864 F.3d 953
United States Court of Appeals,
Eighth Circuit.

PLANNED PARENTHOOD OF ARKANSAS & EASTERN OKLAHOMA, on behalf of itself and its patients, doing business as Planned Parenthood Great Plains; Stephanie Ho, MD, on behalf of herself and her patients, Plaintiffs-Appellees
v.
Larry JEGLEY, Prosecuting Attorney for Pulaski County, in his official capacity, his agents and successors; Matt Durrett, Prosecuting Attorney for Washington County, in his official capacity, his agents and successors, Defendants-Appellants
American Public Health Association; American College of Obstetricians and Gynecologists, Amici on Behalf of Appellee(s)

No. 16-2234
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Attorneys and Law Firms

Counsel who presented argument on behalf of the appellants was Nicholas Jacob Bronni, Deputy Solicitor General, of Little Rock, AR. In addition to Mr. Bronni, the following attorney(s) appeared on the appellants' brief; Mindy D. Pipkin, Senior Assistant Attorney General, of Little Rock, AR.

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The following attorney(s) appeared on the amici brief of American Public Health Association and American College of Obstetricians and Gynecologists in support of appellees; Shannon R. Selden, of New York, NY., Johanna N. Skrzypczyk, of New York, NY., Joshua E. Roberts, of New York, NY., and John T. Chisholm, of Washington, D.C.

Before RILEY, Chief Judge,[1] GRUENDER, Circuit Judge, and GRITZNER, District Judge.[2]

Opinion

GRUENDER, Circuit Judge.

Prosecuting Attorneys for Pulaski County and Washington County, Arkansas ("the State") appeal the district court's grant of a preliminary injunction preventing the enforcement of an Arkansas statute

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[1] The Honorable William Jay Riley stepped down as Chief Judge of the United States Court of Appeals for the Eighth Circuit at the close of business on March 10, 2017. He has been succeeded by the Honorable Lavenski R. Smith.

[2] The Honorable James E. Gritzner, United States District Judge for the Southern District of Iowa, sitting by designation.

requiring medication-abortion providers to contract with a physician who has hospital admitting privileges. Because the district court failed to make factual findings estimating the number of women burdened by the statute, we vacate the preliminary injunction and remand for further proceedings.

I. BACKGROUND

In 2015, Arkansas enacted the Abortion-Inducing Drugs Safety Act ("the Act"). Ark. Code Ann. §§ 20-16-1501-1510. The Arkansas Legislature made findings that abortion-inducing drugs present significant medical risks, including "abdominal pain, cramping, vomiting, headache, fatigue, uterine hemorrhage, viral infections, and pelvic inflammatory disease." *Id.* § 1502(14). It further determined that medication abortions are "associated with an increased risk of complications relative to surgical abortion[s]" and found that, based on a 2011 United States Food and Drug Administration report, complications included eight deaths attributed to severe bacterial infection, 612 hospitalizations, 339 blood transfusions, and 256 infections. *Id.* §§ 1502(15)-(17).

To address these health concerns, the Act created new requirements for physicians providing medication abortions. Section 1504(d) sets forth the "contract-physician requirement," which is the subject of the current appeal.[3] The provision requires that:

> (1) The physician who gives, sells, dispenses, administers, or otherwise provides or prescribes the abortion-inducing drug shall have a signed contract with a physician who agrees to handle complications and be able to produce that signed contract on demand by the patient or by the Department of Health.
>
> (2) The physician who contracts to handle emergencies shall have active admitting privileges and gynecological/surgical privileges at a hospital designated to handle any emergencies associated with the use or ingestion of the abortion-inducing drug.
>
> (3) Every pregnant woman to whom a physician gives, sells, dispenses, administers, or otherwise provides or prescribes any abortion-inducing drug shall receive the name and phone number of the contracted physician and the hospital at which that physician

[3] The Act also requires physicians administering medication abortions to follow an FDA-approved regimen, which differed from the one Planned Parenthood used. The district court enjoined this portion of the Act along with the contract-physician requirement. Following the issuance of the preliminary injunction, the FDA updated its regimen to one that reflected Planned Parenthood's regimen. As a result, Planned Parenthood withdrew its challenge to this provision, and, thus, the requirement that physicians follow FDA regulations is not before us.

> maintains admitting privileges and which can handle any emergencies.

Id. § 1504(d). The Act imposes civil and criminal penalties for violations of the contract-physician requirement. *See id.* §§ 1506-1507.

Planned Parenthood of Arkansas & Eastern Oklahoma ("PPAEO") provides medication abortions in Arkansas at its two facilities, one in Fayetteville and the other in Little Rock. The only other Arkansas abortion provider, Little Rock Family Planning Services ("LRFP"), administers both medication and surgical abortions at its Little Rock facility. PPAEO and one of its physicians, Stephanie Ho, M.D., (collectively "Planned Parenthood") filed suit seeking to enjoin enforcement of the Act days before it was set to take effect, claiming that the contract-physician requirement unduly burdens their patients' right to an abortion.

Both parties submitted affidavits concerning the medical benefits of the contract-physician requirement and the burdens on abortion access purportedly caused by the requirement. The district court found that Planned Parenthood's protocols provided continuity of care because patients with concerns could call Planned Parenthood's twenty-four-hour hotline to speak with nurses, Planned Parenthood referred patients experiencing complications to clinics or health centers for surgical completion, and Planned Parenthood physicians could consult with emergency-room physicians in the case of serious complications.

The district court thus concluded that the contract-physician requirement provided few, if any, tangible medical benefits over Planned Parenthood's continuity-of-care protocols such that "the [S]tate's overall interest in the regulation of medication abortions through the [contract-physician] requirement is low and not compelling." *Planned Parenthood Ark. & E. Okla. v. Jegley*, No. 4:15-cv-00784-KGB, 2016 WL 6211310, at *20 (E.D. Ark. Mar. 14, 2016).

The district court then turned to the requirement's alleged burdens on abortion access. The court first concluded that Planned Parenthood could not find a physician to contract with and that, as a result, the Planned Parenthood facilities in Little Rock and Fayetteville would stop offering abortion services.[4] It also found that medication abortion would no longer exist in Arkansas and that LRFP would be the sole abortion provider in Arkansas and would only administer surgical abortions. The district court and the parties generally treated LRFP's surgical-abortion services as a viable alternative to medication abortions, and as a result, the court determined the contract-physician requirement would not burden most Arkansas women seeking medication abortions because they already would have traveled to Little Rock prior to the enactment of the contract-physician

[4] Planned Parenthood's efforts to recruit a contract physician did not include any offer of financial compensation. It is unclear whether the district court considered this fact in its assessment.

requirement.[5] The district court, however, found that the closure of PPAEO's Fayetteville facility would force "women in the Fayetteville area" to make two, 380-mile round trips to obtain an abortion at LRFP.[6] *Id.* at *4. As a result of the increased travel distances, the district court determined that "some women" in the Fayetteville area would postpone the procedures, leading to an increased risk of complications, while others would forgo abortions entirely. *Id.* at *8. The court further noted that the record did not allow a finding as to whether LRFP would be able to "absorb such an increase in the number of procedures or whether [LRFP] will be able to cover fully the needs of women who might have sought care at [Planned Parenthood]." *Id.* at *30.

Balancing the benefits of the contract-physician requirement against its burdens, the district court concluded that the requirement was a "solution in search of a problem." *Id.* at *18. It thus held that Planned Parenthood was likely to succeed on the merits, that it and its patients faced irreparable harm, that the equities weighed in its favor, and that the public interest

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[5] The court noted that medication abortions could be medically indicated for women with specific health conditions. However, it also acknowledged that the record was "unclear" as to "what percentage of the patient population that may be." *Jegley*, 2016 WL 6211310, at *30.

[6] A separate Arkansas statute requires women to receive state-mandated information forty-eight hours before their abortion procedure. *See* Ark. Code Ann. § 20-16-1703(b)(1), (2). This information must be given "orally and in person," thereby possibly necessitating another trip. *Id.*

weighed in its favor. As a result, the district court granted Planned Parenthood a preliminary injunction, preventing Arkansas from enforcing the contract-physician requirement. The State timely appealed.

II. DISCUSSION

This court has jurisdiction under 28 U.S.C. § 1292(a)(1) to review an interlocutory order granting a preliminary injunction. We review such an order for an abuse of discretion. *Planned Parenthood Minn., N.D., S.D. v. Rounds*, 530 F.3d 724, 733 (8th Cir. 2008) (en banc). A district court abuses its discretion when it fails to consider a relevant factor that should have been given significant weight, when it considers and gives significant weight to an irrelevant or improper factor, or when it considers only proper factors – and no improper ones – but in weighing those factors commits a clear error of judgment. *Novus Franchising, Inc. v. Dawson*, 725 F.3d 885, 893 (8th Cir. 2013).

Generally, in issuing a preliminary injunction, the district court considers: (1) the threat of irreparable harm to the moving party, (2) the balance between this harm and the injury that granting the injunction will inflict on the non-moving party, (3) the probability that the moving party will succeed on the merits, and (4) the public interest. *See Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 114 (8th Cir. 1981) (en banc). Where a preliminary injunction is sought to enjoin the implementation of a duly enacted state statute, however, the moving party must make a more rigorous showing that

it is "likely to prevail on the merits." *Rounds*, 530 F.3d at 732-33. This is necessary "to ensure that preliminary injunctions that thwart a state's presumptively reasonable democratic processes are pronounced only after an appropriately deferential analysis." *Id.* at 733. Thus, we must analyze whether Planned Parenthood demonstrated that it is likely to prevail on the merits of its undue burden claim. *See id.* at 732.

"A finding of an undue burden is a shorthand for the conclusion that a state regulation has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus." *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 877, 112 S.Ct. 2791, 120 L.Ed.2d 674 (1992). In *Whole Woman's Health v. Hellerstedt*, the Supreme Court clarified that this undue burden analysis "requires that courts consider the burdens a law imposes on abortion access together with the benefits those laws confer." ___ U.S. ___, 136 S.Ct. 2292, 2309, 195 L.Ed.2d 665 (2016). The Court explained that after the passage of Texas House Bill 2 ("H.B. 2"), the abortion regulation at issue, the number of Texas facilities providing abortions decreased from approximately forty to about seven or eight. *Id.* at 2312, 2316. These closures led to increased driving distances, though the additional driving distances alone were not dispositive. *Id.* at 2313 ("We recognize that increased driving distances do not always constitute an 'undue burden.'" (citing *Casey*, 505 U.S. at 885-87, 112 S.Ct. 2791)). Instead, the closures burdened abortion access because women seeking abortions also faced "fewer doctors, longer

waiting times, and increased crowding." *Id.* Furthermore, patients would be "less likely to get the kind of individualized attention, serious conversation, and emotional support" at the abortion facilities. *Id.* at 2318. As a result, the Supreme Court struck down H.B. 2 because its numerous burdens substantially outweighed its benefits. *See id.* at 2313, 2318. At the same time, because *Hellerstedt* expressly relied on *Gonzales v. Carhart*, *see id.* at 2310, the Court preserved its command that "state and federal legislatures [have] wide discretion to pass legislation in areas where there is medical and scientific uncertainty," 550 U.S. 124, 163, 127 S.Ct. 1610, 167 L.Ed.2d 480 (2007).

In the present case, the district court abused its discretion because it failed to consider whether Planned Parenthood satisfied the requirements necessary to sustain a facial challenge to an abortion regulation. "Facial challenges are disfavored," *Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 449, 128 S.Ct. 1184, 170 L.Ed.2d 151 (2008), and generally, they can only succeed if the proponent establishes that "no set of circumstances exists under which the [statute] would be valid," *United States v. Salerno*, 481 U.S. 739, 745, 107 S.Ct. 2095, 95 L.Ed.2d 697 (1987). For challenges to abortion regulations, however, the Supreme Court has fashioned a different standard under which the plaintiff can prevail by demonstrating that "in a large fraction of the cases in which [the law] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion." *Casey*, 505 U.S. at 895, 112 S.Ct. 2791. The

Supreme Court has clarified that "cases in which the provision at issue is *relevant*" is a narrower category than "all women," "pregnant women," or even "*women seeking abortions* identified by the State." *Hellerstedt*, 136 S.Ct. at 2320 (quoting *Casey*, 505 U.S. at 894-95, 112 S.Ct. 2791). Thus, because the contract-physician requirement only applies to medication-abortion providers, the "relevant denominator" here is women seeking medication abortions in Arkansas. *See id.* (finding that the "relevant denominator" must be "those women for whom the provision is an actual rather than an irrelevant restriction" (internal alterations omitted)). Accordingly, in order to sustain a facial challenge and grant a preliminary injunction, the district court was required to make a finding that the Act's contract-physician requirement is an undue burden for a large fraction of women seeking medication abortions in Arkansas.

