

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

PLANNED PARENTHOOD OF
INDIANA AND KENTUCKY, INC.,

Plaintiff,

V.

No. 1:13-cv-1335

COMMISSIONER, INDIANA STATE
DEPARTMENT OF HEALTH, in his
official capacity;
PROSECUTOR, TIPPECANOE COUNTY,
INDIANA, in his official capacity;

Defendants.

Complaint for Declaratory and Injunctive Relief / Notice of Challenge to Constitutionality of Indiana Statute

Introduction

1. Indiana law, Indiana Code § 16-21-2-2.5, requires that the Indiana State Department of Health (“Department”) establish licensing qualifications and standards for abortion clinics. Prior to July 1, 2013, the statute defined abortion clinics as freestanding entities that perform surgical abortions. Ind. Code § 16-18-2-1.5 (amended eff. July 1, 2013). The regulations promulgated by the Department that regulate abortion clinics, Ind. Admin. Code tit. 410, art. 26, establish, among other things, requirements and standards for the physical plant of the clinics and demand separate recovery rooms and scrub facilities in each such facility. Planned Parenthood of Indiana and Kentucky, Inc. (“PPINK”), operates a number of surgical abortion clinics in Indiana and they are fully licensed as required by Indiana law and comply with all applicable regulations for abortion clinics. PPINK also operates an office, in Lafayette, Indiana, that does not perform surgical abortions. However, a physician in the clinic does prescribe and dispense, as a tiny percentage

of the medications prescribed at the office, medication through the first nine weeks after a woman's last menstrual period that induces an abortion after the medication is taken and the patient leaves the office. On information and belief, the PPINK Lafayette Clinic is the only freestanding entity in Indiana where this form of abortion, referred hereafter as a "non-surgical abortion," is offered in a setting where surgical abortions are not also performed.

2. Effective July 1, 2013, Indiana Code § 16-18-2-1.5(a) has been amended to define abortion clinic to include any entity that, as of January 1, 2014, provides an abortion inducing medication, even if the facility is not a surgical facility. And, Indiana law, Indiana Code § 16-21-2-2.5, has been amended to add a section (b) that specifically requires that the physical plant requirements of the Department's regulations apply to all abortion clinics, even those that do not offer surgical abortions. Upon information and belief the Department is not planning, prior to January 1, 2014, to have any new regulations in effect that differentiate between surgical abortion clinics and clinics that only provide abortion inducing medication and, therefore, the result of the statutory amendments will be that all of the regulations binding surgical abortion clinics will bind a clinic that only provides non-surgical abortions. Accordingly, as of January 1, 2014, the Lafayette clinic will have to conform to regulations and requirements designed for, and imposed upon, surgical clinics, even though the Lafayette clinic does not perform any surgical procedures. Imposing requirements for such things as surgical scrub facilities and surgical recovery rooms, when there is no surgical procedure ever performed at the clinic, is not only unreasonable, it is utterly irrational and unrelated to any legitimate objective the State seeks to attain by imposing such requirements, and to the extent that Indiana law and the Department's regulations impose these requirements on PPINK's Lafayette clinic the law and regulations are unconstitutional. Moreover, to the extent that Indiana law exempts from the Department's

regulations a physician's office that does not primarily engage in surgical abortions or the dispensing or prescribing of abortion-inducing drugs, but includes PPINK's Lafayette clinic that performs no surgical abortions and only a miniscule percentage of its dispensed or prescribed medications are abortion inducing medications, and does not allow a waiver of these requirements while allowing all other regulatory requirements to be waived by the Department, Indiana law is unconstitutional as violating equal protection. Appropriate injunctive and declaratory relief must, therefore, issue.

Jurisdiction, venue, cause of action

3. This Court has jurisdiction of this matter pursuant to 28 U.S.C. §§ 1331, 1343.
4. Venue is proper in this district pursuant to 28 U.S.C. § 1391.
5. Declaratory relief is authorized by 28 U.S.C. §§ 2201 and 2202 and by Rule 57 of the Federal Rules of Civil Procedure.
6. This action is brought pursuant to 42 U.S.C. § 1983 to redress the deprivation, under color of state law, of rights secured by the Constitution of the United States.

