology & Reprod. Biology 200 (2011); Shana L. Maier,

people in abusive relationships, a medication abortion, which results in what looks identical to a miscarriage, is essential to protecting themselves from violence and retaliation for their decision to have an abortion.

90. Delaying abortion also increases costs because the cost of the abortion procedure increases as the pregnancy advances. As a result, patients who are delayed in obtaining care as they save money for the procedure may find that even more money is needed for the delayed, more expensive procedure, necessitating *even more* delay.

91. Securing funding for abortion care is already made difficult by a web of federal and state laws. For example, federal law bars the use of Medicaid and Medicare funds for most abortions.<sup>36</sup> State law imposes a similar restriction on the use of state Medicaid and Medicare funds. N.C. Gen. Stat. §§ 143C-6-5.5, 135-48.50. State law also prohibits private insurance plans offered on the North Carolina health insurance exchange from including coverage for abortion services except in the case of rape, incest, or life of the mother. *Id.* § 58-51-63.

92. Many people experience substantial difficulty obtaining money to pay for their abortion. This problem is more common as the pregnancy progresses, in part because the procedures become more expensive.<sup>37</sup>

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*“I Have Heard Horrible Stories . . .”*: Rape Victim Advocates’ Perceptions of the Revictimization of Rape Victims by the Police and Medical System, 14 Violence Against Women 786, 790 (2008).

<sup>36</sup> Consolidated Appropriations Act, 2019, Pub L. No. 116-6, §§ 202–203, 133 Stat. 13, 117 (2019).

<sup>37</sup> See Jessica W. Kiley et al., *Delays in Request for Pregnancy Termination: Comparison of Patients in the First and Second Trimesters*, 81 Contraception 446–51 (2010); Finer et al., *supra* note 30, at 334.

93. Thus, delay sends patients—particularly the majority of abortion patients who have limited financial means—into a vicious cycle.<sup>38</sup>

94. For some, the obstacles imposed and compounded by delay will prevent them from obtaining an abortion altogether. Being forced to remain pregnant after making the decision to have an abortion has a negative impact on a person’s mental and emotional well-being,<sup>39</sup> and the inability to receive care has been shown to lead to sustained increase in financial distress for years following the unobtained abortion.<sup>40</sup> When patients are denied an abortion, they are less likely to make or achieve aspirational life plans, like getting a better job or finishing school,<sup>41</sup> and are also more likely to live in poverty than patients who were able to receive an abortion.<sup>42</sup>

95. To avoid forced pregnancy and childbirth, some patients may use unsafe means to attempt to end their pregnancies without the involvement of a medical provider. Others may travel to states with later gestational age limits, entailing more expense and, during the COVID-19 pandemic, more risk. Still others may be forced to carry their pregnancies to term, resulting in a deprivation of their fundamental right to determine when and whether to have a child or to add to

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<sup>38</sup> Rachel K. Jones & Jenna Jerman, *Time to Appointment and Delays in Accessing Care Among U.S. Abortion Patients*, Guttmacher Inst. (Aug. 2016), [https://www.guttmacher.org/sites/default/files/report\\_pdf/delays-in-accessing-care.pdf](https://www.guttmacher.org/sites/default/files/report_pdf/delays-in-accessing-care.pdf).

<sup>39</sup> M. Antonia Biggs et al., *Women’s Mental Health and Well-Being 5 Years After Receiving or Being Denied an Abortion: A Prospective, Longitudinal Cohort Study*, 74 JAMA Psychiatry 169 (2017); M. Antonia Biggs et al., *Perceived Abortion Stigma and Psychological Well-Being Over Five Years After Receiving or Being Denied an Abortion*, 15 PLOS ONE (2020); M. Antonia Biggs et al., *Five-Year Suicidal Ideation Trajectories Among Women Receiving or Being Denied an Abortion*, 175 Am. J. Psychiatry 845 (2018).

<sup>40</sup> Diana G. Foster et al., *Socioeconomic Outcomes of Women Who Receive and Women Who Are Denied Wanted Abortions in the United States*, 108 Am. J. Pub. Health 407, 412 (2018).

<sup>41</sup> Ushma D. Upadhyay et al., *The Effect of Abortion on Having and Achieving Aspirational One-Year Plans*, 15 BMC Women’s Health 102, 108–09 (2015) [hereinafter “Upadhyay 2015”].

<sup>42</sup> Foster et al., *supra* note 40, at 410; *see also* Upadhyay 2015, *supra* note 41, at 108–09.

their existing families. As discussed below, forced pregnancy and childbirth will have a disproportionate impact on Black North Carolinians.

96. ACOG and other well-respected medical professional organizations have affirmed that abortion “is an essential component of comprehensive health care” and “a time-sensitive service for which a delay of several weeks, or in some cases days, may increase the risks [to patients] or potentially make it completely inaccessible.”<sup>43</sup>

97. As shown below, the **Abortion Restrictions**, far from enhancing patient health and safety, threaten patient health and well-being by creating and compounding delays in access to care, increasing all of the above-enumerated risks to abortion patients.

## V. Abortion in North Carolina

98. In 2018, 23,018 abortions were provided to North Carolina residents, amounting to 11.3 abortions per 1,000 North Carolina women aged 15 to 44.<sup>44</sup>

99. The vast majority of abortions occur in the first trimester. In North Carolina, 85.9% of abortions in 2018 occurred before 12 weeks.<sup>45</sup>

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<sup>43</sup> ACOG et al., *Joint Statement on Abortion Access During the COVID-19 Outbreak* (Mar. 18, 2020), <https://www.acog.org/news/news-releases/2020/03/joint-statement-on-abortion-access-during-the-covid-19-outbreak>.

<sup>44</sup> DHHS, *2018 NC Resident Abortion Rates: Females Ages 15-44 by Race/Ethnicity, Perinatal Care Regions, and County of Residence* (2018), <https://schs.dph.ncdhhs.gov/data/vital/pregnancies/2018/abort1544.pdf> [hereinafter “DHHS 2018 Abortion Rates Report”]. Nationally, the abortion rate was 13.5 abortions per 1,000 women aged 15 to 44 in 2017 (or 862,320 total abortions). Guttmacher Inst., *supra* note 24.

<sup>45</sup> DHHS, *NC Resident Abortions: Characteristics of Women Receiving Abortions* (2018), <https://schs.dph.ncdhhs.gov/data/vital/pregnancies/2018/abortioncharacteristics.pdf>. National data is similar; in 2016, 65.4% of abortions in the United States occurred before eight weeks, and 88.3% before 12 weeks. Guttmacher Inst., *supra* note 24.

100. In 2018, 45.3% of abortions were provided to Black North Carolinians, at a rate of 20.8 abortions per 1,000 Black reproductive age women; 32.2% of abortions were provided to white North Carolinians, at a rate of 6.2; 12.2% of abortions were provided to Hispanic North Carolina residents, at a rate of 12.5; and 1.1% of abortions were provided to Native American North Carolina residents, at a rate of 9.7.<sup>46</sup>

101. In North Carolina, the maternal mortality rate for Black women (37.3 deaths per 100,000 live births) is three times as high as the rate for white women (12.3 deaths per 100,000 live births).<sup>47</sup>

102. Similarly, in North Carolina, the preterm birth rate among Black women is 48% higher than the rate among all other women.<sup>48</sup>

103. PPSAT's abortion patients travel, on average, about 81 miles round trip for their abortion appointments, excluding out-of-state patients. Similarly, the AWC Clinics' patients travel from across North Carolina to access abortion care, from Wilmington, Asheville, and Fayetteville, among other places. Over half of the AWC Clinics' patients travel over an hour one way to the AWC Clinics, and a quarter of the AWC Clinics' patients travel over two hours one way to access care.

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<sup>46</sup> DHHS 2018 Abortion Rates Report, *supra* note 44. Nationally, in 2016, 46.7% of abortions were provided to white patients, at a rate of 6.2 abortions per 1000 white reproductive age women, and 42% of abortions were provided to Black patients., at a rate of 23.6 abortions per 1000 Black reproductive-age women. Tara C. Jatlaoui et al., *Abortion Surveillance — United States, 2016*, 68 Morbidity Mortality Weekly Rep. Surveillance Summaries (2019), <https://www.cdc.gov/mmwr/volumes/68/ss/pdfs/ss6811a1-H.pdf>.

<sup>47</sup> See DHHS Pregnancy-Related Mortality Report, *supra* note 8; see also United Health Found., *supra* note 8. This mirrors national data, which similarly reports wide gaps between Black women (37.3 deaths per 100,000 live births) and white women (14.9 deaths per 100,000 live births). Hoyert & Miniño, *supra* note 8.

<sup>48</sup> March of Dimes, *supra* note 9.

104. For patients who lack access to a car, public transportation would take significantly longer and may often be impossible. In North Carolina, 5.9% of households lack access to a car.<sup>49</sup>

105. These travel burdens are particularly acute for the approximately 60,000 North Carolinians who live on islands off the coast of the state. For example, a resident of Hatteras would have to drive more than 110 miles round trip to obtain an abortion at the nearest health center in Virginia Beach (and may also have to take a ferry).

## STATUTORY FRAMEWORK AND CHALLENGED PROVISIONS

### I. APC Ban

#### A. *Advanced Practice Clinicians' Scope of Practice in North Carolina*

106. APCs, including Plaintiff Bass, are highly qualified clinicians who, based on advanced education and training, have a broad scope of practice including extensive prescriptive authority and the ability to perform a range of complex medical procedures.

107. North Carolina strictly regulates APCs, a category that includes NPs, CNMs, and PAs, and delegates broad authority to them through the Medical Board and Board of Nursing.

108. Despite their qualifications, North Carolina law prevents APCs from prescribing a medication abortion or performing an aspiration abortion, even though their scope of practice includes nearly identical functions in other contexts, including miscarriage care. Indeed, abortion is the *only* context in which APCs are statutorily prevented from providing care that is otherwise

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<sup>49</sup> U.S. Census Bureau, *2014-2018 American Community Survey 5-Year Estimates: Selected Housing Characteristics*, <https://data.census.gov/cedsci/table?q=North%20Carolina%20Housing&tid=ACSDP5Y2018.DP04&hidePreview=false> (last visited Sept. 2, 2020).

within their scope of practice under the Medical Board and Board of Nursing, consistent with their training and experience.

109. For example, it is within APCs' scope of practice to prescribe and oversee the utilization of medications such as misoprostol and/or mifepristone for miscarriage management and cervical ripening for IUD insertion. There is no logical reason to prevent APCs from prescribing and overseeing these same medications for a medication abortion.

110. It is also within APCs' scope of practice to provide miscarriage management through uterine aspiration, a procedure identical to aspiration abortion.<sup>50</sup> There is no logical reason to prevent APCs from performing the same procedure for purposes of abortion, consistent with their training and experience.

111. The **APC Ban** has no medical justification and serves only to restrict access to abortion, harming people in need of abortion care in North Carolina, and violating North Carolinians' constitutional rights.

### **1. Nurse Practitioners**

112. The Board of Nursing and the Medical Board jointly oversee NPs through regulations that require that an NP have a valid license as a registered nurse ("RN"), be certified by a national credentialing body, hold a master's or higher degree in nursing, and have completed a graduate-level NP education program.<sup>51</sup>

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<sup>50</sup> While APCs' scope of practice includes miscarriage care, Plaintiff PPSAT's APCs have not been trained to perform this procedure because of how infrequently the procedure arises in their practice.

<sup>51</sup> 21 N.C. Admin. Code 36.0803; 21 N.C. Admin. Code 32M.0103.

113. NPs have a broad scope of practice by virtue of their advanced education and training. Under North Carolina regulations, NPs' scope of practice includes performing medical procedures and prescribing controlled substances, appropriate to their training and experience.<sup>52</sup>

114. By virtue of their skill and competency, North Carolina authorizes NPs to practice independently, so long as they have entered into a collaborative practice agreement with a primary supervising physician. The primary or back-up supervising physician must be "continuously available" to the NP "for consultation by direct communication or telecommunication,"<sup>53</sup> but this does not require the physician's physical presence.

115. NPs are authorized by law to independently prescribe controlled substances, so long as the supervising physician has provided written instructions and a policy for periodic review.<sup>54</sup> NPs are also "authorized to order medications, tests and treatments in hospitals, clinics, nursing homes and other health facilities" without prior consultation with the supervising physician, so long as these medications, tests, and treatments are within the scope of the existing collaborative practice agreement.<sup>55</sup>

116. For example, it is within NPs' scope of practice in North Carolina, consistent with their training and experience, to perform endometrial biopsy, which involves inserting a sterile tube through a patient's cervix into the uterus and suctioning a small piece of tissue from the uterine lining.

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<sup>52</sup> 21 N.C. Admin. Code 36.0801; 21 N.C. Admin. Code 32M.0101 ("Such medical acts are in addition to those nursing acts performed by virtue of registered nurse (RN) licensure.").

<sup>53</sup> 21 N.C. Admin. Code 36.0810; 21 N.C. Admin. Code 32M.0110.

<sup>54</sup> N.C. Gen. Stat. § 90-18.2.

<sup>55</sup> *Id.*



117. Similarly, it is within NPs' scope of practice in North Carolina, consistent with their training and experience, to perform colposcopies—the use of instruments to magnify the cervix and, when appropriate, to remove tissue for biopsy.

118. It is also within NPs' scope of practice in North Carolina, consistent with their training and experience, to perform loop electrosurgical excision procedures (“LEEPs”) to remove abnormal cells by using a thin wire loop that acts like a scalpel. An electric current is passed through the loop, which cuts away a thin layer of the cervix.

119. It is similarly within NPs' scope of practice in North Carolina, consistent with their training and experience, to insert and remove IUDs and contraceptive implants, which are both long-acting reversible contraceptive devices.

120. For each of these procedures, it is within NPs' scope of practice in North Carolina, consistent with their training and experience, to provide lidocaine cervical blocks, a type of local analgesic (painkiller).