The district court did not make this finding. The court correctly held that individuals for whom the contract-physician requirement was an actual, rather than an irrelevant, restriction were women seeking medication abortions in Arkansas. Nonetheless, it did not define or estimate the number of women who would be unduly burdened by the contract-physician requirement. Instead, it focused on amorphous groups of women to reach its conclusion that the Act was facially unconstitutional.

First, the district court did not determine how many women would face increased travel distances. The court noted that most women residing in Arkansas

and seeking medication abortions would be unaffected by the contract-physician requirement, as they could travel to LRFP for an abortion. However, it found that "women in the Fayetteville area" would have to make two, 380-mile round trips to obtain an abortion from LRFP in Little Rock. *Jegley*, 2016 WL 6211310, at *4. Nonetheless, it is unclear how many women would have to travel these additional distances. For example, the district court did not explain if "women in the Fayetteville area" referred to women residing only in the city of Fayetteville, women residing in Washington County (where Fayetteville is located), or women residing in surrounding counties as well. Additionally, as the Supreme Court acknowledged in *Hellerstedt*, increased travel distances are relevant but may not independently constitute an undue burden. 136 S.Ct. at 2313 (citing *Casey*, 505 U.S. at 885-87, 112 S.Ct. 2791). The Supreme Court found an undue burden in *Hellerstedt* because women seeking abortions faced "fewer doctors, longer waiting times, and increased crowding." 136 S.Ct. at 2313. Here, it is not clear that "women in the Fayetteville area" traveling to LRFP would face "fewer doctors, longer waiting times, and increased crowding." *See id.* As the district court recognized, the record did not demonstrate whether LRFP would be able to "absorb such an increase in the number of procedures or whether [LRFP] [would] be able to cover fully the needs of women who might have sought care

at [Planned Parenthood]."[7] *Jegley*, 2016 WL 6211310, at *30.

Next, the district court failed to estimate the number of women who would forgo abortions. The court cited an affidavit from Dr. Stanley K. Henshaw, Ph.D., who opined that an increased travel distance of 100 miles would cause 20 to 25 percent of women who would have otherwise obtained abortions to forgo them and that "[g]reater distances will be a barrier to an even higher percentage of women." The record is unclear as to whether the 100 miles of increased travel distance refers to round-trip or one-way distances – or whether it concerns single or multiple trips. More fundamentally, however, the district court did not apply this conclusion to estimate the number of women in the Fayetteville area seeking medication abortions who would actually forgo abortions.[8]

Finally, the court did not estimate the number of women who would postpone their abortions. The district court maintained that increased travel distances

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[7] Indeed, in 2014, medication abortions accounted for only 14.3 percent of all abortions in Arkansas.

[8] Although the record does contain evidence that, in 2014, 145 women residing in Washington County had medication abortions, applying the 20 to 25 percent figure would mean that about 29 to 37 women would forgo their abortions – approximately 4.8 to 6.0 percent of all medication abortions provided in Arkansas in 2014. We are skeptical that 4.8 to 6.0 percent is sufficient to qualify as a "large fraction" of women seeking medication abortions in Arkansas. *See Cincinnati Women's Servs., Inc. v. Taft*, 468 F.3d 361, 374 (6th Cir. 2006) (holding that 12 percent does not constitute a "large fraction").

would cause "some women" in the Fayetteville area to postpone their abortions and thereby face an increased risk of complications. *Id.* at *8. The district court again, however, did not explain or estimate how many women constituted "some women." While the record does indicate that delaying abortions can increase the risk of complications, the court failed to estimate the number of women who would face an increased risk of complications.

As a result, we are left with no concrete district court findings estimating the number of women who would be unduly burdened by the contract-physician requirement – either because they would forgo the procedure or postpone it – and whether they constitute a "large fraction" of women seeking medication abortions in Arkansas such that Planned Parenthood could prevail in its facial challenge to the contract-physician requirement. In situations like this, where the district court did not make the necessary factual findings, "[w]e conclude that the better course is to afford the district court an opportunity to make appropriate findings of fact and conclusions of law." *See Phelps-Roper v. Troutman*, 712 F.3d 412, 417 (8th Cir. 2013) (per curiam); *see also Mo. Pac. Joint Protective Bd., Bhd. Ry. Carmen v. Mo. Pac. R.R. Co.*, 730 F.2d 533, 537 (8th Cir. 1984) ("[W]e believe the findings and conclusions should, in the first instance, be made by the district court.").

On remand, we do not require the district court to calculate the exact number of women unduly burdened by the contract-physician requirement. We

acknowledge that the "large fraction" standard is in some ways "more conceptual than mathematical." *Cincinnati Women's Servs., Inc. v. Taft*, 468 F.3d 361, 374 (6th Cir. 2006). Nonetheless, like the Sixth Circuit, we find that this standard is not entirely freewheeling and that we can and should define its outer boundaries. *See id.* ("[T]he term 'large fraction,' which, in a way, is more conceptual than mathematical, envisions something more than the 12 out of 100 women identified here."). Thus, on remand, the district court should conduct fact finding concerning the number of women unduly burdened by the contract-physician requirement and determine whether that number constitutes a "large fraction."[9]

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[9] We find it unnecessary to reach the issue of the contract-physician requirement's benefits, though the district court's method gives us some pause. In determining that the contract-physician requirement's benefits would be "low and not compelling," the district court concluded that Planned Parenthood's current continuity-of-care protocols were adequate. *Hellerstedt*, however, compared H.B. 2 to Texas's pre-existing law, not Texas abortion providers' current protocols. *See* 136 S.Ct. at 2311 ("We have found nothing in Texas' record evidence that shows that, *compared to prior law* (which required a 'working arrangement' with a doctor with admitting privileges), the new law advanced Texas' legitimate interest in protecting women's health." (emphasis added)). Moreover, Planned Parenthood could unilaterally decide to discontinue its twenty-four-hour nurse-staffed phone line, end patient referrals to surgical providers, or stop consultations with emergency-room physicians in the case of serious complications. While we elect not to quantify it at this time, we certainly see some benefit for patients where the State mandates continuity-of-care standards – especially in the face of known complications and where there previously had been no state requirements. For instance, had the State merely mandated Planned

Accordingly, we vacate the district court's grant of a preliminary injunction and remand for further proceedings consistent with this opinion.

Parenthood's existing continuity-of-care protocols, Planned Parenthood likely would not argue that these would be of no significant benefit to its patients. At the very least, codifying Planned Parenthood's continuity-of-care protocols would constitute a benefit because it would set a legal floor to prevent retrenchment in the standard of care. The question here, however, is whether the contract-physician requirement's benefits are substantially outweighed by the burdens it imposes on a large fraction of women seeking medication abortion in Arkansas.

2016 WL 6211310
United States District Court,
E.D. Arkansas, Western Division.

Planned Parenthood Arkansas & Eastern Oklahoma, d/b/a Planned Parenthood of the Heartland; and Stephanie Ho, M.D., on behalf of themselves and their patients, Plaintiffs
v.
Larry Jegley, Prosecuting Attorney for Pulaski County, in his official capacity, his agents and successors; and Matt Durrett, Prosecuting Attorney for Washington County, in his official capacity, his agents and successors, Defendants.

Case No. 4:15-cv-00784-KGB
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Signed 03/14/2016

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PRELIMINARY INJUNCTION ORDER

Kristine G. Baker, United States District Judge

Before the Court is the motion for preliminary injunction filed by plaintiffs Planned Parenthood of Arkansas & Eastern Oklahoma, d/b/a Planned Parenthood of the Heartland ("PPH") and Stephanie Ho, M.D. (Dkt. No. 2). PPH and Dr. Ho supplemented the record with additional supporting affidavits (Dkt. Nos. 28, 29, 30). Defendants Larry Jegley, who is sued in his official capacity as Prosecuting Attorney for Pulaski County, Arkansas, and Matt Durrett, who is sued in his official capacity as Prosecuting Attorney for Washington County, Arkansas, filed a response to the motion for preliminary injunction (Dkt. Nos. 55, 56). PPH and Dr. Ho replied (Dkt. No. 57). PPH and Dr. Ho, on behalf of themselves and their patients, move this Court for a preliminary injunction restraining defendants from enforcing Sections 1504(a) and 1504(d) of Arkansas Act 577, Reg. Sess. (2015) ("Act 577" or "the Act"), codified at Arkansas Code Annotated § 20-16-1501 *et seq.* For the following reasons, the Court grants the motion for preliminary injunction (Dkt. No. 2).

I. Procedural Background

PPH and Dr. Ho bring this action seeking declaratory and injunctive relief on behalf of themselves and their patients under the United States Constitution and 42 U.S.C. § 1983 to challenge Sections 1504(a) and 1504(d) of the Act. This Court has jurisdiction under 28 U.S.C. §§ 1331 and 1343(a)(3). PPH and Dr. Ho claim

specifically that the Act violates their patients' rights guaranteed by the Fourteenth Amendment to the United States Constitution (Dkt. No. 3, at 1).

Based on PPH and Dr. Ho's filings, the Court determined that Federal Rule of Civil Procedure 65(b)(1) was not satisfied by PPH and Dr. Ho's initial filing so as to permit the Court to consider whether to issue a temporary restraining order without notice. Instead, the Court contacted counsel for the parties on December 28, 2015, and set a hearing on the motion for December 30, 2015 (Dkt. No. 14). Mr. Jegley and Mr. Durrett filed no written response to the motion prior to the December 30, 2015, hearing or before the Court issued its written opinion on the request for a temporary restraining order.

The Court held the hearing on December 30, 2015. The Court concluded that, although it held an adversarial rather than an *ex parte* hearing on the motion, it was not the sort of adversarial hearing that included an opportunity to present evidence beyond the affidavits and exhibits filed with PPH and Dr. Ho's motion so as to allow the basis of the relief requested to be strongly challenged. Therefore, the Court only considered initially the motion for temporary restraining order. *See*, *e.g.*, *Piraino v. JL Hein Serv. Inc.*, No. 4:14-CV-00267-KGB (E.D. Ark. May 16, 2014) (citing *McLeodUSA Telecomms. Servs. v. Qwest Corp.*, 361 F. Supp. 2d 912, 918 n.1 (N.D. Iowa 2005)).

The Court granted the request for a temporary restraining order and set the date by which that order

would expire as January 14, 2016, unless the Court, for good cause, extended the order (Dkt. No. 22). The parties filed a joint motion for extension of time of the temporary restraining order (Dkt. No. 24). The parties also proposed a briefing schedule. The Court granted this motion, allowing the temporary restraining order to remain in effect until 5:00 p.m. on March 14, 2016 (Dkt. No. 25).

The Court conducted a hearing on plaintiffs' motion for preliminary injunction on March 2, 2016. The parties agreed among themselves not to present additional evidence at the hearing but instead to present only argument, and the Court agreed to hear only argument (Dkt. No. 53). At the conclusion of the hearing, all parties agreed the matter was ripe for this Court's consideration of whether a preliminary injunction should issue.

II. Findings Of Fact

1. Arkansas women are currently able to access abortion at three health centers in the state: two in Little Rock and one in Fayetteville (Dkt. No. 2, Decl. of Suzanna de Baca in Supp. of Pls.' Mot. For Temporary Restraining Order and/or Prelim. Inj., ¶ 3 ("de Baca Decl.")).

2. There are two methods of performing abortions: medically, by administering drugs, and surgically, using various instruments (Dkt. No. 2, Decl. of Paul M. Fine, M.D., in Supp. of Pls.' Mot. For

Temporary Restraining Order and/or Prelim. Inj., ¶ 6 ("Fine Decl.")).

3. Medication abortion involves a combination of two prescription pills: mifepristone, also known as RU-486 or by its commercial name Mifeprex, which blocks the hormone progesterone, which is necessary to maintain pregnancy. Mifepristone increases the efficacy of the second medication, misoprostol, also known by its brand name Cytotec, which causes the uterus to contract and expel its contents (*Id.*, ¶ 7).