Parties

7. Planned Parenthood of Indiana and Kentucky is a not-for-profit corporation with its principle place of business in Indiana. It brings this action on its behalf and on behalf of its patients.
8. The Commissioner of the Indiana State Department of Health is the duly appointed official in charge of that agency, which is responsible for licensing abortion clinics pursuant to the law and regulations challenged in his action. He is sued in his official capacity and is designated by his official title pursuant to Fed. R. Civ. P. 17(d).
9. The Prosecutor of Tippecanoe County, Indiana, is the duly elected prosecutor of the

county in which Lafayette, Indiana is located and is responsible for prosecuting crimes occurring in the county. He is sued in his official capacity and is designated by his official title pursuant to Fed. R. Civ. P. 17(d).

Legal background

10. Indiana Code § 16-21-2-2(4) requires that the Indiana State Department of Health license and regulate abortion clinics.

11. Prior to July 1, 2013, Indiana law provided that:

(a) The state department [of health] shall adopt rules under IC 4-22-2 to do the following concerning birthing centers and abortion clinics:

(1) Establish minimum license qualifications.

(2) Establish the following requirements:

(A) Sanitation standards.

(B) Staff qualifications.

(C) Necessary emergency equipment.

(D) Procedures to provide emergency care.

(E) Quality assurance standards.

(F) Infection control.

(3) Prescribe the operating policies, supervision, and maintenance of medical records.

(4) Establish procedures for the issuance, renewal, denial, and revocation of licenses under this chapter. The rules adopted under this subsection must address the following:

(A) The form and content of the license.

(B) The collection of an annual license fee.

(5) Prescribe the procedures and standards for inspections.

(b) A person who knowingly or intentionally:

(1) operates a birthing center or an abortion clinic that is not licensed under this chapter; or

(2) advertises the operation of a birthing center or an abortion clinic that is not

licensed under this chapter;

commits a Class A misdemeanor.

Ind. Code § 16-21-2-2.5 (amended eff. July 1, 2013).

12. Indiana law, Indiana Code § 16-21-1-9, allows the Commissioner to waive any of the promulgated rules for good cause shown.

13. Prior to July 1, 2013, Indiana Code § 16-18-2-1.5 (amended eff. July 1, 2013) provided:

(a) “Abortion clinic,” for purposes of IC 16-2-1-2, means a freestanding entity that performs surgical abortion procedures.

(b) The term does not include the following:

(1) A hospital that is licensed as a hospital under IC 16-21-2.

(2) An ambulatory outpatient surgical center that is licensed as an ambulatory outpatient surgical center under IC 16-21-2.

(3) A physician’s office as long as the surgical procedures performed at the physician’s office are not primarily surgical abortion procedures.

14. Pursuant to the statutory mandate of Indiana Code § 16-21-2-2.5, the Department has promulgated detailed regulations governing abortion clinics. Ind. Admin. Code tit. 410, art. 26.

15. Among other things the regulations provide, Ind. Admin. Code tit. 410, r. 26-17-1, *et seq.*, for physical plant, maintenance, equipment, environment, and safety needs.

16. Effective July 1, 2013, Indiana Code § 16-18-2-1.5 was amended so that it now provides:

(a) “Abortion clinic”, for purposes of IC 16-21-2, means a freestanding entity that:

(1) performs surgical abortion procedures; or

(2) beginning January 1, 2014, provides an abortion inducing drug for the purpose of inducing an abortion.

(b) The term does not include the following:

(1) A hospital that is licensed as a hospital under IC 16-21-2.

(2) An ambulatory outpatient surgical center that is licensed as an ambulatory

outpatient surgical center under IC 16-21-2.

(3) A physician's office as long as:

(A) the surgical procedures performed at the physician's office are not primarily surgical abortion procedures; and

(B) abortion inducing drugs are not the primarily dispensed or prescribed drug at the physician's office.

17. In the most recent legislative session the General Assembly amended the law to require that clinics that distributed only abortion-inducing drugs that cause an abortion away from the clinic must comply with all of the surgical abortion clinic requirements, including physical plant requirements, by adding a new section (b) to Indiana Code 16-21-2-2.5, which now provides, in its entirety:

(a) The state department shall adopt rules under IC 4-22-2 to do the following concerning birthing centers and abortion clinics:

(1) Establish minimum license qualifications.

