# Case No. 19-2051

# In the United States Court of Appeals for the Seventh Circuit

WHOLE WOMAN'S HEALTH ALLIANCE; et al.,

Plaintiffs-Appellees,

v.

CURTIS T. HILL, JR., Attorney General of Indiana, in his official capacity; *et al.*,

Defendants-Appellants.

On Appeal from the United States District Court for the Southern District of Indiana No. 1:18-CV-01904-SEB-MJD

# BRIEF OF APPELLEE

Paul M. Eckles Mollie M. Kornreich Michael Leo Pomeranz Four Times Square New York, NY 10036

Kathrine D. Jack JACK LAW OFFICE LLC One Courthouse Plaza P.O. Box 813 Greenfield, IN 46140 Dipti Singh Rupali Sharma Stephanie Toti LAWYERING PROJECT 3371 Glendale Blvd., # 320 Los Angeles, CA 90039 (646) 480-8973 dsingh@lawyeringproject.org

Counsel for Plaintiffs-Appellees

Appellate Court No: 19-2051
Short Caption: Whole Woman's Health Alliance, et al. v. Curtiss T. Hill, Jr., et al.
To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party o amicus curiae, or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.
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Lawyering Project; Jack Law Office LLC; Skadden, Arps, Slate, Meagher & Flom LLP (REVISED)
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ii) list any publicly held company that owns 10% or more of the party's or amicus' stock:  Whole Woman's Health Alliance – N/A; All-Options, Inc. – N/A
Attorney's Signature: /S/ Dipti Singh  Date: August 14, 2019
Attorney's Printed Name: Dipti Singh
Please indicate if you are Counsel of Record for the above listed parties pursuant to Circuit Rule 3(d). Yes No $\underline{X}$
Address: Lawyering Project, 3371 Glendale Blvd., #320, Los Angeles, CA 90039
Phone Number: 646-480-8973 Fax Number: 646-480-8828
E-Mail Address: dsingh@lawyeringproject.org

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Attorney's Signature: /S/Rupali Sharma Date: August 14, 2019
Attorney's Printed Name: Rupali Sharma
Please indicate if you are Counsel of Record for the above listed parties pursuant to Circuit Rule 3(d). Yes X No
Address: Lawyering Project, 99 Silver St., 4-10, Portland, ME 04101
Phone Number: 908-930-6645 Fax Number: 646-408-8833
E-Mail Address: <u>rsharma@lawyeringproject.org</u>

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Attorney's Signature: /S/ Stephanie Toti Date: August 14, 2019
Attorney's Printed Name: Stephanie Toti
Please indicate if you are Counsel of Record for the above listed parties pursuant to Circuit Rule 3(d). Yes No $\underline{X}$
Address: Lawyering Project, 25 Broadway, Fl. 9, New York, NY 10004
Phone Number: 646-490-1083 Fax Number: 646-480-8762
E-Mail Address: stoti@lawveringnroject org

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Attorney's Signature: /S/ Kathrine D. Jack Date: August 14, 2019
Attorney's Printed Name: Kathrine D. Jack
Please indicate if you are Counsel of Record for the above listed parties pursuant to Circuit Rule 3(d). Yes No $X$
Address: <u>Jack Law Office LLC, One Courthouse Plaza, P.O. Box 813, Greenfield, IN 46140</u>
Phone Number: 317-477-2300 Fax Number: 317-515-6377
F-Mail Address: kiack@lawoffice.com

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# APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

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N/A
Attorney's Signature: /s/ Paul M. Eckles Date: August 13, 2019
Attorney's Printed Name: Paul M. Eckles
Please indicate if you are Counsel of Record for the above listed parties pursuant to Circuit Rule 3(d). Yes No
Address: Four Times Square, New York, NY 10036
Phone Number: (212) 735-2578 Fax Number: (917) 777-2578
E-Mail Address: paul.eckles@probonolaw.com

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Attorney's Signature: /s/ Mollie M. Kornreich Attorney's Printed Name: Mollie M. Kornreich
Please indicate if you are <i>Counsel of Record</i> for the above listed parties pursuant to Circuit Rule 3(d). Yes No
Phone Number: (212) 735-2775 Fax Number: (917) 777-2775
E-Mail Address: _mollie.kornreich@probonolaw.com

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Attorney's Signature: /s/Michael Leo Pomeranz Date: August 13, 2019  Attorney's Printed Name: Michael Leo Pomeranz
Please indicate if you are <i>Counsel of Record</i> for the above listed parties pursuant to Circuit Rule 3(d). Yes No
Phone Number: (212) 735-3893 Fax Number: (917) 777-3893
E-Mail Address: michael.pomeranz@probonolaw.com

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#### JURISDICTIONAL STATEMENT

Defendants' jurisdictional statement is not complete and correct.

Plaintiffs Whole Woman's Health Alliance ("WWHA"), All-Options, Inc., and Jeffrey Glazer, M.D., filed this action alleging that certain Indiana abortion laws violate the First and Fourteenth Amendments to the U.S. Constitution. The district court has jurisdiction over this case pursuant to 28 U.S.C. §§ 1331 and 1343.

On May 31, 2019, the district court granted WWHA's motion for preliminary injunction barring enforcement of Indiana Code sections 16-21-2-2(4), 16-21-2-2.5(b) and 16-21-2-10 (collectively, the "Licensing Law") against WWHA's clinic in South Bend, Indiana (the "South Bend Clinic"), during the pendency of this lawsuit. On June 2, 2019, Defendants timely appealed. Appellants' Appendix ("App.") 245. This Court has appellate jurisdiction to review the preliminary injunction under 28 U.S.C. § 1292(a)(1). Proceedings are continuing in the district court.

#### STATEMENT OF THE ISSUES PRESENTED FOR REVIEW

Did the district court properly issue a preliminary injunction where a substantial evidentiary record established that Defendants' application of the Licensing Law to prevent the South Bend Clinic from providing medication abortions likely violates the Due Process and Equal Protection Clauses of the U.S. Constitution and irreparably harms northern Indiana residents seeking abortion care?

#### INTRODUCTION

In Indiana, as nationwide, doctor's offices and clinics are not generally subject to facility licensure requirements. Qualified clinicians may—and routinely do—provide

medical care of equal or greater risk than medication abortion in unlicensed settings. Indeed, Indiana permits clinicians to provide the *very same treatment* used to induce a medication abortion in a doctor's office or clinic not subject to licensure requirements when the purpose of the treatment is to manage an incomplete miscarriage. Indiana, however, has singled out abortion for unique facility licensure requirements, and Defendants are applying Indiana's Licensing Law in an unconstitutional manner that arbitrarily limits abortion access.

WWHA has been seeking a license to provide medication abortions at the South Bend Clinic for nearly two years. After exhausting its administrative remedies, WWHA sought relief from the district court, which concluded—based on a substantial evidentiary record—that WWHA is entitled to a preliminary injunction barring enforcement of the Licensing Law against the South Bend Clinic. The district court's narrowly tailored injunction leaves undisturbed all other Indiana laws regulating abortion.

## STATEMENT OF THE CASE

#### I. Abortion Care is Scarce in Indiana.

Unlike many other states, Indiana generally prohibits physicians from providing abortions outside of a licensed abortion clinic. See Ind. Code § 16-21-2-10; 410 Ind.

<sup>&</sup>lt;sup>1</sup> See Bonnie S. Jones, Sara Daniel, & Lindsay K. Cloud, State Law Approaches to Facility Regulation of Abortion and Other Office Interventions, 108 Am. J. Pub. Health L. & Ethics 486, 488-89 (2018) (finding that fourteen states permit all abortions to be performed in facilities not subject to licensure requirements, and some states with licensure requirements exclude facilities that solely provide medication abortions). Physicians may also provide abortions at hospitals and ambulatory surgical centers, but few do. Fewer than one percent of all Indiana abortions were performed in such facilities in 2018. Ind. State Dep't of Health, Terminated Pregnancy Report 2018 at 18 (2018) [hereinafter ISDH 2018]

Admin. Code 26-2-1(a); see also Ind. Code § 16-21-2-2.5(b)(1). Since 2011, the State has lost nearly half of these clinics.<sup>2</sup> Only six licensed abortion clinics remain for about 1.3 million women of reproductive age.<sup>3</sup> Three of those clinics are in Indianapolis. Whole Woman's Health Alliance v. Hill ("WWHA"), No. 1:18-cv-01904-SEB-MJD, 2019 WL 2329381, at \*3 (S.D. Ind. May 31, 2019).

Abortion care is particularly limited in northern Indiana. Just two licensed abortion clinics operate north of Indianapolis, an area including Gary, South Bend, Elkhart, and Fort Wayne. See id. One of the clinics is in Merrillville, in the northwest corner of the State, and the other is in Lafayette, northwest of Indianapolis, which is at the center of the State. Id. Fort Wayne, Indiana's second most populous city, is in the northeastern corner of the State near the Indiana-Ohio state line. Id. South Bend, Indiana's fourth most populous city, is near the Indiana-Michigan state line approximately halfway between Indiana's western and eastern borders. Id. South Bend is approximately 65 miles from Merrillville, 107 miles from Lafayette, and 150 miles from Indianapolis. Id.

Undisputed evidence establishes that travel within this region is difficult, especially for people without a reliable car. Public and commercial transportation options are limited; for example, there is no direct bus or train service between

Report], https://www.in.gov/isdh/files/2018%20Indiana%20Terminated%20Pregnancy%20Report.pdf.

<sup>&</sup>lt;sup>2</sup> See Rachel K. Jones & Jenna Jerman, Abortion Incidence and Service Availability in the United States, 2014, 49 Persp. on Sexual & Reprod. Health 17, 23 (2017), https://doi.org/10.1363/psrh.12015.

<sup>&</sup>lt;sup>3</sup> ISDH 2018 Report, *supra* note 1, at 10, 18.

South Bend and Merrillville. See App. 54; Appellee's Supplemental Appendix ("Suppl. App.") 14, 26. Even when public or commercial transportation is available, patients face logistical burdens. Buses and trains run on limited schedules; fares can be costly relative to disposable income; and poor road conditions or track work sometimes cause delays or cancellations. See App. 54-55; Suppl. App. 26. People with access to cars also face burdens from long-distance travel. In the winter, icy roads, snow, high winds, and below-freezing temperatures can double the amount of time it takes to complete a drive. See Suppl. App. 25-26. These conditions also increase the risk of a break-down or accident. See id. As a result of these travel burdens, a patient with an early morning appointment may have to travel the day before and stay overnight. See App. 55; Suppl. App. 26. Likewise, someone with a late afternoon appointment may not be able to return until the next day.

The added time away from home can deprive workers of wages, jeopardize their jobs, and cause students to miss class. See App. 55; Suppl. App. 15, 18, 26. Lengthy trips also make childcare and arrangements for other dependents more difficult to secure. See Suppl. App. 15, 26; see also WWHA, 2019 WL 2329381, at \*5. They also increase the risk that an abusive partner will learn of the pregnancy and abortion by forcing patients to explain an extended absence. See Suppl. App. 18.

The need to raise money for long-distance transportation or lodging, efforts to find and pay for extended childcare, and adverse road and weather conditions for long stretches of time can all delay an abortion, which prolongs an unwanted pregnancy. *See id.* 15, 25-26. Although abortion is one of the safest medical

interventions provided in the United States, the medical risks of abortion increase with gestational age. *See id.* 3-4. The cost of an abortion also increases with gestational age, *see id.* 3, 15, and Indiana prohibits public and private health insurance from covering that cost in most circumstances, *see* App. 55-56; Suppl. App. 14; *see also* Ind. Code §§ 12-15-5-1(17), 27-8-13.4-2, 27-8-33-4, 27-13-7-7.5. Delays also threaten to push patients past the gestational limit for obtaining a medication abortion. *See* Suppl. App. 3-4.

The district court found that as a result of the obstacles to obtaining abortions in northern Indiana, some women travel out of state to obtain an abortion in Chicago. *WWHA*, 2019 WL 2329381, at \*5.

## II. The South Bend Clinic's Provision of Medication Abortion.

WWHA is a nonprofit organization with a mission to provide abortion care in underserved communities and shift the stigma around abortion. *See* App. 59; Suppl. App. 28, 30. It operates abortion clinics in Austin, Texas, and Charlottesville, Virginia. *See* App. 60; Suppl. App. 30. Following outreach from a coalition of local community members, WWHA decided to open an abortion clinic in South Bend. *See* App. 62.

Although WWHA would eventually like to provide a full spectrum of abortion care at the South Bend Clinic, while the preliminary injunction remains in place, it will offer medication abortion only. *See id.* 64, 78. In particular, in accordance with the prevailing, evidence-based regimen, WWHA will provide medication abortion to patients who are up to 70 days pregnant. *See* App. 78; Suppl. App. 5, 10. This involves giving patients two medications: mifepristone and misoprostol. *See* App.

78-79; Suppl. App. 4-5. Mifepristone, administered at the clinic, works by blocking the hormone progesterone, which is necessary to maintain pregnancy. *See* App. 79; Suppl. App. 4. Misoprostol, taken 24-48 hours later outside of the clinic, causes the cervix to open and the uterus to contract and expel its contents, thereby completing the abortion. *See* App. 79; Suppl. App. 4.

The South Bend Clinic's Medical Director, Dr. Glazer, is a Board-certified ob-gyn licensed to practice medicine in Indiana, Kentucky, and Ohio. See App. 63, 77-78. He has more than three decades of experience as an ob-gyn and has provided abortion care in Indiana for more than five years. See App. 77-78. He currently provides surgical and medication abortion at an abortion clinic in Indianapolis. See App. 78; Suppl. App. 42.