4. In March 2015, Arkansas enacted Act 577, titled the Arkansas Abortion-Inducing Drugs Safety Act, codified at Ark. Code Ann. § 20-16-1501 *et seq.* (Dkt. No. 47, at 2).

5. This Court entered a temporary restraining order, temporarily enjoining enforcement of the Act, and the parties agreed to extend that order to 5:00 p.m. on March, 14, 2016.

6. The Arkansas General Assembly stated, when it enacted this law, that the alleged purpose was to "[p]rotect women from the dangerous and potentially deadly off-label use of abortion-inducing drugs" and "[e]nsure [] that physicians abide by the protocol for such abortion-inducing drugs, as outlined in the drug labels." Ark. Code Ann. § 20-16-1502(b).

7. Violations of the Act can result in severe penalties for those, other than the pregnant woman upon whom the drug-induced abortion is performed, who intentionally, knowingly, or recklessly violate the Act,

including civil liability and criminal prosecution. Ark. Code Ann. §§ 20-16-1506, 1507.

8. Section 1504(d) of the Act, the "contracted physician requirement," requires medication abortion providers to "have a signed contract with a physician who agrees to handle complications." Ark. Code Ann. § 20-16-1504(d). This contracted physician "shall have active admitting privileges and gynecological/surgical privileges at a hospital designated to handle any emergencies associated with the use or ingestion of the abortion-inducing drug." *Id.* It also mandates that every medication abortion patient "receive the name and phone number for the contracted physician and the hospital at which that physician maintains admitting privileges and which can handle any emergencies." *Id.*

9. Section 1504(a) of the Act, the "FPL mandate," requires medication abortion providers to "satisf[y] the protocol authorized by the United States Food and Drug Administration, as outlined in the final printed labeling for the [abortion-inducing] drug or drug regimen" when providing or prescribing abortion-inducing drugs. Ark. Code Ann. § 20-16-1504(a). The "final printed labeling for Mifeprex" is defined to "include[ ] the United States Food and Drug Administration-approved dosage and administration instructions for both mifepristone and misoprostol." Ark. Code Ann. § 20-16-1504(a)(2).

10. In 2000, the United States Food and Drug Administration ("FDA") approved Mifeprex for

marketing as an abortion-inducing drug in the United States (Dkt. No. 2, Fine Decl., ¶ 18).

11. In accordance with FDA protocol, Mifeprex was approved with a final printed labeling ("FPL"), an informational document that provides guidance to physicians about the use for which the drug sponsor requested and received FDA approval.

12. PPH or predecessor organizations have provided a range of reproductive health services in Arkansas for over 30 years (Dkt. No. 2, de Baca Decl., ¶ 3).

13. PPH operates two of the three abortion-providing health centers in the State of Arkansas, one located in Little Rock, Arkansas, and the other in Fayetteville, Arkansas (Dkt. No. 2, de Baca Decl., ¶ 3).

14. PPH employs two physicians who provide care in Arkansas, one of whom is Dr. Ho. Dr. Ho is a physician licensed by the state of Arkansas who, along with another physician, provides medication abortion services at PPH's health centers (Dkt. No. 2, de Baca Decl., ¶ 4). PPH has been providing medication abortion services in Arkansas since 2008 (Dkt. No. 2, de Baca Decl., ¶ 3).

15. Dr. Ho is experienced in providing medication abortions. Dr. Ho began providing care in Arkansas in 2008, has her own private practice in Arkansas where she sees patients, and has worked with PPH to also offer services through PPH since 2013 (Dkt. No. 2, de Baca Decl., ¶ 3). Her supervisor at PPH, who is board certified in obstetrics and gynecology; who was a

faculty member at a medical school before becoming the Medical Director of PPH; and who is licensed to practice medicine in Arkansas, Iowa, Nebraska, and Oklahoma, is an experienced provider of both surgical and medication abortions (Dkt. No. 29, Declaration of Stephanie A. Ho, M.D., In Support of Plaintiffs' Motion For A Preliminary Injunction, ¶ 4 ("Ho Decl."); Dkt. No. 57-1, Rebuttal Declaration of Suzanna de Baca In Support of Plaintiffs' Motion For Preliminary Injunction, ¶ 4 ("de Baca Rebuttal Decl.")).

16. PPH currently does not provide surgical abortion in Arkansas (Dkt. No. 2, de Baca Decl., ¶ 4).

17. In Arkansas, as long as patients are no more than nine weeks pregnant, they currently have the option of choosing between a surgical procedure in Little Rock at a center operated by an entity other than PPH and a procedure using medications alone offered in both Little Rock and Fayetteville (Dkt. No. 3, at 2). There is only one surgical abortion provider in the state (Dkt. No. 2, de Baca Decl., ¶ 10). The common current practice, both in Arkansas and elsewhere in the United States, is for a patient to take 200 mg of mifepristone at a healthcare facility and approximately 24 to 48 hours later, at a comfortable location of her choosing, to take 800 micrograms of misoprostol. This regimen is offered to women through at least 63 days, or 9 weeks, after the first day of the woman's last menstrual period ("LMP"). This is referred to as the "evidence-based regimen" because it is based on a large body of evidence regarding safety and effectiveness (Dkt. No. 2, Fine Decl., ¶¶ 8, 20).

18. Based on data reported to the Arkansas Department of Health for the Center for Health Statistics' annual report on induced abortions, there were 4,235 total abortions in the State of Arkansas in 2014 (Dkt. No. 55-8, Affidavit of Priya Kakkar, ¶ 6 ("Kakkar Aff.")). Of those, 3,307 abortions were obtained by in-state residents (Kakkar Aff., ¶ 6). Of the total abortions, 608 were medication abortions; the remaining abortions were surgical (Kakkar Aff., ¶ 6).

19. According to PPH and Dr. Ho, "[c]ombined, these tables show that 402 medication abortions in 2014 were performed in the 7th week of pregnancy or later, in other words, between 49 and 63 days LMP. This is approximately 66% of the medication abortions performed statewide in 2014." (Dkt. No. 57, at 32-33).

20. Of the 303 medication abortions provided at PPH's Fayetteville health center in 2014, 247 of those abortions, or approximately 81.5%, were provided between 50 and 63 days LMP and could not be provided under the FPL regimen (Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 19).

21. PPH and Dr. Ho represent that these figures are approximate because medication abortions performed at 49 days LMP are counted as part of the 7th week of pregnancy in these tables and by PPH (Dkt. No. 57, at 33 nn.23, 24).

22. If PPH's Fayetteville health center stops providing abortions all together due to an inability to meet the contracted physician requirement, women in the Fayetteville area will be required to travel 380

miles to make one round trip to Little Rock to access surgical abortion services (Dkt. No. 2, Fine Decl., ¶ 52; de Baca Decl., ¶ 18).

23. Because of a different Arkansas abortion restriction that requires all women seeking abortions – medication or surgical – to receive certain state-mandated information in person at least 48 hours prior to the abortion, all women seeking abortions will have to make the trip to access abortion services more than once. *See* Ark. Code Ann. § 20-16-1703.

24. Arkansas law provides no exceptions to this requirement for receiving state-mandated information in person at least 48 hours prior to the abortion based on distance traveled for the procedure. *See* Ark. Code Ann. § 20-16-1703.

25. PPH and Dr. Ho contend that, as with any outpatient medical procedure, when patients opting for medication abortion are sent home from the health center, they are sent home with specific instructions for home care, directions on how to contact PPH if they are experiencing any concerns or complications, and an appointment for follow-up with PPH clinicians (Dkt. No. 2, de Baca Decl., ¶¶ 7-8; Dkt. No. 57-1, de Baca Rebuttal Decl., ¶¶ 2-3).

26. Record evidence demonstrates that PPH instructs patients that, if they are experiencing a complication or concern, they should call PPH and speak to nurses who are available 24 hours a day. There is record evidence that those nurses can access patient charts and can consult, as needed, with Dr. Ho, the

PPH physician who provides medication abortions in Little Rock, or the PPH medical director (Dkt. No. 57-1, de Baca Rebuttal Decl., ¶¶ 3, 4, 6). As necessary, the physician can speak directly to the patients (*Id.*, ¶ 3).

27. In most cases, according to the record evidence presented by PPH and Dr. Ho, patients can be reassured over the phone or, if need be, arrangements are made for the patient to return to the health center for care (Dkt. No. 2, de Baca Decl., ¶ 9).

28. PPH and Dr. Ho include record evidence that only a small subset of medication abortion patients experience complications (Dkt. No. 57-2, Rebuttal Declaration of Paul Fine, M.D., In Support Of Plaintiffs' Motion For Preliminary Injunction, ¶ 3 ("Fine Rebuttal Decl.")). There is record evidence that, for most of the small number of patients who experience complications or need follow-up care, many can be, and are, treated at the clinic or health center, not a hospital (Dkt. No. 2, Fine Decl., ¶¶ 14-16; Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 3).

29. PPH and Dr. Ho can and do refer patients in need of care to other providers and specifically "a clinician trained in surgical abortion" (Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 7; Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 9). PPH and Dr. Ho maintain that, in a small number of cases and after a repeat dose of medication if the patient chooses, patients will need a surgical procedure after their medication abortion has failed or is incomplete (Dkt. No. 29, Ho Decl., ¶ 17; Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 7). Record evidence

establishes that the evidence-based regimen has a failure rate of less than 2%, far lower than the 8% failure rate of the FPL regimen (Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 37). PPH and Dr. Ho make arrangements for referral of patients to other providers, depending on where the patient lives, for the surgical abortion (Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 7). The only surgical abortion provider in Arkansas is Little Rock Family Planning Services (*Id.*).

30. PPH and Dr. Ho also maintain that surgical completion does not require urgent or hospital-based care, and PPH and Dr. Ho state that they do not just refer their patients to the emergency department, despite defendants' claim (Dkt. No. 29, Ho Decl. ¶¶ 11-19, Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 7).

31. In what PPH and Dr. Ho describe as "a rare case of concerns that warrant more immediate treatment," PPH staff will refer a patient to a local emergency department, where she will obtain any necessary treatment from the hospital-based physicians (Dkt. No. 2, de Baca Decl., ¶ 9). PPH and Dr. Ho contend that their protocols for treating a patient experiencing a rare complication after medication abortion are both consistent with the standard of care and provide continuity of care (Dkt. No. 29, Ho Decl., ¶¶ 11-19; Dkt. No. 2, Fine Decl., ¶¶ 32-39).

32. In Arkansas, if a medication abortion patient is referred to a local emergency department, at least one of PPH's physicians is notified (Dkt. No. 29, Ho Decl., ¶¶ 16-18; Dkt. No. 57-1, de Baca Rebuttal Decl.,

¶ 5). There is record evidence that the PPH staff always follows-up with the patient the next day, requests a release for hospital records from the patient, and arranges for the patient to receive any necessary follow-up care recommended by hospital physicians (Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 5). Further, there is record evidence that, if a hospital physician ever needed information about a patient who arrived at the hospital, that physician could also reach PPH nurses and PPH on-call physicians as necessary either during business hours or after hours, and PPH staff have access to patient health records, which are maintained electronically, even when they are out of the office (Dkt. No. 29, Ho Decl., ¶¶ 16-18; Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 6).

33. PPH and Dr. Ho maintain that this practice complies with the standard of care provided by other providers of outpatient care (Dkt. No. 29, Ho Decl., ¶ 19; Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 5).

34. Further, if the medication abortion patient takes her additional pill or pills to complete the medication abortion procedure and has complications later near her home, she is likely to access emergency medical care near her home, which is unlikely to be a hospital at which the contracted physician under this provision would be likely to have admitting privileges given the patient population and distances patients travel as described by PPH and Dr. Ho (Dkt. No. 2, de Baca Decl., ¶ 4).

35. The types of issues that arise in rare emergent care situations, according to record evidence, are identical to those suffered by women experiencing miscarriage, who receive treatments in hospitals every day through emergency physicians and on-call specialists, if necessary (Dkt. No. 2, Fine Decl., ¶ 34; Dkt. No. 56, Amended Affidavit of Lee G. Wilbur, M.D., FAAEM, ¶¶ 11-12 ("Wilbur Amend. Aff.")).