121. If a patient is experiencing a miscarriage, it is within NPs' scope of practice in North Carolina, consistent with their training and experience, to use aspiration to complete the miscarriage by fully evacuating the uterus (which reduces bleeding as well as the risk of infection and other complications).

## **2. Certified Nurse-Midwives**

122. Midwifery is defined in North Carolina as “the act of providing prenatal, intrapartum, postpartum, newborn and interconceptional care.”<sup>56</sup> Like NPs, CNMs are jointly regulated by the Board of Nursing and Medical Board.<sup>57</sup>

123. In order to practice, CNMs must “have an unencumbered registered nurse license and midwifery license or approval to practice in all jurisdictions in which a license/approval to practice is or has ever been held.”<sup>58</sup> CNMs must also be certified by the American College of Nurse-Midwives.<sup>59</sup>

124. By virtue of their skill and competency, North Carolina authorizes CNMs to practice independently, so long as they have in place “mutually agreed upon written clinical practice guidelines” with a supervising physician that define the CNM’s responsibilities and the scope of the CNM’s clinical practice.<sup>60</sup> Like NPs, this does not require the physician’s physical presence.<sup>61</sup>

125. North Carolina statutes expressly permit CNMs to prescribe medications; attend patients in uncomplicated labor; and perform procedures associated with childbirth, i.e. amniotomy, episiotomy and repair, and repair of lacerations.<sup>62</sup>

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<sup>56</sup> N.C. Gen. Stat. § 90-178.2(3).

<sup>57</sup> *Id.* § 90-178.4.

<sup>58</sup> 21 N.C. Admin. Code 33.0103.

<sup>59</sup> N.C. Gen. Stat. § 90-178.5; 21 N.C. Admin. Code 33.0103.

<sup>60</sup> 21 N.C. Admin. Code 33.0104; *see* N.C. Gen. Stat. § 90-178.5.

<sup>61</sup> 21 N.C. Admin. Code 33.0104; *see* N.C. Gen. Stat. § 90-178.5.

<sup>62</sup> N.C. Gen. Stat. §§ 90-178.2, 90-178.3(b).

126. Like NPs, it is within CNMs' scope of practice in North Carolina, consistent with their training and experience, to insert and remove IUDs; insert and remove contraceptive implants; and perform vaginal, cervical, or endometrial biopsy; LEEPs; and colposcopies.

### 3. Physician Assistants

127. PAs are also APCs. PAs are regulated by the Medical Board, must be licensed, must complete an accredited Physician Assistant Education Program (most, if not all, of which are master's programs), and must complete 100 hours of continuing medical education every two years.<sup>63</sup>

128. PAs are permitted to perform "those medical acts, tasks or functions, including prescribing and dispensing of drugs and medical devices, that are delegated by the supervising physician in his or her individualized supervisory arrangement."<sup>64</sup>

129. By virtue of their skill and competency, North Carolina authorizes PAs to practice independently, so long as they practice under a "supervising physician." Like NPs and CNMs, this does not require the physician's physical presence.<sup>65</sup>

130. Like NPs and CNMs, it is within PAs' scope of practice in North Carolina, consistent with their training and experience, to insert and remove IUDs; insert and remove contraceptive implants; and perform vaginal, cervical, or endometrial biopsy; LEEPs; and colposcopies.

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<sup>63</sup> 21 N.C. Admin. Code 32S.0202.

<sup>64</sup> N.C. Med. Bd., *Resources & Information, Physician Assistant*, [https://www.ncmedboard.org/resources-information/faqs/physician\\_assistant](https://www.ncmedboard.org/resources-information/faqs/physician_assistant) (last visited Sept. 2, 2020); *see* 21 N.C. Admin. Code 32S.0212.

<sup>65</sup> N.C. Med. Bd., *supra* note 64; 21 N.C. Admin. Code 32S.0213(b).

**B. *The APC Ban Unjustifiably Prevents APCs from Providing Abortion Care***

131. PPSAT’s North Carolina health centers are currently staffed with NPs, CNMs, and PAs.

132. PPSAT’s APCs, including Plaintiff Bass, perform procedures—including contraceptive implants, IUD insertion, difficult IUD removal, and endometrial biopsies—that are comparable to aspiration abortion in both complexity and risk.

133. PPSAT’s APCs, including Plaintiff Bass, are highly qualified and trained clinicians who, but for the **APC Ban**, would be trained to provide safe medication and early aspiration abortion care through the appropriate collaborative practice and supervisory arrangements with physicians.

134. But for the **APC Ban**, PPSAT would hire additional trained APCs to provide this care and further expand services.

135. But for the **APC Ban**, the AWC Clinics would also hire trained APCs to provide this care.

136. Prohibiting qualified APCs from providing aspiration or medication abortion care is not medically justified; APCs are capable of providing aspiration and medication abortion care safely and effectively.<sup>66</sup> The National Academies of Sciences, Engineering, and Medicine concluded in their 2018 consensus report that “[b]oth trained physicians . . . and APCs (physician assistants, certified nurse-midwives, and nurse practitioners) can provide medication and aspiration

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<sup>66</sup> See, e.g., Yanow, *supra* note 22, at 15; Tracy A. Weitz et al., *Safety of Aspiration Abortion Performed by Nurse Practitioners, Certified Nurse Midwives, and Physician Assistants Under a California Legal Waiver*, 103 Am. J. Pub. Health 454, 458–59 (2013); Freedman et al., *supra* note 22, at 553; Goldman et al., *supra* note 22, at 1355–56.

abortion care in the United States.”<sup>67</sup>

137. Leading medical authorities, including ACOG,<sup>68</sup> the American Public Health Association (“APHA”),<sup>69</sup> and the World Health Organization (“WHO”),<sup>70</sup> have concluded that laws prohibiting qualified APCs from providing these services are without medical foundation, and that these restrictions represent a barrier to accessing safe abortion care.<sup>71</sup>

138. Indeed, the FDA, which has regulatory authority over the medications that comprise a medication abortion, has recognized that there is no medical need for physician-only restrictions on medication abortion. In 2016, the FDA amended the label for Mifeprex to clarify that, based on published research, non-physician health care providers could safely prescribe and dispense the drug.<sup>72</sup>

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<sup>67</sup> National Academies Report, *supra* note 12, at 14.

<sup>68</sup> ACOG, *Committee Opinion No. 613: Increasing Access to Abortion* (Nov. 2014; reaff’d 2017), <https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2014/11/increasing-access-to-abortion.pdf>.

<sup>69</sup> APHA, *Policy Statement No. 20112: Provision of Abortion Care by Advanced Practice Nurses and Physician Assistants* (Nov. 1, 2011), <https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2014/07/28/16/00/provision-of-abortion-care-by-advanced-practice-nurses-and-physician-assistants>.

<sup>70</sup> WHO, *Health Worker Roles in Providing Safe Abortion Care and Post-Abortion Contraception* (2015), [https://apps.who.int/iris/bitstream/handle/10665/181041/9789241549264\\_eng.pdf](https://apps.who.int/iris/bitstream/handle/10665/181041/9789241549264_eng.pdf).

<sup>71</sup> See also Inst. of Med. of the Nat’l Acad. of Scis., Eng’g & Med., *The Future of Nursing: Leading Change, Advancing Health* 9 (2011), <https://www.nap.edu/read/12956/chapter/1>; Nat’l Governors Ass’n, *The Role of Nurse Practitioners in Meeting Increasing Demand for Primary Care* 11 (2012), <https://www.nga.org/wp-content/uploads/2019/08/1212NursePractitionersPaper.pdf>; Fed. Trade Comm’n, *Policy Perspectives: Competition and the Regulation of Advanced Practice Nurses* 3–4 (2014), <https://www.ftc.gov/system/files/documents/reports/policy-perspectives-competition-regulation-advanced-practice-nurses/140307aprnpolicypaper.pdf>.

<sup>72</sup> FDA, Ctr. for Drug Evaluation & Res., *Application Number: 020687Orig1s020 Medical Review(s) 7* (Mar. 29, 2016), [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2016/020687Orig1s020MedR.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf) [hereinafter “FDA Mifeprex Review”].

139. Numerous states allow APCs to provide abortion care, including California, Colorado, Illinois, Maine, Montana, New Hampshire, New York, Oregon, Vermont, Virginia, Washington (aspiration and medication abortion), Connecticut, Hawaii, Maryland, New Jersey, Rhode Island and the District of Columbia (medication abortion).<sup>73</sup>

140. Accordingly, there is neither a medical justification for nor a demonstrable health benefit to prohibiting APCs' providing medication and aspiration abortion care. As explained below, by unjustifiably limiting the pool of available abortion providers in North Carolina, the **APC Ban** significantly restricts access to abortion care, thereby jeopardizing patient health and safety and imposing significant financial and logistical burdens on clinics and patients.

**C. *The APC Ban Unjustifiably Reduces the Pool of Available Providers, Limits the Locations Around the State Where Abortion Can Be Provided, and Harms Patients***

141. There is a nationwide shortage of abortion-providing physicians, and North Carolina is no exception.

142. In particular, it is generally very difficult to recruit physicians to work in rural locations—a challenge not unique to abortion services. New doctors, for a variety of reasons including but not limited to skyrocketing levels of student-loan debt, increasingly decline to practice in rural areas. These challenges are exacerbated by qualified physicians choosing not to include

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<sup>73</sup> Cal. Bus. & Prof. Code §§ 2253, 2725.4, 3502.4; S.B. 25, 101st Gen. Assemb. (Ill. 2019); Me. Rev. Stat. Ann. tit. 22, § 1598; *Armstrong v. State of Montana*, 989 P.2d 364 (Mont. 1999); *Weems v. State by & through Fox*, 440 P.3d 4 (Mont. 2019); N.Y. Pub. Health Law § 2599-bb; Vt. Op. Att'y Gen. No. 2005-1, 2005 WL 6083035 (Mar. 14, 2005); Letter from Harry Chen, Comm'r, Vt. Dep't of Health, to Fred Upton, Chairman, U.S. House of Representatives Comm. on Energy & Com. (June 12, 2013), [https://checkmyclinic.org/wp-content/uploads/2019/05/Vermont\\_Department\\_of\\_Health\\_1.pdf](https://checkmyclinic.org/wp-content/uploads/2019/05/Vermont_Department_of_Health_1.pdf); Conn. Op. Att'y Gen. No. 2001-015, 2001 WL 790037 (July 2, 2001); Md. Op. Att'y Gen. No. 105 OAG 003, 2020 WL 3100082 (Jan. 10, 2020); 216 R.I. Code R. § 20-10-6.3; Kaiser Fam. Found., *The Availability and Use of Medication Abortion* (June 8, 2020), <https://www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion/>.

abortion care in their practices due to the harassment and stigma associated with being an abortion provider.

143. Throughout North Carolina, APCs and other non-physician clinicians, working in person and through telemedicine, increasingly fill gaps in rural health care produced by these physician shortages.

144. Currently, PPSAT has only two staff physicians to serve its nine North Carolina locations, and both must divide their time between clinical and administrative responsibilities. PPSAT tries to make up for this shortage by using part-time contract physicians.

145. For example, PPSAT is able to provide abortion care at its Asheville and Wilmington health centers only four times per month, and at its Fayetteville, Winston-Salem, and Charlotte health centers only eight days per month.

146. By contrast, PPSAT employs 20 APCs licensed in North Carolina.

147. The AWC Clinics have also experienced difficulty locating and hiring physicians to provide abortion care. Some of the AWC Clinics' physicians also provide care elsewhere, and ensuring coverage is challenging, particularly during the ongoing pandemic.

148. But for the **APC Ban**, PPSAT and the AWC Clinics could expand the pool of qualified professionals able to provide abortion care in North Carolina to include APCs. This would mean North Carolinians would have a much larger pool of providers and locations available from which to obtain abortion care, reducing burdens like wait times and distances they would have to travel to obtain abortion care. For example, PPSAT could perform significantly more abortion procedures on more days of the month at more locations, i.e., it could offer medication abortion services at its Asheville, Chapel Hill, Charlotte, Fayetteville, Wilmington, and Winston-Salem health centers every day those health centers are open, which includes evening and weekend hours.

Currently, those health centers each provide medication abortion only on the limited days that procedural abortions are offered due to scheduling constraints.

149. Moreover, but for the **APC Ban**, as well as the **TRAP Scheme**, as set forth below, PPSAT would start providing medication abortion at its three health centers in Greensboro, Durham, and Raleigh, which currently do not offer any abortion services at all.

150. The medically unnecessary delays caused by the **APC Ban** harm patients' health and push some patients past the gestational age limit for medication abortion and/or past the limits to which their closest clinic provides care.

151. For example, PPSAT patients experience delays averaging as many as 25 days from the day they request an appointment to the appointment day (using the industry standard of "third next available" appointment<sup>74</sup>), depending on which health center they visit and which method of abortion they prefer.

152. In Wilmington, a patient must wait an average of 25 days for an appointment for either a medication or procedural abortion. In Asheville, the wait is 19 days for a medication abortion and 12 days for a procedural abortion. In Charlotte, a patient must wait on average 11 days

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<sup>74</sup> According to the Institute for Healthcare Improvement, "third next available" appointment refers to:

Average length of time in days between the day a patient makes a request for an appointment with a physician and the third available appointment for a new patient physical, routine exam, or return visit exam. The "third next available" appointment is used rather than the "next available" appointment since it is a more sensitive reflection of true appointment availability. For example, an appointment may be open at the time of a request because of a cancellation or other unexpected event. Using the "third next available" appointment eliminates these chance occurrences from the measure of availability.

Inst. for Healthcare Improvement, *Third Next Available Appointment*, <http://www.ihl.org/resources/Pages/Measures/ThirdNextAvailableAppointment.aspx> (last visited Sept. 2, 2020).



for a medication abortion or for a procedural abortion at 14–14.6 weeks LMP (and 4 days for procedural abortion at 0–13.6 weeks LMP).