Like abortion overall, medication abortion is extremely safe. See Suppl. App. 3, 36-37; see also Planned Parenthood of Wis., Inc. v. Schimel, 806 F.3d 908, 912-13 (7th Cir. 2015). Serious complications are rare, occurring in less than one percent of patients. See Suppl. App. 37; see also Schimel, 806 F.3d at 912-13. In fact, medication abortion entails a much lower risk of complications than many other medical interventions commonly provided in outpatient settings. See Suppl. App. 3; see also Whole Woman's Health v. Hellerstedt, 136 S. Ct. 2292, 2315 (2016). Requiring that the medications used to induce a medication abortion be dispensed at a licensed facility does not enhance the safety of the treatment. See App. 73, 79; Suppl. App. 6. Because the medications take time to exert their effects, the abortion

occurs after the patient has left the facility.<sup>4</sup> Suppl. App. 8; accord Whole Woman's Health, 136 S. Ct. at 2315. Additionally, medication abortion requires no anesthesia or sedation. See App. 78-79; Suppl. App. 7.

Rigorous scientific research has established that medication abortion does not increase a person's risk of depression or other mental health disorders. *See* Suppl. App. 38-39. On the other hand, childbirth can cause postpartum depression. *See id.* 38.

Indiana permits miscarriage patients to receive the same regimen of medications used to induce a medication abortion in unlicensed doctor's offices. *See* Suppl. App. 7; *see also* Ind. Code § 16-18-2-1.5(a).

## III. Indiana's Licensing Law.

Indiana did not require abortions clinics to be licensed until 2005. *See* Act of Apr. 26, 2005, Pub. L. No. 96-2005, §§ 2, 5-10, 14, 2005 Ind. Acts 1897, 1899-1903 (codified in relevant part at Ind. Code §§ 16-18-2-1.5, 16-21-2-1(a), 16-21-2-2(4), 16-21-2-2.5, 16-21-2-10, 16-21-2-11(2), 16-21-2-14). Even then, the licensing requirement applied only to facilities providing surgical abortion. *See id.* § 2, 2005 Ind. Acts at 1899.

In 2013, Indiana extended the licensing requirement to certain facilities providing medication abortion. *See* Act of May 1, 2013, Pub. L. No. 136-2013, §§ 2, 4, 2013 Ind. Acts 1002, 1002-03 (codified in relevant part at Ind. Code §§ 16-18-2-

<sup>&</sup>lt;sup>4</sup> There is no evidence that medication abortion became safer or more effective in Indiana after 2015, when the current Licensing Law took effect. Similarly, there is no evidence that medication abortion is safer in Indiana than in states that do not require licensure of abortion clinics. *See* App. 73; *see also* Jones *et al.*, *supra* at note 1, at 488-89.

1.5, 16-21-2-2.5). But its enforcement was enjoined on equal protection grounds. See Planned Parenthood of Ind. & Ky., Inc. v. Comm'r, Ind. State Dep't of Health, 984 F. Supp. 2d 912, 916, 931 (S.D. Ind. 2013) (entering preliminary injunction); Planned Parenthood of Ind. & Ky., Inc. v. Comm'r, Ind. State Dep't of Health, 64 F. Supp. 3d 1235, 1260 (S.D. Ind. 2014) (granting partial summary judgment to the plaintiff).

Indiana did not enact the current licensing requirement until 2015. See Act of Apr. 30, 2015, Pub. L. No. 92-2015, §§ 1, 4, 2015 Ind. Acts 633 (codified in relevant part at Ind. Code §§ 16-18-2-1.5, 16-21-2-2.5). The requirement defines "[a]bortion clinic" as "a health care provider . . . that: (1) performs surgical abortion procedures; or (2) . . . provides an abortion inducing drug for the purpose of inducing an abortion." Ind. Code § 16-18-2-1.5(a). It excludes from that definition any "health care provider that provides, prescribes, administers, or dispenses an abortion inducing drug to fewer than five (5) patients per year for the purposes of inducing an abortion." Id. § 16-18-2-1.5(b)(3). Operating an abortion clinic without a license is a crime under the current licensing requirement. See id. § 16-21-2-2.5(b).

# IV. The Department's Refusal to Grant a License to the South Bend Clinic.

WWHA first applied to the Indiana State Department of Health (the "Department") for a license to provide medication abortions at the South Bend Clinic on August 11, 2017. See WWHA, 2019 WL 2329381, at \*11; App. 64. At the Department's request, it submitted a revised application containing additional detail on October 6, 2017. See WWHA, 2019 WL 2329381, at \*11; App. 64. On October 27, 2017, the Department asked WWHA to provide additional information, including "a complete ownership structure or description pertaining to the

applicant, including, but not limited to, any individuals and/or any parent, affiliate or subsidiary organizations." Suppl. App. 70. The Department also requested a "list of all the abortion and health care facilities currently operated by [the] applicant, including its parent, affiliate or subsidiary organizations." *Id*.

On December 8, 2017, WWHA responded to the Department in writing, explaining that it is a nonprofit corporation, it has no owners, and its governing authority is vested in its Board of Directors. See id. 73-74. WWHA also provided the addresses and state license numbers of the abortion clinics it operates in Texas and Virginia, see id., and gave the Department copies of its governance documents, including its Certificate of Formation and Bylaws. See id. 80-107. In addition, WWHA disclosed that it contracts with Whole Woman's Health, LLC (the "Management Company"), a healthcare management company that services abortion clinics across the country, and gave the Department a copy of the agreement governing the Management Company's services to the South Bend Clinic. See App. 62, 66; Suppl. App. 74, 101-07. The Management Company is part of Whole Woman's Health, a consortium of limited liability companies involved in the provision of abortion care. See App. 60. Although Amy Hagstrom Miller is the President and CEO of both WWHA and Whole Woman's Health, the two

<sup>&</sup>lt;sup>5</sup> These companies are all held by The Booyah Group, LLC, a corporation wholly owned by Amy Hagstrom Miller (and named for a communally prepared stew). *See WWHA*, 2019 WL 2329381, at \*10. "Whole Woman's Health" is the consortium's doing business name. *See* App. 60. Over the course of its sixteen-year history, Whole Woman's Health has owned abortion clinics in Illinois, Maryland, Minnesota, and Texas. *See id.* 61.

organizations are legally and financially independent and conduct business at arm's length. App. 58, 62; Suppl. App. 31.

On January 3, 2018, the Department denied WWHA's license application after finding that the organization's failure to characterize WWHA and Whole Woman's Health as "affiliates" reflected a lack of "reputable and responsible character." *See* Suppl. App. 108-09.

On January 22, 2018, WWHA appealed the Department's denial of its license application. See WWHA, 2019 WL 2329381, at \*14. Indiana permits liberal discovery in such administrative proceedings, akin to Federal Rule of Civil Procedure 26. See Ind. R. Trial P. 26. During discovery, among other things, WWHA identified its Board members, see Suppl. App. 162; described Ms. Hagstrom Miller's relationship to WWHA and Whole Woman's Health, see id. 142-48, 151-56; and produced agreements between WWHA and the Management Company, see id. 121. The Department also sent document subpoenas to Whole Woman's Health. Though these subpoenas were procedurally deficient and unenforceable, Whole Woman's Health voluntarily produced over 130 pages of documents in response, including certificates of formation, ownership ledgers, and articles of operation concerning its constituent companies. See App. 66-67.

On August 22-23, 2018, an administrative law judge ("ALJ") for the Department held a hearing at which the Department had the opportunity to examine three of WWHA's corporate officers, including Ms. Hagstrom Miller. See Suppl. App. 110. The ALJ issued an order recommending that the Department grant WWHA's

license application because WWHA had shown that its responses to the Department's October 27, 2017, requests were complete and accurate. *See id.* 110-17. On November 28, 2018, a divided appellate panel voted to reverse the ALJ's order. *See* App. 101.

At the Department's invitation, WWHA reapplied for an abortion clinic license on January 16, 2019, see App. 67, 91-92; WWHA, 2019 WL 2329381, at \*16. In connection with its application, WWHA provided all information the Indiana Code specifically requires. See Ind. Code § 16-21-2-11. Among other things, WWHA affirmed that it has never operated an abortion clinic that closed due to patient health and safety concerns; none of its Board members or clinic staff members has ever been convicted of a felony; and none of its Board members or clinic staff members has ever been employed by a facility owned or operated by WWHA that closed as a result of administrative or legal action. See Suppl. App. 50; see also Ind. Code § 16-21-2-11(d). Additionally, WWHA provided copies of all inspection reports and plans of correction concerning its Austin and Charlottesville clinics and the names and addresses of all clinics owned by Whole Woman's Health. See App. 67.

On February 25, 2019, the Department notified WWHA that it would not evaluate WWHA's application further unless, among other things, WWHA satisfied a set of broad document demands concerning Whole Woman's Health. *See id.* 67, 75-76. On March 15, 2019, WWHA informed the Department that its document demands were overbroad and unduly burdensome, calling for the production of hundreds of thousands of pages, including privileged materials. *See id.* 67; Suppl.

App. 46. With cooperation from Whole Woman's Health, WWHA nevertheless produced a subset of responsive documents. See e.g., Suppl. App. 47, 53-56. Further, Ms. Hagstrom Miller attested that: Whole Woman's Health operates clinics in three states that require abortion clinics to be licensed; no Whole Woman's Health clinic has ever been denied a state license; and except for a quickly corrected error by the Texas Department of State Health Services ("Texas Department"), no Whole Woman's Health clinic has ever had its license suspended or revoked. See App. 68; Suppl. App. 52. Twelve days later, after the Department refused to proceed on WWHA's licensure application, WWHA moved the district court for a preliminary injunction.

## V. Procedural History.

On June 21, 2018, while WWHA was still exhausting administrative remedies, it joined Dr. Glazer and All-Options, Inc., in this lawsuit, challenging the constitutionality of certain Indiana abortion laws, including the Licensing Law. *See* App. 1-44.

On March 27, 2019— after nearly two years of seeking licensure through Indiana's application process—WWHA asked the district court to enjoin Defendants from enforcing the licensing requirement against the South Bend Clinic pending final judgment in this case. *See id.* 45-48.

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<sup>&</sup>lt;sup>6</sup> On November 29, 2006, the Texas Department issued an Emergency Order revoking the license of a Whole Woman's Health clinic in Beaumont, Texas, based on erroneous inspection findings. After Whole Woman's Health notified the Texas Department of the errors, it lifted the revocation order on December 7, 2006—eight days after the revocation order had been issued. See App. 68; Suppl. App. 52-56.

On May 31, 2019, the district court granted WWHA's motion on due process and equal protection grounds. *See WWHA*, 2019 WL 2329381, at \*33. The district court's preliminary injunction applies only to the requirement that WWHA obtain a license before providing five or more medication abortions at the South Bend Clinic. *Id.* (enjoining enforcement of "Indiana Code § 16-21-2-2(4) (requiring Department to license); Indiana Code § 16-21-2-2.5(b) (penalty for unlicensed operation); and Indiana Code § 16-21-2-10 (necessity of license) against WWHA with respect to the South Bend Clinic").

Defendants subsequently filed a Notice of Appeal, App. 245, and moved to stay the preliminary injunction pending appeal. Motion for Stay Pending Appeal, *Whole Woman's Health Alliance v. Hill*, No. 1:18-cv-10904-SEB-MJD (S.D. Ind. filed June 2, 2019), ECF No. 119. The district court denied Defendants' motion on June 7, 2019. App. 247-57. Defendants then moved this Court to stay the preliminary injunction. Mot. for Stay of Prelim. Inj. Pending Appeal, ECF No. 3. On June 21, 2019, this Court modified the preliminary injunction to ensure that it applies only to "facilities that provide medical abortions . . . and only with respect to the proposed clinic in South Bend." Order at 2, ECF No. 10. It heard oral argument on Defendants' Motion to Stay on July 11, 2019.

WWHA is currently providing medication abortions at the South Bend Clinic pursuant to the preliminary injunction. It has served dozens of patients to date.

#### SUMMARY OF ARGUMENT

Although the Constitution generally permits states to require licensure of healthcare facilities—including abortion clinics—licensing laws that impose an

undue burden on abortion access or create classifications that run afoul of the Equal Protection Clause are impermissible. Similarly, arbitrary and discriminatory enforcement of an otherwise valid licensing law violates the Constitution. At this stage of the proceedings, WWHA seeks only as applied relief from the Licensing Law that would enable it to provide medication abortions at the South Bend Clinic pending final judgment.

The district court did not abuse its discretion in granting WWHA a preliminary injunction. WWHA demonstrated a likelihood of success on the merits of its claims. First, it showed that Defendants' application of the Licensing Law to prevent the South Bend Clinic from providing medication abortions imposes an undue burden on northern Indiana residents. WWHA presented extensive evidence demonstrating that people in northern Indiana face substantial obstacles when seeking abortion care from a distant provider. Meanwhile, Defendants failed to demonstrate that their arbitrary and unreasonable application of the Licensing Law provides sufficient benefits as an *ex ante* credentialing mechanism or an *ex post* enforcement mechanism to justify the burden it imposes on abortion access. Contrary to Defendants' assertions, the Department's ability to inspect an abortion clinic is not tied to the Licensing Law. The Department may therefore inspect the South Bend Clinic while the Licensing Law is enjoined.

Second, WWHA showed that the Licensing Law's differential treatment of abortion patients and miscarriage patients violates the Equal Protection Clause.

Dr. Glazer may treat a miscarriage patient at the South Bend Clinic with

mifepristone and misoprostol, but the Licensing Law prohibits him from treating an abortion patient with the exact same regimen of medications unless the clinic first obtains a license. Defendants have failed to justify this disparate treatment, which infringes on patients' right to abortion.

Third, WWHA showed that Defendants have applied the Licensing Law—which grants unfettered discretion to the Department—in an arbitrary and discriminatory manner in violation of the vagueness doctrine. Although the district court did not rely on WWHA's vagueness claim in issuing the preliminary injunction, that claim provides an alternate ground for affirmance.