36. PPH and Dr. Ho's experts and at least one of defendants' experts agree that patients are usually frank about their medical history and that hospital physicians are trained to elicit information from reluctant patients (Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 25, Dkt. No. 56, Wilbur Amended Aff., ¶ 9).

37. The American College of Obstetricians and Gynecologists ("ACOG") Practice Bulletin 143 states:

> Women who undergo medical abortion may need to access emergency surgical intervention, and it is medically appropriate to provide referral to another health care provider. However, state or local laws may have additional requirements.
>
> Clinicians who wish to provide medical abortion services either should be trained in surgical abortion or should be able to refer to a clinician trained in surgical abortion.

http://www.acog.org/-/media/Practice-Bulletins/Committee-on-Practice-Bulletins-Gynecology/Public/pb143.pdf (the "ACOG Practice Bulletin 143").

38. There is record evidence that "the vast majority" of hospitals do not provide abortions and do not provide admitting privileges to physicians who provide abortions (Dkt. No. 57-2, Fine Rebuttal Decl., ¶¶ 13-14).

39. There is record evidence, and other courts have determined, that although competence may be a factor in determining whether to grant admitting privileges, other considerations are involved, many of which have nothing to do with competence, such as where a physician resides, whether the physician can meet a minimum number of admissions each year, or whether the physician has any faculty appointments (Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 13). *See*, *e.g.*, *Little Rock Cardiology Clinic PA v. Baptist Health*, 591 F.3d 591 (8th Cir. 2009) (involving an economic credentialing policy and alleging as a result antitrust claims against the nonprofit hospital operator, nonprofit mutual insurance company and its subsidiary, operator of health maintenance organization, and health maintenance organization operator's owner). *See also Planned Parenthood of Wis., Inc. v. Van Hollen*, 94 F.Supp.3d 949, 953 (W.D. Wis. 2015), *aff'd sub nom. Planned Parenthood of Wis. v. Schimel*, 806 F.3d 908 (7th Cir. 2015); *W. Ala. Women's Ctr. v. Williamson*, 120 F.Supp. 3d. 1296, 1316 (M.D. Ala. 2015); *Planned Parenthood Se., Inc. v. Strange*, 33 F. Supp. 3d 1330, 1338 (M.D. Ala. 2014).

40. The evidence-based regimen of medication abortion that PPH and Dr. Ho use has been declared by the American College of Obstetricians and

Gynecologists ("ACOG") and the American Medical Association to be superior and safer, and to cause fewer complications, as compared to the FPL regimen required by the Act. *See* ACOG Practice Bulletin 143; (*see also* Dkt. No. 2, Fine Decl., ¶ 25).

41. Based on the record before the Court at this stage of the proceeding, the Court understands that the ACOG, the American Medical Association, the World Health Organization, and the Royal College of Obstetricians and Gynecologists have all endorsed the use of an alternative regimen through 63 days LMP (Dkt. No. 2, Fine Decl., ¶ 25).

42. There is no evidence in the record before the Court that the FDA has ever taken steps to restrict the evidence-based regimens for medication abortion. Instead, there is evidence in the record that the FDA has expressly recognized that the evidence-based use of medications is an appropriate part of medical practice (Dkt. No. 57-2. Fine Rebuttal Decl., ¶¶ 27-34).

43. The FDA confirms that Subpart H approval does not preclude doctors from prescribing a drug off-label. 57 Fed. Reg. 58942 (Dec. 11, 1992).

44. There is record evidence citing studies and statistics that casts doubt on the Arkansas Legislature's findings regarding the Act (Dkt. No. 2, Fine Decl., ¶¶ 40-50). For example, Dr. Fine explains that, "[o]f the over two million patients who have had a medication abortion, eight contracted a fatal infection" (Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 39). He contends there is no established causal link between

mifepristone or misoprostol and these infections, and he maintains that, even if there was, these figures indicate a very low risk (Dkt. No. 57-2, Fine Rebuttal Decl., ¶¶ 39-43).

45. Further, there is record evidence that the expulsion under the FPL regimen takes far longer to complete than under the evidence-based regimen and that clinical observation for that extended period of time may not be feasible for patients (Dkt. No. 57-2, Fine Rebuttal Decl., ¶¶ 52-53).

46. If the FPL mandate portion of the Act goes into effect, women with gestational ages of 49 days LMP or fewer for whom medication abortion remains an option would have to undergo the FPL procedure. These women would be required to make an additional trip to the clinic for completion of the FPL regimen because unlike the evidence-based regimen it requires an additional clinic visit, increasing the expenses and other burdens associated with medication abortion (Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 38).

47. There is an additional increased cost with the FPL regimen aside from an additional trip to the clinic, as the evidence-based regimen requires only 200 mg of mifepristone while the FPL regimen requires 600 mg; there is record evidence that mifepristone is a very expensive medicine (Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 38).

48. On the record before the Court, the Court determines that, if the FPL mandate portion of the Act only goes into effect, women with gestational ages

between 50 and 63 days LMP would not be able to access medication abortions, causing all of those women in Arkansas to have to travel to Little Rock to obtain a surgical abortion in Arkansas (Dkt. No. 2, Fine Decl., ¶ 25).

50. Each time these women travel to access abortion services, they will have to arrange the necessary funds, transportation, child care, and time off work required to travel (*See* Dkt. No. 2, Fine Decl., ¶¶ 53, 56).

51. There is evidence in the record before the Court that increased travel distances and costs – both monetary and otherwise – for those who must travel to a clinic multiple times to obtain an abortion may cause women who otherwise would have obtained an abortion not to obtain one at all (Dkt. No. 28, Declaration of Stanley K. Henshaw, Ph.D., In Support Of Plaintiffs' Motion For Preliminary Injunction, ¶ 11 ("Henshaw Decl.") (citing studies that show an increased travel burden of 100 miles or more will cause 20-25% of women who would have otherwise obtained an abortion not to obtain one and that longer distances will cause an even higher proportion of women not to obtain an abortion)).

52. Some women would seek abortion services will be delayed by the increased travel distances and increases in costs, forcing these women into later abortions that are both riskier and more expensive, if they can obtain them at all (Dkt. No. 2, Fine Decl., ¶¶ 53-54; Dkt. No. 29, Ho Decl., ¶¶ 20-24). There is evidence in

the record supporting this (Dkt. No. 28, Henshaw Decl. ¶ 20; Dkt. No. 2, Fine Decl. ¶ 54).

53. Inability to travel to the sole remaining clinic in the state will lead some women to take desperate measures, such as attempting to self-abort or seeking care from unsafe providers, which would further put their health at risk (Dkt. No. 2, Fine Decl., ¶ 55).

54. The Court has before it record evidence that "42.4% of abortion patients [nationally] have incomes below the poverty line" and that "cost is a significant barrier to access" (Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 38).

55. There is evidence in the record that far fewer women choose medication abortion – or can access medication abortion – in states that restrict doctors to the FPL regimen (Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 38).

56. Further, because many women do not discover they are pregnant until 49 days LMP, which is the last day the FPL regimen is available under the Act, the Act may ban effectively medication abortions for some women.

57. There is evidence in the record that most of PPH and Dr. Ho's medication abortion patients are between 50 and 63 days LMP (Dkt. No. 2, de Baca Decl., ¶ 16). Under the FPL mandate, these women will not be able to obtain a medication abortion, despite such an option being medically safe and otherwise available to them. Arkansas law will prohibit it.

58. If PPH is required to follow the FPL regimen, record evidence indicates PPH likely would stop providing abortion services at both Arkansas health centers (Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 9).

59. PPH and Dr. Ho claim that, if required to perform medication abortion according to the FPL regimen only, the number of medication abortions would decrease while the cost of medication abortion would increase. Given these factors, PPH represents that "it would not be possible for us to retain our physicians to provide abortion to such a small number of patients who will be left able to access this service" (Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 9). In other words, there is record evidence that these clinics likely will likely stop providing abortion services if the Act takes effect. There also is record evidence that, if the Act takes effect, all three abortion-providing health centers in Arkansas would no longer offer medication abortions and there would be only one health center in the state in Little Rock offering surgical abortion (Dkt. No. 2, Fine Decl., ¶ 52; Dkt. No. 2. De Baca Decl., ¶ 13).

60. The FPL mandate has no stated exception for cases where the procedure, in the considered judgment of the patient's physician, is necessary to preserve a woman's life or health. The ban applies equally to victims of rape, incest, other forms of sexual abuse, and domestic violence, who may choose medication abortion to feel more in control of the experience and to avoid trauma from having instruments placed in their vagina (Dkt. No. 2, Fine Decl., ¶ 12). The ban also applies to women with medical reasons why medication

abortion is better for them than surgical abortion, including but not limited to certain medical conditions identified in the record that make medication abortion a safer option with a lower risk of complications and failure than surgical abortion (Dkt. No. 2, Fine Decl., ¶ 13).

61. PPH and Dr. Ho maintain that they have exhausted their limited network of friendly physician contacts throughout Arkansas by reaching out to certain obstetricians and gynecologists in the state in an effort to locate a contracted physician (Dkt. No. 29, Ho Decl., ¶¶ 6-10). In January 2016, PPH sent a letter to approximately 225 obstetricians and gynecologists in the state, asking if these individuals would be willing to be the contracted physician (Dkt. No. 29, Ho Decl., ¶ 10; Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 10). To date, PPH has received no positive response (Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 10).

62. PPH and Dr. Ho eliminated from their request physicians affiliated with the University of Arkansas for Medical Sciences ("UAMS") system, as Dr. Ho understood the chair of the obstetrics and gynecology department there communicated to PPH that UAMS physicians would not be permitted to work with PPH (Dkt. No. 29, Ho Decl., ¶ 6). This is supported by record evidence (Dkt. No. 55, Ex. 2).

63. There is evidence in the record that physicians who provide abortions or associate with physicians who provide abortions risk being ostracized from their communities and face harassment and violence

toward themselves, their family, and their private practices (Dkt. No. 30, Declaration of Debra Stulberg, M.D., In Support Of Plaintiffs' Motion For Preliminary Injunction, ¶¶ 13-17 ("Stulberg Decl.")).

64. Even if a physician is willing to take on these risks, there is evidence in the record that many private practice groups, hospitals, HMOs, and health networks will not permit physicians working for them to associate with abortion providers (Dkt. No. 30, Stulberg Decl., ¶¶ 9-12).

65. To begin to provide surgical abortions in Fayetteville or Little Rock, the record evidence indicates that PPH's current health centers do not have sufficient space to accommodate surgical abortion services, so that PPH would need to relocate its current health centers and renovate the new location to meet its needs, as well as the state regulatory requirements for surgical abortion providers (Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 8); Ark. Code R. 007.05.2-12(G).

66. PPH represents in the record that it does not have a sufficient budget to make these moves (Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 8). Further, PPH maintains that the stigma against abortion providers in Arkansas makes it extremely difficult for PPH to locate and secure real estate, as landlords and sellers are unwilling to work with PPH (Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 8; Dkt. No. 30, Stulberg Decl., ¶ 14). Even if PPH had the necessary office space to provide surgical abortions, it does not currently have physicians who are trained and available to provide surgical

abortions in Arkansas (Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 8).

67. None of the out-of-state abortion providers defendants cite are within the same metropolitan area as the current Arkansas providers.

68. One of the out-of-state providers relied upon by defendants in argument, the provider in Jackson, Mississippi, is only able to operate currently because of an injunction against an abortion restriction, and many of the other out-of-state providers upon which defendants rely are in states in which abortion restrictions have been passed in recent years (Dkt. No. 57, at 38 n.28).