153. Based on these wait times, a patient in Wilmington who finds out they are pregnant at 10.6 weeks LMP and calls PPSAT’s Wilmington health center the next day to schedule a procedural abortion will have to wait 25 days, on average, before they can get their appointment. This is because there are only two abortion providers who service that location, and only on two days a month. But because the Wilmington health center provides abortion to only 13.6 weeks LMP, this patient will be unable to get an abortion in Wilmington due to the appointment delay and the gestational age of the pregnancy. Instead, they will have to travel to a health center that provides abortions beyond 13.6 LMP, such as Chapel Hill, 157 miles away.<sup>75</sup> Indeed, from May 1, 2020 through August 20, 2020, the average distance traveled by an in-state patient seeking an abortion in Chapel Hill at 15 weeks LMP or later was 205 miles round trip. Depending on timing, the patient may also have to undergo a two-day rather than a one-day procedure because of the delay.

154. Similarly, if a patient in Asheville finds out they are pregnant at 8.6 weeks LMP and wants a medication abortion, even if they call PPSAT’s Asheville health center the next day to schedule an appointment, they will not be able to obtain the medication abortion in Asheville. That health center’s 19-day average wait will push them past the 11-week gestational age limit for medication abortion. Instead, to obtain a medication abortion, they will have to travel to a farther-away health center with shorter wait times for appointments. For some patients closer to the 11-week limit, these wait times may prevent them from obtaining a medication abortion altogether.

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<sup>75</sup> PPSAT’s health centers currently provide abortions up to 13.6 weeks LMP in Asheville, Fayetteville, Wilmington, and Winston-Salem; 14.0 weeks LMP in Charlotte; and 21.6 weeks in Chapel Hill, requiring patients to travel farther for care (if they can) and, in some cases, preventing them from accessing an abortion altogether. *See supra* ¶¶ 82–96; *infra* ¶ 154.

155. If APCs in PPSAT's Wilmington and Asheville health centers provided medication and aspiration abortion, these health centers could provide patients abortion services every day they are open and these extreme delays would be significantly reduced, if not eliminated.

156. Even those of PPSAT's patients who are not precluded from obtaining medication abortion or forced to travel farther for care experience unjustified delays with wait times as long as 25 days. *See supra* ¶¶ 151–53.

157. As noted above, seven physicians typically provide abortion care across the three AWC Clinics. However, two of these physicians travel from out of state, and one travels within North Carolina to provide care at all three of the AWC clinics. Scheduling is always challenging and is particularly so during the ongoing pandemic. But for the **APC Ban**, the AWC Clinics would hire APCs with the proper training to provide abortion care. Additional capacity would allow for greater flexibility and coverage at the AWC Clinics, including when one of their physicians is ill or otherwise unavailable.

158. Adding capacity through APCs would substantially reduce delay for PPSAT's and the AWC Clinics' patients by allowing the clinics to offer additional appointments and more flexible and timely scheduling. By allowing more patients to obtain care closer to home, this additional capacity would greatly reduce burdens on patients.

159. In sum, the **APC Ban** unjustifiably reduces the pool of available providers and limits the locations around the state where abortion can be provided.

160. On its own and in combination with the other **Abortion Restrictions**, the **APC Ban** interferes with North Carolinians' fundamental constitutional right to abortion. It subjects abortion patients to unnecessary delays that increase risks to their health, add to the financial and logistical burdens of obtaining an abortion, and prevent some patients from obtaining an abortion altogether.

161. Moreover, the **APC Ban** unjustifiably interferes with the rights of PPSAT and the AWC Clinics and highly qualified clinicians, such as Plaintiff Bass, to conduct their business, pursue their profession, and enjoy the fruits of their labors.

## **II. Telemedicine Ban**

### ***A. Telemedicine Is a Safe, Effective Way of Delivering Health Care***

162. Telemedicine involves a medical professional in one location using video conferencing or web-based or other electronic communication tools to provide medical care to a patient in a different location.

163. Telemedicine facilitates access to health care for patients. By enabling clinicians to meet patients' time-sensitive medical needs remotely, telemedicine also prevents delays in care that would lead to worse health outcomes and/or necessitate more intensive treatment down the road.

164. North Carolina has recognized the need for and demonstrated a commitment to expanding telemedicine access across the state.

165. For instance, telemedicine has been firmly promoted by North Carolina Governor Roy Cooper, among others, as a way to “use technology to help people lead healthier lives.”<sup>76</sup>

166. In fact, in a 2017 report, DHHS recommended “that North Carolina adopt an aggressive statewide telemedicine policy that will improve health for all people by increasing access to high quality care,” and concluded that a “robust telemedicine infrastructure could provide significant benefits to the State,” including “[s]upport of individuals in their homes and communities rather than traveling long distances, improving work attendance, avoiding loss of

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<sup>76</sup> N.C. Dep't of Info. Tech., *NC DIT, DHHS Win Grant to Help Expand Telehealth Opportunities for Western NC* (Feb. 22, 2019), <https://it.nc.gov/news/press-releases/2019/02/22/nc-dit-dhhs-win-grant-help-expand-telehealth-opportunities-western-nc>.

income due to childcare and lost time at work, and transportation costs”; and “[i]ncreased engagement of rural providers with their colleagues thus improving quality care for their patients and decreasing provider isolation and improving retention in the communities that need services the most.”<sup>77</sup>

167. Likewise, in 2019, the Medical Board affirmed its position that telemedicine “can provide important benefits to patients, including: increased access to health care, expanded utilization of specialty expertise, rapid availability of patient records, and the potential of reduced healthcare costs, increased efficiency, and improved overall healthcare outcomes.”<sup>78</sup>

168. The same year, the Appalachian Regional Commission (“ARC”), which includes North Carolina and 12 other states, issued a \$98,273 grant to DHHS’s Office of Rural Health and the Department of Information Technology’s Broadband Infrastructure Office to “conduct a 12-month study of opportunities, challenges and gaps for broadband and health care infrastructure in the ARC region in hopes of providing the telehealth infrastructure it needs.”<sup>79</sup>

169. The COVID-19 pandemic has affirmed the utility and success of telemedicine as a way to facilitate access to care, especially during a public health crisis when public health experts counsel avoidance of unnecessary in-person contact. In response to the pandemic, Governor Cooper

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<sup>77</sup> DHHS, *Report on Telemedicine Study and Recommendations: SL 2017-133, Section 2*, at 2, 9 (Oct. 1, 2017), [https://d3n8a8pro7vhmx.cloudfront.net/fiscalhealthnc/pages/1443/attachments/original/1507145896/SL\\_2017-133\\_Section\\_2\\_DHHS\\_Study\\_and\\_Recommend\\_a\\_Telemedicine\\_Policy\\_10-2-17\\_%28002%29.pdf?1507145896](https://d3n8a8pro7vhmx.cloudfront.net/fiscalhealthnc/pages/1443/attachments/original/1507145896/SL_2017-133_Section_2_DHHS_Study_and_Recommend_a_Telemedicine_Policy_10-2-17_%28002%29.pdf?1507145896); *see also* N.C. Dep’t of Info. Tech., *supra* note 76 (“Health happens outside the four walls of a hospital or a doctor’s office, and health care providers in North Carolina need greater access to use telemedicine to treat their patients. . . . Increasing access to care for North Carolinians will help them live healthier, more productive lives.”).

<sup>78</sup> N.C. Med. Bd., *Position Statement: Telemedicine* (adopted 2010; amended 2019), <https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/telemedicine>.

<sup>79</sup> N.C. Dep’t of Info. Tech., *supra* note 76.

has lifted restrictions on the use of telemedicine and has encouraged health care providers to move to remote care.<sup>80</sup>

170. Despite the extensive evidence confirming both telemedicine’s safety and its important role in facilitating access to health care, particularly for rural and medically underserved populations, North Carolina has categorically banned telemedicine exclusively in the context of abortion care.

171. North Carolina law singles out and prevents abortion providers and patients from utilizing telemedicine for medication abortion by unnecessarily requiring the prescribing clinician (which due to the **APC Ban** must be a physician) to be physically present when the first pill used in a medication abortion is “administered”—i.e., to watch the patient swallow it. N.C. Gen. Stat. § 90-21.82(1)(a).

**B. *Medication Abortion Through Telemedicine Is a Safe and Accepted Practice***

172. There is no medical basis for requiring a patient to whom a medication abortion has been prescribed to be in the physical presence of the prescriber when they are handed the medications or when they swallow the first pill.

173. Indeed, the FDA has determined that patients may safely take the first pill—mifepristone—without clinical supervision at a location of their choosing,<sup>81</sup> and has long authorized the same chemical compound used in mifepristone (when used for a different purpose) to be

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<sup>80</sup> N.C. Exec. Order No. 130 (Apr. 8, 2020), <https://files.nc.gov/governor/documents/files/EO130-Meeting-North-Carolinas-Health-and-Human-Services-Needs.pdf>; *see also* N.C. Exec. Order No. 143 (June 4, 2020), <https://files.nc.gov/governor/documents/files/EO143-Addressing-the-Disproportionate-Impact-of-COVID-19-on-Communities-of-Color.pdf> (“[A]ccess to telehealth services is essential to North Carolina’s fight against COVID-19.”).

<sup>81</sup> *See* FDA Mifeprex Review, *supra* note 72, at 62.

distributed directly to the patient for at-home, self-administration in far greater quantities than it is used for medication abortion.<sup>82</sup>

174. Without the **Telemedicine Ban**, patient access to medication abortion could be expanded because (1) the prescribing clinician and patient could communicate through web-based or other electronic communication tools, such as video conferencing, rather than having to be in the same physical location; and (2) the patient may take the first medication at home if they so desire.

175. Guidelines and practices for providing medication abortion via telemedicine have been successfully developed and deployed in the United States since at least 2008.<sup>83</sup>

176. Medication abortion via telemedicine is just as safe and effective as when the health care provider is located in the same health center as the patient,<sup>84</sup> and it serves to improve access to early abortion.<sup>85</sup>

177. According to ACOG's standard of care for medication abortion, providers should confirm the pregnancy, estimate the gestational age, and assess whether the patient is displaying any symptoms or has any risk factors for an ectopic pregnancy. Providers need only obtain

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<sup>82</sup> See *id.* at 10; FDA, Ctr. for Drug Evaluation & Res., *Application Number: 202107Orig1s000, Risk Assessment and Risk Mitigation Review(s)* 7 (Jan. 27, 2012), [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2012/202107Orig1s000RiskR.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202107Orig1s000RiskR.pdf).

<sup>83</sup> Daniel Grossman et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine*, 118 *Obstetrics & Gynecology* 296, 297 (2011).

<sup>84</sup> See, e.g., National Academies Report, *supra* note 12, at 57–58, 79; Julia Kohn et al., *Medication Abortion Provided Through Telemedicine in Four U.S. States*, 134 *Obstetrics & Gynecology* 343 (2019); Daniel Grossman & Kate Grindlay, *Safety of Medical Abortion Provided Through Telemedicine Compared with In Person*, 130 *Obstetrics & Gynecology* 778 (2017); Daniel Grossman et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine*, 118 *Obstetrics & Gynecology* 296 (2011); Kate Grindlay et al., *Women's and Providers' Experiences with Medical Abortion Provided Through Telemedicine: A Qualitative Study*, 23 *Women's Health Issues* e117 (2013).

<sup>85</sup> See, e.g., National Academies Report, *supra* note 12, at 58; ACOG & Soc'y of Fam. Plan., *Practice Bulletin No. 225: Medication Abortion Up to 70 Days of Gestation*, 136 *Obstetrics & Gynecology* 1, 5 (2020).

bloodwork from a patient or perform a clinical or ultrasound examination in certain circumstances.<sup>86</sup> All of this information is usually gathered by a non-physician clinician or other qualified staff member and can be accessed by the prescribing clinician by reviewing a patient's records remotely.<sup>87</sup> Telemedicine is also consistent with the protocol outlined on the FDA-approved label for Mifeprex, including for follow-up visits.<sup>88</sup>

178. Moreover, the effects of mifepristone, the first pill in a medication abortion, do not begin until hours after ingestion, and most pregnant people will expel the pregnancy within two to 24 hours of taking the *second pill*, misoprostol (i.e., typically 24 to 48 hours after taking the mifepristone). Therefore, regardless of where patients take the mifepristone, they will not be with their prescriber by the time they experience the medication's effects. As such, requiring the administration of the first pill to take place in person has no bearing on whether a patient will experience one of the "exceedingly rare" complications of medication abortion,<sup>89</sup> nor on how such a complication would be managed.

179. Plaintiffs Farris and Bass both regularly perform medication abortion via telehealth for Virginia PPSAT patients.

**C. *The Telemedicine Ban Restricts Access to Constitutionally Protected Abortion Care***

180. The **Telemedicine Ban** does not promote but rather demonstrably harms patient health.

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<sup>86</sup> ACOG & Soc'y of Fam. Plan., *supra* note 85, at 3.

<sup>87</sup> *Id.* at 4.

<sup>88</sup> FDA Mifeprex Review, *supra* note 72, at 6.

<sup>89</sup> *Id.* at 47.

181. By preventing PPSAT and the AWC Clinics and their staff from implementing a telemedicine program for medication abortion, the **Telemedicine Ban** prevents PPSAT and the AWC Clinics and their staff from expanding access to care by offering appointments on days when a prescribing clinician is not physically present at the clinic or health center.

182. As discussed *supra* ¶¶ 144–45, PPSAT’s health centers that currently provide medication abortions can only do so on limited days per month because of physician availability.

183. As a result, *see supra* ¶¶ 150–56, patients experience unnecessary delays in accessing abortion care, pushing some patients past the point at which they can even access a medication abortion.

184. But for the **Telemedicine Ban**, PPSAT and the AWC Clinics and their staff could, for example, use telemedicine to provide medication abortion to patients at the location that works best for the patient, regardless of whether the prescribing clinician is physically present at that location. This would expand access and reduce delays and travel burdens for patients, who could visit their local health center instead of the health center where the physician has availability. For example, a patient in Wilmington (where abortion is provided only four times per month) could go to their local PPSAT health center for a medication abortion instead of traveling to Fayetteville to see a prescribing clinician with an available appointment, because they could connect by videoconference to another center with an available prescribing clinician.