WWHA also satisfied the other requirements for a preliminary injunction.

Northern Indiana residents who are delayed in accessing abortion or denied access altogether suffer irreparable harm. That harm outweighs any harm that the preliminary injunction may cause the State, especially given that the injunction does not prevent the Department from inspecting the South Bend Clinic. Further, the public interest is served by protecting constitutional rights.

Finally, as-applied relief from the Licensing Law is an appropriate remedy; indeed, precedent holds that as-applied relief is generally preferable to facial relief. Thus, the district court properly granted a narrowly tailored injunction that bars enforcement of the Licensing Law against the South Bend Clinic but leaves all other Indiana laws regulating abortion undisturbed. Those laws continue to apply to the South Bend Clinic and the clinicians providing care there.

## **ARGUMENT**

## I. Standard of Review.

This court reviews the grant or denial of a preliminary injunction for abuse of discretion. See Whitaker ex rel. Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ., 858 F.3d 1034, 1044 (7th Cir. 2017). This Court reviews the district court's legal conclusions de novo, see 1st Source Bank v. Neto, 861 F.3d 607, 610 (7th Cir. 2017), findings of fact for clear error, see Valencia v. City of Springfield, 883 F.3d 959, 966 (7th Cir. 2018), and gives substantial deference to the district court's analysis of the balancing of harms. See Whitaker, 858 F.3d at 1054. The presence or absence of irreparable harm is a factual finding, not a legal one, and is thus subject to clear error review. See Girl Scouts of Manitou Council, Inc. v. Girl Scouts of U.S., Inc., 549 F.3d 1079, 1087 (7th Cir. 2008). When the district court does not commit an error of law or a clear error of fact, this Court "accord[s] a district court's decisions during the balancing phase of the analysis great deference." Valencia, 883 F.3d at 966 (citation omitted).

- II. WWHA is Likely to Succeed on the Merits of Its Claims.
  - A. WWHA is Likely to Succeed on the Merits of Its Due Process Claim.
    - 1. The Undue Burden Standard Applies to WWHA's Due Process Claim.

In an unbroken line of precedent spanning nearly five decades, the Supreme Court has held that the right to end a pregnancy is a fundamental component of the liberty protected by the Due Process Clause. *See, e.g., Whole Woman's Health*, 136 S. Ct. at 2309-10; *Lawrence v. Texas*, 539 U.S. 558, 573-74 (2003); *Planned* 

Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 851-53 (1992) (opinion of the Court); Roe v. Wade, 410 U.S. 113, 152-54 (1973). Laws that infringe on the abortion right are subject to the undue burden standard set forth in Casey, which provides that a law is unconstitutional if it "has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus." Casey, 505 U.S. at 877 (joint opinion of O'Connor, J., Kennedy, J. & Souter, J.). The Supreme Court recently clarified that "[t]he rule announced in Casey... requires that courts consider the burdens a law imposes on abortion access together with the benefits those laws confer." Whole Woman's Health, 136 S. Ct. at 2309. Where the burdens are disproportionate to the benefits, the law is unconstitutional. See id. at 2300, 2309-10; Schimel, 806 F.3d at 919-20. "[C]ourts must apply the undue burden balancing test . . . to all abortion regulations," and in so doing, they must "consider the evidence in the record—including, expert evidence." Planned Parenthood of Ind. & Ky., Inc. v. Comm'r of Ind. State Dep't of Health ("PPINK"), 896 F.3d 809, 818 (7th Cir. 2018), petition for cert. docketed, No. 18-1019 (U.S. Feb. 4, 2019).

The undue burden standard is a form of heightened scrutiny. See Whole Woman's Health, 136 S. Ct. at 2309-10. To satisfy it, the State cannot merely assert that the Licensing Law is rationally related to a valid state interest. Id. at 2309 ("[It] is wrong to equate the judicial review applicable to the regulation of a constitutionally protected personal liberty with the less strict review applicable where, for example, economic legislation is at issue."); Schimel, 806 F.3d at 921 ("The statute may not be irrational, yet may still impose an undue burden—a

burden excessive in relation to the aims of the statute and the benefits likely to be conferred by it—and if so it is unconstitutional."). Instead, the State must demonstrate that the law actually advances the asserted interest—and that it does so to an extent sufficient to justify the burdens that it imposes on abortion access. Whole Woman's Health, 136 S. Ct. at 2300, 2309-10; PPINK, 896 F.3d at 827 ("To determine whether a burden is undue, the court must 'weigh the burdens against the state's justification, asking whether and to what extent the challenged regulation actually advances the state's interests. If a burden significantly exceeds what is necessary to advance the state's interests, it is "undue," and thus unconstitutional." (quoting Schimel, 806 F.3d at 919)).

When assessing the extent to which a law furthers a valid state interest, a court must consider the extent to which the interest is served by other laws currently in force. See Whole Woman's Health, 136 S. Ct. at 2311 ("We have found nothing in Texas' record evidence that shows that, compared to prior law... the new law advanced Texas' legitimate interest in protecting women's health." (emphasis added)); PPINK, 896 F.3d at 826. It is the marginal benefit of the law under review that must be weighed against the law's burdens. See PPINK, 896 F.3d at 826, 828-30 (assessing the marginal benefit of an eighteen-hour waiting period in light of an existing ultrasound requirement).

#### 2. The Undue Burden Standard is Fact-Dependent.

Defendants erroneously contend that cases upholding other states' licensing laws preclude a finding that Indiana's Licensing Law is unconstitutional as applied

to the South Bend Clinic. See Appellants' Br. at 20-21, ECF No. 24. The undue burden standard is fact-dependent. As this Court recently explained: "[B]oth Whole Woman's Health and Casev stress that the undue burden test is context specific. An abortion statute valid as to one set of facts and external circumstances can be invalid as to another." PPINK, 896 F.3d at 817 (citations omitted); accord Comprehensive Health of Planned Parenthood Great Plains v. Hawley, 903 F.3d 750, 756 (8th Cir. 2018). The district court properly evaluated WWHA's undue burden claim on the record before it concerning the particular benefits and burdens that flow from Defendants' application of Indiana's Licensing Law to prevent the South Bend Clinic from providing medication abortions. See App. 251 (Order on Defs.' Mot. to Stay) ("[O]ur analysis does not purport to assess the constitutionality of requiring licensure as a general matter; it assesses the constitutionality of Indiana's licensing scheme specifically as applied to the facts of this case."). The cases cited by Defendants are factually distinguishable and do not support a per se approval of every application of a licensing requirement.

- 3. The Benefits of the Licensing Law—As Applied by Defendants—Are Insufficient to Justify the Burdens It Imposes.
  - a. WWHA Has Shown That Defendants' Application of the Licensing Law to Prevent the South Bend Clinic from Providing Medication Abortions Imposes Heavy Burdens on Northern Indiana Residents Who Want to End Their Pregnancies.

WWHA presented extensive evidence concerning the obstacles that people in northern Indiana must overcome to obtain abortion care, and the district court made detailed factual findings about those obstacles. *WWHA*, 2019 WL 2329381, at \*3-5, 31; *see supra* at 2-5. Defendants do not dispute the credibility or admissibility

of the record evidence on which the district court relied. Instead, they contend that a law does not violate the undue burden standard unless it *prevents* individuals from having abortions. Their position cannot be reconciled with controlling caselaw, which holds that an undue burden is "a burden excessive in relation to the aims of the statute and the benefits likely to be conferred by it." *Schimel*, 806 F.3d at 921. This Court has made clear that lengthy travel and the hardships that stem from it are burdens that must be weighed against a law's benefits to determine if the law imposes an undue burden on abortion access. *See, e.g., PPINK*, 896 F.3d at 819 (affirming a preliminary injunction against enforcement of the challenged law) ("All of the burden in this case originates from the lengthy travel that is required of some women who have to travel far distances for an ultrasound appointment at least eighteen hours prior to an abortion.").7

Defendants also wrongly contend that the district court erred by evaluating the impact of the Licensing Law in light of the factual and legal context in which it operates, rather than in the abstract. *See* Appellants' Br. at 31-35. This Court's precedents make clear that a court applying the undue burden standard must

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<sup>&</sup>lt;sup>7</sup> Contrary to Defendants' assertions, *Casey* did not establish a floor that travel distances must exceed to constitute an undue burden. *See* Appellants' Br. at 32. Instead, it held that the factual record before the Court was not detailed enough to establish that the travel necessitated by Pennsylvania's mandatory waiting-period law constituted an undue burden "even for the women who are most burdened by it," in light of the valid state interests served by the law. *Casey*, 505 U.S. at 887 ("[O]n the record before us, and in the context of this facial challenge, we are not convinced that the 24-hour waiting period constitutes an undue burden."). *Casey* does not preclude a finding that the evidence presented in this asapplied challenge establishes that Defendants' application of the Licensing Law to prevent the South Bend Clinic from providing medication abortions constitutes an undue burden for those who are most burdened by it.

consider the real-world context in which an abortion restriction operates. See, e.g., PPINK, 896 F.3d at 824 ("Courts must consider the impact of the . . . law based on the reality of the abortion provider and its patients, not as it could if providers and patients had unlimited resources."). The district court correctly focused its analysis on those individuals—such as "women in northern Indiana who [do not] enjoy ample financial means, supportive personal relationships, and power over their own conditions of labor and movement," WWHA, 2019 WL 2329381, at \*4—who will be most acutely burdened by the inability of the South Bend Clinic to provide abortion care. See Casey, 505 U.S. at 894 ("The proper focus of constitutional inquiry is the group for whom the law is a restriction, not the group for whom the law is irrelevant."). That approach is consistent with this Court's application of the undue burden standard in *PPINK* and *Schimel*, which considered the impact of the challenged laws on low-income women and those with employment or childcare responsibilities. See PPINK, 896 F.3d at 819-20; Schimel, 806 F.3d at 919. Likewise, the district court was correct to consider how the need to comply with Indiana's mandatory waiting-period law contributes to the obstacles that northern Indiana residents must overcome to access abortion care absent a local provider. See Planned Parenthood of Wis., Inc. v. Van Hollen, 738 F.3d 786, 796 (7th Cir. 2013) ("When one abortion regulation compounds the effects of another, the aggregate effects on abortion rights must be considered.").

Defendants' reliance on *Harris v. McRae*, 448 U.S. 297, 316 (1980) to support their position is misplaced. *Harris* merely holds that Indiana need not provide its

residents with the financial resources necessary to obtain an abortion. *See id.* at 316. It does not authorize Indiana to enforce restrictions on abortion access that place substantial obstacles in the path of individuals seeking previability abortion. *See id.* Such action is plainly prohibited by *Casey* and its progeny. *See* 505 U.S. at 877-78.8

In addition, Defendants wrongly contend that the burdens imposed by their application of the Licensing Law are mitigated by the ability of northern Indiana residents to obtain abortion care in other states. See Appellants' Br. at 32-33. This Court has repeatedly held that harm to a constitutional right cannot be measured by the extent to which it can be exercised in another jurisdiction. See Schimel, 806 F.3d at 918-19; Ezell v. City of Chicago, 651 F.3d 684, 697 (7th Cir. 2011) ("It's hard to imagine anyone suggesting that Chicago may prohibit the exercise of a free-speech or religious-liberty right within its borders on the rationale that those rights may be freely enjoyed in the suburbs.").9

<sup>&</sup>lt;sup>8</sup> Defendants also cite *June Medical Services L.L.C. v. Gee*, 905 F.3d 787, 810-11 (5th Cir. 2018), *petition for cert. docketed*, No. 18-1323 (U.S. Apr. 19, 2019), and *conditional cross-petition for cert. docketed*, No. 18-1460 (U.S. May 23, 2019) to support their position, but they fail to inform the Court that the Supreme Court stayed the Fifth Circuit's mandate in that case pending the filing and disposition of the plaintiffs' petition for a writ of certiorari, *June Med. Servs., L.L.C. v. Gee*, 139 S. Ct. 663 (2019). The petition was docketed on April 19, 2019, No. 18-1323, and remains pending.

<sup>&</sup>lt;sup>9</sup> Defendants erroneously assert that "even though [Plaintiff's witness Jane Doe] obtained her abortion in Chicago, there is no basis for concluding that she could not have gotten an abortion in Merrillville—only 65 miles away." Appellants' Br. at 33. The record contains undisputed evidence that there is no direct public or commercial transportation connecting South Bend and Merrillville, making it extremely difficult for some people in South Bend to travel to Merrillville. See Suppl. App. 25-27. The district court relied on this evidence in finding that "[n]o direct lines of public transportation connect South Bend to Merrillville," WWHA, 2019 WL 2329381 at \*4, and "[t]he obstacles to obtaining abortions in northern

b. Defendants Have Failed to Show That Their Application of the Licensing Law Advances Valid State Interests to an Extent Sufficient to Justify the Resulting Burdens.

Defendants contend that the Licensing Law advances the State's interests in patient health and potential life<sup>10</sup> by creating an *ex ante* credentialing mechanism for abortion providers and an *ex post* enforcement mechanism for Indiana's abortion laws. *See* Appellants' Br. at 26-31. But they have shown, at most, "little more than *de minimis* marginal advancement" of these interests. *WWHA*, 2019 WL 2329381, at \*30. The burdens resulting from Defendants' application of the Licensing Law are thus disproportionate to the benefits and therefore unconstitutional. *See Whole Woman's Health*, 136 S. Ct. at 2300, 2309-10; *Schimel*, 806 F.3d at 919-20.

i. The Licensing Law Provides Little or No Marginal Benefit as an *Ex Ante* Credentialing Mechanism.

To support their claim that the Licensing Law confers benefits as an *ex ante* credentialing mechanism, Defendants offer only a vague assertion, unsupported by evidence: "The Licensing Law apprehends and addresses potential concerns before any damage occurs—ensuring compliance and preventing injuries and illness rather

Indiana are such that women find it easier to travel out of state to Chicago, bypassing nearby Merrillville, to obtain abortions there." *Id.* at \*5.