(2) Establish the following requirements:

(A) Sanitation standards.

(B) Staff qualifications.

(C) Necessary emergency equipment.

(D) Procedures to provide emergency care.

(E) Quality assurance standards.

(F) Infection control.

(3) Prescribe the operating policies, supervision, and maintenance of medical records.

(4) Establish procedures for the issuance, renewal, denial, and revocation of licenses under this chapter. The rules adopted under this subsection must address the following:

(A) The form and content of the license.

(B) The collection of an annual license fee.

(5) Prescribe the procedures and standards for inspections.

(b) The state department may not exempt an abortion clinic from the requirements

described in subsection (a) of the licensure requirements set forth in an administrative rule, including physical plant requirements. This subsection applies to a person applying for a license as an abortion clinic after December 31, 2013.

(c) A person who knowingly or intentionally:

(1) operates a birthing center or an abortion clinic that is not licensed under this chapter; or

(2) advertises the operation of a birthing center or an abortion clinic that is not licensed under this chapter;

commits a Class A misdemeanor.

Facts

18. Planned Parenthood of Indiana and Kentucky, Inc. (“PPINK”), operates numerous health centers in Indiana and Kentucky where thousands of women, men, and teens receive reproductive health care services and comprehensive sexuality education.

19. At the current time PPINK operates three health care centers or clinics in Indiana, located in Bloomington, Merrillville, and Indianapolis, that offer surgical abortion services.

20. The three surgical abortion clinics also provide non-surgical abortions through 63 days (nine weeks) after a women’s last menstrual period.

21. PPINK operates one Indiana clinic, in Lafayette, that does not provide surgical abortions but does offer non-surgical abortions by using medication.

22. The Lafayette clinic has a physician present part-time with an advanced practice nurse operating in collaboration with a physician the remainder of the time the clinic is open.

23. Although there are abortion providers in Indiana other than PPINK, upon information and belief, PPINK’s Lafayette clinic is the only place in Indiana where non-surgical abortions, but not also surgical abortions, are available.

24. When a woman has chosen a non-surgical abortion at PPINK, including at the Lafayette

clinic, she follows the following protocol after meeting with a health care provider, having an ultrasound performed, and providing the informed consent required by Indiana law:

- A physician prescribes and dispenses and the woman takes the medication, mifepristone, sometimes known as RU-486 or by its trade name Mifeprex, at the clinic in pill form. The medication works by blocking the hormone progesterone that is needed to maintain the pregnancy. The body will begin to react to the mifepristone within a few hours. However, no reaction will occur while the woman is still in the clinic.
- After taking the mifepristone and receiving detailed instructions and scheduling a follow-up appointment the patient will leave the office. Before leaving the office she will receive, but not take, another medication – misoprostol, which is a prostaglandin that will cause uterine contractions that expel the uterine contents. The woman will take the misoprostol, as instructed, approximately 24 hours later at a location of her choosing outside of the clinic.
- Within approximately two to three weeks the woman will return to the clinic for a follow-up appointment.

25. The mifepristone non-surgical abortion, following the protocol used at PPINK, is extremely effective with 95-98% of the women taking the two medications having an abortion. In the extremely rare case where the medication abortion does not terminate the pregnancy, or the woman does not wish to wait for the contents of the uterus to fully expel, she will need to have a surgical procedure to complete the abortion which would not take place at the Lafayette clinic as it does not provide surgical abortions.

26. Serious side effects from these non-surgical abortions are extremely rare and will arise after the woman has taken the mifepristone and left the clinic.

27. The rate of death for these non-surgical abortions is also extremely low – less than 1 in 100,000 cases – a rate that is significantly less than the rate of maternal mortality associated with pregnancy. Again, any complications that could result in a fatality would arise long after the woman has taken the mifepristone and left the clinic.

28. In PPINK's Lafayette clinic, as in all of its health centers, women who choose these non-

surgical abortions are given detailed instructions about the procedure.