185. This would, in turn, reduce costs due to transportation and/or lodging expenses, time away from work or school, and childcare, and alleviate the burdens that fall disproportionately on patients who have limited financial means and/or need to keep their health care decisions confidential.



186. Incorporating telemedicine would also allow for more flexibility with scheduling and staffing for PPSAT and the AWC Clinics, thus increasing access and reducing burdens for patients.

187. Moreover, but for the **Telemedicine Ban**, PPSAT and the AWC Clinics and their staff could expand their practices to see more patients earlier in pregnancy, thereby reducing other harms related to delay.

188. Plaintiff Farris has direct experience providing medication abortion using telemedicine. Planned Parenthood affiliates have launched numerous such programs including in nearby states and could readily expand the program into North Carolina but for the **Telemedicine Ban**.

189. Moreover, if the **TRAP Scheme** discussed *infra* was enjoined as unconstitutional, PPSAT could use telemedicine to provide medication abortion at three more health centers—in Greensboro, Raleigh, and Durham—thus further increasing access and reducing burdens and harmful, unnecessary delays throughout the state.

190. On its own and in combination with the remaining **Abortion Restrictions**, the **Telemedicine Ban** interferes with North Carolinians’ fundamental constitutional rights. It subjects abortion patients to unnecessary delays that increase risks to their health and adds to the financial and logistical burdens of obtaining an abortion.

191. The **Telemedicine Ban** also violates the constitutional rights of health care providers such as Plaintiffs to conduct their business and enjoy the fruits of their labors.

### **III. TRAP Scheme**

192. In addition to the **APC Ban** and **Telemedicine Ban**, the **TRAP Scheme** (N.C. Gen. Stat. § 14-45.1(a)) unconstitutionally and arbitrarily singles out non-hospital-affiliated abortion

providers, such as PPSAT and the AWC Clinics, and subjects them to a thicket of extensive and bureaucratic rules and regulations that are onerous and medically unnecessary.<sup>90</sup>

193. This arbitrary regulation of facilities where abortions are provided is without medical basis and at odds with statements from professional standard-setting bodies, including the American Medical Association and ACOG.<sup>91</sup>

194. Abortion care is safely provided on an outpatient basis, with extremely low complication rates.<sup>92</sup> In fact, unlike many other procedures provided on an outpatient basis, procedural abortion does not involve incision and does not need to be performed in a sterile field. And, as described above, a medication abortion is not a procedure at all; the patient need not take any medications at the clinic, and even if they take the first medication at the clinic, the effects are not felt until two to 24 hours after the *second* pill is taken.

195. The doctors, nurses, and medical professionals who provide or assist in the provision of abortion care are already subject to North Carolina's generally applicable professional licensure, health, and tort laws and regulations. For instance, the Medical Board has the power to place physicians and PAs on probation, impose other sanctions, or suspend or revoke their licenses for a variety of acts or conduct. N.C. Gen. Stat. § 90-14. The Nursing Board has the power to place nurses on probation, impose other sanctions, or suspend or revoke their licenses for a broad range of activity that the Nursing Board may deem unethical. *Id.* § 90-171.37. The **TRAP Scheme** limits

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<sup>90</sup> See, e.g., N.C. Gen. Stat. § 14-45.1(a); 10A N.C. Admin. Code 14E.0101–.0402.

<sup>91</sup> Brief of Amici Curiae American College of Obstetricians and Gynecologists, American Medical Association, et al. in Support of June Medical Services, L.L.C., et al. at 20, *June Med. Servs. LLC v. Russo*, 140 S.Ct. 2103 (2020) (Nos. 18-1323, 18-1460); ACOG, *New Guidelines for Facilities Performing Office-Based Procedures Including Abortion* (Jan. 24, 2019), <https://www.acog.org/news/news-releases/2019/01/new-guidelines-for-facilities-performing-office-based-procedures-including-abortion>.

<sup>92</sup> See, e.g., Jones et al., *supra* note 13, at 16 (finding that over 96% of abortions are provided in outpatient settings); *supra* ¶¶ 67–69 and notes 19–20.

the ability of PPSAT and the AWC Clinics and their staffs to provide safe and affordable abortion care, and unjustifiably prevents PPSAT and its staff from providing *any* medication or procedural abortions at its Greensboro, Raleigh, and Durham locations.

196. In North Carolina, non-abortion procedures performed in the office-based setting (*i.e.*, one that is not an ambulatory surgical center (“ASC”) or other specialized facility)<sup>93</sup> include invasive procedures and include procedures where general anesthesia is used. Such procedures are more invasive than abortion and have higher complication rates than abortion, including liposuction (5% complication rate); breast augmentation (10.6% complication rate for most common complication<sup>94</sup>); abdominoplasty (10–20% complication rate<sup>95</sup>); gluteal fat grafting (mortality rate of one in 3,000,<sup>96</sup> compared to 0.58 in 100,000 for abortion<sup>97</sup>). All of these procedures are currently performed in office-based, non-ASC facilities in North Carolina.

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<sup>93</sup> Such settings include dialysis facilities, cancer treatment facilities, and plastic surgery practices.

<sup>94</sup> Hannah Headon et al., *Capsular Contracture after Breast Augmentation: An Update for Clinical Practice*, 42 *Archives Plastic Surgery* 532 (2015).

<sup>95</sup> Pedro Vidal et al., *Abdominoplasty: Risk Factors, Complication Rates, and Safety of Combined Procedures*, 44 *Archives Plastic Surgery* 457 (2017).

<sup>96</sup> Am. Soc’y of Plastic Surgeons, *Plastic Surgery Societies Issue Urgent Warning About the Risks Associated with Brazilian Butt Lifts* (Aug. 6, 2018), <https://www.plasticsurgery.org/news/press-releases/plastic-surgery-societies-issue-urgent-warning-about-the-risks-associated-with-brazilian-butt-lifts>.

<sup>97</sup> Jatlaoui et al., *supra* note 46, at 11.

197. The Medical Board sets guidelines for such office-based procedures, which they differentiate into Level I,<sup>98</sup> II,<sup>99</sup> and III<sup>100</sup> procedures based on, for example, the type of sedation used and risk of complications for a particular procedure.

198. By contrast, the **TRAP Scheme** mandates that any facility that provides abortions (even solely medication abortions) must comply with myriad restrictions completely unrelated to health or safety.

199. For example, a clinic that provides *any* procedural or medication abortions and has more than one floor must have at least one elevator that can accommodate a stretcher, 10A N.C. Admin. Code 14E.0203, even though stretchers are not used in abortion care and the rate of serious complications that would require a stretcher is “far below 0.1%.”<sup>101</sup> Likewise, patient-use corridors in any facility that provides abortions must be no less than 60 inches wide, again to facilitate stretcher use, 10A N.C. Admin. Code 14E.0204, and the minimum width of doors to all rooms needing access for stretchers must be three feet, 10A N.C. Admin. Code 14E.0205.

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<sup>98</sup> Level I office-based procedures are defined as “any surgical or special procedures” that (1) “do not involve drug-induced alteration of consciousness”; (2) “where preoperative medications are not required or used other than minimal preoperative tranquilization of the patient (anxiolysis of the patient)”; (3) “where the anesthesia required or used is local, topical, digital block, or none”; and (4) “where the probability of complications requiring hospitalization is remote.” N.C. Med. Bd., *Position Statements: Office-Based Procedures* (last amended May 2011), [https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/office-based\\_procedures](https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/office-based_procedures) [hereinafter “Medical Board Guidelines for Office-Based Procedures”].

<sup>99</sup> Level II office-based procedures are defined as “any surgical or special procedures” that (1) “require the administration of local or peripheral nerve block, minor conduction blockade, Bier block, minimal sedation, or conscious sedation”; and (2) “where there is only a moderate risk of surgical and/or anesthetic complications and the need for hospitalization as a result of these complications is unlikely.” *Id.*

<sup>100</sup> Level III office-based procedures are defined as “any surgical or special procedures” that (1) “require, or reasonably should require, the use of major conduction blockade, deep sedation/analgesia, or general anesthesia”; and (2) have “only a moderate risk of surgical and/or anesthetic complications and the need for hospitalization as a result of these complications is unlikely.” *Id.*

<sup>101</sup> FDA Mifeprex Review, *supra* note 72, at 47.

200. In striking down a Texas state law that imposed similarly onerous restrictions on facilities that provide abortions, the United States Supreme Court observed that “abortions taking place in an abortion facility are safe—indeed, safer than numerous procedures that take place outside hospitals” and yet are not subject to similar facility requirements. *Whole Woman’s Health v. Hellerstedt*, 136 S.Ct. 2292, 2315 (2016).

201. PPSAT’s Raleigh, Greensboro, and Durham health centers are unable to meet these physical requirements,<sup>102</sup> as they would require near-total renovation of the three health centers, and therefore these centers do not provide any abortions; they cannot even dispense the pills that comprise a medication abortion.

202. There is no medical reason or justification for requiring facilities that provide medication abortion, which do not even occur in the facility, or procedural abortions, which have lower complication rates than comparable office-based procedures,<sup>103</sup> to accommodate stretchers while other medical offices do not face the same requirement.

203. The **TRAP Scheme** also imposes strict ventilation and air supply requirements. *See* 10A N.C. Admin. Code 14E.0206. PPSAT’s Raleigh, Greensboro, and Durham health centers are likewise unable to comply with these requirements and thus, as above, cannot even dispense the medications that comprise a medication abortion, as they would necessitate expensive renovations.

204. Specifically, the ventilation and air supply requirements are targeted at ensuring a sterile field for surgeries, which is unnecessary for the provision of abortion care. While Plaintiff Providers of course sterilize equipment and maintain clean environments, the sterile field required

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<sup>102</sup> The Durham health center is a single-floor facility, so the elevator requirement does not apply to it.

<sup>103</sup> *See, e.g.*, National Academies Report, *supra* note 12, at 74–75 (“Abortion-related mortality is also lower than that for colonoscopies (2.9 per 100,000), plastic surgery (0.8 to 1.7 per 100,000), dental procedures (0.0 to 1.7 per 100,000), and adult tonsillectomies (2.9 to 6.3 per 100,000).”).

for surgery is unnecessary for a procedural abortion as it does not entail an incision into the body, but rather insertion of instruments into a body cavity through a natural orifice. And medication abortion, as explained above, merely consists of handing the patient pills.

205. Further, unlike any other provider of office-based medical procedures, the **TRAP Scheme** requires non-hospital-affiliated facilities that provide abortions to have a multitude of separate, specially designated spaces—including a receiving area, examining room, preoperative preparation and holding room, procedure room, recovery room, clean workroom, soiled workroom, a space with patient lockers, and “nourishment station with storage and preparation area for serving meals or in-between meal snacks.” 10A N.C. Admin. Code 14E.0207.

206. While PPSAT’s Raleigh, Durham, and Greensboro health centers have receiving areas and exam rooms, they do not have a separate preoperative preparation and holding room, procedure room, recovery room, clean workroom, or soiled workroom—nor is there any medical reason why these would need to all be separate spaces. These three health centers also do not have patient lockers or “nourishment station[s],” neither of which are necessary to provide procedural or medication abortion care.

207. Indeed, because PPSAT’s Winston-Salem and Wilmington health centers predate the **TRAP Scheme**, they are exempt from its requirements. PPSAT safely provides medication and procedural abortions up to 14.6 LMP in these health centers with extremely low complication rates on par with those of its health centers that comply with the **TRAP Scheme**. If they were bound by the **TRAP Scheme**, they would be unable to provide abortions because, for example, neither has an elevator as required, their hallways are too narrow, and the bathrooms used by staff do not have the water supply spout at least five inches from the rim of the fixture as required. Wilmington’s doors are 35.5 inches wide, while the **TRAP Scheme** requires doors to be 36 inches wide.

208. These onerous and unnecessary facility requirements also complicate the process of moving to a new location. Securing a new location is already difficult because of the stigma associated with providing abortion care. The facility requirements compound this difficulty because a clinic moving to a new location would have to ensure that that location meets these physical requirements, even though they are not medically necessary.

209. Additionally, because of the **TRAP Scheme**, health care facilities that provide abortions must have a licensed RN supervise and organize nursing staff, and there must be at least one licensed RN with experience in post-operative or post-partum care on duty at all times that patients are in the clinic. 10A N.C. Admin. Code 14E.0307. A health facility that provides abortion care is not exempt from this requirement even if one or more clinicians of comparable or even *higher-level* training (e.g. a physician or an APC) are present. This means that regardless of who else is available, if there is no RN on duty, or if the RN has to leave suddenly, patients cannot have an abortion. This blanket RN requirement serves no medical purpose, and it limits the ability of PPSAT and the AWC Clinics to provide care. Indeed, it completely prevents PPSAT's Greensboro, Raleigh, and Durham health centers from being able to provide abortion, as none of these facilities has an RN on staff, while they do have APCs.

210. But for the **TRAP Scheme**, patients could access medication and procedural abortion in PPSAT's Greensboro, Raleigh and Durham health centers instead of having to go elsewhere.

211. The multitude of onerous and unnecessary **TRAP Scheme** requirements are set forth in a chart, attached as an Appendix. By way of illustration, they are compared against the guidelines issued by the Medical Board as to Level I, II, and III office-based procedures.

212. The chart provides a stark illustration of just some examples of the unnecessary and burdensome requirements that North Carolina imposes on abortion facilities through its **TRAP Scheme**.

#### **IV. 72-Hour Mandatory Delay and Biased Counseling Requirement**

213. Finally, the **72-Hour Mandatory Delay and Biased Counseling Requirement** work in tandem with the other abortion restrictions to further burden, discriminate against, and endanger the health of abortion patients.

214. The **72-Hour Mandatory Delay and Biased Counseling Requirement** dictate that, except in a medical emergency, an abortion cannot be provided until at least 72 hours *after* the patient receives certain state-mandated information. N.C. Gen. Stat. § 90-21.82.