<sup>&</sup>lt;sup>10</sup> Defendants actually contend that application of the Licensing Law to the South Bend Clinic advances the State's interest in "fetal" life. See e.g., Appellants' Br. at 26. This terminology is incorrect. According to the Department's own Abortion Informed Consent Brochure, fetal life does not begin until 14 weeks, measured from the first day of a woman's last menstrual period ("lmp"). Ind. State Dep't of Health, Abortion Informed Consent Brochure 3 (2018), https://www.in.gov/isdh/files/Abortion\_Informed\_Consent\_Brochure.pdf. The South Bend Clinic, however, only provides medication abortion through ten weeks lmp. See supra at 5. From four to fourteen weeks lmp, a developing human entity is called an embryo. Abortion Informed Consent Brochure, supra, at 2-3. From implantation in the uterus to three weeks lmp, it is called a blastocyst. Id. at 2.

than merely reacting to violations." Appellants' Br. at 28. Their subsequent allegations of misconduct in a *licensed* abortion clinic belies this contention. *See id.* at 30.<sup>11</sup> Moreover, independently of the Licensing Law, Indiana law provides that only licensed physicians may provide abortions. *See* Ind. Code § 16-34-2-1(a)(1)(A), (a)(2). Violation of this requirement constitutes a felony. *Id.* § 16-34-2-7(a). To obtain a license to practice medicine in Indiana, a physician must satisfy rigorous requirements concerning the physician's competence and character. *See id.* § 25-22.5-3-1; 844 Ind. Admin. Code § 4-4.5-7. In light of Indiana's requirement that abortion *providers* be licensed, the additional requirement that abortion *clinics* be licensed provides little or no marginal benefit as a credentialing mechanism.

Further, the Department's rationale for withholding a license from the South Bend Clinic is not reasonably related to the State's interest in ensuring that abortion providers are properly credentialed. Defendants assert that "[s]everal issues gave the Department concern over the suitability of granting Whole Women's

<sup>&</sup>lt;sup>11</sup> Bad doctors can, unfortunately, be found in all medical specialties. See, e.g., Brett Kelman, After 5 Deadly Overdoses, Tennessee Doctor Now Practicing in Indiana, Tennessean, Jan. 24, 2019, https://www.tennessean.com/story/news/investigations/2019/01/ 24/opioid-overdose-deaths-tennessee-doctor-darrel-rinehart-indiana/2452093002/; Ariana Eunjung Cha, Fertility Fraud: People Conceived Through Errors, Misdeeds in the Industry Are Pressing for Justice, Wash. Post, Nov. 22, 2018 ("Jacoba Ballard was conceived in a brick office building on 86th Street in Indianapolis when fertility doctor Donald Cline inseminated her mother with his own sperm instead of the donor sperm he had promised."), https://www.washingtonpost.com/national/health-science/fertility-fraud-peopleconceived-through-errors-misdeeds-in-the-industry-are-pressing-for-justice/2018/11/ 22/02550ab0-c81d-11e8-9b1c-a90f1daae309 story.html?utm term=.23e1447bf696; Danny Robbins, Abused and Sterilized by Her Doctor: Indiana Patient Is a Victim Whose Harm Cannot Be Undone, Atlanta Journal-Constitution, Dec. 13, 2016, http://doctors.ajc.com/indiana\_patient\_abused\_sterilized/. The record contains no evidence that abortion providers are more likely to engage in misconduct than other physicians, who may practice in doctor's offices and clinics not subject to licensure requirements.

Health [sic] a license." Appellants' Br. at 23. First, they claim that "the Department was alarmed to find out that the anticipated clinic administrator [named on WWHA's first license application had previously worked at the clinic of Ulrich Klopfer," an Indiana physician who had been disciplined by the Medical Licensing Board of Indiana (the "Medical Board"). *Id.* But the Department did not seek any documents or information concerning the prospective clinic administrator, see App. 65, and it did not cite this issue in the Notice of License Application Denial that it sent WWHA, see Suppl. App. 108-09. Notably, none of the supplemental questions that the Department posed to WWHA on October 27, 2017, concerned the prospective clinic administrator's background, qualifications, or role at Dr. Klopfer's clinic. Id. 70-71. Following the denial of WWHA's first license application, WWHA could no longer afford to pay the prospective clinic administrator's salary and had to let her go. App. 63-64. She subsequently found a new job. *Id.* 64. During the administrative appeal, WWHA notified the Department of this, and it named a new clinic administrator on its second license application. Suppl. App. 50. Defendants have failed to explain why the identity of the original clinic administrator provides grounds for withholding a license from the South Bend Clinic.

Second, Defendants assert that WWHA's failure to fully satisfy the Department's February 25, 2019, document demands concerning the Whole Woman's Health clinics prevents them from approving WWHA's second license application. See supra at 11-12. But they have failed to explain what specific information the Department needs to make a licensure determination that it does

not already have and what specific steps it would take if it obtained that information. In connection with its two license applications and the administrative appeal following denial of the first license application, WWHA has provided the Department with extensive information concerning its corporate structure; the clinics it operates; its relationship with Whole Woman's Health; and the safety record of its own abortion clinics and the Whole Woman's Health clinics. See supra at 8-12. In addition, WWHA has provided the Department with information about Dr. Glazer, the clinic's Medical Director and primary abortion provider. See supra at 6, 8, 11-12. The information and document demands made by the Department on February 25, 2019, are cumulative, unduly burdensome, and not reasonably related to ascertaining the credentials of WWHA or Dr. Glazer. Moreover, if provided to the Department, most of the requested documents would be subject to public disclosure under Indiana's access-to-public-records law. See Ind. Code §§ 5-14-3-1, 5-14-3-4.

The first demand requires "copies of all reports, complaints, forms, correspondence, and other documents that concern, mention, or relate to any investigation, inspection, or survey of [any Whole Woman's Health clinic] by any state or other regulatory authorities at any time since and including January 1, 2014." App. 76. At the time it was made, Whole Woman's Health operated five abortion clinics in four states. *Id.* 61. Each was subject to regulatory oversight by multiple state and federal agencies. *See* Suppl. App. 46. To provide every document that "concern[s], mention[s], or relate[s] to" any "investigation, inspection, or survey" by a regulator over a five-year period would be an unwarranted intrusion

into the internal affairs of Whole Woman's Health, especially since the demand makes no exception for communications with counsel or patient medical records. In response, WWHA submitted a declaration from Amy Hagstrom Miller stating that no Whole Woman's Health clinic had ever been denied a license, and apart from an erroneous action in Texas, no Whole Woman's Health clinic had ever had its license suspended. 12 *Id.* 52. Defendants have failed to establish that full satisfaction of this document demand would provide any marginal benefit in enabling the Department to assess the credentials of WWHA and Dr. Glazer, given the information that the Department already possesses.

The second demand requires "copies of all forms, correspondence, reports, and other documents that concern, mention, or relate to any application(s) by [any Whole Woman's Health clinic] for licensure of or other permission to operate an abortion clinic at any time since and including January 1, 2014." App. 76. Like the first document demand, this one is overly broad, potentially capturing everything from the organization's strategic plans to minutes of internal meetings to financial reports. WWHA and Ms. Hagstrom Miller have already identified all clinics operated by WWHA or Whole Woman's Health in states that require abortion clinic licensure, and they have attested that, other than the South Bend Clinic, no WWHA or Whole Woman's Health clinic has ever been denied a license. *See supra* at 12. Again, Defendants have failed to establish that full satisfaction of this document

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<sup>&</sup>lt;sup>12</sup> Ms. Hagstrom Miller provided documentation concerning the Texas action, in which the Texas Department revoked a clinic's license based on erroneous inspection findings and then restored the license eight days later. Suppl. App. 53-56.

demand would provide any marginal benefit in enabling the Department to assess the credentials of WWHA and Dr. Glazer, given the information about them that the Department already possesses.

The third demand by the Department requires "copies of all orders, submissions, correspondence and other documents that concern, mention, or relate to any regulatory or administrative enforcement action, or administrative, civil or criminal court action involving [any Whole Woman's Health clinic] at any time since and including January 1, 2014." App. 76. Whole Woman's Health has served as a plaintiff in several federal court challenges to unconstitutional abortion restrictions. Id. 61. Thus, there are hundreds of thousands of responsive documents relating to the organization's affirmative litigation alone, which include privileged communications. Moreover, WWHA has already produced the non-sealed portions of the evidentiary record in Whole Woman's Health v. Hellerstedt, in which federal courts all the way up to the U.S. Supreme Court scrutinized the health and safety record of Whole Woman's Health's Texas clinics, see id.; and Ms. Hagstrom Miller attested that, apart from the erroneous action in Texas, no Whole Woman's Health clinic has ever had a state license suspended, see supra at 12. Defendants have utterly failed to explain how this demand for a voluminous production of documents concerning Whole Woman's Health's advocacy and litigation activities will aid its assessment of WWHA's and Dr. Glazer's credentials.

The fourth demand requires "the legal name and current address of each person who, at any time since and including January 1, 2014, has been an organizer, manager, director, owner, and/or officer of [any Whole Woman's Health clinic] affiliate." *Id.* 76. WWHA has provided this information to the Department on multiple occasions. *See* Suppl. App. 46-47. Defendants have not explained if or how they have utilized this information.

In short, the Department's February 25, 2019, document would do little, if anything, to advance the State's interest in ascertaining the credentials of WWHA and Dr. Glazer given the extensive information about them that the Department already possesses.

# ii. The Licensing Law Provides Little or No Marginal Benefit as an *Ex Post* Enforcement Mechanism.

Defendants' evidence fails to establish that the marginal benefit of the Licensing Law in enforcing Indiana's other abortion laws is significant.

First, Defendants' contention that the Department may not inspect the South Bend Clinic while it operates pursuant to the preliminary injunction is erroneous. Indiana law provides that the Department "shall inspect an abortion clinic at least one (1) time per calendar year and may conduct a complaint inspection as needed." Ind. Code § 16-21-2-2.6. The definition of "abortion clinic" is not limited to licensed facilities. Instead, it encompasses any "health care provider" that "performs surgical abortion procedures" or "provides an abortion inducing drug for the purpose of inducing an abortion" except a licensed hospital, a licensed ambulatory outpatient surgical center, or "[a] health care provider that prescribes, administers, or

dispenses an abortion inducing drug to fewer than five (5) patients per year for the purposes of inducing an abortion." *Id.* § 16-18-2-1.5. "Health care provider" is in turn defined, in relevant part, as "[a]n individual . . . authorized by the state to provide health care or professional services as a licensed physician." *Id.* § 16-18-2-163(d)(1). Dr. Glazer undoubtedly satisfies the definition of "health care provider," and any doctor's office or clinic at which he provides five or more medication abortions per year constitutes an abortion clinic that is subject to inspection. If there were any doubt, this Court could direct the district court to add language to the preliminary injunction stating that it shall not be construed to prevent the Department from inspecting the South Bend Clinic to the extent otherwise authorized by section 16-21-2-2.6 of the Indiana Code. WWHA does not contest the Department's authority to inspect the South Bend Clinic pursuant to section 16-21-2-2.6 of the Indiana Code while the preliminary injunction is in force.

Second, Indiana's informed consent laws have enforcement mechanisms that are independent of the Licensing Law. Under Indiana law, all "physicians have a duty to disclose to their patients information material to a proposed course of treatment." *Spar v. Cha*, 907 N.E.2d 974, 984 (Ind. 2009). "A physician must disclose the facts and risks of a treatment which a reasonably prudent physician would be expected to disclose under like circumstances, and which a reasonable person would want to know." *Id.* Failure to provide a patient with the required information subjects a

physician to professional discipline by the Medical Board, *see* 844 Ind. Admin. Code 5-1-3, as well as civil liability, <sup>13</sup> *see Spar*, 907 N.E.2d at 979-80.<sup>14</sup>

In addition to generally applicable law concerning informed consent, Indiana has enacted a statute providing that "consent to an abortion is voluntary and informed only if" abortion patients are provided with certain specific information. Ind. Code § 16-34-2-1.1(a). Providing an abortion to a patient who has not received the required information is punishable as a Class A infraction. See Ind. Code § 16-34-2-7(c); see generally id. § 34-28-5-4(a) ("A judgment of up to ten thousand dollars (\$10,000) may be entered for a violation constituting a Class A infraction."). A separate Indiana statute makes it a "criminal act" to perform an abortion without the consent of the patient, except when "the abortion is necessary to preserve the life of the woman." Id. § 16-34-2-1(a)(1)(B). Defendants have presented no evidence that the enforcement mechanisms for these statutes are insufficient to deter Dr. Glazer from violating them.

Notably, these statutes were respectively enacted in 1995 and 1993. See S.B. 311, 109th Leg., 1st Reg. Sess. (Ind. 1995) (enacted as Pub. L. 187-1995, § 4); S.B. 24, 108th Leg., 1st Reg. Sess. (Ind. 1993) (enacted as Pub. L. 2-1993, § 17). But

<sup>&</sup>lt;sup>13</sup> For example, in *Perez v. Hu*, a patient whose newborn was injured during a vaginal delivery sued her ob-gyn for failing to adequately disclose the risks of vaginal birth relative to caesarian section for someone with her specific risk factors. 87 N.E.3d 1130, 1132-33 (Ind. Ct. App. 2017). The Indiana Court of Appeals denied the physician's request for a directed verdict. *Id.* at 1139.

<sup>&</sup>lt;sup>14</sup> In light of these authorities, Defendants' unsupported assertion that "the failure to obtain informed consent before performing an abortion . . . may not constitute traditional torts such as medical malpractice or negligence," Appellants' Br. at 29, is not credible.