29. In the 12 months ending July 1, 2013, 54 women chose to have a mifepristone non-surgical abortion at PPINK's Lafayette clinic.

30. During this same time period, other medications – primarily contraceptives – were dispensed or prescribed more than 10,000 times at the clinic.

31. In addition to not performing surgical abortions, PPINK's Lafayette clinic does not offer any other surgical procedures.

32. Therefore, the clinic, which is in rented space, does not have, and does not need, such things as rooms for surgical procedures, scrub facilities, or recovery rooms.

33. The clinic consists of a waiting room and receptionist area, four examination rooms, a patient and employee restroom, four small offices, storage areas, and a staff break room.

34. It would be a significant and unnecessary expense to renovate the clinic space to add such things as procedure and recovery rooms that would not be used at all for those purposes.

35. Nevertheless, the July 1, 2013, change in Indiana Code § 16-18-2-1.5, defining “abortion clinic” to include a clinic that does nothing more than distribute abortion inducing drugs, combined with the Department's existing regulations and the statutory change prohibiting exemption from those regulations after December 31, 2013, Indiana Code § 16-21-2-2.5(b), means that PPINK's Lafayette clinic must comply with numerous requirements designed for surgical abortions, even though the abortions performed at the clinic are non-surgical and involve only medication that does not take effect until after the patient leaves the Lafayette clinic.

36. These legislative changes were made specifically to target PPINK's Lafayette clinic as the fact that the clinic was the only non-surgical abortion facility in Indiana that prescribed and dispensed abortion inducing drugs was frequently mentioned during legislative debates.

37. Among other things, the above statutory changes, combined with the Department's regulations, mean that the Lafayette clinic must have:

- a “procedure room” at least 120 square feet in size with a hand washing station in each procedure room. 410 IAC 26-17-2(d)(1), (2). At the current time medications are discussed with, and dispensed to, patients in an office or examination room that is less than 120 square feet in size.
- “scrub facilities” near the entrance of procedure rooms. 410 IAC 26-17-2(d)(3). At this point, of course, there are no procedure rooms in the Lafayette clinic and hand-washing sinks are available near the clinician office and in all examination rooms.
- a “separate recovery room or area” with a minimum clear area of 2 feet 6 inches, around three sides of each recovery cart or lounge chair as well as a method for providing privacy for each patient in the room or area and a work station with, among other things, a countertop, space for supplies, and a communication system. 410 IAC 26-17-2(d)(4). Inasmuch as the Lafayette clinic does not engage in any surgical procedures or procedures utilizing anesthesia, it does not have or need a recovery room or recovery area.
- the following equipment available to the procedure and recovery areas:
 - emergency call system
 - oxygen
 - resuscitation equipment

410 IAC 26-13-3(b). Although the Lafayette clinic does possess oxygen and resuscitation equipment it does not have an emergency call system – a system allowing emergency communications from procedure or recovery rooms – as it does not perform surgical procedures.

- a toilet room containing a lavatory for hand washing accessible from the examination and procedure rooms. 410 IAC 26-17-2(d)(6). If the clinic has no more than 3 examination and procedure rooms, the patient toilet may also be the toilet for the waiting area. *Id.* The Lafayette clinic, with four examination rooms at the current time, has one patient lavatory that is used by those in both the clinical area and the waiting area and is adequate for the services offered.
 - a housekeeping room with a service sink and adequate storage for housekeeping supplies and equipment. 410 IAC 26-17-2(e)(1). At the current time the Lafayette clinic has adequate storage for housekeeping supplies and equipment in the staff break area, but it does not have a separate housekeeping room.
38. The ostensible purpose of these regulatory requirements is to protect the health of the

woman obtaining an abortion.

39. However, requiring a facility that only offers non-surgical abortions to meet these requirements is not reasonably related to increasing patient safety and is medically unnecessary.

40. PPINK has sought, for its Lafayette clinic, a license and formal waiver from the Department of certain regulatory requirements. The licensure and waiver request is attached.

41. The granting of the waiver will “not adversely affect the health, safety and welfare of the residents or patients.” Ind. Code § 16-21-1-9.