215. The medical emergency exception is narrowly defined as “[a] condition which, in reasonable medical judgment, so complicates the medical condition of the pregnant woman as to necessitate the immediate abortion of her pregnancy to avert her death or for which a delay will create serious risk of substantial and irreversible physical impairment of a major bodily function, not including any psychological or emotional conditions.” *Id.* § 90-21.81(5).

216. The state-mandated information must be provided orally by a physician or “qualified professional,”<sup>104</sup> and includes the following:

- That medical assistance benefits “may be available” for prenatal care, childbirth, and neonatal care;

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<sup>104</sup> A qualified professional is defined as “[a]n individual who is a registered nurse, nurse practitioner, or physician assistant licensed in accordance with Article 1 of this Chapter, or a qualified technician acting within the scope of the qualified technician's authority as provided by North Carolina law and under the supervision of a physician.” N.C. Gen. Stat. § 90-21.81(8).



- That other public assistance programs “may or may not be available”;
- That “the father is liable to assist in the support of the child, even if the father has offered to pay for the abortion”;
- That the patient has the right to view certain state-printed materials that “describe the unborn child and list agencies that offer alternatives to abortion.”

*Id.* § 90-21.82(2); *see also id.* § 90-21.82(1) (imposing additional mandatory disclosures).

217. The law does not provide patients with the right to decline any of the state-mandated information or to obtain an abortion in less than 72 hours—regardless of their circumstances or how certain they are in their decision.

218. By the same token, except in a medical emergency, health care providers are prohibited from exercising any medical judgment regarding whether to provide some or all of this information, based on their careful consideration of a patient’s individual circumstances, or whether to schedule the abortion less than 72 hours after providing the state-mandated information.

219. For example, patients who are pregnant as a result of rape, who are experiencing intimate partner violence, or who are seeking an abortion after receiving a fetal diagnosis, are all subject to the **72-Hour Mandatory Delay** and **Biased Counseling Requirement**.

220. Failure to comply with these requirements exposes physicians who perform abortions, such as Plaintiff Providers, to civil damages, as well as a court-ordered prohibition on their ability to provide abortion care in North Carolina. *Id.* § 90-21.88. It also exposes them to potential licensing penalties, including revocation of their medical license. *Id.* § 90-14(a)(2).

221. **The 72-Hour Mandatory Delay and Biased Counseling Requirement** provide no medical benefit. Instead, these provisions undermine the health and safety of people who have

abortions by imposing unjustified delays in accessing care; violate abortion patients’ right to privacy and autonomy; and discriminate against and stigmatize people who have abortions.

**A. *The 72-Hour Mandatory Delay Inflicts Significant and Unjustified Harms on Abortion Patients***

222. North Carolina law imposes a **72-Hour Mandatory Delay** on people seeking abortions, among the most extreme abortion “waiting periods” in the country.<sup>105</sup>

223. There is no medical evidence to support imposing a mandatory delay prior to abortion, let alone a delay of 72 hours.<sup>106</sup>

224. In Plaintiff Providers’ collective experience, their patients have given an extraordinary amount of care and thought to their decision to have an abortion *before* they even call to schedule their appointment, with most of Plaintiff Providers’ patients having already made their decision by the time they call.<sup>107</sup> Plaintiff Providers’ patients are all capable decision-makers who are competent to determine how much time they do or do not need to make the decision to have an abortion.

225. Indeed, as discussed *supra* ¶¶ 71, the decision to have an abortion is based on a variety of personal and familial factors that the patient (not the State) is in the best position to assess. And, as discussed *infra* ¶¶ 242–47, fundamental ethical principles of informed consent, existing

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<sup>105</sup> Only five other states impose a 72-hour mandatory delay on abortion patients: Arkansas, Missouri, Oklahoma, South Dakota, and Utah. *See* Ark. Code Ann. § 20-16-1703 (permitting the omission of certain information in cases of rape or incest); Mo. Ann. Stat. § 188.027; Okla. Stat. Ann. tit. 63, § 1-738.2; S.D. Codified Laws § 34-23A-56; Utah Code Ann. § 76-7-305 (permitting waiver of the requirement under certain conditions); *see also* Guttmacher Inst., *Counseling and Waiting Periods for Abortion* (Sept. 1, 2020), [www.guttmacher.org/state-policy/explore/counseling-and-waiting-periods-abortion](http://www.guttmacher.org/state-policy/explore/counseling-and-waiting-periods-abortion).

<sup>106</sup> *See, e.g.*, National Academies Report, *supra* note 12, at 77–78, 163–64.

<sup>107</sup> Plaintiff Providers’ clinical experiences are reflective of scientific study on the issue. *See e.g.*, Ann M. Moore et al., *What Women Want From Abortion Counseling in the United States: A Qualitative Study of Abortion Patients in 2008*, 50 *Social Work in Health Care* 424 (2011).

North Carolina law, and Plaintiff Providers' own practices ensure that every patient's decision to have an abortion is voluntary and informed, without the need for a state-enforced delay.

226. In fact, evidence shows that waiting periods can be detrimental to a patient's mental health. *See supra* ¶ 94 and note 39.<sup>108</sup>

227. No other medical procedure is subject to a blanket, mandatory delay requirement under North Carolina law.

228. While any mandatory delay is unnecessary, the 72-hour delay is often much longer in practice.

229. For example, many of Plaintiffs Deans's and Swartz's patients are forced to delay patient care by a week, if not longer, due solely to the state-mandated delay. Even though Plaintiffs Deans and Swartz provide abortion care four days a week, between Tuesday and Friday, if patients do not happen to call to schedule an appointment on a Monday or a Tuesday, they are necessarily unable to obtain care until the following week. This delay may be further compounded by other factors—i.e., the patient's ability to take time off of work, obtain childcare, secure transportation, and gather the funds needed to pay for the abortion, childcare, and transportation.

230. For other Plaintiffs who provide abortion, including those with less physician availability, the wait can be even longer.

231. Far from enhancing patient health and safety, the **72-Hour Mandatory Delay** threatens patient health and well-being.

232. When a patient contacts one of the AWC Clinics, they are told that a registered nurse will call them back within 24 hours to provide the information mandated by the **Biased**

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<sup>108</sup> *See also* Tex. Pol'y Evaluation Project, *Impact of Abortion Restrictions in Texas* (Apr. 2013), [http://www.utexas.edu/cola/txpep/\\_files/pdf/TxPEP-ResearchBrief-ImpactofAbortionRestrictions.pdf](http://www.utexas.edu/cola/txpep/_files/pdf/TxPEP-ResearchBrief-ImpactofAbortionRestrictions.pdf).

**Counseling Requirement.** The clinic often has to explain to the patient why the patient cannot make an appointment for the next day to obtain abortion care and must instead first talk to the nurse and then wait 72 hours. Moreover, the **Biased Counseling Requirement** can create additional delays for the AWC Clinics' patients because people who work or go to school may not be available when the nurse calls. The nurses may have to try calling the patient multiple times to reach them at a time when they can speak, which can cause patients to experience anxiety because if they miss their counseling, they will be forced to wait even longer.

233. As described *supra*, costs increase as abortion is delayed later into pregnancy. For example, the cost of care for Plaintiffs Deans's and Swartz's patients increase if they are no longer eligible for a medication abortion and must have a procedural abortion. And the cost of procedural abortion care increases as the pregnancy advances. Moreover, for patients of Plaintiffs Deans's and Swartz's hospital-based practice, the cost of abortion after 14.6 weeks LMP significantly increases. After 14.6 weeks LMP, abortion care is only available at their hospital or its affiliated ASC, both of which significantly increase the cost of care.

234. By singling out abortion care and requiring patients to wait 72 hours in order to demonstrate "informed consent," the mandatory delay perpetuates the false and stigmatizing belief that people who have abortions are uniquely unable to make an informed decision about this medical procedure for themselves and their families without state intervention.

235. The mandatory delay also perpetuates the false and discriminatory stereotype that women are more in need of paternalistic state intervention to assist them in making informed decisions about their health care than are men.

236. Accordingly, the **72-Hour Mandatory Delay** only serves to inflict physical, psychological, and financial harms on abortion patients, while providing no conceivable medical benefit.

**B. *The Biased Counseling Requirement Discriminates Against and Harms Abortion Patients***

237. The **Biased Counseling Requirement** forces health care providers to recite state-mandated language designed to influence (rather than inform) a patient's abortion decision.

238. By reflecting the state's bias against abortion, the **Biased Counseling Requirement** also stigmatizes patients who seek abortion care.

239. Further, this one-size-fits-all requirement, which prevents health care providers from considering a patient's individual circumstances, mandates that providers force potentially traumatizing information on their patients.

240. In so doing, the **Biased Counseling Requirement** violates fundamental principles of informed consent and medical ethics; undermines the provider-patient relationship; and prevents people who have abortions from receiving patient-centered care that reflects their health care provider's best medical judgment.

241. The **Biased Counseling Requirement** thus provides no medical benefit.

242. Health care providers are required to adhere to well-established medical-ethics principles. Informed consent, which is derived from these principles, demonstrates respect for patients as autonomous agents with control over their bodies, lives, and values.

243. The informed consent process is the mechanism by which a patient authorizes a medical intervention or course of treatment after a discussion of (i) what will happen during a medical procedure; (ii) the risks and benefits associated with the medical procedure; and (iii) available alternatives to the medical procedure.

244. Providers must be able to exercise their medical judgment to tailor the informed-consent process to the patient’s individual needs and circumstances.

245. Outside of communicating the core information that underpins informed consent, health care providers allow the patient to guide the discussion, creating a space for patients to share any concerns or questions they have. These actions also support the core principle of patient autonomy and further build trust between the patient and the provider. Indeed, studies indicate that trust improves patient outcomes.<sup>109</sup>

246. As health care providers practicing in North Carolina, Plaintiff Providers, their clinicians, and their staff routinely obtain informed consent for medical treatment and procedures, consistent with these ethical obligations and North Carolina’s general informed consent statute. *See* N.C. Gen. Stat. § 90-21.13. For example, Plaintiff Providers, their clinicians, and their staff give all patients information sufficient to give a reasonable person “a general understanding of the procedures or treatments and of the usual and most frequent risks and hazards inherent in the proposed procedures or treatments which are recognized and followed by other health care providers engaged in the same field of practice in the same or similar communities.” *Id.* § 90–21.13(a)(2).

247. In addition, Plaintiff Providers, their clinicians, and their staff already offer all of their patients multiple opportunities to ask questions and discuss any concerns regarding their care. Plaintiff Providers, their clinicians, and their staff take care to ensure that each patient is certain about their decision before proceeding with any treatment or procedure.

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<sup>109</sup> *See, e.g.,* Ngaire Kerse et al., *Physician-Patient Relationship and Medication Compliance: A Primary Care Investigation*, 2 *Annals Fam. Med.* 455, 459 (2004); *cf.* Sheldon Greenfield et al., *Expanding Patient Involvement in Care: Effects on Patient Outcomes*, 102 *Annals Internal Med.* 520, 526 (1985) (finding that increased patient involvement in care resulted in improved patient outcomes).

248. By contrast, the **Biased Counseling Requirement**, which is unique to abortion, forces health care providers, such as Plaintiff Providers, their clinicians, and their staff, to engage in conduct that is antithetical to informed consent and fundamental medical-ethical principles.

249. The **Biased Counseling Requirement** forces health care providers to foist the state-scripted information on *all* patients, regardless of individual circumstances, values, and needs. In so doing, it turns health care providers into mouthpieces for the state, forcing them to stigmatize patients by conveying information that is clearly designed to reflect the state’s preference that every patient continue their pregnancy to term, rather than have an abortion.

250. The **Biased Counseling Requirement** also forces health care providers to inflict psychological and emotional harm on their patients. For example, it requires health care providers to tell a patient carrying a wanted pregnancy who has received a lethal fetal diagnosis that “the woman has other alternatives to abortion, including keeping the baby or placing the baby for adoption”—even though the fetus has no chance of survival. *Id.* § 90-21.82(2)(d). Similarly, it requires health care providers to suggest to every victim of rape or incest that they consider approaching “the father” who forcibly impregnated them for child support, rather than have an abortion. *Id.* § 90-21.82(2)(c).

251. Even with respect to the mandated information that is traditionally considered to be part of informed consent, the **Biased Counseling Requirement** contravenes basic medical-ethical principles by dictating the timing and format of the disclosures in a one-size-fits-all approach and preventing the patient from exercising their autonomy to determine what information is actually relevant to their decision.

252. No other medical procedure is subject to a comparable **Biased Counseling Requirement**.

253. Outside of the abortion context, North Carolina informed consent law is consistent with the principles of informed consent. *See id.* § 90-21.13. For example, outside of the abortion context, North Carolina law does not require health care providers to adhere to a specific script when obtaining informed consent or otherwise attempt to dictate the content, form, or timing of the information that must be provided to *every* patient. *Id.* Nor does it require other health care providers to force information on patients against their will, particularly when doing so causes psychological and/or emotional harm. *See id.*

254. There is no justification for singling out abortion, and abortion patients, for such an unethical, stigmatizing, and harmful requirement.

255. As with the **72-Hour Mandatory Delay**, the **Biased Counseling Requirement** perpetuates the false and stigmatizing belief that people who have abortions cannot be trusted to determine what information is relevant to their decision without intervention. It likewise perpetuates stereotypes that women require paternalistic state intervention in order to make informed decisions about their health care.

256. For all these reasons, the **72-Hour Mandatory Delay** and **Biased Counseling Requirement** work in tandem to further burden, discriminate against people seeking abortion care, and endanger the constitutional rights of abortion patients while serving no legitimate, let alone compelling, purpose.



## COUNTS

### COUNT I – ARTICLE 1, SECTION 1 OF THE NORTH CAROLINA CONSTITUTION

257. Plaintiffs reaffirm and reallege each and every allegation made above as if set forth fully herein.

258. Article 1, Section 1 of the North Carolina Constitution guarantees “[t]he equality and rights of persons” and recognizes that “all persons” possess “certain inalienable rights,” such as “liberty, the enjoyment of the fruits of their own labor, and the pursuit of happiness.”