Indiana abortion clinics providing surgical abortions were not subject to licensure until 2005, and Indiana abortion clinics solely providing medication abortion were not subject to licensure until 2015. *See supra* at 7-8. There is no evidence in the record that abortion providers failed to comply with their informed consent obligations in the intervening decades, or that any person in Indiana was harmed as the result of a physician's failure to obtain informed consent for an abortion during that time period.

It is also noteworthy that the mandatory disclosure statute permits a "referring physician" or qualified delegate who practices outside of a licensed abortion clinic—including in an office-based setting not subject to any licensure requirement—to provide the required information. See Ind. Code §§ 16-34-2-1.1(a)(1), (4).

Further, while the State may legitimately advance its interest in potential life through measures "calculated to inform the woman's free choice," *Casey*, 505 U.S. at 877, its interest in ensuring informed consent to abortion is no different than its interest in ensuring informed consent to other medical interventions, such as treatment of an incomplete miscarriage, *see id.* at 884 ("[A] requirement that a doctor give a woman certain information as part of obtaining her consent to an abortion is, for constitutional purposes, no different from a requirement that a doctor give certain specific information about any medical procedure."). Indiana's failure to require licensure of all medical practices providing procedures that require a patient's informed consent undermines the State's argument that facility licensure materially enhances the State's ability to ensure informed consent.

Third, the other Indiana laws governing abortion providers also have enforcement mechanisms that are independent of the Licensing Law. See, e.g., Ind. Code § 16-34-2-7 (imposing criminal penalties for violations of any requirement set forth in Indiana Code Title 16, Article 34, Chapter 2, which is titled, "Requirements for Performance of Abortion; Criminal Penalties"). In addition, a licensed physician such as Dr. Glazer who performs an abortion that fails to comply with any provision of Indiana law is subject to license revocation or other disciplinary action by the Medical Board. See Ind. Code §§ 25-1-9-4(a)(3), 25-22.5-8-6(b).

# 4. Defendants' Smear Campaign Against WWHA and Dr. Glazer is Belied by the Evidentiary Record.

Throughout these proceedings, Defendants have engaged in a series of unjustified smears against WWHA and Dr. Glazer. The district court rightfully rejected Defendants' efforts to defame these plaintiffs as inaccurate and unsupported by evidence. *See WWHA*, 2019 WL 2329381, at \*28-29.

Although Dr. Glazer has been providing abortion care at licensed abortion clinics in Indiana for more than five years, Defendants now imply that he is incompetent and unscrupulous. See Appellants' Br. at 12-13. Prior to Dr. Glazer's participation in this lawsuit, neither the Department nor the Medical Board raised any concerns

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<sup>&</sup>lt;sup>15</sup> Defendants contend that it is not "clear that all regulatory violations would trigger Indiana's criminal prohibition against unlawful abortions." Appellants' Br. at 29. They fail, however, to identify any specific statutory or regulatory requirement that lacks an independent enforcement mechanism, much less demonstrate that the marginal benefit from the Licensing Law in enforcing such a requirement would justify the burdens on abortion access that flow from preventing the South Bend Clinic from providing medication abortions.

about Dr. Glazer's character or the quality of abortion care that he provides. See App. 78.

Most of Defendants' attacks on Dr. Glazer stem from his unwillingness to answer questions at his deposition about documents that he was not given the opportunity to review. For example, Defendants' counsel presented Dr. Glazer with an American College of Obstetricians and Gynecologists Practice Bulletin ("ACOG Practice Bulletin") concerning medication abortion but did not give him an opportunity to read it from beginning to end. See id. 151-52. The document is 18 pages long. See id. 179-96. Similarly, Defendants' counsel presented Dr. Glazer with the National Abortion Federation's 2018 Clinical Policy Guidelines for Abortion Care ("NAF Guidelines"), but did not give him an opportunity to read them from beginning to end. See id. 153-54. That document is 57 pages long. See NAF Guidelines, https://5aa1b2xfmfh2e2mk03kk8rsx-wpengine.netdna-ssl.com/wpcontent/uploads/2018\_CPGs.pdf. Defendants' counsel then proceeded to quiz Dr. Glazer about the specific contents of the documents. See, e.g., App. 154 ("Q: Do you know if the NAF Clinical Policy Guidelines conflict with the ACOG guidelines at all?"). Dr. Glazer declined to answer these questions without the opportunity to thoroughly review the documents. See, e.g., id. 154 ("A: I would have to look at the specific—everything and review it to make sure that I was following it."); id. 154 ("A: Again, I haven't reviewed it, so I don't know."). Dr. Glazer's answers demonstrate that he is careful and precise, but Defendants selectively quote his testimony to make it seem like he is careless and uninformed.

Additionally, Defendants contend that Dr. Glazer "was unsure if he was certified as required by the FDA to prescribe Mifeprex." Appellants' Br. at 12. Dr. Glazer's confusion is understandable given that the FDA does not certify doctors to prescribe Mifeprex, the trade name for mifepristone. *See* Suppl. App. 39-40. Defendants' confusion, on the other hand, is inexcusable.

The district court found that "the evidence overall suggests that Plaintiff Glazer is a competent, responsible provider of ob/gyn care generally and abortion care specifically." WWHA, 2019 WL 2329381, \*29. After noting that Dr. Glazer has provided medication abortions at licensed abortion clinics in Indiana "without a whisper of concern on the Department's part," the district court further concluded that "[i]f Defendants have only in the course of this litigation unearthed causes for concern with Plaintiff Glazer's practice, that says little or nothing about the benefits derived from the Licensing Law as written." Id.

In addition to slinging mud at Dr. Glazer, Defendants mischaracterize the findings of inspection reports issued to WWHA and WWH clinics to make it seem like those clinics are not operating safely. When a state health department inspects a licensed healthcare facility, it typically issues a report identifying "deficiencies," or instances in which the facility failed to meet the letter or spirit of a regulatory standard. See Suppl. App. 35. It is rare for an inspection process to conclude without noting deficiencies. See id. In response to an inspection report noting deficiencies, a healthcare facility must typically submit a "plan of correction" to the

health department. See id. The health department accepts a plan of correction when it believes that the plan will fully address the deficiency. See id.

Deficiencies, in and of themselves, do not signify a threat to patient health or safety. See id. If a health department identifies an ongoing threat to patient health and safety at a licensed healthcare facility, it will typically take disciplinary action against the facility, such as suspension or revocation of its license. See id. Texas law, for example, authorizes the State health department to suspend or revoke an abortion clinic's license for 14 different reasons, including: "the facility or its employees commits an act which causes immediate jeopardy to the health and safety of a patient," 25 Tex. Admin. Code § 139.32(b)(3); "the facility is cited for deficiencies and fails to submit an acceptable plan of correction," id. § 139.32(b)(4); and "the facility has a history of failure to comply with the rules adopted under this chapter," id. § 139.32(b)(13).

Except for an incident in 2006 in which the license of a Whole Woman's Health clinic in Beaumont, Texas, was revoked erroneously and then quickly restored, no WWHA or Whole Woman's Health clinic has ever had its license suspended or revoked. *See* App. 68. This shows that state health departments did not consider any deficiencies issued to these clinics to be threats to patient health or safety.

Moreover, Defendants mischaracterize many of the deficiencies that they cite. For example, Defendants assert that an inspection report from WWHA's Austin clinic found, among other things, that the "facility failed to ensure proper sterilization procedure for loads and instruments." *Id.* 117; *accord* Appellants' Br. at

23-24. But what the inspectors actually found was: "Review of the autoclave logs for May, June, and July 2017 revealed that pressure, temperature and duration of exposure at desired temperature and pressure of the sterilized logs was not documented." Suppl. App. 62. The inspection report further noted that "the facility was utilizing old logs that did not contain a prompt to document this information." *Id.* 63. Thus, this deficiency concerned a paperwork error, not failure to properly sterilize instruments.

In addition, Defendants provided incomplete inspection reports to the district court, omitting the text from the "plan of correction" column, which is the healthcare provider's response to the alleged deficiency. *See, e.g., id.* 57-69.

Omitting that text is misleading. For example, Defendants assert that WWHA's Austin clinic "fail[ed] to account for Fentanyl, a highly addictive Schedule II drug." Appellants' Br. at 45. The clear insinuation is that the clinic lost track of or potentially diverted a narcotic drug. But the plan of correction, which the Texas Department accepted, indicates that the source of the issue was a clerical error, not missing doses of the drug. "WWHA provided this inspection report with the plan of

<sup>&</sup>lt;sup>16</sup> The complete inspection report including the plan of correction is attached hereto as Exhibit A. The clinic's response to the alleged Fentanyl deficiency notes that: "The error identified by the surveyors was related to a clerical miscount, and not to any missing doses." Ex. A, at 2. The clinic's response to the alleged sterilization deficiency discussed above notes that "Whole Woman's Health Alliance has accurate confirmation that all instruments have been properly sterilized. In addition to the autoclave load logs the facility uses special sterilization pouches, sterilization strips, and sterilization tape that automatically confirms instruments are properly sterile without requiring staff documentation." *Id.* at 4. The Texas Department accepted the plan of correction in its entirety and took no further action.

correction to the Department as part of its second license application, see App. 67, but Defendants nonetheless provided an incomplete version of the inspection report to the court.<sup>17</sup>

#### 5. As-Applied Relief Is Permissible in Abortion Cases.

As-applied relief is generally preferable to facial relief. See Ayotte v. Planned Parenthood of N. New Eng., 546 U.S. 320, 328-29 (2006). "It is axiomatic that a 'statute may be invalid as applied to one state of facts and yet valid as applied to another." Id. at 329 (quoting Dahnke-Walker Milling Co. v. Bondurant, 257 U.S. 282, 289 (1921)). "Accordingly, the 'normal rule' is that 'partial, rather than facial, invalidation is the required course,' such that a 'statute may . . . be declared invalid to the extent that it reaches too far, but otherwise left intact." Id. (alteration in original) (quoting Brockett v. Spokane Arcades, Inc., 472 U.S. 491, 504 (1985)).

Defendants' contention that only facial relief is permissible under the undue burden standard is wholly unsupported by legal authority and utterly meritless. In *Gonzales v. Carhart*, 550 U.S. 124 (2007), for example, the Supreme Court rejected the plaintiffs' facial challenge to a statute banning a method of abortion but held that "[t]he Act is open to a proper as-applied challenge in a discrete case." *Id.* at 168. Defendants' contention that as-applied relief from an unduly burdensome abortion law cannot be granted to a particular clinic also lacks merit. In *Whole Woman's Health*, the district court held the challenged admitting-privileges requirement

<sup>17</sup> Amici States similarly mischaracterize deficiencies and cite incomplete inspection reports

that omit the plans of correction. Br. for the States of Texas *et al.* at 10-17, ECF No. 26. Had the cited deficiencies been as serious as *amici* now claim, Texas undoubtedly would have taken disciplinary action against the clinics. It did not.

unconstitutional as applied to particular clinics in McAllen, Texas, and El Paso, Texas. Whole Woman's Health v. Lakey, 46 F. Supp. 3d 673, 687 (W.D. Tex. 2014), aff'd in part, vacated in part, rev'd in part sub nom. Whole Woman's Health v. Cole, 790 F.3d 563 (5th Cir. 2015), modified, 790 F.3d 598 (5th Cir. 2015), rev'd sub nom. Whole Woman's Health v. Hellerstedt, 136 S. Ct. 2292 (2016). Although the Supreme Court ultimately concluded that the law was unconstitutional in all of its applications, Whole Woman's Health, 136 S. Ct. at 2300, it did not disturb the district court's judgment for purposes of the State's motion for a stay pending appeal. To the contrary, it vacated the stay that had been entered by the court of appeals, demonstrating that the as-applied relief awarded by the district court was permissible. Whole Woman's Health v. Lakey, 135 S. Ct. 399, 399 (2014) ("The Court of Appeals' stay order with reference to the district court's order enjoining the admitting-privileges requirement as applied to the McAllen and El Paso clinics [is] vacated.").

#### B. WWHA Is Likely To Succeed on the Merits of Its Equal Protection Claim.

The Licensing Law treats individuals who seek medication abortion differently than individuals who seek medical management of a miscarriage using the exact same regimen of mifepristone and misoprostol. See WWHA, 2019 WL 2329381, at \*1-2, 27, 30. Northern Indiana residents in the latter category may obtain treatment in any doctor's office or clinic, but pursuant to the Licensing Law, northern Indiana residents in the former category must obtain treatment in a licensed facility. See id. Given the paucity of licensed facilities providing abortion care in northern Indiana, see supra at 2, the Licensing Law makes it significantly

harder for abortion patients in northern Indiana to access mifepristone and misoprostol than for miscarriage patients in northern Indiana.

# 1. WWHA's Equal Protection Claim Is Independent of Its Due Process Claim and Warrants Heightened Scrutiny.

"The Due Process Clause and the Equal Protection Clause . . . set forth independent principles." Obergefell v. Hodges, 135 S. Ct. 2584, 2602-03 (2015) ("Rights implicit in liberty and rights secured by equal protection may rest on different precepts and are not always co-extensive, yet in some instances each may be instructive as to the meaning and reach of the other."); see also Lawrence v. Texas, 539 U.S. 558, 575 (2003) ("Equality of treatment and the due process right to demand respect for conduct protected by the substantive guarantee of liberty are linked in important respects . . . . "). The Due Process Clause prohibits the state from infringing individual autonomy absent a sufficient justification. *Obergefell*, 135 U.S. at 2597. The Equal Protection Clause protects against inequality by prohibiting the state from treating similarly situated persons differently without an adequate justification. City of Cleburne v. Cleburne Living Ctr., 473 U.S. 432, 439 (1985); Vision Church v. Vill. of Long Grove, 468 F.3d 975, 1000 (7th Cir. 2006). The protection afforded the abortion right under the Due Process Clause does not render protection under the Equal Protection Clause superfluous.