III. Conclusions Of Law

When determining whether to grant a motion for preliminary injunction, this Court considers: (1) the threat of irreparable harm to the movant; (2) the movant's likelihood of success on the merits; (3) the balance between the harm to the movant and the injury that granting an injunction would cause other interested parties; and (4) the public interest. *Kroupa v. Nielsen*, 731 F.3d 813, 818 (8th Cir. 2013) (quoting *Dataphase Sys. Inc. v. CL Sys.*, 640 F.2d 109, 114 (8th Cir. 1981)). Preliminary injunctive relief is an extraordinary remedy, and the party seeking such relief bears the burden of establishing the four *Dataphase* factors. *Watkins Inc. v. Lewis*, 346 F.3d 841, 844 (8th Cir. 2003). The focus is on "whether the balance of the equities so favors the movant that justice requires the court to

intervene to preserve the *status quo* until the merits are determined." *Id.*

A. Standing

This Court concludes that, whether this is examined as a facial challenge or an as-applied challenge, PPH and Dr. Ho have standing. There are many cases recognizing that an abortion provider, such as PPH, may sue to enjoin as violations of the United States Constitution or federal law through 42 U.S.C. § 1983 state laws that restrict abortion. "These cases emphasize not the harm to the abortion clinic of making abortions very difficult to obtain legally, though that might be an alternative ground for recognizing a clinic's standing, but rather 'the confidential nature of the physician-patient relationship and the difficulty for patients of directly vindicating their rights without compromising their privacy,' as a result of which 'the Supreme Court has entertained both broad facial challenges and pre-enforcement as-applied challenges to abortion laws brought by physicians on behalf of their patients.'" *Schimel*, 806 F.3d at 910 (quoting *Isaacson v. Horne*, 716 F.3d 1213, 1221 (9th Cir. 2013)).

Further, the United States Supreme Court held in *Doe v. Bolton*, 410 U.S. 179, 188 (1973), that abortion doctors have first-party standing to challenge laws limiting abortion when, as in *Doe* and the current case, the doctors are subject to penalties for violation of the laws. *See Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 903-04, 909 (1992)

(plurality opinion); *Schimel*, 806 F.3d, at 911; *Abbott II*, 748 F.3d at 589; *Van Hollen*, 738 F.3d at 794; *Planned Parenthood of Central Missouri v. Danforth*, 428 U.S. 52, 62 (1976).

In their filings, defendants make several arguments challenging standing in this case. Defendants did not argue standing at the hearing. Defendants contend that plaintiffs cannot demonstrate a "close relation" with abortion patients because they are challenging laws that were enacted to protect the health and safety of those patients. Defendants claim that this presents a conflict of interest between providers and patients, and third-party standing is forbidden if the interests of the litigant and the third-party rights-holder are even "potentially in conflict." *Elk Grove Unified Sch. Dist. v. Newdow*, 542 U.S. 1, 15 (2004); *see also* Kowalski v. Tesmer, 543 U.S. 125, 135 (2004) (Thomas, J., concurring) (noting that third-party standing is disallowed when the litigants "may have very different interests from the individuals whose rights they are raising"); *Canfield Aviation, Inc. v. Nat'l Transp. Safety Bd.*, 854 F.2d 745, 748 (5th Cir. 1988) ("[C]ourts must be sure . . . that the litigant and the person whose rights he asserts have interests which are aligned.").

This argument was rejected by the Fifth Circuit Court of Appeals recently. *See Abbott II*, 748 F.3d at 589 n.9. This claim could be made with respect to any abortion regulation that purports to advance a valid state interest, but courts have repeatedly allowed abortion providers to challenge such laws, determining that the

providers' and women's interests are aligned and not adverse. *See*, *e.g.*, *Bellotti v. Baird*, 443 U.S. 622, 627 n.5 (1979) (holding that a physician plaintiff had standing to raise his minor patients' claims to determine whether a parental consent law should be upheld to protect the alleged vulnerability of minors); *Charles v. Carey*, 627 F.2d 772, 779 n.10 (7th Cir. 1980) (rejecting the state's claim of conflict of interest in a challenge to a counseling law designed to "protect women from abusive medical practices"). This has not defeated a providers' standing to challenge contraception restrictions. *See Carey v. Population Servs. Int'l*, 431 U.S. 678, 683-84, 690 (1977) (granting third-party standing where the government defended a contraception restriction based on its interest in protecting health); *Eisenstadt v. Baird*, 405 U.S. 438, 445-46, 450 (1972) (allowing a plaintiff to raise the rights of others seeking contraception where the government defended a restriction as "regulating the distribution of potentially harmful articles").

Defendants also contend that, even if plaintiffs could somehow avoid these limits on third-party litigation, they still cannot assert third-party rights under 42 U.S.C. § 1983 because, defendants claim, § 1983 extends only to litigants who assert their *own* rights. Based on this, defendants contend the third-party claims may proceed only under the implied right of action established by the Supremacy Clause, and the claims cannot serve as a basis for attorneys' fees. *See Planned Parenthood of Houston & Se. Tex. v. Sanchez*, 480 F.3d 734, 739-40 (5th Cir. 2007); *Planned*

Parenthood of Houston & Se. Tex. v. Sanchez, 403 F.3d 324, 333 (5th Cir. 2005).

There is no language in the statute that supports this argument. *See* 42 U.S.C. § 1983 (providing in pertinent part, "Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress. . . ."). This Court agrees with the reasoning of the Seventh Circuit Court of Appeals on this point and rejects defendants' argument regarding standing under § 1983. *See Van Hollen*, 738 F.3d at 794-95.

B. Facial Versus An As-Applied Challenge

PPH and Dr. Ho's complaint does not specify whether this action is brought as a "facial" constitutional challenge to the Act or as an "as-applied" challenge (Dkt. No. 1). In the hearing on the motion for temporary restraining order, PPH and Dr. Ho stated that they bring this action as a facial challenge, but if the Court rejects that argument, they wish the Court to then consider the challenge to the Act as an as-applied challenge. At that stage of the proceeding, the Court opted to confine its review to an as-applied challenge. Now, having received filings from all parties, the

Court clarifies the controlling law applicable to a facial challenge to an abortion statute and confirms that the Court reviews this request for a preliminary injunction as a facial challenge.

In regard to facial challenges in general, the majority of courts have adopted a definition of facial challenges as those seeking to have a statute declared unconstitutional in all possible applications. *See*, *e.g.*, *Sabri v. United States*, 541 U.S. 600, 609 (2004); *United States v. Salerno*, 481 U.S. 739, 745 (1987); *Steffel v. Thompson*, 415 U.S. 452, 474 (1974). As-applied challenges are construed as an argument that the Act is unconstitutional as applied to these precise plaintiffs. The Supreme Court has made clear that as-applied challenges are preferred. *See Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 448-451 (2008) (discussing the preference for as-applied challenges as opposed to facial challenges). In *Salerno*, the Supreme Court stated that a "facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully" and will only succeed if a litigant can "establish that no set of circumstances exists under which the Act would be valid." 481 U.S. at 745.

The standard that controls this facial challenge to an abortion statute is somewhat different than that applicable to facial challenges in general. The Eighth Circuit Court of Appeals has recognized that facial challenges to abortion statutes can succeed only if a plaintiff can show that "in a large fraction of the cases in which [the law] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an

abortion." *Casey*, 505 U.S. at 895. *See also Planned Parenthood Minn., N.D., S.D. v. Rounds*, 653 F.3d 662, 667-68 (8th Cir. 2011), *vacated in part on reh'g en banc sub nom. Planned Parenthood Minn., N.D., S.D. v. Rounds, 662* F.3d 1072 (8th Cir. 2011) and *in part on reh'g en banc sub nom. Planned Parenthood Minn., N.D., S.D. v. Rounds*, 686 F.3d 889 (8th Cir. 2012); *see also Planned Parenthood Minn., N.D., S.D. v. Rounds*, 530 F.3d 725, 733 n.8 (8th Cir. 2008) ("*Rounds* cases"). By adopting this standard for facial challenges to abortion statutes, the Eighth Circuit Court of Appeals joined every other circuit which has decided the issue by "adopt[ing] the standards enunciated by the *Casey* plurality opinion as controlling precedent in abortion cases." *Rounds*, 530 F.3d at 734 n.8. For these reasons, the Court will examine this as a facial challenge to the provisions of the Act and will apply the legal standard recognized by the Eighth Circuit.

To the extent defendants argue that a higher legal standard should apply to facial challenges to abortion statutes, the Court rejects the argument. The Eighth Circuit's decisions control this Court's decisions, and the Eighth Circuit has applied this same standard to a facial challenge to an abortion statute since the decision in *Gonzales v. Carhart*, 550 U.S. 124, 168 (2007). *See Rounds* cases. The Court rejects defendants' suggestion that facial relief is not available when "there is uncertainty over whether the barred procedure is ever necessary to preserve a woman's health, given the availability of other abortion procedures that are considered to be safe alternatives." (Dkt. No. 55, at 9

(citing *Gonzales*, 550 U.S. at 166-67)). The test defendants call for was employed by the Supreme Court in *Gonzales* after the Court rejected a facial challenge to the statute at issue there because it did not ban the vast majority of abortion procedures at issue. 550 U.S. at 156, 167-68. The Supreme Court enunciated the test that defendants put forth only to address the *Gonzales* plaintiffs' specific argument that the banned procedure was necessary to preserve women's health in certain circumstances and that as-applied relief would be the appropriate remedy if it could be shown in "discrete and well-defined instances a particular condition has or is likely to occur in which the procedure prohibited by the Act must be used." *Id.* at 167. Those circumstances are not presented by this case.

Further, the distinctions between facial and as-applied challenges have more to do with "the breadth of the remedy" ultimately employed by the court, rather than the sufficiency of the plaintiff's initial pleadings. *Citizen's United v. Fed. Election Com'n*, 558 U.S. 310, 330-333 (2010). Regardless of how the parties characterize their dispute, a reviewing court is obligated to consider the facial validity of the statute. If it is not capable of constitutional application, a determination of facial invalidity becomes a matter of "judicial responsibility." *Id.* at 333.

The Court notes that it would be difficult, given the realities of the situation, for any individual abortion seeker to maintain an as-applied challenge. Medication abortions are only available for a short period of time, very early in the pregnancy. The record indicates

that most providers, including PPH and Dr. Ho, do not offer this procedure after 63 days LMP. The opportunity for a medication abortion would pass before an as-applied challenge could be heard and decided. Here, PPH and Dr. Ho argue that the challenged provisions of the Act would ban medication abortion entirely in Arkansas for every woman, thereby eliminating abortion access at two of the three health centers in the state and leaving surgical abortion as the only procedure available – and available only in Little Rock. PPH and Dr. Ho contend that the facial relief they seek is appropriate for the additional reason that, in the absence of facial relief here, PPH and Dr. Ho will no longer offer abortion in Fayetteville, and no provider will offer medication abortion anywhere in Arkansas (Dkt. No. 2, de Baca Decl., ¶¶ 12-13).

C. Modified *Dataphase* Factors

Having determined that PPH and Dr. Ho have standing to bring a facial challenge to these provisions of the Act, the Court turns to examine the *Dataphase* factors as applied to their request for preliminary injunctive relief. *See Dataphase*, 640 F.2d at 109. Under *Dataphase*, no one factor is determinative. *Id.* at 113. The Eighth Circuit recently revised the *Dataphase* test when applied to challenges to laws passed through the democratic process. Those laws are entitled to a "higher degree of deference." *Rounds*, 530 F.3d at 732. In such cases, it is never sufficient for the moving party to establish that there is a "fair chance" of success. Instead, the appropriate standard, and threshold

showing that must be made by the movant, is "likely to prevail on the merits." *Id.* Only if the movant has demonstrated that it is likely to prevail on the merits should the Court consider the remaining factors. *Id.*

1. Likelihood Of Prevailing On The Merits

Federal constitutional protection of reproductive rights is based on the liberty interest derived from the due process clause of the Fourteenth Amendment. *Casey*, 505 U.S. at 846. The United States Supreme Court, when recognizing this right, stated:

> We forthwith acknowledge our awareness of the sensitive and emotional nature of the abortion controversy, of the vigorous opposing views, even among physicians, and of the deep and seemingly absolute convictions that the subject inspires. One's philosophy, one's experiences, one's exposure to the raw edges of human existence, one's religious training, one's attitudes toward life and family and their values, and the moral standards one establishes and seeks to observe, are all likely to influence and to color one's thinking and conclusions about abortion.
>
> In addition, population growth, pollution, poverty, and racial overtones tend to complicate and not to simplify the problem.

Roe v. Wade, 410 U.S. 113, 116 (1973).