259. The ability to make fundamental decisions about reproductive autonomy, families, and childbearing—including the decision to have an abortion—is central to the liberty, equality, and pursuit of happiness of all persons.

260. By burdening and restricting the ability of North Carolinians (including Plaintiffs’ patients and members) to access abortion, and by unconstitutionally discriminating against and stereotyping North Carolinians (including Plaintiffs’ patients and members) seeking abortions, the challenged **Abortion Restrictions**—the **APC Ban**, **Telemedicine Ban**, **TRAP Scheme**, **72-Hour Mandatory Delay**, and **Biased Counseling Requirement**—violate Article 1, Section 1 of the North Carolina Constitution.

261. Further, by imposing onerous and medically unjustified restrictions on their ability to practice medicine, the **APC Ban**, **Telemedicine Ban**, and **TRAP Scheme** violate the rights of Plaintiffs PPSAT and the AWC Clinics and their staff to “the fruits of their own labor” under Article 1, Section 1 of the North Carolina Constitution.

### COUNT II – ARTICLE 1, SECTION 19 OF THE NORTH CAROLINA CONSTITUTION

262. Plaintiffs reaffirm and reallege each and every allegation made above as if set forth fully herein.

263. Article 1, Section 19 guarantees that “[n]o person shall be denied the equal protection of the laws.” Article 1, Section 19 also guarantees that “[n]o person shall . . . be deprived of his . . . liberty,” including the liberty of contract and to pursue and earn one’s livelihood, contrary to “the law of the land.”

264. The challenged **Abortion Restrictions**—the **APC Ban, Telemedicine Ban, TRAP Scheme, 72-Hour Mandatory Delay, and Biased Counseling Requirement**—single out and subject North Carolinians who have abortions (including Plaintiffs’ patients and members) to unconstitutionally onerous, harmful, and medically unnecessary restrictions. The law does not impose comparable restrictions on any other medical procedure, including miscarriage management, prenatal care, and childbirth.

265. Further, the challenged Abortion Restrictions—the **APC Ban, Telemedicine Ban, TRAP Scheme, 72-Hour Mandatory Delay, and Biased Counseling Requirement**—unconstitutionally discriminate against Plaintiffs’ patients and members on the basis of sex because they disproportionately impact women and/or are based on and perpetuate outdated and impermissible sex and gender stereotypes.

266. The **APC Ban, Telemedicine Ban, and TRAP Scheme** also single out and subject North Carolinians who provide abortions (including Plaintiffs PPSAT, the AWC Clinics, Farris, and Bass) to unconstitutionally onerous and medically unnecessary restrictions that limit their ability to contract and pursue and earn their livelihood. The law does not impose comparable restrictions on any other medical procedure, including miscarriage management, prenatal care, and childbirth.

267. As such, the challenged **Abortion Restrictions**—the **APC Ban, Telemedicine Ban, TRAP Scheme, 72-Hour Mandatory Delay, and Biased Counseling Requirement**—violate Article 1, Section 19 of the North Carolina Constitution.

### PRAYER FOR RELIEF

Wherefore, Plaintiffs respectfully request that this Court:

- A. Enter a judgment declaring that the **Abortion Restrictions**—the **APC Ban, Telemedicine Ban, TRAP Scheme, 72-Hour Mandatory Delay, and Biased Counseling Requirement**—are unconstitutional under Article 1, Section 1 and Article 1, Section 19 of the North Carolina Constitution.
- B. Permanently enjoin the **Abortion Restrictions**—the **APC Ban, Telemedicine Ban, TRAP Scheme, 72-Hour Mandatory Delay, and Biased Counseling Requirement**—as unconstitutional under Article 1, Section 1 and Article 1, Section 19 of the North Carolina Constitution; and
- C. Award Plaintiffs such other or further relief as this Court deems just, proper, and equitable.

Dated: September 3, 2020

Respectfully submitted,

/s/ Jaclyn Maffetore

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**APPENDIX<sup>1</sup>**

**TRAP Scheme for Abortion Facilities Compared to Medical Board Guidelines for Office-Based Procedures**

	<b>TRAP Scheme for Abortion Facilities</b>	<b>Medical Board Guidelines for Level I Procedures</b>	<b>Medical Board Guidelines for Level II Procedures</b>	<b>Medical Board Guidelines for Level III Procedures</b>
<b>Physical Requirements</b>	<p>“(a) The physical plant for a clinic shall meet or exceed minimum requirements of the North Carolina State Building Code for Group B occupancy (business office facilities) which is incorporated herein by reference including subsequent amendments and editions.</p> <p>(b) The requirements contained in this Section shall apply to new clinics and to any alterations, repairs, rehabilitation work, or additions which are made to a previously certified facility.”            10A N.C. Admin. Code 14E.0201.</p> <p>“Clinics that are certified by the Division to perform abortions shall comply with the Rules governing the sanitation of hospitals, nursing homes, adult care homes, and other institutions, contained in 15A N.C. Admin. Code 18A.1300 which is hereby incorporated by reference including subsequent amendments and editions.”            10A N.C. Admin. Code 14E.0202.</p> <p>Clinic must have receiving area; examining room; preoperative preparation and holding room; individual patient locker facilities or equivalent;</p>	None.	None.	None.

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<sup>1</sup> Unless otherwise noted, all information in the columns regarding Medical Board guidelines for office-based procedures can be found in N.C. Med. Bd., *Position Statements: Office-Based Procedures* (last amended May 2011), [https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/office-based\\_procedures](https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/office-based_procedures).

	<b>TRAP Scheme for Abortion Facilities</b>	<b>Medical Board Guidelines for Level I Procedures</b>	<b>Medical Board Guidelines for Level II Procedures</b>	<b>Medical Board Guidelines for Level III Procedures</b>
	<p>procedure room; recovery room; clean workroom; soiled workroom; medicine room (which may be part of the clean workroom if certain requirements are met); separate and distinct areas for storage and handling clean and soiled linen; patient toilet; personnel lockers and toilet facilities; laboratory; nourishment station with storage and preparation area for serving meals or in-between meal snacks; janitor's closets; adequate space and equipment for assembling, sterilizing, and storing medical and surgical supplies; storage space for medical records; and office space for nurses' charting, doctors' charting, communications, counseling, and business functions. <i>See</i> 10A N.C. Admin. Code 14E.0207.</p> <p>Any facility that provides abortions that has more than one floor must have at least one elevator that can accommodate a stretcher (six-and-one-half feet with an opening of no less than three feet in width). <i>See</i> 10A N.C. Admin. Code 14E.0203.</p> <p>Patient-use corridors in any facility that provides abortions must be no less than 60 inches wide. <i>See</i> 10A N.C. Admin. Code 14E.0204.</p> <p>The minimum width of doors to all rooms needing access for stretchers must be three feet. <i>See</i> 10A N.C. Admin. Code 14E.0205.</p> <p>A facility that provides abortion must comply with strict ventilation and air supply</p>			

	<b>TRAP Scheme for Abortion Facilities</b>	<b>Medical Board Guidelines for Level I Procedures</b>	<b>Medical Board Guidelines for Level II Procedures</b>	<b>Medical Board Guidelines for Level III Procedures</b>
	<p>requirements. <i>See</i> 10A N.C. Admin. Code 14E.0206.</p> <p>“When there is written indication that services are to be shared or purchased, appropriate modifications or deletions in space requirements may be anticipated.” 10A N.C. Admin. Code 14E.0208.</p>			
<b>License &amp; Fee Requirements</b>	<p>“Before proceeding with construction and operational plans, a potential sponsor or owner of a freestanding abortion clinic shall discuss with the staff of the Division of Health Service Regulation the scope of the proposed facility. This will provide an opportunity for the owner and the Division’s staff to discuss certification requirements.” 10A N.C. Admin. Code 14E.0102.</p> <p>“All stages of the plans from schematics through working drawings shall be reviewed by the Division's staff each time a change is made.” 10A N.C. Admin. Code 14E.0103.</p> <p>“Approval from the Division of Health Service Regulation, the Division of Environmental Health, and the Department of Insurance should be obtained before construction is commenced.” 10A N.C. Admin. Code 14E.0105.</p> <p>“Prior to issuance of a certificate pursuant to Rule .0107 of this Section, a clinic shall submit two copies of the building plans to the Division for certification purposes when the clinic requires a review by the Division and the Department of</p>	None.	Physician performing Level II procedures in an office “should be able to demonstrate, upon request by the Board, substantial compliance with these guidelines, or should obtain accreditation of the office setting by an approved accreditation agency or organization.”	Physician performing Level III procedures in an office “should be able to demonstrate, upon request by the Board, substantial compliance with these guidelines, or should obtain accreditation of the office setting by an approved accreditation agency or organization.”

	<b>TRAP Scheme for Abortion Facilities</b>	<b>Medical Board Guidelines for Level I Procedures</b>	<b>Medical Board Guidelines for Level II Procedures</b>	<b>Medical Board Guidelines for Level III Procedures</b>
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	<p>Insurance, according to the North Carolina Administration and Enforcement Requirements Code, 2012 edition, including subsequent amendments and editions. When the local jurisdiction has authority from the North Carolina Building Code Council to review the plans, the clinic shall submit only one copy of the plans to the Division. In that case, the clinic shall submit an additional set of plans directly to the local jurisdiction.” 10A N.C. Admin. Code 14E.010.</p> <p>“(a) Prior to the admission of patients, an application from the clinic for certification shall be submitted to and approved by the Division.</p> <p>(b) Application forms may be obtained by contacting the Division.</p> <p>(c) The application form shall set forth the ownership, staffing patterns, clinical services to be rendered, professional staff in charge of services, and general information that would be helpful to the Division’s understanding of the clinic’s operating program.</p> <p>(d) After construction requirements in Section .0200 of this Subchapter have been met and the application for certification has been received and approved, the Division shall conduct an on-site, certification survey.</p> <p>(e) Each certificate must be renewed at the beginning of each calendar year. The governing authority shall file an application for renewal of certification with the Division at least 30 days prior to the date of expiration on</p>			
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	<b>TRAP Scheme for Abortion Facilities</b>	<b>Medical Board Guidelines for Level I Procedures</b>	<b>Medical Board Guidelines for Level II Procedures</b>	<b>Medical Board Guidelines for Level III Procedures</b>
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	<p>forms furnished by the Division. Failure to file a renewal application shall result in expiration of the certificate to operate.” 10A N.C. Admin. Code 14E.0106.</p> <p>“(a) The Division shall issue a certificate if it finds the facility can:</p> <ul style="list-style-type: none"> <li>(1) Comply with all requirements described in this Subchapter; and</li> <li>(2) Assure that, in the event that complications arise from the abortion procedure, an OB-GYN board certified or board eligible physician shall be available.</li> </ul> <p>(b) Each certificate shall be issued only for the premises and persons or organizations named in the application and shall not be transferable.</p> <p>(c) The governing authority shall notify the Division in writing, within 10 working days, of any change in the name of the facility or change in the name of the administrator.</p> <p>(d) The facility shall report to the Division all incidents, within 10 working days, of vandalism to the facility such as fires, explosions or other action causing disruption of services.” 10A N.C. Admin. Code 14E.0107.</p> <p>“Certificates shall be posted in a conspicuous place on the premises.” 10A N.C. Admin. Code 14E.0108.</p> <p>“Any certificate holder or prospective applicant desiring to make specified types of alteration or addition to a clinic or to construct a new clinic, before commencing such</p>			
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	<b>TRAP Scheme for Abortion Facilities</b>	<b>Medical Board Guidelines for Level I Procedures</b>	<b>Medical Board Guidelines for Level II Procedures</b>	<b>Medical Board Guidelines for Level III Procedures</b>
	<p>alteration, addition or new construction shall submit plans and specifications therefor to the Division for preliminary inspection and approval or recommendations with respect to compliance with the regulations and standards herein authorized.” 10A N.C. Admin. Code 14E.0112.</p> <p>Clinic must be certified by DHHS as suitable for performance of abortions. Each certificate renewable annually upon renewal of application, payment of fee, and approval of DHHS. N.C. Gen. Stat. § 14-45.1(a); 10A N.C. Admin. Code 14E.0109.</p>			
<b>Inspection &amp; Investigation Authority</b>	<p>“The Department shall deny, suspend, or revoke a certificate in any case where it finds that substantial failure to comply with these regulations renders the facility unsuitable for the performance of abortions.” 10A N.C. Admin. Code 14E.0110.</p> <p>“Any clinic certified by the Division to perform abortions shall be inspected by representatives of the Division annually and as it may deem necessary as a condition of holding such license. An inspection shall be conducted whenever the purpose of the inspection is to determine whether the clinic complies with the rules of this Subchapter or whenever there is reason to believe that some condition exists which is not in compliance with the rules of this Subchapter.” 10A N.C. Admin. Code 14E.0111(a).</p>	None.	None.	None.

	<b>TRAP Scheme for Abortion Facilities</b>	<b>Medical Board Guidelines for Level I Procedures</b>	<b>Medical Board Guidelines for Level II Procedures</b>	<b>Medical Board Guidelines for Level III Procedures</b>
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<b>Immediate Access to Investigate, Inspect Facility and Review Patient Medical Records</b>	<p>“(b) The Division shall have authority to investigate any complaint relative to the care, treatment, or complication of any patient.</p> <p>(c) Representatives of the Division shall make their identities known to the person in charge prior to inspection of the clinic.</p> <p>(d) Representatives of the Division may review any records in any medium necessary to determine compliance with the rules of this Subchapter, while maintaining the confidentiality of the complainant and the patient, unless otherwise required by law.</p> <p>(e) The clinic shall allow the Division to have immediate access to its premises and the records necessary to conduct an inspection and determine compliance with the rules of this Subchapter.</p> <p>(f) A clinic shall file a plan of correction for cited deficiencies within 10 business days of receipt of the report of the survey. The Division shall review and respond to a written plan of correction within 10 business days of receipt of the corrective action plan.”</p> <p>N.C. Admin. Code 10A 14E.0111(b)–(f).</p>	None.	None.	None.
<b>Enforcement Mechanism</b>	<p>“The Department shall deny, suspend, or revoke a certificate in any case where it finds that substantial failure to comply with these regulations renders the facility unsuitable for the performance of abortions.” 10A N.C. Admin. Code § 14E.0110.</p>	None.	Failure to substantially comply with guidelines “creates the risk of disciplinary action by the Board.”	Failure to substantially comply with guidelines “creates the risk of disciplinary action by the Board.”