Contrary to Defendants' assertions, WWHA does not ask the Court to apply a "super-standard under equal protection," Appellants' Br. at 37. Instead, it asks the Court to apply heightened scrutiny to a *classification* drawn by the Licensing Law that implicates the abortion right, just as the Court must apply heightened scrutiny

in determining whether the law in and of itself violates the abortion right. See supra at 17-18. The Supreme Court has developed a vast body of jurisprudence concerning application of the Equal Protection Clause to statutory classifications that burden fundamental rights, holding that such classifications are subject to heightened review. See, e.g., Obergefell, 135 S. Ct. at 2602-04; Harper v. Va. State Bd. of Elections, 383 U.S. 663, 670 (1966) ("We have long been mindful that where fundamental rights and liberties are asserted under the Equal Protection Clause, classifications which might invade or restrain them must be closely scrutinized and carefully confined."); Skinner v. Okla. ex rel. Williamson, 316 U.S. 535, 541 (1942). Defendants offer no credible rationale for why the abortion right should be singled out from all other fundamental rights for exclusion from this jurisprudence.

As explained above, the undue burden standard is a form of intermediate scrutiny. See supra at 17-18. WWHA asked the district court to apply traditional intermediate scrutiny to evaluate the infringement of patients' equal protection rights, which would require the State to show "at least that the [challenged] classification serves 'important governmental objectives and that the discriminatory means employed' are 'substantially related to the achievement of those objectives." United States v. Virginia, 518 U.S. 515, 533 (1996) (alteration in original) (citations omitted). The district court instead applied the undue burden standard, reasoning that "the standard under the Equal Protection Clause is the same as that under the Due Process Clause." WWHA, 2019 WL 2329381, at \*25; see also Planned Parenthood of Great Nw. & Hawaiian Islands v. Wasden, Case No. 1:18-cv-00555,

2019 WL 3325800, at \*6 (D. Idaho July 24, 2019) (assessing equal protection claim on behalf of abortion patients under *Casey's* undue burden test). In the context of an equal protection claim, the undue burden standard requires the State to show that a challenged classification serves legitimate state interests to an extent sufficient to justify any burdens on abortion access that it imposes. <sup>18</sup> *See Whole Woman's Health*, 136 S. Ct. at 2300. The choice between the two variants of intermediate scrutiny makes little practical difference. As explained below, the Licensing Law's differential treatment of abortion patients and miscarriage patients fails both formulations.

# 2. The Licensing Law's Differential Treatment of Abortion Patients and Miscarriage Patients Violates the Equal Protection Clause.

As explained above, traditional intermediate scrutiny requires Defendants to prove that the differential treatment of abortion patients and miscarriage patients is substantially related to the achievement of an important governmental objective. See supra at 41. WWHA does not contest that, under existing precedent, promoting patient health and potential life are important governmental objectives. But Defendants have failed to prove that singling out abortion clinics for a licensure requirement not imposed on medical practices that treat miscarriages is substantially related to the achievement of these objectives.

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<sup>&</sup>lt;sup>18</sup> The district court correctly recognized that even if the same standard applies to abortion patients' equal protection and due process rights, they remain separate rights. *WWHA*, 2019 WL 2329381, at \*27-30 (evaluating equal protection claim).

With respect to the State's interest in patient physical health, mifepristone and misoprostol are no more dangerous when dispensed from an abortion clinic than when dispensed from a doctor's office or clinic providing treatment of miscarriages. Supra at 6-7. Defendants do not argue otherwise. Based on the factual record, the district court found that the "medical and physiological impacts are identical or practically identical in both cases." WWHA, 2019 WL 2329381, at \*30.

The crux of Defendants' argument appears to be that the Licensing Law's differential treatment is permissible because abortion, unlike miscarriage, implicates the State's interest in (1) protecting mental health and (2) promoting potential life. Appellants' Br. at 40-41. With respect to the State's interest in protecting mental health, rigorous scientific research has found that having an abortion does not increase a person's risk of depression or other mental health disorders. Suppl. App. 38-39. Although some of Defendants' declarants described experiencing depression or post-traumatic stress after obtaining abortions outside of Indiana, they did not state whether their abortions were performed in unlicensed facilities. See App. 211-241. The testimony, which the district court considered, see WWHA, 2019 WL 2329381, at \*3, therefore does not support Defendants' argument that requiring WWHA's licensure will diminish the risk of mental health harm to patients. Notably, this Court recently affirmed another district court's rejection of Indiana's claims that abortion has a negative impact on mental health. See PPINK, 896 F.3d at 809 ("[T]he district court rejected the State's evidence regarding women's mental health . . . [and] chose to credit instead two mental health

organizations that conducted a comprehensive review of studies on mental health and abortion and concluded that 'on the best evidence available . . . [t]he rates of mental health problems for women with unwanted pregnancy were the same whether they had an abortion or gave birth." (alteration in original) (citations omitted)).

Moreover, Defendants fail to demonstrate how requiring licensure of the South Bend Clinic would diminish the alleged risk of mental harm to its patients. They assert, without evidentiary support, that: "The Licensing Law increases the likelihood that abortion providers will comply with the informed-consent and waiting-period requirements both through *ex ante* screening for reputable and responsible character and through *ex post* inspections and license-revocation consequences." Appellants' Br. at 41. The statutory informed consent requirement, however, imposes duties, not on the abortion clinic, but on "the physician who will perform the abortion," who must already be licensed by the Medical Board, or a "referring physician," who, while also licensed by the Medical Board, may work at a doctor's office or clinic that is not subject to the Licensing Law or any licensure requirements at all. *See* Ind. Code §§ 16-34-2-1.1(a)(1), (4).19

Defendants argue that the State's interest in potential life is advanced through enforcing informed consent requirements. But they fail to show how the Licensing

<sup>&</sup>lt;sup>19</sup> The "physician who is to perform the abortion" or the "referring physician" may also direct a licensed physician assistant, advance practice registered nurse, or certified nurse midwife—who works at the abortion clinic or an unlicensed referring facility—to provide the required disclosures. *See* Ind. Code § 16-34-2-1.1(a)(1), (4).

Law is substantially related to enforcing Indiana's informed consent laws. See supra at 29-33. Further, Defendants do not dispute that both abortion and miscarriage management treatments implicate the State's interest in ensuring informed patient choice. Yet, they fail to provide an adequate justification for Indiana's differential treatment of abortion and miscarriage given that patients are similarly situated in this regard. Defendants also contend that inspections are necessary to monitor abortion providers' compliance with Indiana's informed consent requirements. But, as explained above, the preliminary injunction does not prevent the Department from inspecting the South Bend Clinic. See supra at 29-30. The Licensing Law's classification thus fails to satisfy traditional intermediate scrutiny.

It fares no better under the undue burden standard which, in the equal protection context, requires Defendants to show that treating abortion patients differently than miscarriage patients provides benefits sufficient to justify the burdens that such treatment imposes on abortion access. The district court found that Defendants' application of the Licensing Law to the South Bend Clinic imposed heavy burdens on abortion access for northern Indiana residents. WWHA, 2019 WL 2329381, at \*3-7, 31. But Defendants have failed to establish that requiring mifepristone and misoprostol to be dispensed from licensed facilities when used for medication abortion advances any legitimate state interest more than requiring those medications to be dispensed from licensed facilities when used for miscarriage management would. See supra at 6-7. Thus, the benefits of treating abortion

patients differently than miscarriage patients are insufficient to justify the heavy burdens that the Licensing Law—as applied here—imposes on northern Indiana residents seeking medication abortion.

# C. WWHA's Vagueness Claim Provides an Alternative Ground for Affirmance.

WWHA's vagueness claim provides an alternative ground for affirming entry of the preliminary injunction. Although the district court found that WWHA's likelihood of success on that claim is negligible, *see WWHA*, 2019 WL 2329381, at \*19-23, this Court is free to consider its legal merit *de novo*, *see supra* at 16.

A law is unconstitutionally vague if it gives inadequate notice of the conduct it prohibits or invites arbitrary and discriminatory enforcement. See Johnson v. United States, 135 S. Ct. 2551, 2557 (2015). The second criterion is "more important" than the first and perhaps the most meaningful aspect of the "vagueness doctrine." Kolender v. Lawson, 461 U.S. 352, 358 (1983); Smith v. Goguen, 415 U.S. 566, 574 (1974). Laws invite arbitrary and discriminatory enforcement when they lack objective enforcement standards. See Kolender, 461 U.S. at 358, 361 (invalidating a statute that "contain[ed] no standard for determining what a suspect has to do in order to satisfy the requirement to provide a 'credible and reliable' identification"); Coates v. City of Cincinnati, 402 U.S. 611, 612 (1971) (invalidating an ordinance prohibiting three or more people from assembling and "annoying" passersby because, though "annoying" is a "widely used and well understood word," the ordinance gave the police unfettered discretion to apply it). Courts must apply a "more stringent vagueness test" when a challenged law "threatens to inhibit the

exercise of constitutionally protected rights." Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc., 455 U.S. 489, 499 (1982); accord Colautti v. Franklin, 439 U.S. 379, 390-96 (1979).

The risk of arbitrary and discriminatory enforcement is especially high in the context of abortion because it is a "constitutionally protected right that has been a traditional target of hostility." *Women's Med. Ctr. of Nw. Hous. v. Bell*, 248 F.3d 411, 421-22 (5th Cir. 2001) (holding that abortion providers were likely to succeed on the merits of their claim that laws conditioning abortion clinic licensure on subjective standards were unconstitutionally vague); see also Colautti, 439 U.S. at 381, 393-96.

Here, WWHA does not challenge the Licensing Law on its face; rather, it contends that Defendants' particular application of the Licensing Law to deny the South Bend Clinic a license violates the vagueness doctrine. There are no standards limiting how the Department may determine whether an applicant for a license to operate an abortion clinic has demonstrated reputable and responsible character, and the Licensing Law gives the Department unfettered discretion to demand information and documents from an applicant in connection with this determination. See Ind. Code § 16-21-2-11(a)(1); 410 Ind. Admin. Code 26-2-4(b); id. 26-2-5(1). Although the law may be applied in a legitimate fashion, the Department has applied it against WWHA in an arbitrary and discriminatory fashion.

First, the Department concluded that WWHA's good-faith efforts to answer the Department's October 27, 2017 question about its ownership structure amounted to

a lack of reputable and responsible character because the Department disagreed with WWHA about whether the for profit companies in the Whole Woman's Health consortium are "affiliates" of nonprofit WWHA. See supra at 9-10; WWHA, 2019 WL 2329381, at \*12-15. The Department reached this conclusion even though the questions it propounded to WWHA did not define the term "affiliate," see Suppl. App. 70-71; "there was no applicable statutory definition of 'affiliate" at the time, WWHA, 2019 WL 2329381, at \*13; and the Department did not pose any direct questions about the relationship between WWHA and Whole Woman's Health, see Suppl. App. 70-71. Defendants told the district court that "the Department's failure to furnish guidance to WWHA" concerning the information it sought was "part of lits] investigative technique." WWHA, 2019 WL 2329381, at \*13 (alteration in original) (citation omitted). The Department's conduct is the epitome of arbitrary and discriminatory enforcement.

Second, the Department has refused to grant WWHA a license to provide medication abortions at the South Bend Clinic unless it complies with overly broad, unduly burdensome, and exceptionally intrusive document demands that are not reasonably related to determining whether WWHA has reputable and responsible character. Supra at 25-29. While the Department may be applying the reputable and responsible character requirement to other applicants in a constitutional manner, the record evidence shows it has used the prerequisite to withhold licensure from WWHA unless it submits to a costly and burdensome fishing expedition that threatens to expose confidential and proprietary information to the

Department and, by operation of Indiana's public records law, the general public. See Ind. Code §§ 5-14-3-1, 5-14-3-2(q)–(r), 5-14-3-4; cf. Law Students Civil Rights Research Council, Inc. v. Wadmond, 401 U.S. 154, 158, 167 (1971) (rejecting vagueness challenge to character and fitness requirements where the state had "shown every willingness to keep [its] investigations within constitutionally permissible limits" and no applicant had "ever been unjustifiably denied permission to practice law"). And even if WWHA were able to satisfy this latest demand, Defendants maintain that the Licensing Law permits the Department to continue to demand further information and additional documents. This, too, constitutes arbitrary and discriminatory enforcement of a standardless grant of authority.

This Court should apply a "stringent" vagueness test to WWHA's claim because the Department's enforcement of the Licensing Law against WWHA inhibits northern Indiana residents from exercising their "constitutionally protected right" to obtain an abortion. *Vill. of Hoffman Estates*, 455 U.S. at 499; *see supra* at 2-5, 10-12, 19-22.

- III. The Other Requirements for a Preliminary Injunction Are Met.
  - A. Absent the Preliminary Injunction, Residents of Northern Indiana Would Face Irreparable Harm for Which There Is No Adequate Remedy at Law.

Absent the preliminary injunction, the Department's application of the Licensing Law to the South Bend Clinic will cause northern Indiana residents irreparable injury. When a constitutional right is "threatened or [] impaired," no further showing of irreparable injury is necessary. *Elrod v. Burns*, 427 U.S. 347, 373 (1976). Here, relying on substantial record evidence, the district court concluded that

enforcing the Licensing Law against the South Bend Clinic would harm northern Indiana residents who will be unable to obtain an abortion in South Bend, forcing them to travel further to obtain care and resulting in delayed or forgone care.

WWHA, 2019 WL 2329381, at \*3-5; see PPINK, 896 F.3d at 832 ("For... patients who lose the opportunity to exercise their constitutional right to an abortion, the irreparability of the harm is clear. Even an extended delay in obtaining an abortion can cause irreparable harm by 'result[ing] in the progression of a pregnancy to a stage at which an abortion would be less safe, and eventually illegal." (alteration in original) (quoting Van Hollen, 738 F.3d at 796)).