As this Court recognized in its temporary restraining order, unless and until *Roe* is overruled by the United States Supreme Court, a state statute is unconstitutional "if its purpose or effect is to place a substantial obstacle in the path of a woman seeking an abortion before the fetus attains viability." *Casey*, 505 U.S. at 878. "Only where state regulation imposes an undue burden on a woman's ability to make this decision does the power of the State reach into the heart of the liberty protected by the Due Process Clause." 505 U.S. at 874 (citations omitted). *See also Stenberg v. Carhart*, 530 U.S. 914, 930 (2000); *Mazurek v. Armstrong*, 520 U.S. 968, 872-73 (1997) (per curiam). "[T]he means chosen by the State to further the interest in potential life must be calculated to inform the woman's free choice, not hinder it." *Casey*, 505 U.S. at 877. In *Casey*, the Supreme Court examined state statutes purported to advance the state's interest in fetal life. Here, the Act purports to advance Arkansas's interest in women's health. Ark. Code Ann. § 20-16-1502(b)(1). The same must be true for these laws; they must be calculated to advance women's health, not hinder it.

This Court rejects defendants' argument that the only analysis applicable to the state's asserted interest in the challenged provisions of the Act is "rational basis" review (Dkt. No. 55, at 13). Here, defendants argue that the challenged provisions of the Act must be upheld if there is "any reasonably conceivable state of facts" that support the provisions, leaving courts to presume that the law in question is valid when faced with a constitutional challenge (Dkt. No. 55, at 13). In

support, defendants cite two decisions from the same case before the Fifth Circuit Court of Appeals, *Abbott*, 734 F.3d 406 (5th Cir. 2013) (*Abbott I*), *and Abbott II*, 748 F.3d 583. As all parties are aware, the standard applied by the Fifth Circuit in these cases is being reviewed by the Supreme Court. *See Whole Woman's Health v. Cole*, 790 F.3d 563 (5th Cir. 2015), *cert. granted*, 136 S. Ct. 499 (2015).

At this stage, the Court rejects rational basis review because this standard is inconsistent with controlling precedents that inform the nature of a woman's right to decide whether to continue a pregnancy or to abort a nonviable fetus. *See Casey*, 505 U.S. at 834, 851 (the "decision whether to bear or beget a child" is one of those "fundamental[]" choices that is "central to the liberty protected by the Fourteenth Amendment") (citing *Eisenstadt*, 405 U.S. at 453); *Lawrence v. Texas*, 539 U.S. 558, 565 (2003) (determining that the right to abortion has "real and substantial protection as an exercise of [a woman's] liberty under the Due Process Clause"). Further, every other court to consider this issue other than the Fifth Circuit has recognized that rational basis review in this context is not appropriate. *See Schimel*, 806 F.3d 908, 919-20; *Van Hollen*, 738 F.3d at 798; *Planned Parenthood Ariz., Inc. v. Humble*, 753 F.3d 905, 911 (9th Cir. 2014), *cert. denied*, 135 S. Ct. 870 (2014); *Strange*, 33 F.Supp.3d at 1338. Even *Gonzalez*, which defendants contend supports the use of rational basis review, the Supreme Court did not apply rational basis review to the

regulation challenged in that case. *See Gonzalez*, 550 U.S. at 158, 160, 161.

Under the standard that the Court will apply in this case, "[t]he court retains an independent constitutional duty to review [a legislature's] factual findings where constitutional rights are at stake. . . . Uncritical deference to [the legislature's] factual findings in these cases is inappropriate." *Id.* at 165, 167.

Generally, the state has the burden of demonstrating a link between the legislation it enacts and what it contends are the state's interests. *See Akron v. Akron Center for Reproductive Health, Inc.*, 462 U.S. 416, 430 (1983), *overruled on other grounds by Casey*, 505 U.S. 833 (describing the burden as that of the state); *Doe*, 410 U.S. 179 (same); *see also Strange*, 33 F.Supp.3d at 1340-41 (describing the holding in *Doe* as requiring "more than general statements of concern and claims that the regulations conceivably might, in some cases, lead to better health outcomes; rather the Court required the state to establish, through evidence, that the regulation really was strongly justified"); *Van Hollen*, 738 F.3d at 798 (requiring evidence that "the medical grounds are legitimate"). "The State's interest in regulating abortion previability is considerably weaker than postviability." *Stenberg*, 530 U.S. at 930 (citing *Casey*, 505 U.S. at 870). An abortion-restricting statute sought to be justified on medical grounds requires not only reason to believe that the medical grounds are valid but also reason to believe that the restrictions, and the medical benefits that the restrictions are believed to confer, do not impose an

"undue burden" on women seeking abortions. *See Gonzales*, 550 U.S. at 146, 157-58; *Stenberg*, 530 U.S. at 938; *Casey*, 505 U.S. at 874, 877. PPH and Dr. Ho, who challenge the provisions of the Act, retain the ultimate burden of proving the unconstitutionality of the provisions. *Mazurek*, 520 U.S. at 972 (reversing appellate court for enjoining abortion restriction where plaintiffs had not proven that the requirement imposed an undue burden); *Casey*, 505 U.S. at 884 (affirming provision where "there is no evidence on this record" that the restriction would amount to an undue burden).

"An undue burden is an unconstitutional burden." *Casey*, 505 U.S. at 877. In *Casey*, the Supreme Court described the "undue burden" test as follows: "[a] finding of an undue burden is a shorthand for the conclusion that a state regulation has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus." *Id.* The *Gonzalez* Court then simplified *Casey's* description, settling on the effects test. 505 U.S. at 158. To show an undue burden, plaintiffs must show that "in a large fraction of the cases in which [the law] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion." *Casey*, 505 U.S. at 895. A court limits its inquiry to "the group for whom the law is a restriction, not the group for whom the law is irrelevant." *Id.* at 894. The parties dispute the scope of the group for whom the Act is a restriction. This Court turns to examine this dispute when conducting the undue burden analysis, *infra.*

Defendants also argue that the Court should not engage in a balancing test when conducting the undue burden analysis (Dkt. No. 55, at 14). Defendants contend that, if the challenged provision survives the minimal rational basis scrutiny defendants advocate, the provision may be struck only based on the effects and that, in evaluating these effects, the Court may not evaluate the strength of the asserted state interests against these effects. Defendants again rely for this proposition solely on Fifth Circuit precedent that is currently being reviewed by the Supreme Court. *See Whole Woman's Health v. Lakey*, 769 F.3d 285, 297 (5th Cir. 2014). Other courts that have considered challenges similar to the challenges here have determined that courts are "require[d] to weigh the extent of the burden against the strength of the state's justification." *Humble*, 753 F.3d at 914. *See also Schimel*, 806 F.3d at 919; *Williamson*, 120 F.Supp.3d. at 1318; *Strange*, 33 F.Supp.3d at 1338.

Under the standard defendants advocate, they claim throughout their arguments regarding both the contracted physician requirement and the FPL mandate that they have established "medical disagreement" about the relative safety of the current state of affairs and what the provisions require. The Court is unconvinced at this stage, based on the record evidence now before it, that defendants' evidence creates a "medical disagreement." Even if it does, as the Supreme Court acknowledged in *Casey*, "[i]t is conventional constitutional doctrine that where reasonable people disagree the government can adopt one position

or the other. . . . That theorem, however, assumes a state of affairs in which the choice does not intrude upon a protected liberty." 505 U.S. at 851. There is a protected liberty interest at stake here. For these reasons, this Court does not accept at this stage defendants' argument regarding medical disagreement.

The Court will begin its analysis of the merits by examining each provision and the asserted state justification for each provision. The Court will then examine the alleged undue burden of the provisions. This Court concludes that, whether this Court weighs the asserted state interests against the effects of the provisions or examines only the effects of the provisions, PPH and Dr. Ho have carried their burden of demonstrating at this stage of the litigation that they are likely to prevail on the merits and to establish that the Act's provisions create an undue burden in that the Act's provisions have the effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus.

a. Contracted Physician Requirement

Section 1504(d) of the Act requires medication abortion providers to "have a signed contract with a physician who agrees to handle complications . . . " Ark. Code Ann. § 20-16-1504(d). This contracted physician "shall have active admitting privileges and gynecological/surgical privileges at a hospital designated to handle any emergencies associated with the use or ingestion of the abortion-inducing drug." *Id.* It also

mandates that every medication abortion patient "receive the name and phone number for the contracted physician and the hospital at which that physician maintains admitting privileges and which can handle any emergencies." *Id.*

At the outset of this analysis and as it did in the Temporary Restraining Order, the Court acknowledges precedent from the Eighth Circuit Court of Appeals in *Women's Health Center of West County, Inc. v. Webster*, 871 F.2d 1377 (8th Cir. 1989), in which the court addressed a Missouri statute requiring abortion providers to have admitting privileges. The Court is mindful that *Webster* was decided before *Casey* and before many other legal, social, and medical changes surrounding abortion. The Court also is aware that the evidence in *Webster* was that only one doctor state-wide could not comply with the requirement and that other doctors at that same clinic could comply with the requirement, resulting in little impact to patients and little to no effect on access to abortions statewide. *Id.* at 1381. As a result, the Court will examine Section 1504(d) in the light of all controlling current authorities and on the current record evidence before it.

In regard to the state's interests, defendants' main argument is that this provision purportedly ensures continuity of care for the woman having the abortion (Dkt. No. 55, at 25). Defendants also claim that the Act's contracted physician requirement "protects not only the health of the woman having the abortion, but also the integrity, ethics, and reputation of the medical

provider who performs it for her." (Dkt. No. 55, at 5). *See* Ark. Code Ann. § 20-16-1502(b).

As for continuity of care, at the temporary restraining order stage, the Court found that, in the case of medication abortion, any benefit of a contracted physician with admitting privileges in terms of continuity of care was incrementally small. Defendants acknowledge that the Court made this finding based on the record as it stood at that earlier stage of the proceeding (Dkt. No. 55, at 24). Based upon this finding at the temporary restraining order stage, defendants now argue that any benefit, no matter how small, passes the rational basis test (Dkt. No. 55, at 24). The record evidence has changed; the record is more developed now at the preliminary injunction stage than at the temporary restraining order stage.

The Court begins its analysis of the state's claimed interest by examining the language of this provision in the Act. Nothing in this provision requires a contracted physician who has admitting privileges to care for a patient who has complications from a medication abortion or to see the patient before the complications arise, accompany the patient to the hospital, treat her there, visit her, or call her. Nothing in this provision ensures the contracted physician will be familiar with the details of the patient's case or be able to access timely and effectively her medical records. The contracted physician would be agreeing to be continuously on call, a difficult commitment. There is nothing in this provision that requires the contracted physician to manage his or her calls any differently than the record evidence

establishes that PPH and Dr. Ho manage such calls, which is to staff the telephone line with a nurse competent to answer questions and skilled enough to elevate concerns as necessary to a doctor trained and able to respond.

Further, if the medication abortion patient takes her additional pill or pills to complete the medication abortion procedure and has complications later near her home, not the clinic or the location where the contracted physician has admitting privileges, the patient is just as apt to call PPH's nurses or physicians or, in cases where necessary, go to the nearest hospital emergency room if she is experiencing complications – a hospital at which the contracted physician under this provision is not likely to have admitting privileges, especially in this case based on the patient population and the distances traveled by those patients as described by PPH and Dr. Ho (Dkt. No. 2, de Baca Decl., ¶ 4). Given the mandatory language of the provision, it is unclear whether medication abortion providers would be required to provide only the contracted physician's phone number and hospital with admitting privileges, regardless of the distance involved or the level of emergency, or whether the option would still exist to provide the information and guidance PPH and Dr. Ho currently provide their patients, including their contact information and advice to proceed to the nearest emergency room for troubling complications. Nothing in the statute requires that the contracted physician have the ability or experience necessary to provide a surgical abortion; that is not a statutory

requirement. PPH and Dr. Ho contend that "the vast majority" of hospitals do not provide abortions and do not provide admitting privileges to physicians who provide abortions (Dkt. No. 57-2, Fine Rebuttal Decl., ¶¶ 13-14).

The contract would be available to many upon demand, thereby assuring the identity of the contracted physician. There is record evidence that physicians who provide abortion services, or otherwise associate themselves with this practice, subject themselves and their staff to protestors, harassment, potential violence, and professional isolation (Dkt. No. 30, Stulberg Decl., ¶¶ 13-17). Even if a willing physician could be found, there is record evidence that clinics or hospitals associated with the physician are not likely to be similarly inclined, and the provision requires disclosure of the hospital at which the contracted physician maintains admitting privileges and which can handle any emergencies. There is record evidence that at least one Arkansas hospital system, University of Arkansas for Medical Sciences ("UAMS"), did not permit its physicians to work with PPH (Dkt. No. 29, Ho Decl., ¶ 6).