42. The Department has, to date, not acted upon this license application or waiver request.

43. Effective January 1, 2014, Indiana Code §§ 16-21-1-9, 16-21-2-2.5(b) will allow the Commissioner to grant waivers of any regulatory requirement for good cause shown, except for waivers pertaining to requirements for abortion clinics, provided that the waiver will “not adversely affect the health, safety, and welfare.”

44. If the Lafayette clinic ceases to provide non-surgical abortions, the nearest locations where women in and around Lafayette may obtain an abortion are Indianapolis (approximately 60 miles from Lafayette) and Merrillville (approximately 85 miles from Lafayette).

45. Having to seek an abortion farther away increases the costs of and delays the abortion. Although abortion is an extremely safe procedure, the risk of complications (as well as the cost of the procedure) increases as the pregnancy advances. For some women, having to travel farther will mean that the non-surgical abortion using medication, which is only available very early in pregnancy, will no longer be an option.

46. At all times defendants have acted and have failed to act under color of state law.

47. The actions and the inactions of the defendants are causing PPINK and its patients irreparable harm for which there is no adequate remedy at law.

Legal claims

48. To the extent that Indiana Code §§ 16-18-2-1.5(a)(2) and 16-21-2-2.5(b) and the regulations promulgated by the Commissioner of the Indiana State Department of Health pursuant to Indiana Code 16-21-2-2.5(a) require that the Lafayette clinic of Planned Parenthood of Indiana and Kentucky, Inc., meet requirements that are of any relevance only to clinics that perform surgical abortions, the statutes and regulations are not reasonably related to any legitimate purpose and are therefore unconstitutional as an unreasonable regulation of medicine in violation of women's right to privacy protected by the Fourteenth Amendment to the United States Constitution.

49. To the extent that Indiana Code §§ 16-18-2-1.5(a)(2) and 16-21-2-2.5(b) and the regulations promulgated by the Commissioner of the Indiana State Department of Health pursuant to Indiana Code 16-21-2-2.5(a) require that the Lafayette clinic of Planned Parenthood of Indiana and Kentucky, Inc., meet requirements that are of any relevance only to clinics that perform surgical abortions, the statutes and regulations are unconstitutional as being arbitrary and irrational in violation of the substantive due process guaranteed by the Fourteenth Amendment to the United States Constitution.

50. To the extent that Indiana Code § 16-18-2-1.5 excludes an office that does not primarily perform surgical abortions and does not primarily dispense or prescribe abortion inducing drugs, but includes within the definition of "abortion clinic" the Lafayette clinic of Planned Parenthood of Indiana and Kentucky, Inc., a clinic where only a tiny minority of its dispensed or prescribed medications are abortion inducing medications, the statute irrationally and invidiously discriminates against Planned Parenthood of Indiana and Kentucky, Inc., and violates the equal protection clause of the Fourteenth Amendment to the United States Constitution.

51. To the extent that Indiana Code § 16-21-1-9 and § 16-21-2-2.5(b) allow the Commissioner to grant waivers of any regulatory requirement for good cause shown, provided that the waiver will “not adversely affect the health, safety, and welfare” for all health care facilities except abortion clinics, the statute irrationally and invidiously discriminates against Planned Parenthood of Indiana and Kentucky, Inc., and violates the equal protection clause of the Fourteenth Amendment to the United States Constitution.

Request for relief

WHEREFORE, plaintiff requests that this Court:

1. Accept jurisdiction of this case and set it for hearing at the earliest opportunity.
2. Declare that defendants are violating the constitutional rights of plaintiff and its patients for the reasons stated above.
3. Enter a preliminary injunction, later to be made permanent, enjoining Indiana Code §§ 16-18-2-1.5 and 16-21-2-2.5(b) and/or relevant portions of the State Department of Health’s regulations so that the Lafayette clinic of Planned Parenthood of Indiana and Kentucky, Inc., may continue to dispense abortion inducing medications and enjoining the defendants from taking any adverse actions against Planned Parenthood of Indiana and Kentucky, Inc., for continuing to perform medication abortions without complying with the aforementioned regulations.
4. Award plaintiff its reasonable attorneys’ fees and costs.
5. Award all other appropriate and proper relief.

/s/ Kenneth J. Falk
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