# B. Public Interest and the Balance of Harms Favor WWHA and Its Patients.

The district court correctly found that the public interest and balance of harms weigh in favor of the preliminary injunction. *WWHA*, 2019 WL 2329381, at \*32-33. An injunction protecting constitutional rights serves the public interest and the State does not have a valid interest in upholding unconstitutional laws. *See Joelner v. Vill. of Wash. Park*, 378 F.3d 613, 620 (7th Cir. 2004).

Defendants' arguments about the balance of harms all derive from their assertion that the State has no way to oversee the South Bend Clinic and the Department has no authority to inspect the South Bend Clinic absent licensure. As explained above and in the district court's opinion, Defendants are wrong as a matter of law. Supra at 29-30; WWHA, 2019 WL 2329381, at \*30 (concluding that Defendants failed to show that "abortion clinics . . . operated with 'little or no meaningful regulatory oversight" absent licensure (citation omitted)); id.

("Defendants place great reliance on the Department's authority to inspect . . . abortion clinics, but have not shown how that authority is contingent on the clinics' licensure.").

Finally, as the district court found, Defendants' contention that "Whole Woman's Health clinics have failed to operate safely . . . is not well supported" by the record. 

WWHA, 2019 WL 2329381, at \*29 (citation omitted). Defendants flagrantly 
mischaracterize the findings of inspection reports issued to WWHA and Whole 
Woman's Health clinics in other states to suggest that the clinics pose a threat to 
patient safety, but the health departments in those states did not reach that 
conclusion and took no adverse action against the clinics. See supra at 36, 38.

In sum, the threat of irreparable harm to northern Indiana residents from continued enforcement of the Licensing Law to prevent the South Bend Clinic from providing medication abortion significantly outweighs any harm to Defendants from the preliminary injunction. Thus, the balance of harms favors the injunction. *See PPINK*, 896 F.3d at 816.

#### CONCLUSION

For the reasons set forth above, WWHA respectfully asks this Court to affirm the preliminary injunction entered by the district court.

#### Respectfully submitted,

#### /S/Dipti Singh

Dipti Singh LAWYERING PROJECT 3371 Glendale Blvd., #320 Los Angeles, CA 90039 (646) 480-8973 dsingh@lawyeringproject.org

Rupali Sharma LAWYERING PROJECT 99 Silver St., 4-10 Portland, ME 04101 (908) 930-6645 rsharma@lawyeringproject.org

Stephanie Toti LAWYERING PROJECT 25 Broadway, Fl. 9 New York, NY 10004 (646) 490-1083 stoti@lawyeringproject.org Kathrine D. Jack JACK LAW OFFICE LLC One Courthouse Plaza P.O. Box 813 Greenfield, IN 46140 (317) 477-2300 kjack@lawoffice.com

Paul M. Eckles
Mollie M. Kornreich
Michael Leo Pomeranz
Four Times Square
New York, NY 10036
(212) 735-2578 (PME)
(212) 735-2775 (MMK)
(212) 735-3893 (MLP)
paul.eckles@probonolaw.com
mollie.kornreich@probonolaw.com
michael.pomeranz@probobolaw.com

Attorneys for Plaintiffs-Appellees

#### CERTIFICATE OF COMPLIANCE

1. This document complies with the type-volume limit of Circuit Rule 32(c) because, excluding the parts of the document exempted by Federal Rule of Appellate Procedure 32(f), this document contains 13,875 words.

2. This document complies with the typeface requirements of Circuit Rule 32(b) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 12-point Century font.

#### CERTIFICATE OF SERVICE

I hereby certify that, on August 14, 2019, the foregoing document was served on all counsel of record via the Court's CM/ECF system.

/S/ Dipti Singh

Dipti Singh Attorney for Plaintiffs-Appellees

# EXHIBIT A

Case: 19-2051

Document: 33

Filed: 08/14/2019

Pages: 78

TX Department of Aging and Disability Services Regulatory Services

## STATEMENT OF LICENSING VIOLATIONS AND PLAN OF CORRECTION

Form DADS 3724 July 2015

PRINTED: 07/26/2017 1:50:31PM

(X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY STATEMENT OF DEFICIENCIES , COMPLETED AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING: B. WING 07/24/2017 140013 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 8401 NORTH IH 35 SUITE 200 WHOLE WOMAN'S HEALTH ALLIANCE **AUSTIN, TX 78753** SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID COMPLETE IEACH DEFICIENCY MUST BE PRECEDED BY FULL PREF X (EACH CORRECTIVE ACTION SHOULD BE PREFIX CROSS-REFERENCED TO THE APPROPRIATE DATE REGULATORY OR USC IDENTIFYING INFORMATION) TAG TAG DEFICIENCY) A 000 A 000 TAC 139 Initial Comments Note: The State Form is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately. An entrance conference was held with the Clinic Nurse Manager the morning of 7-24-17. The purpose and process of the initial licensure survey were discussed, and an opportunity given for questions. Initial licensure is recommended, with an approved plan of correction. An exit conference was held with the Clinic Nurse Manager and the Director of Clinical Services on the alternoon of 7-24-17. Preliminary findings of the survey were discussed, and an opportunity given for questions. A 126 TAC 139.41(a) Policy Development and Review A 126 (a) The licensee shall be responsible for the conduct of the licensed abortion facility and shall assume full legal responsibility for developing, implementing, enforcing, and monitoring written policies governing the facility's total operation, and for ensuring that these policies comply with the Act and the applicable provisions of this chapter and are administered so as to provide health care in a safe and professionally acceptable environment. These written policies shall include at a minimum the following:

SOD - State Form
LABORATORY DIRECTOR'S OR PROVIDER SUPPLIER REPRESENTATIVE'S SIGNATURE

LABORATORY DIRECTOR'S OR PROVIDER SUPPLIER S

Pages: 78 Case: 19-2051 Document: 33 Filed: 08/14/2019

TX Department of Aging and Disability Services Regulatory Services

#### STATEMENT OF LICENSING VIOLATIONS **AND PLAN OF CORRECTION**

Form DADS 3724

July 2015

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MANE OF PROVIDEROR SUPPLIER  STREET ADDRESS, CITY STATE, AP CODE  MOTOR WOMAN'S HEALTH ALLIANCE  AUSTIN, TX 78733  PROVIDERS PLANGE CORRECTION PRESS REFERENCE AND SEPERATOR OF DETRICEMENTS.  REGULATORY OR LSC IDENTIFYING INFORMATION)  A 126  Confinued From page 1  This Requirement is not met as evidenced by: Based on a review of documentation and an interview with staff, the licensee failed to be responsible for implementing and enforcing written policies governing the facility's total operation and for ensuring that these policies are administered so as to provide health care in a safe and professionally acceptable environment.  Findings were:  During a tour of the facility on 7-24-17, a random count of Fentanyl (as Schedule II narootic medication) was performed. 150 ml of Fentanyl was present in an unopened vial (not in a box). 2 syringss, each pre-filled with 0.5 ml of the drug, represented 1 ml of Fentanyl count on 7-24-17 was verified by staff #37, present during the locur and the narcotic count. The narcotic count sheet indicated that 154 ml of Fentanyl had been present during the closing count conducted on 7-21-17 (which had been verified and signed off on by staff #37 nether during the locur sheet indicated that 154 ml of Fentanyl had been present during the closing count conducted on 7-21-17 (which had been verified and signed off on by staff #37 nether member was able to explain the 1 ml Fentanyl count on choucted on 7-21-17 (which had been verified and signed off on by staff #36 and staff #9). In an interview with staff members #8.8 #7, nether member was able to explain the 1 ml Fentanyl discoverance and the narcotic count. The netrotic count sheet indicated that no patients had been seen since 7-21-17.  According to hittps://www.deadversion.usdoj.gov/schedules/. a Schedule III Northfield Substances (22N)  Substances in this schedule have a high potential				A BUILDING	COMP	CETED	
MANE OF PROVIDEROR SUPPLIER  STREET ADDRESS, CITY STATE, AP CODE  400 HONTH HI 35 SUITE 200  AUSTIN, TX 78753  PROVIDERS FLAND TRANSPORT OF DEFICIENCES  (EACH DEFICIENCY MAST'S REPORTED BY PRUIT  REQUIZIONY OR LSC IDENTIFYING INFORMATION)  This Requirement is not met as evidenced by: Based on a review of documentation and an interview with staff, the licensee failed to be responsible for implementing and enforcing written policies governing the facility's total operation and for ensuring that these policies are administered so as to provide health care in a safe and professionally acceptable environment.  Findings were:  During a tour of the facility on 7-24-17, a random count of Fentanyl (as Schedule II nancolo medication) was persent in boxed vials. 2 ml of Fentanyl was present in boxed vials. 2 ml of Fentanyl was present in an unopened vial (not in a box). 2 syringse, each pre-filled with 0.5 ml of the drug, represented 1 ml of Fentanyl for a total of 153 ml of Fentanyl. The Fentanyl count on 7-24-17 was verified by staff #37, present during the local sheet indicated that 154 ml of Fentanyl had been present during the closing count conducted on 7-21-17 (which had been verified and signed off on by staff #61 and staff #9). In an interview with staff members #6 8, #7, neither member was able to explain the 1 ml Fentanyl count on chaused on 7-21-17.  According to https://www.deadiversion.usdoj.gov/schedules/, a Schedule II drug is described as follows: "Schedule III flug is described as follows: "Schedule IIII Notnotified Substances (2/2N)  Substances in this schedule have a high potential	140013		B WING	8 WING			
MHOLE WOMAN'S HEALTH ALLIANCE  SUMMARY STATEMENT OF DEPICEMOIES PRETX TAG  SUMMARY STATEMENT OF DEPICEMOIES PRETX TAG  Continued From page 1  A 126  Continued From page 1  This Requirement is not met as evidenced by: Based on a review of documentation and an interview with staff, the licensee failed to be reaponsible for implementing and enforcing written policies governing the facility to total operation and for ensuring that these policies are administered so as to provide health care in a safe and professionally acceptable environment.  Findings were:  During a tour of the facility on 7-24-17, a random count of Fentanyl (a Schedule II narcotic medication) was performed. 150 ml of Fentanyl was present in a box 2 ml of Fentanyl was present in a unopened vial (not in a box). 2 syringes, each pre-filled with 0.5 ml of fentanyl was present in an unopened vial (not in total of 153 ml of Fentanyl). The Fentanyl from the fentanyl for a total of 153 ml of Fentanyl. The Fentanyl from the fentanyl for a total of 153 ml of Fentanyl from the fentanyl for a total of 153 ml of Fentanyl from the fentanyl for a total of 153 ml of Fentanyl from the fentanyl for a total of 153 ml of Fentanyl from the fentanyl for a total of 153 ml of Fentanyl from the fentanyl for a total of 153 ml of Fentanyl from the fentanyl for a total of 153 ml of Fentanyl from the fentanyl for a total of 153 ml of Fentanyl from the fentanyl for a total of 153 ml of Fentanyl from the fentanyl for a total of 153 ml of Fentanyl from the fentanyl for a total of 153 ml of Fentanyl from the fentanyl for a total of 153 ml of Fentanyl from the fentanyl fro	NAME OF D	BOWDER OD SWEET				24/201/	
A 126  Continued From page 1  A 126  Continued From page 1  A 126  This Requirement is not met as evidenced by: Based on a review of documentation and an interview with staff, the license palled to be responsible for implementing and enforcing written policies governing the facility's total operation and for ensuring that these policies are administrated so as to provide health care in a safe and professionally acceptable environment.  Findings were:  During a tour of the facility on 7-24-17, a random count of Ferilanyl (a Schedule II hancold medication) was performed. 150 ml of Ferilanyl was present in a nunopened vial (not in a bod). 2 syringes, each pre-filled with 0.5 ml of the drug, represented in mile Ferilanyl than tour and the narcole count. The narcote count is ferilanyl than for the count on 7-24-17 was verified by staff #7, present during the clour and the narcole count. The narcote count sheet indicated that 154 ml of Ferilanyl had been presented during the clour mobile staff stated that no palients had been seen since 7-21-17.  According to https://www.deadiversion.usdoj.gow/schedules/, a Schedule II thrug is described as follows: "Schedule III hardow with staff members #8 & #7, neither member was able to explain the 1 ml Ferilanyl fraction multiple for the facility of the country of the coun	NAME OF F	HOVIDEN ON SUPPLIER					
DATE (REACH DEFIGENCY MAST SET RECEDED BY FULL RECOURT PYING INFORMATION)  A 128  Continued From page 1  A 128  Continued From page 1  This Requirement is not met as evidenced by: Based on a review of documentation and an interview with staff, the licensee failed to be responsible for implementing and enforcing written policies governing the facility's total operation and for ensuring that these policies are administered so as to provide health care in a safe and professionally acceptable environment.  Findings were:  During a tour of the facility on 7-24-17, a random count of Fentanyl (a Schedule II narcotic medication) was performed. 150 mt of Fentanyl was present in bowed vials. 2 mt of Fentanyl was present in one of Fentanyl for a total of 153 mt of Fentanyl. The Fentanyl count on 7-24-17 was verified by staff #7, present during the tour and the narcotic count. The narcotic count sheet indicated that 154 mt of Fentanyl had been present during the closing count conducted on 7-21-17 (which had been verified and signed off on by staff #6 and staff #9), in an interview with staff members #6 & #7, neither member was able to explain the 1 mt Fentanyl discrepancy and both staff stated that no patients had been seen since 7-21-17.  According to https://www.deadiversion.usdoj.gov/schedules/, a Schedule II/IM Controlled Substances (2/2N)  Substances in this schedule have a high potential	WHOLE W	OMAN'S HEALTH ALLI	ANCE		TE 200		
PREEX TXA  A 126  Continued From page 1  This Requirement is not met as evidenced by: Based on a review of documentation and an interview with staff, the licensee failed to be responsible for implementing and enforcing written policles governing the facility's total operation and for ensuring that these policies are administered so as to provide health care in a safe and professionally acceptable environment.  Findings were:  During a tour of the facility on 7-24-17, a random count of Fentanyl (a Schedule II narcolic medication) was performed. 150 ml of Fentanyl was present in box of Pentanyl. The Fentanyl count on 7-24-17 was verified by staff #7, present during the tour and the narcolic count. The narcotic count sheet indicated that 154 ml of Fentanyl had been present during the closing count conducted on 7-21-17 (which had been verified and signed off on by staff #8 and staff #9). In an interview with staff members #8 & 87, neither member was able to explain the 1 ml Fentanyl idorespency and both staff stated that no patients had been seen since 7-21-17.  According to https://www.deadwersion.usdoj.gov/schedules/, a Schedule II drug is described as follows: "Schedule II drug is described as follows: "Schedul	/YALD	SUMMARY ST			PROVIDENC OLAN DE COORTENDO		
This Requirement is not met as evidenced by: Based on a review of documentation and an interview with staff members 48 & 47, neither member was able to explain the 1 mt Fentanyl discrepancy and both staff stated that no patients had been seen since 7-21-17.  According to https://www.deadwiversion.usdoj.gov/schedules/, a Schedule II/IIN Controlled Substances (2/2N)  Substances in this schedule have a high potential	PREF X	(EACH DEFICIENC)	MUST BE PRECEDED BY FULL	PREFIX	(EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE	COMPLETE	
Eased on a review of documentation and an interview with staff, the licensee failed to be responsible for implementing and enforcing written policies governing the facility's total operation and for ensuring that these policies are administered so as to provide health care in a safe and professionally acceptable environment.  Findings were:  During a tour of the facility on 7-24-17, a random count of Fentanyl (a Schedule II narcotic medication) was performed. 150 ml of Fentanyl was present in an unopened vial (not in a box). 2 syringes, each pre-filled with 0.5 ml of the drug, represented 1 ml of Fentanyl, for a total of 153 ml of Fentanyl. The Fentanyl count on 7-24-17 was verified by staff #7, present during the tour and the narcotic count. The narcotic count sheet indicated that 154 ml of Fentanyl had been present during the closing count conducted on 7-21-17 (which had been verified and signed off on by staff #8 and astaff #9). In an interview with staff stated that no patients had been seen since 7-21-17.  According to https://www.deadiversion.usdoj.gov/schedules/, a Schedule II //IIN Controlled Substances (2/2N)  Substances in this schedule have a high potential	A 126	Continued From page	1	A 126			
for abuse which may lead to severe psychological		Based on a review of interview with staff, the responsible for implet written policies governoperation and for ensadministered so as to safe and professional Findings were:  During a tour of the facount of Fentanyl (a Smedication) was perfect was present in boxed present in an unopen syringes, each pre-fife for Fentanyl. The Fent verified by staff #7, profesent during the clop-sent during the staff stated that no par-sent stated that no par-sent during to https://www.deadivers.schedule.ll drug is de "Schedule II/IIN Controls."	documentation and an se licensee failed to be menting and enforcing ning the facility's total uring that these policies are provide health care in a ly acceptable environment.  Actility on 7-24-17, a random Schedule II narcotic bridged. 150 ml of Fentanyl was ed vial (not in a box). 2 ed with 0.5 ml of the drug, entanyl, for a total of 153 ml anyl count on 7-24-17 was esent during the tour and se narcotic count sheet of Fentanyl had been sing count conducted on een verified and signed off iff #9). In an interview with 7, neither member was able ntanyl discrepancy and both tients had been seen since		The Clinic Manager is responsible for ensuring compliance with all policies governing the facility operations.  Whole Woman's Health Alliance (WWHA) complies with the policy and review requirement for abortion facilities by developing and following The WWHA Medication Therapy Practices. The error identified by the surveyors was related to a clerical miscount, and not to any missing doses. The Clinic Manager conducted and audit of the controlled substances during the survey, and found the miscount error which was immediately corrected.  A staff in-service was facilitated on 7/24/17 in order to train staff on how to properly count, document the medications, and to reinforce understanding of the existing Medication Therapy Practices policy.  In our order to monitor compliance, in addition to the daily open and close counts, a monthly audit of the control substances log will be conducted by the Clinical Coordinator and reviewed by the	07/24/17	