PPH and Dr. Ho maintain that their protocols already guarantee continuity of care (Dkt. No. 29, Ho Decl., ¶¶ 11-19). As an initial matter, PPH and Dr. Ho include record evidence that only a small subset of medication abortion patients experience complications (Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 3). There is record evidence that, for most of the small number of patients who experience complications or need follow-up care, many can be, and are, treated at the clinic or

health center, not a hospital (Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 3). In those cases, a contracted physician could provide no benefit (Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 3).

PPH and Dr. Ho contend that, as with any outpatient medical procedure, when patients are sent home from the health center, they are sent home with specific instructions for home care, directions on how to contact PPH if they are experiencing any concerns or complications, and an appointment for follow-up with PPH clinicians (Dkt. No. 2, de Baca Decl., ¶¶ 7-8; Dkt. No. 57-1 de Baca Rebuttal Decl., ¶¶ 2-3). Contrary to defendants' assertions, there is no record evidence that those instructions direct patients just to go to the emergency department if they need care or indicate these patients are abandoned (Dkt. No. 29, Ho Decl., ¶¶ 11-19).

Rather, the record evidence demonstrates that PPH instructs patients that, if they are experiencing a complication or concern, they should call PPH and speak to nurses who are available 24 hours a day. There is record evidence that those nurses can access patient charts and can consult, as needed, with Dr. Ho, the PPH physician who provides medication abortions in Little Rock, or the PPH medical director, who is board certified in obstetrics and gynecology, licensed to practice medicine in Arkansas, Iowa, Nebraska, and Oklahoma, and a provider of both medication and surgical abortion (Dkt. No. 57-1, de Baca Rebuttal Decl., ¶¶ 3, 4, 6). As necessary, the physician can speak directly to the patients (Dkt. No. 57-1, de Baca rebuttal

Decl., ¶ 3). In most cases, according to the record evidence presented by PPH and Dr. Ho, patients can be reassured over the phone or, if need be, arrangements are made for the patient to return to the health center for care (Dkt. No. 2, de Baca Decl., ¶ 9). In what PPH and Dr. Ho describe as "a rare case of concerns that warrant more immediate treatment," PPH staff will refer a patient to a local emergency department, where she will obtain any necessary treatment from the hospital-based physicians (Dkt. No. 2, de Baca Decl., ¶ 9). In Arkansas, if a medication abortion patient is referred to a local emergency department, at least one of PPH's physicians is notified (Dkt. No. 29, Ho Decl., ¶¶ 16-18; Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 5). There is record evidence that the PPH staff always follows-up with the patient the next day, requests a release for hospital records from the patient, and arranges for the patient to receive any necessary follow-up care recommended by hospital physicians (Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 5). Further, there is record evidence that, if a hospital physician ever needed information about a patient who arrived at the hospital, that physician could also reach PPH nurses and PPH on-call physicians as necessary either during business hours or after hours, and PPH staff have access to patient health records, which are maintained electronically, even when they are out of the office (Dkt. No. 29, Ho Decl., ¶¶ 16-18; Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 6). PPH and Dr. Ho maintain that this practice complies with the standard of care provided by other providers of outpatient care (Dkt. No. 29, Ho Decl., ¶ 19; Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 5).

They also maintain that this practice complies with the American College of Obstetricians and Gynecologists ("ACOG") Practice Bulletin 143 which states:

> Women who undergo medical abortion may need to access emergency surgical intervention, and it is medically appropriate to provide referral to another health care provider. However, state or local laws may have additional requirements.
>
> Clinicians who wish to provide medical abortion services either should be trained in surgical abortion or should be able to refer to a clinician trained in surgical abortion.

http://www.acog.org/-/media/Practice-Bulletins/Committee-on-Practice-Bulletins-Gynecology/Public/pb143.pdf (the "ACOG Practice Bulletin 143").

Defendants dispute that PPH and Dr. Ho comply with the ACOG's recommendation but, in this Court's view, fail to cite with specificity what is missing from the protocol that the ACOG recommends. Contrary to defendants' assertions, this Court is not swayed on the record evidence before it currently that PPH and Dr. Ho's practice is inconsistent with the ACOG Practice Bulletin 143 (Dkt. No. 55, at 27-28). Consistent with the ACOG's recommendation, PPH and Dr. Ho can and do refer patients in need of care to other providers and specifically "a clinician trained in surgical abortion" (Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 7; Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 9). PPH and Dr. Ho maintain that, in a small number of cases and after a repeat dose of medication if the patient chooses, patients will need

a surgical procedure after their medication abortion has failed or is incomplete (Dkt. No. 29, Ho Decl., ¶ 17; Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 7). Record evidence establishes that the evidence-based regimen has a failure rate of less than 2%, far lower than the 8% failure rate of the FPL regimen (Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 37). PPH and Dr. Ho make arrangements for referral of patients to other providers, depending on where the patient lives, for the surgical abortion (Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 7). The only surgical abortion provider in Arkansas is Little Rock Family Planning Services (Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 7). PPH and Dr. Ho also maintain that surgical completion does not require urgent or hospital-based care, and PPH and Dr. Ho state that they do not just refer their patients to the emergency department, despite defendants' claim (Dkt. No. 29, Ho Decl. ¶¶ 11-19, Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 7). PPH and Dr. Ho contend that their protocols for treating a patient experiencing a rare complication after medication abortion are both consistent with the standard of care and provide continuity of care (Dkt. No. 29, Ho Decl., ¶¶ 11-19; Dkt. No. 2, Fine Decl., ¶¶ 32-39).

Given the record evidence presented at this stage, the Court is skeptical about any benefit conferred by this provision. Instead, this Court at this stage and on the record before it tends to agree with the district judge who considered a similar restriction in Wisconsin and determined that the contracted physician requirement was a "solution in search of a problem." *Van*

Hollen, 94 F.Supp.3d at 953 (citation and internal quotation marks omitted).

The limitations in the provision as identified by the Court seem not to be acknowledged or addressed by defendants' experts. Defendants' experts also do not specifically identify in relation to PPH and Dr. Ho's protocol what should be modified or how the contracted physician provision in the Act serves to effectuate that modification. These witnesses' testimony offered by affidavit seems disconnected with the contracted physician provision and evidences unfamiliarity with PPH and Dr. Ho's protocol. Regardless of which party bears the burden in relation to the state's interest, the lack of specificity makes defendants' experts' submissions less compelling at this stage.

Defendants' expert, Donna Harrison, M.D., the executive director of the American Association of Pro-Life Obstetricians and Gynecologists ("AAPLOG"), states that "[s]ince complications from medical abortions are common, not rare, it is reasonable and medically necessary that the abortion provider have a concrete plan to quickly and effectively handle the predictable complications that arise after drug-induced abortion." (Dkt. No. 55, Decl. of Donna Harrison, M.D., in Supp. of Dft.' Response in Opposition to Pit's Mot. For TRO and/or Prelim. Inj. ¶ 40 ("Harrison Decl.")). Defendants argue that PPH's management of patient emergencies is insufficient to ensure continuity of care. (*Id.*, ¶ 45). Given the record in this case, Dr. Harrison's view of what PPH and Dr. Ho offer patients appears inaccurate and incomplete.

Defendants also cite to an affidavit from Kevin Breniman, M.D., who is of the opinion that the Act "ensures the continuity of care" (Dkt. No. 55, Aff. of Kevin Breniman, M.D., in Supp. of Dft.' Response in Opposition to Plt's Mot. For TRO and/or Prelim. Inj. ¶ 7) ("Breniman Aff."). He states that admitting privileges "ensure that a physician is qualified and competent in his or her stated area of practice." (Breniman Aff., ¶ 4). Scott Archer, M.D., who is Chief of Emergency Medicine for Saline Memorial Hospital and another defense expert, implies that admitting privileges are based on qualifications and competence as a practitioner (Dkt. No. 55, Aff. of Scott Archer, M.D., in Supp. of Dft.' Response in Opposition to Plt's Mot. For TRO and/or Prelim. Inj. ¶ 3) ("Archer Aff."). There is record evidence, and other courts have determined, that although competence may be a factor in admitting privileges, other considerations are involved, many of which have nothing to do with competence, such as where a physician resides, whether the physician can meet a minimum number of admissions each year, or whether the physician has any faculty appointments (Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 13). *See*, *e.g.*, *Little Rock Cardiology Clinic PA v. Baptist Health*, 591 F.3d 591 (8th Cir. 2009) (involving an economic credentialing policy and alleging as a result antitrust claims against the nonprofit hospital operator, nonprofit mutual insurance company and its subsidiary, operator of health maintenance organization, and health maintenance organization operator's owner). *See also Van Hollen*, 94 F.Supp.3d at 953; *Williamson*, 120 F.Supp.3d. at 1316; *Strange*, 33 F.Supp.3d at 1338.

Defendants also submit an affidavit from Lee G. Wilbur, M.D., a Professor of Emergency Medicine and Vice Chairman for the Department of Emergency Medicine at University of Arkansas for Medical Sciences, who agrees with defendants' other experts that the Act's contracted physician requirement promotes continuity of care for medication abortion patients. Dr. Wilbur notes that "[s]maller facilities located in less populated, rural areas are less equipped to provide the highest level of care because of the availability of providers or specialists and the availability of equipment is limited." (Dkt. No. 55, Amend. Aff. Of Lee G. Wilbur, M.D., in Supp. of Dft.' Response in Opposition to Plt's Mot. For TRO and/or Prelim. Inj. ¶ 6) ("Wilbur Amend. Aff."). Dr. Wilbur also states that "[t]he contracted physician requirement establishes a line of communication between the physician and a contracted physician with greater expertise." (*Id.*, ¶ 10). Dr. Wilbur contends that "[n]o other physician specialty, other than obstetrics/gynecology, receives specific training in the procedure, anticipated effects, or complication related to medication-induced abortion . . . Identifying an expert in medication-induced abortion available for consultation will improve the care that [Dr. Wilbur] can provide to these patients." (*Id.*, ¶ 11). Dr. Wilbur also contends that, "[w]ithout this contracted physician requirement, [Dr. Wilbur] is left to arrange follow up with a local obstetrician/gynecologist that is unfamiliar with the patient, unfamiliar with the medication regimen she received, and unfamiliar with the staff and capabilities of the facility that provided the original procedure." (*Id.*, ¶ 16).

It remains unclear to the Court why Dr. Ho and PPH's physicians would not be able to serve this function of a line of communication, given there is record evidence that they do. Any suggestion that the contracted physician would provide a better line of communication under these circumstances is not supported by record evidence at this point. According to the materials presented to the Court at this stage, the contracted physician likely will not have experience in providing abortions, will not have had prior contact with the patient, and will not have access to her records. Dr. Ho is experienced in providing medication abortions and her supervisor at PPH, who is board certified in obstetrics and gynecology and who was a faculty member at a medical school before becoming the Medical Director of PPH, is an experienced provider of both surgical and medication abortions (Dkt. No. 29, Ho Decl., ¶ 4; Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 4).

Further, based on the record before the Court at this stage of the proceeding, the Court concludes, at least preliminarily, that emergency room physicians are well qualified to evaluate and treat most complications that can arise after a medication abortion and, when necessary, have immediate access to consultation with on-call specialists (Dkt. No. 2, Fine Decl., ¶ 34; Dkt. No. 29, Ho Decl., ¶¶ 11-19). The types of issues that arise in rare emergent care situations, according to record evidence, are identical to those suffered by women experiencing miscarriage, who receive treatments in hospitals every day through emergency

physicians and on-call specialists, if necessary (Dkt. No. 2, Fine Decl., ¶ 34). Dr. Wilbur, an emergency physician and expert for defendants, appears to acknowledge this (Dkt. No. 55, Wilbur Amend. Aff., ¶¶ 12, 14). Nothing in Dr. Wilbur's affidavit explains why the contracted physician requirement is better than the protocol PPH and Dr. Ho have in place currently (Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 26). Again, regardless of which party bears the burden in relation to the state's interest, the lack of specificity makes defendants' experts' submissions less compelling at this stage.