	<b>TRAP Scheme for Abortion Facilities</b>	<b>Medical Board Guidelines for Level I Procedures</b>	<b>Medical Board Guidelines for Level II Procedures</b>	<b>Medical Board Guidelines for Level III Procedures</b>
<b>Medical Staff Organization &amp; Personnel Requirements</b>	<p>“(c) All persons having direct responsibility for patient care shall be at least 18 years of age.  (d) The clinic shall provide an orientation program to familiarize each new employee or contractual employee with the clinic, its policies, and the employee's job responsibilities.  (e) The governing authority shall be responsible for implementing health standards for employees, as well as contractual employees, which are consistent with recognized professional practices for the prevention and transmission of communicable diseases.” 10A N.C. Admin. Code 14E.0306(c)–(e).</p> <p>“(b) The nursing supervisor shall be responsible and accountable to the chief executive officer or designee for:  (1) provision of nursing services to patients; and  (2) developing a nursing policy and procedure manual and written job descriptions for nursing personnel.  (c) The clinic shall have the number of licensed and ancillary nursing personnel on duty to assure that staffing levels meet the total nursing needs of patients based on the number of patients in the clinic and their individual nursing care needs.” 10A N.C. Admin. Code 14E.0307(b)–(c).</p>	None.	<p>Physician performing procedure or other health care professional present <i>should</i> be ACLS certified, and at least one other health care professional <i>should</i> be BCLS certified.  “Recovery <i>should</i> be monitored by a registered nurse or other health care professional practicing within the scope of his or her license or certification who is BCLS certified and has the capability of administering medications as required for analgesia, nausea/vomiting, or other indications.” (emphases added).</p>	<p>An anesthesiologist or a CRNA supervised by a physician <i>should</i> administer anesthesia. The physician cannot administer the anesthesia. Physician performing procedure or the anesthesia provider <i>should</i> be ACLS certified, and <i>at least one other health care professional should</i> be BCLS certified.  “Recovery from a Level III procedure <i>should</i> be monitored by an ACLS certified (PALS or APLS certified when appropriate) health care professional using appropriate criteria for the level of anesthesia. <i>At least one health care professional</i> who is ACLS certified <i>should</i> be immediately available during postoperative monitoring and until the patient meets discharge criteria.” (emphases added).</p>
<b>Patient Transfer Agreement</b>	<p>“(a) Each clinic shall have a written plan for the transfer of emergency cases from the clinic to a nearby hospital when hospitalization becomes necessary.  [...]</p>	None.	<p>No written agreement required; physician should assure that a transfer protocol is in place, preferably with a hospital licensed in the same jurisdiction</p>	<p>No written agreement required; physician should assure that a transfer protocol is in place, preferably with a hospital licensed in the same jurisdiction</p>

	<b>TRAP Scheme for Abortion Facilities</b>	<b>Medical Board Guidelines for Level I Procedures</b>	<b>Medical Board Guidelines for Level II Procedures</b>	<b>Medical Board Guidelines for Level III Procedures</b>
	<p>(c) The clinic shall have a written agreement between the clinic and a hospital to facilitate the transfer of patients who are in need of emergency care. A clinic that has documentation of its efforts to establish such a transfer agreement with a hospital that provides emergency services and has been unable to secure such an agreement shall be considered to be in compliance with this Rule.” 10A N.C. Admin. Code 14E.0310(a), (c).</p> <p>“Any patient not discharged within 12 hours following the abortion procedure shall be transferred to a general hospital.” 10A N.C. Admin. Code 14E.0304(c).</p> <p>“Any patient having an adverse condition or complication known or suspected to have occurred during or after the performance of the abortion shall be transferred to a hospital for evaluation or admission.” 10A N.C. Admin. Code 14E.0313(b).</p>		and within reasonable proximity.	and within reasonable proximity.
<b>Requirements for Medical Records</b>	<p>Must maintain complete and permanent record containing:</p> <ul style="list-style-type: none"> <li>● Date/time of admission and discharge;</li> <li>● Patient’s name, address, date of birth, emergency contact information, diagnoses, duration of pregnancy, and condition on admission and discharge;</li> <li>● Signed consent form;</li> <li>● “[P]atient’s history and physical examination including identification of pre-existing or</li> </ul>	None.	<p>Medical record should include: procedure code or narrative description of procedure; “sufficient information to identify the patient, support the diagnosis, justify the treatment, and document the outcome and required follow-up care”; “Medical history, physical examination, lab studies obtained within 30 days of the</p>	<p>Medical record should include: procedure code or narrative description of procedure; “sufficient information to identify the patient, support the diagnosis, justify the treatment, and document the outcome and required follow-up care”; “Medical history, physical examination, lab studies obtained within 30 days of the</p>

	<b>TRAP Scheme for Abortion Facilities</b>	<b>Medical Board Guidelines for Level I Procedures</b>	<b>Medical Board Guidelines for Level II Procedures</b>	<b>Medical Board Guidelines for Level III Procedures</b>
	<p>current illnesses, drug sensitivities or other idiosyncrasies having a bearing on the procedure or anesthetic to be administered.”</p> <p>10A N.C. Admin. Code 14E.0305(a).</p> <p>Must maintain daily procedure log containing patients’ name, length of gestation, type of procedure, name of physician, name of Registered Nurse on duty, and date/time of procedure. 10A N.C. Admin. Code § 14E.0305(e).</p> <p>Clinics must preserve or retain medical records in North Carolina for at least 10 years from the date of the most recent discharge. For minors, clinics must maintain such records until three years after the patient turns eighteen. 10A N.C. Admin. Code § 14E.0305(f).</p>		<p>scheduled procedure, and pre-anesthesia examination and evaluation information and data”; written documentation of informed consent.</p> <p>No daily procedure log requirement.</p> <p>No requirement that medical records be kept any length of time.</p>	<p>scheduled procedure, and pre-anesthesia examination and evaluation information and data”; written documentation of informed consent.</p> <p>No daily procedure log requirement.</p> <p>No requirement that medical records be kept any length of time.</p>

	<b>TRAP Scheme for Abortion Facilities</b>	<b>Medical Board Guidelines for Level I Procedures</b>	<b>Medical Board Guidelines for Level II Procedures</b>	<b>Medical Board Guidelines for Level III Procedures</b>
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<b>Requirements for Personnel Records</b>	<p>“(a) Personnel Records:  (1) A record of each employee shall be maintained that includes the following:  (A) employee's identification;  (B) application for employment that includes education, training, experience and references;  (C) resume of education and work experience;  (D) verification of valid license (if required), education, training, and prior employment experience; and  (E) verification of references.  (2) Personnel records shall be confidential.  (3) Notwithstanding the requirement found in Subparagraph (b)(2) of this Rule, representatives of the Division conducting an inspection of the clinic shall have the right to inspect personnel records.  (b) Job Descriptions:  (1) The clinic shall have a written description that describes the duties of every position.  (2) Each job description shall include position title, authority, specific responsibilities, and minimum qualifications. Qualifications shall include education, training, experience, special abilities, and valid license or certification required.  (3) The clinic shall review annually and, if needed, update all job descriptions. The clinic shall provide the updated job description to each employee or contractual employee assigned to the position.  [...]  (f) Employee and contractual employee records for health screening as defined in Rule .0101(7) of this Subchapter, education, training, and</p>	None.	None.	None.
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	<b>TRAP Scheme for Abortion Facilities</b>	<b>Medical Board Guidelines for Level I Procedures</b>	<b>Medical Board Guidelines for Level II Procedures</b>	<b>Medical Board Guidelines for Level III Procedures</b>
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	verification of professional certification shall be available for review by the Division.” 10A N.C. Admin. Code 14E.0306(a)–(b), (f).			
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<b>Governing Authority Requirements</b>	<p>“The ownership of the abortion clinic shall be fully disclosed to the Division.” 10A N.C. Admin. Code 14E.0301.</p> <p>“(a) The governing authority, as defined in Rule .0101(6) of this</p>	None.	None.	None.
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	<b>TRAP Scheme for Abortion Facilities</b>	<b>Medical Board Guidelines for Level I Procedures</b>	<b>Medical Board Guidelines for Level II Procedures</b>	<b>Medical Board Guidelines for Level III Procedures</b>
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	<p>Subchapter, shall appoint a chief executive officer or a designee of the clinic to represent the governing authority and shall define his or her authority and duties in writing. This person shall be responsible for the management of the clinic, implementation of the policies of the governing authority and authorized and empowered to carry out the provisions of these Rules.</p> <p>(b) The chief executive officer or designee shall designate, in writing, a person to act on his or her behalf during his or her absence. In the absence of the chief executive officer or designee, the person on the grounds of the clinic who is designated by the chief executive officer or designee to be in charge of the clinic shall have access to all areas in the clinic related to patient care and to the operation of the physical plant.</p> <p>(c) When there is a planned change in ownership or in the chief executive officer, the governing authority of the clinic shall notify the Division in writing of the change.</p> <p>(d) The clinic's governing authority shall adopt operating policies and procedures that shall:</p> <p>(1) specify the individual to whom responsibility for operation and maintenance of the clinic is delegated and methods established by the governing authority for holding such individuals responsible;</p> <p>(2) provide for at least annual meetings of the governing authority, for which minutes shall be maintained; and</p>			
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	<b>TRAP Scheme for Abortion Facilities</b>	<b>Medical Board Guidelines for Level I Procedures</b>	<b>Medical Board Guidelines for Level II Procedures</b>	<b>Medical Board Guidelines for Level III Procedures</b>
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	<p>(3) maintain a policies and procedures manual designed to ensure professional and safe care for the patients which shall be reviewed, and revised when necessary, at least annually, and shall include provisions for administration and use of the clinic, compliance, personnel quality assurance, procurement of outside services and consultations, patient care policies, and services offered.</p> <p>(e) When the clinic contracts with outside vendors to provide services such as laundry, or therapy services, the governing authority shall be responsible to assure the supplier meets the same local and state standards the clinic would have to meet if it were providing those services itself using its own staff.</p> <p>(f) The governing authority shall provide for the selection and appointment of the professional staff and the granting of clinical privileges and shall be responsible for the professional conduct of these persons.</p> <p>(g) The governing authority shall be responsible for ensuring the availability of supporting personnel to meet patient needs and to provide safe patient care.” 10A N.C. Admin. Code 14E.0302.</p> <p>“(a) The following essential documents and references shall be on file in the administrative office of the clinic: (1) documents evidencing control and ownerships, such as deeds, leases, or incorporation or partnership papers; (2) policies and procedures of the governing authority, as</p>			
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	<b>TRAP Scheme for Abortion Facilities</b>	<b>Medical Board Guidelines for Level I Procedures</b>	<b>Medical Board Guidelines for Level II Procedures</b>	<b>Medical Board Guidelines for Level III Procedures</b>
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	<p>required by Rule .0302 of this Section;</p> <p>(3) minutes of the governing authority meetings;</p> <p>(4) minutes of the clinic's professional and administrative staff meetings;</p> <p>(5) a current copy of the rules of this Subchapter;</p> <p>(6) reports of inspections, reviews, and corrective actions taken related to licensure; and</p> <p>(7) contracts and agreements related to licensure to which the clinic is a party.</p> <p>(b) All operating licenses, permits, and certificates shall be displayed on the licensed premises.</p> <p>(c) The governing authority shall prepare a manual of clinic policies and procedures for use by employees, medical staff, and contractual physicians to assist them in understanding their responsibilities within the organizational framework of the clinic. These shall include:</p> <p>(1) patient selection and exclusion criteria; and clinical discharge criteria;</p> <p>(2) policy and procedure for validating the full and true name of the patient;</p> <p>(3) policy and procedure for each type of abortion procedure performed at the clinic;</p> <p>(4) policy and procedure for the provision of patient privacy in the recovery area of the clinic;</p> <p>(5) protocol for determining gestational age as defined in Rule .0101(5) of this Subchapter;</p> <p>(6) protocol for referral of patients for whom services have been declined; and</p> <p>(7) protocol for discharge instructions that informs patients</p>			
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	<b>TRAP Scheme for Abortion Facilities</b>	<b>Medical Board Guidelines for Level I Procedures</b>	<b>Medical Board Guidelines for Level II Procedures</b>	<b>Medical Board Guidelines for Level III Procedures</b>
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	who to contact for post-procedural problems and questions.” 10A N.C. Admin. Code 14E.0303.			
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<b>Required Information to Patient</b>	<p>“(d) Following admission and prior to obtaining the consent for the procedure, representatives of the clinic's management shall provide to each patient the following information:</p> <p>(1) a fee schedule and any extra charges routinely applied;</p> <p>(2) the name of the attending physician(s) and hospital admitting privileges, if any. In the absence of admitting privileges a statement to that effect shall be included;</p> <p>(3) instructions for post-procedure problems and questions as outlined in Rule .0313(d) of this Section;</p> <p>(4) grievance procedures a patient may follow if dissatisfied with the care and services rendered; and</p> <p>(5) the telephone number for Complaint Intake of the Division.” 10A N.C. Admin. Code 14E.0304(d).</p> <p>“(d) Written instructions shall be issued to all patients in accordance with the orders of the physician in charge of the abortion procedure and shall include the following:</p> <p>(1) symptoms and complications to be looked for; and</p> <p>(2) a dedicated telephone number to be used by the patients should any complication occur or question arise. This number shall be answered by a person 24 hours a day, seven</p>	None.	<p>“The patient should receive verbal instruction understandable to the patient or guardian, confirmed by written post-operative instructions and emergency contact numbers. The instructions should include:</p> <ul style="list-style-type: none"> <li>• the procedure performed;</li> <li>• information about potential complications;</li> <li>• telephone numbers to be used by the patient to discuss complications or should questions arise;</li> <li>• instructions for medications prescribed and pain management;</li> <li>• information regarding the follow-up visit date, time and location; and</li> <li>• designated treatment hospital in the event of emergency.”</li> </ul> <p>“If the licensee is not going to be available after hours, the licensee must provide</p>	<p>“The patient should receive verbal instruction understandable to the patient or guardian, confirmed by written post-operative instructions and emergency contact numbers. The instructions should include:</p> <ul style="list-style-type: none"> <li>• the procedure performed;</li> <li>• information about potential complications;</li> <li>• telephone numbers to be used by the patient to discuss complications or should questions arise;</li> <li>• instructions for medications prescribed and pain management;</li> <li>• information regarding the follow-up visit date, time and location; and</li> <li>• designated treatment hospital in the event of emergency.”</li> </ul> <p>“If the licensee is not going to be available after hours, the licensee must provide clear instructions to</p>
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	<b>TRAP Scheme for Abortion Facilities</b>	<b>Medical Board Guidelines for Level I Procedures</b>	<b>Medical Board Guidelines for Level II Procedures</b>	<b>Medical Board Guidelines for Level III Procedures</b>
	days a week.” 10A N.C. Admin. Code 14E.0313(d).		clear instructions to the patient for securing after-hours care. It is the responsibility of the licensee to ensure that the patient has sufficient information regarding how to secure after-hours care.” <sup>2</sup>	the patient for securing after-hours care. It is the responsibility of the licensee to ensure that the patient has sufficient information regarding how to secure after-hours care.” <sup>3</sup>
<b>Quality Assurance</b>	<p>“(a) The governing authority shall establish a quality assurance program for the purpose of providing standards of care for the clinic. The program shall include the establishment of a committee that shall evaluate compliance with clinic procedures and policies.</p> <p>(b) The committee shall determine corrective action, if necessary.</p> <p>(c) The committee shall consist of at least one physician who is not an owner, the chief executive officer or designee, and other health professionals. The committee shall meet at least once per quarter.</p> <p>(d) The functions of the committee shall include development of policies for selection of patients, approval for adoption of policies, review of credentials for staff privileges, peer review, tissue inspection, establishment of infection control procedures, and approval</p>	None.	<p>“A performance improvement program should be implemented to provide a mechanism to review yearly the current practice activities and quality of care provided to patients.”</p> <p>“Performance improvement activities should include, but are not limited to, review of mortalities; the appropriateness and necessity of procedures performed; emergency transfers; reportable complications, and resultant outcomes (including all postoperative infections); analysis of patient satisfaction</p>	<p>“A performance improvement program should be implemented to provide a mechanism to review yearly the current practice activities and quality of care provided to patients.”</p> <p>“Performance improvement activities should include, but are not limited to, review of mortalities; the appropriateness and necessity of procedures performed; emergency transfers; reportable complications, and resultant outcomes (including all postoperative infections); analysis of patient satisfaction</p>