TX Department of Aging and Disability Services Regulatory Services

## STATEMENT OF LICENSING VIOLATIONS AND PLAN OF CORRECTION

Form DADS 3724 July 2015

PRINTED: 07/26/2017 1:50:31PM STATEMENT OF DEFICIENCIES (XI) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER. COMPLETED A. BUILDING B. WING 140013 07/24/2017 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS CITY, STATE, ZIP CODE 8401 NORTH IH 35 SUITE 200 WHOLE WOMAN'S HEALTH ALLIANCE **AUSTIN, TX 78753** SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX PREFIX (EACH CORRECTIVE ACTION SHOULD BE COMPLETE REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG TAG DEFICIENCY A 126 Continued From page 2 A 126 or physical dependence. Examples of Schedule II narcotics include: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), and fentanyl (Sublimaze®, Duragesic®). Other Schedule II narcotics include: morphine, opium, codeine, and hydrocodone. Examples of Schedule IIN stimulants include: amphetamine (Dexedrine®, Adderatt®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin@). Other Schedule II substances include: amobarbital, glutethimide, and pentobarbital." Facility policy titled "Medication Therapy Practices" stated, in part: "Controlled Medications Closing Count" 1. Each day that Controlled Medications are administered, at the end of the day, two staff will open the safe and count each drug on the Controlled Medication log. 8. Any discrepancies between the actual closing count and the anticipated closing count should be resolved and reported to the clinical manager. Discrepancies that cannot be resolved should generate a Narcotics Deviation Report, Deviation reports of concern, i.e. that indicate missing drugs or careless handling, should be shared with the Medical Director/Consultant and included in the Quarterly Review." The above was confirmed in an interview with staff #6 and staff #7 on the afternoon of 7-24-17.

TX Department of Aging and Disability Services Regulatory Services

## STATEMENT OF LICENSING VIOLATIONS AND PLAN OF CORRECTION

Form DADS 3724 July 2015

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STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY  COMPLETED				
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A 257	Continued From page	e 3	A 257			
A 257	TAC 139.49(d)(5)(L)( Standards	(ii)(I - V) Infection Control	A 257	A 257		
	operation for pressure desired temperature as the maintained either generated and shall in (I) the sterilizer identiful (II) sterilization date as (III) load number; (IV) duration and tempers	all be monitored during e, temperature, and time at and pressure. Arecord shall manually or machine nclude: ication; and time; perature of exposure phase stilizer recording charts);		The Clinic Manager is responsible for monitoring proper documentation of infection control standards.  Whole Woman's Health Alliance has accurate confirmation that all instruments have been properly sterilized.  In addition to the autoclave load logs the facility uses special sterilization pouches, sterilization strips, and sterilization tape that automatically confirms instruments are properly sterile without requiring staff documentation.  The autoclave load log in question has been updated to include the pressure, temperature,		
	Based on a review of interview, the facility of sterilizer was monitor pressure, temperature temperature and prestact that a record was included: duration and	not met as evidenced by: performance records and lailed to ensure that each ed during operation for e, and time at desired soure, as evidenced by the to not maintained that d temperature of exposure d on sterilizer recording		and time of sterilization process.  A staff in-service will be facilitated on 08/09/17 in order to train staff on the updated log and how to properly document.  In order to monitor compliance, the Clinical Coordinator will conduct a monthly audit of the logs, any findings needing attention will be presented to the clinic manager to address proper documentation is in place.		
	July 2017 revealed the and duration of expose and pressure of the second documented.  In an interview on 07/2 stated that the new are	ave logs for May, June, and lat pressure, temperature, sure at desired temperature terilized logs was not (24/17, staff member #7 utoclave forms have an area sure and temperature,	0			

TX Department of Aging and Disability Services Regulatory Services

## STATEMENT OF LICENSING VIOLATIONS AND PLAN OF CORRECTION

Form DADS 3724 July 2015

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A 257	Continued From page	9 4	A 257		- Alexander	
	not contain a prompt information. The new area to document du phase.  With no documentation unknown if these loa effectively sterilized.  Facility policy titled "I Disinfection, Steriliza Supplies" states, in p "Performance Record Performance records maintained for each two years.(sic) These	reforms also did not have an ration of the exposure on of these elements it is ds and instruments were Decontamination, altion, and Storage of Sterile part:			okano mano mano mano dagrafika da e mano para para para da mano da mano da mano da mano da mano da mano da man	
	for pressure, temperature and pre- record will include: -Sterilizer identification- -Sterilization date -Sterilization time -Load number -Pack ID# -Duration and tempe -Identification of ope -Results of biologica -Time/temperature re- sterilizer"	rature of exposed phase rator I tests and dates performed ecording charts from each we confirmed on 07/24/17 in				

TX Department of Aging and Disability Services Regulatory Services

## STATEMENT OF LICENSING VIOLATIONS AND PLAN OF CORRECTION

Form DADS 3724 July 2015

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STATEMENT OF DEFICIENCIES (X2) MULTIPLE CONSTRUCTION (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED A, BUILDING: B. WING 140013 07/24/2017 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE ZIP CODE 8401 NORTH IH 35 SUITE 200 WHOLE WOMAN'S HEALTH ALLIANCE **AUSTIN, TX 78753** SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL EACH CORRECTIVE ACTION SHOULD BE COMPLETE PREFIX PREF X REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) A 315 A 315 Continued From page 5 A 315 House Bill 2 Medical and Clinical Services A 315 A physician must provider the pregnant woman with: a) a telephone number by which the pregnant woman may reach the physician, 24 hours a day to request assistance for any complications that arise from the abortion or ask health-related questions regarding the abortion; and b) the name and telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion would be treated. This Requirement is not met as evidenced by: Based on a review of clinical records and an A 315 interview with staff, the physician failed to provide the pregnant women with the name and The Clinic Manager is responsible for ensuring compliance with all policies regarding medical telephone number of the nearest hospital to the and clinical services. home of the pregnant woman at which an emergency arising from the abortion would be Whole Woman's Health Alliance complies with treated. the requirements set forth in House Bill 2 by providing patients with the written name and Findings were: phone number of the hospital nearest to them at the time of their discharge from our care. During a review of 21 clinical records, 10 of the 21 records (patients #2, #3, #4, #5, #6, #12, #13, A staff in service will be facilitated on 08/09/17 to 08/09/17 #14, #15 and #16) contained no documentation re train staff to document this information on the that the patient had been furnished with the name discharge section of the patient's abortion record. and/or telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion would be In order to monitor compliance, patient charts treated. will be audited at the end of every clinic day, as well as a random monthly chart audit conducted -Patients #2, #3, #4, #5 and #6 had been by clinic staff under the supervision of the Clinic provided with a hospital name but no telephone Manager. number for the hospital. -Patients #12, #13, #14, #15 and #16 had been

TX Department of Aging and Disability Services Regulatory Services

## STATEMENT OF LICENSING VIOLATIONS AND PLAN OF CORRECTION

Form DADS 3724 July 2015

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA	(X2) MULTIPLE	(X2) MULTIPLE CONSTRUCTION (X3)		
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A 315	Continued From page	9 6	A 315		orana as	
	provided with neither telephone number for	a hospital name nor a rthe hospital.			e parameter delicity de la constantina del con	
	The above was confident staff #7 on the afternoon	rmed in an interview with oon of 7-24-17.				
A 327	House Bill 2 Medical	and Clinical Services	A 327		771	
St.	Physicians must ensure that abortion-inducing drugs are used according to FDA regulations that require the women to visit the physician in person for each of the two doses of the abortion pill, as well as for a follow-up appointment within 14 days. The physician must provide the woman with a copy of the final printed label of the abortion-inducing drug.					
	A					
(v			The state of the s			
	Based on a review of interview with staff, the	not met as evidenced by: clinical records and an ne physician failed to ensure scheduled for a follow-up 4 days.				
	Findings were:			45	[ ]	
i	(patient #1) was not s	of 21 clinical records, 1 of 21 scheduled to return to the risit within the required 14				

TX Department of Aging and Disability Services
Regulatory Services

## STATEMENT OF LICENSING VIOLATIONS AND PLAN OF CORRECTION

Form DADS 3724 July 2015

STATEMENT OF DEFICIENCIES		(X1) PROVIDER/SUPPLIER/CLIA	(X2) MULTIP		(X3) DATE SURVEY	
AND PLAN OF CORRECTION		IDENTIFICATION NUMBER:	A. BUILDING	(1.17)	LETEO	
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WWOLEN	VOMAN'S HEALTH ALLI	2404.440	RTH IH 35 SUI	·		
WHOLE	TONIAN S NEALTH ALL	ANUE	TX 78753			
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A 327	Continued From page	∍7	A 327	A327		
A 327	Continued From page 7 days (appointment was scheduled for 21 days after).  The above was confirmed in an interview with slaff #7 on the afternoon of 7-24-17.		A 327	The Clinic Manager is responsible for ensuring compliance with all medical and clinical services requirements.  Whole Woman's Health Alliance had taken a proactive approach to schedule follow up appointments by working with the patient's availability to ensure they could return to the clinic for their follow up. Effective immediately, we will schedule follow up appointments for patients receiving the medical abortion pill to be 14 days without exception.  In order to monitor compliance with this requirement the Administrative Coordinator will supervise the patient follow up schedule on a weekly basis.  A staff in-service will be facilitated on 08/09/17 in order to ensure staff understanding of this requirement.		