<sup>2</sup> N.C. Med. Bd., *Availability of Licensees to Their Patients* (last amended May 2012), [https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/availability\\_of\\_licensees\\_to\\_their\\_patients](https://www.ncmedboard.org/resources-information/professional-resources/laws-rules-position-statements/position-statements/availability_of_licensees_to_their_patients).

<sup>3</sup> *Id.*

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	<p>of additional procedures to be performed in the clinic.</p> <p>(e) Records shall be kept of the activities of the committee for a period not less than 10 years. These records shall include:</p> <p>(1) reports made to the governing authority;</p> <p>(2) minutes of committee meetings including date, time, persons attending, description and results of cases reviewed, and recommendations made by the committee; and</p> <p>(3) information on any corrective action taken.</p> <p>(f) Orientation, training, or education programs shall be conducted to correct deficiencies that are uncovered as a result of the quality assurance program.”</p> <p>10A N.C. Admin. Code 14E.0308.</p>		<p>surveys and complaints; and identification of undesirable trends (such as diagnostic errors, unacceptable results, follow-up of abnormal test results, medication errors, and system problems). Findings of the performance improvement program should be incorporated into the practice’s educational activity.”</p>	<p>surveys and complaints; and identification of undesirable trends (such as diagnostic errors, unacceptable results, follow-up of abnormal test results, medication errors, and system problems). Findings of the performance improvement program should be incorporated into the practice’s educational activity.”</p>
<b>Laboratory Services Requirement</b>	<p>“(a) Each clinic shall have the capability to provide or obtain laboratory tests required in connection with the procedure to be performed.</p> <p>(b) The governing authority shall establish written policies requiring examination by a pathologist of all surgical specimens except for those types of specimens that the governing authority has determined do not require examination.</p> <p>(c) Each patient shall have the following performed and a record of the results placed in the patient’s medical record prior to the abortion:</p> <p>(1) pregnancy testing, except when a positive diagnosis of pregnancy has been established by ultrasound;</p> <p>(2) anemia testing (hemoglobin or hematocrit); and</p> <p>(3) Rh factor testing.</p>	None.	“Appropriate laboratory studies should be obtained within 30 days of the planned surgical procedure.”	“Appropriate laboratory studies should be obtained within 30 days of the planned surgical procedure.”

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	<p>(d) Patients requiring the administration of blood shall be transferred to a local hospital having blood bank facilities.</p> <p>(e) The clinic shall maintain a manual in a location accessible by employees, that includes the procedures, instructions, and manufacturer's instructions for each test procedure performed, including:</p> <p>(1) sources of reagents, standard and calibration procedures, and quality control procedures; and</p> <p>(2) information concerning the basis for the listed 'normal' ranges.</p> <p>(f) The clinic shall perform and document, at least quarterly, calibration of equipment and validation of test results.”</p> <p>10A N.C. Admin. Code 14E.0309.</p>			
<b>Medical Requirements</b>	<p>“(b) The clinic shall have procedures, personnel, and suitable equipment to handle medical emergencies which may arise in connection with services provided by the clinic. [...]</p> <p>(d) The clinic shall provide intervention for emergency situations. These provisions shall include:</p> <p>(1) basic cardio-pulmonary life support;</p> <p>(2) emergency protocols for:</p> <p>(A) administration of intravenous fluids;</p> <p>(B) establishing and maintaining airway support;</p> <p>(C) oxygen administration;</p> <p>(D) utilizing a bag-valve-mask resuscitator with oxygen reservoir;</p> <p>(E) utilizing a suction machine; and</p>	None.	<p>“All office personnel should be familiar with and capable of carrying out written emergency instructions. The instructions should be followed in the event of an emergency, any untoward anesthetic, medical or surgical complications, or other conditions making hospitalization of a patient necessary. The instructions should include arrangements for immediate contact of emergency medical services when indicated and when advanced</p>	<p>“All office personnel should be familiar with and capable of carrying out written emergency instructions. The instructions should be followed in the event of an emergency, any untoward anesthetic, medical or surgical complications, or other conditions making hospitalization of a patient necessary. The instructions should include arrangements for immediate contact of emergency medical services when indicated and when advanced</p>

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	<p>(F) utilizing an automated external defibrillator;  (3) emergency lighting available in the procedure room as set forth in Rule .0206 of this Subchapter; and  (4) ultrasound equipment.”  10A N.C. Admin. Code 14E.0310(b), (d).</p> <p>“(a) The procedure room shall be maintained exclusively for surgical procedures and shall be so designed and maintained to provide an atmosphere free of contamination by pathogenic organisms. The clinic shall establish procedures for infection control and universal precautions.  (b) Tissue Examination:  (1) The physician performing the abortion is responsible for examination of all products of conception (P.O.C.) prior to patient discharge. Such examination shall note specifically the presence or absence of chorionic villi and fetal parts, or the amniotic sac. The results of the examination shall be recorded in the patient's medical record.  (2) If adequate tissue is not obtained based on the gestational age, ectopic pregnancy or an incomplete procedure shall be considered and evaluated by the physician performing the procedure.  (3) The clinic shall establish procedures for obtaining, identifying, storing, and transporting specimens.”  10A N.C. Admin. Code 14E.0311.</p> <p>“(a) Medication</p>		<p>cardiac life support is needed. When emergency medical services are not indicated, the instructions should include procedures for timely escort of the patient to the hospital or to an appropriate practitioner.”</p> <p>“A physician who performs surgical or special procedures in an office requiring the administration of anesthesia services should be credentialed to perform that surgical or special procedure by a hospital, an ambulatory surgical facility, or substantially comply with criteria established by the Board.”</p> <p>“If the physician administers the anesthetic as part of a surgical or special procedure (Level II only), he or she also should have documented competence to deliver the level of anesthesia administered.”</p>	<p>cardiac life support is needed. When emergency medical services are not indicated, the instructions should include procedures for timely escort of the patient to the hospital or to an appropriate practitioner.”</p> <p>“A physician who performs surgical or special procedures in an office requiring the administration of anesthesia services should be credentialed to perform that surgical or special procedure by a hospital, an ambulatory surgical facility, or substantially comply with criteria established by the Board.”</p>



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	<p>(1) No medication or treatment shall be given except on written order of a physician.</p> <p>(2) Medications must be administered in accordance with the Nurse Practice Act of the State of North Carolina, and must be recorded in the patient's permanent record.</p> <p>(b) Anesthesia</p> <p>(1) The anesthesia must be administered only under the direct supervision of a licensed physician.</p> <p>(2) Flammable anesthetics shall be prohibited except when construction, storage and equipment meet the standards of the National Fire Protection Association (N.F.P.A.) incorporated in Bulletin No. 56, 'Code for Use of Flammable Anesthetics.'" 10A N.C. Admin. Code 14E.0312.</p>			

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<b>Post-Operative Discharge Requirements</b>	<p>“(a) A patient whose pregnancy is terminated on an ambulatory basis shall be observed in the clinic to ensure that no post-operative complications are present. Thereafter, patients may be discharged according to a physician's order and the clinic's protocols. [...]</p> <p>(c) The following criteria shall be documented prior to discharge: (1) the patient shall be ambulatory with a stable blood pressure and pulse; and (2) bleeding and pain shall be controlled. [...]</p> <p>(e) The clinic shall have a defined protocol for triaging post-operative calls and complications. This protocol shall establish a pathway for physician contact to ensure ongoing care of complications that the operating physician is incapable of managing.” 10A N.C. Admin. Code 14E.0313(a), (c), (e).</p>	None.	<p>“Criteria for discharge for all patients who have received anesthesia should include the following:</p> <ul style="list-style-type: none"> <li>● confirmation of stable vital signs;</li> <li>● stable oxygen saturation levels;</li> <li>● return to pre-procedure mental status;</li> <li>● adequate pain control;</li> <li>● minimal bleeding, nausea and vomiting;</li> <li>● resolving neural blockade, resolution of the neuraxial blockade; and</li> <li>● eligible to be discharged in the company of a competent adult.”</li> </ul>	<p>“Criteria for discharge for all patients who have received anesthesia should include the following:</p> <ul style="list-style-type: none"> <li>● confirmation of stable vital signs;</li> <li>● stable oxygen saturation levels;</li> <li>● return to pre-procedure mental status;</li> <li>● adequate pain control;</li> <li>● minimal bleeding, nausea and vomiting;</li> <li>● resolving neural blockade, resolution of the neuraxial blockade; and</li> <li>● eligible to be discharged in the company of a competent adult.”</li> </ul>
<b>Sanitation Requirements</b>	<p>“(a) All supplies and equipment used in patient care shall be properly cleaned or sterilized between use for different patients. (b) Methods of cleaning, handling, and storing all supplies and equipment shall be such as to prevent the transmission of infection through their use.” 10A N.C. Admin. Code 14E.0314.</p> <p>“Clinics that are certified by the Division to perform abortions shall meet the standards for sanitation as required by the Division of Public Health,</p>	None.	<p>“The practice should comply with state and federal regulations regarding infection control. For all surgical and special procedures, the level of sterilization should meet applicable industry and occupational safety requirements. There should be a procedure and schedule for cleaning, disinfecting and sterilizing equipment and patient care items. Personnel</p>	<p>The practice should comply with state and federal regulations regarding infection control. For all surgical and special procedures, the level of sterilization should meet applicable industry and occupational safety requirements. There should be a procedure and schedule for cleaning, disinfecting and sterilizing equipment and patient care items. Personnel</p>

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	<p>Environmental Health Section, in the rules and regulations governing the sanitation of hospitals, nursing homes, adult care homes, and other institutions, set forth in 15A N.C. Admin. Code 18A .1300, including subsequent amendments and editions, with special emphasis on the following:</p> <p>(1) the floors, walls, woodwork and windows must be cleaned, and accumulated waste material must be removed at least daily;</p> <p>(2) the premises must be kept free from rodents and insect infestation;</p> <p>(3) bath and toilet facilities must be maintained in a clean and sanitary condition at all times; and</p> <p>(4) linen that comes directly in contact with the patient shall be provided for each individual patient. No such linen shall be interchangeable from one patient to another before being cleaned, sterilized, or laundered.”</p> <p>10A N.C. Admin. Code 14E.0315.</p>		<p>should be trained in infection control practices, implementation of universal precautions, and disposal of hazardous waste products. Protective clothing and equipment should be readily available.”</p>	<p>should be trained in infection control practices, implementation of universal precautions, and disposal of hazardous waste products. Protective clothing and equipment should be readily available.”</p>
<b>Food Service</b>	<p>“(a) Nourishments shall be available and offered to all patients.</p> <p>(b) Sanitary conditions shall be maintained in accordance with regulations of the North Carolina Sanitation Code administered by the Division of Environmental Health.” 10A N.C. Admin. Code 14E.0316.</p>	None.	None.	None.