Defendants argue that abortion patients are unwilling to acknowledge they have had an abortion. This statement is repeated by defendants without record support. Even if the Court assumes it to be true at this stage of the proceeding, it is unclear what the contracted physician requirement would do to change this circumstance. Whether the contracted physician requirement is implemented or not, if the patient does not acknowledge she has had a medication abortion and provide information to the treating emergency room physician, it appears to matter little if there is a contracted physician or a PPH physician on stand-by to consult. Further, there is evidence in the record that this should not impact the ability of the hospital physician to care for these patients, given the similarity of miscarriage management to post-medication-abortion follow-up care (Dkt. No. 29, Ho Decl., ¶ 13; Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 25). Dr. Fine and Dr. Wilbur agree that patients are usually frank about their

medical history and that hospital physicians are trained to elicit information from reluctant patients (Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 25, Dkt. No. 55, Wilbur Amend. Aff., ¶ 9).

The Court rejects defendants' alternative argument that the contracted physician requirement furthers the "integrity, ethics and reputation of the medical provider" who performs the abortion (Dkt. No. 55, at 5). On this record, there is no evidence the Act furthers this interest any more than the asserted interest of women's health.

At this point, on the record before it, the Court reaffirms that PPH's protocol casts doubt as to any benefit gained from a contracted physician requirement (Dkt. No. 2, de Baca Decl., ¶¶ 8-11). A careful review and balancing of the existing record evidence suggests that the state's overall interest in the regulation of medication abortions through the contracted physician requirement is low and not compelling.

Regardless of whether this Court examines if the Act furthers the legislature's stated purpose, and even if this Court were to accept that this portion of the Act meets rational basis review as defendants advocate, the Court is persuaded, for now, that PPH and Dr. Ho have carried their burden of demonstrating at this stage of the litigation that they are likely to prevail on the merits and establish that the Act's contracted physician requirement creates an undue burden in that this provision has the effect of placing a substantial obstacle in the path of a woman seeking an abortion of

a nonviable fetus. *See Williamson*, 120 F.Supp.3d. at 1315.

b. FPL Mandate

PPH and Dr. Ho also challenge the FPL mandate provision in the Act. Section 1504(a) of the Act requires medication abortion providers to "satisf[y] the protocol authorized by the United States Food and Drug Administration, as outlined in the final printed labeling for the [abortion-inducing] drug or drug regimen" when providing or prescribing abortion-inducing drugs. Ark. Code Ann. § 20-16-1504(a). According to PPH and Dr. Ho, because mifepristone is the only medication that has received FDA approval for marketing as an abortion-inducing drug, it is the only medication with an FPL describing an abortion regimen (Dkt. No. 2, Fine Decl., ¶ 18). The "final printed labeling for Mifeprex" is defined to "include[ ] the United States Food and Drug Administration-approved dosage and administration instructions for both mifepristone and misoprostol." Ark. Code Ann. § 20-16-1504(a)(2). According to PPH and Dr. Ho, this means that, under the Act, abortion providers must follow the FPL regimen when providing medication abortion. Violations of the Act can result in severe penalties for those, other than the pregnant woman upon whom the drug-induced abortion is performed, who intentionally, knowingly, or recklessly violate the Act, including civil liability and criminal prosecution. Ark. Code Ann. §§ 20-16-1506, 1507.

PPH and Dr. Ho have submitted affidavits from experts discussing the evidence-based regimen and studies evaluating that regimen. Defendants have submitted affidavits from several experts, as well.

As an initial matter, PPH does not follow the FPL currently. The common current practice, both in Arkansas and elsewhere in the United States, is for a patient to take 200 mg of mifepristone at a healthcare facility and approximately 24 to 48 hours later, at a comfortable location of her choosing, to take 800 micrograms of misoprostol. This regimen is offered to women through at least 63 days, or 9 weeks, after the first day of the woman's LMP. This is referred to as the "evidence-based regimen" because it is based on a large body of evidence regarding safety and effectiveness (Dkt. No. 2, Fine Decl., ¶¶ 8, 20).

Defendants first submit an affidavit from Dr. Harrison. PPH and Dr. Ho urge this Court to discount Dr. Harrison's opinions, claiming among other things that she has taken inconsistent positions on these issues that belie her bias and that "she is an anti-abortion activist who has been discredited by other courts and has not practiced medicine since 2000." (Dkt. No. 57, at 17 n.9; at 26 n. 18 (contending that, despite now claiming the FPL regimen is superior, Dr. Harrison has petitioned the FDA to withdraw approval of the medication entirely in the past, arguing that the FPL regime posed a risk to women's health); at 27 at n.19 ("when Dr. Harrison was advocating for the FDA to remove mifepristone from the market, she asserted the very opposite of what she asserts here – namely, that

costridium sordellii infections following medication abortion were probably caused by *mifepristone*, and were *unrelated* to alternative routes of administration of misoprostol")). PPH and Dr. Ho cite this Court to other courts that have been critical of testimony offered by Dr. Harrison.

Defendants also submit affidavits from Dr. Archer, who addresses both the FPL mandate and the contracted physician requirement; Dr. Breniman, who addresses both the FPL mandate and the contracted physician requirement; and Dr. Wilbur, who addresses the contracted physician requirement only as described above.

Dr. Archer takes the position: "It makes no rational medical sense to use the FPL mandate with these women because there is no medical advantage up to 49 days LMP for the off-label usage. The ACOG Practice Bulletin 143 states that it is only 'after 49 days of gestation (that the) evidence-based regimens have advantages over the FDA-approved regimens and are medically preferable." (Dkt. No. 55, Archer Aff., ¶ 8). He fails to acknowledge or address that the ACOG Practice Bulletin Number 143 states that, "[b]ased on efficacy and the adverse effect profile, evidence-based protocols for medical abortion are superior to the FDA-approved regimen." Although Dr. Archer states that "it is well reported that past 49 days LMP, complications vastly increase," he cites no supporting authority for this statement (Dkt. No. 55, Archer Aff., ¶ 9). He also cites Arkansas Department of Health vital statistics, but as PPH and Dr. Ho point out and as this Court

explores *infra*, defendants generally misinterpret these statistics in their submissions by not adding together all statistics provided and by inaccurately assessing days LMP based on how the information is required under Arkansas law to be reported (Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 57).

Dr. Breniman takes the position that "[w]hile drugs are used off label, it does not make the final printed label of drugs below the standard of care." (Dkt. No. 55, Breniman Aff., ¶ 11). He contends that the ACOG Practice Bulletin Number 143 "notes that the off label use of the medications for medical abortions have 'similar efficacy and lower costs compared with these that use mifepristone at 600 mg'" but acknowledges that the "similar efficacy continues to the 49th day." (Dkt. No. 55, Breniman Aff., ¶ 11). He does not address what occurs past 49 days LMP. He also fails to acknowledge or address that the ACOG Practice Bulletin Number 143 states that, "[b]ased on efficacy and the adverse effect profile, evidence-based protocols for medical abortion are superior to the FDA-approved regimen." In addition, Dr. Breniman takes the position that "[t]he final printed label regimen provides a standard protocol available and accessible in emergent care or to on-call OB-GYNs providers, which is critical when the patient has no contracted physician responsible for either the care or the communication of critical information." (Dkt. No. 55, Breniman Aff., ¶ 12).

The Court concludes at this stage of the proceeding that it has some medical evidence supporting both

sides, with each side of this dispute urging the Court to give more weight and credence to its position. If the Court had only this evidence upon which to base its decision, at this point, the record tilts in favor of PPH and Dr. Ho, as the affidavits they submit are detailed; evidence-based in that they cite experience, supporting studies, and what appears to be research; and tied to the language of the provisions. Neither Dr. Archer, Dr. Beniman, nor Dr. Wilbur cite studies or statistics in support of their positions, only Dr. Harrison does. Dr. Fine's rebuttal affidavit explains why the studies Dr. Harrison cites, for a variety of reasons, do not support her position (Dkt. No. 57-2, Fine Rebuttal Decl., ¶¶ 43-48, 56-57). For example, she claims that misoprostol "has most recently been implicated in the massive fatal infections seen after some medication abortions" (Dkt. No. 55, Harrison Aff., ¶ 16). However, there is record evidence that calls this assertion into doubt. Dr. Fine explains that, "[o]f the over two million patients who have had a medication abortion, eight contracted a fatal infection" (Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 39). He contends there is no established causal link between mifepristone or misoprostol and these infections, and he maintains that, even if there was, these figures indicate a very low risk (Dkt. No. 57-2, Fine Rebuttal Decl., ¶¶ 39-43).

As another example, Dr. Harrison claims that women should have to take the misoprostol at the clinic so that they can be observed during the expulsion, but this requirement of observing the patient in the clinic during the expulsion is not in the FPL

regimen (Dkt. No. 57-2, Fine Rebuttal Decl., ¶ 52). Further, there is record evidence that the expulsion under the FPL regimen takes far longer to complete than under the evidence-based regimen and that clinical observation for that extended period of time may not be feasible for patients (Dkt. No. 57-2, Fine Rebuttal Decl., ¶¶ 52-53). Overall, at this stage of the proceeding, the affidavits submitted by defendants are nonspecific, cite very little evidence in the form of supporting studies or research, and do not acknowledge the limitations in the language and requirements of the provision.

This is not all of the record evidence upon which the Court must base its decision at this stage of the proceeding, however. At this point, the Court may consider, and is swayed by, the record evidence presented that the evidence-based regimen that PPH and Dr. Ho use has been declared by the American College of Obstetricians and Gynecologists ("ACOG") and the American Medical Association to be superior and safer, and to cause fewer complications, as compared to the FPL regimen required by the Act (Dkt. No. 2, Fine Decl. ¶ 25). Based on the record before the Court at this stage of the proceeding, the Court understands that the ACOG, the American Medical Association, the World Health Organization, and the Royal College of Obstetricians and Gynecologists have all endorsed the use of an alternative regimen through 63 days LMP (Dkt. No. 2, Fine Decl., ¶ 25). The ACOG has declared that "[b]ased on the efficacy and the adverse effect profile, evidence-based protocols for medication abortion

are superior to the FDA-approved regimen." Am. Coll. of Obstetricians & Gynecologists, Practice Bulletin No. 143: Medical Management of First Trimester Abortion 2 (Mar. 2014) (*See also* Dkt. No. 2, Fine Decl., ¶ 25). At this stage, these authorities seem to support uniformly the conclusion that properly performed evidenced-based medication abortions are safe and effective through 63 days LMP.

Defendants have not attempted to refute or undercut the representation regarding the ACOG and the AMA's positions on the evidence-based regimen. Defendants offer no justification for why, in legislation, the State of Arkansas would reject the evidence-based protocols for medication abortion in the light of this evidence regarding the ACOG and the AMA. Further, in determining whether regulations actually further women's health, the Supreme Court has repeatedly looked at the generally accepted standards for medicine set by the nation's major health organizations. *See*, *e.g.*, *Simopoulos v. Virginia*, 462 U.S. 506, 517 (1983) (considering American College of Obstetricians and Gynecologists and other standards).

This Court is also mindful of a point which no party has addressed. Under Arkansas law, medical negligence or malpractice actions arise when a provider renders care that falls below the acceptable standard of care, which in most litigated cases must be established by expert testimony provided by a medical care provider of the degree of skill and learning ordinarily possessed and used by members of the profession of the medical care provider in good standing,

engaged in the same type of practice in the locality in which he or she practices or in a similar locality. *See* Ark. Code Ann. § 16-114-206. *But see Broussard v. St. Edward Mercy Health Sys., Inc.*, 2012 Ark. 14 (determining that the portion of Ark. Code Ann. § 16-114-206 that required expert testimony in malpractice actions to be given by medical care providers of the same specialty as the defendant violated the separation of powers and was unconstitutional). Based on the record before the Court at this stage of the proceeding, the Court is persuaded that the standard of care under Arkansas law likely equates to what PPH and Dr. Ho, as well as abortion providers around the country, use today as the evidence-based method for medication abortion, not the FPL regimen (Dkt. No. 2, Fine Decl., ¶ 20). This situation exemplifies why it is difficult to reconcile the state's asserted interest with this provision of the Act. Interests the state has every reason to protect, such as the ability of physicians to base treatment decisions on the best available medical evidence; the development and implementation of safer, more effective, or less expensive medical protocols; and the discovery of new uses for drugs initially marketed for some other purpose, seem at odds with this provision. *See Cline v. Oklahoma Coalition for Reproductive Justice*, 133 S.Ct. 2887, 2887 (2013) (affirming the Oklahoma County district judge's opinion that a state statute restricting "abortion inducing drugs, medicines, or other substances in the manner and to the regimen set forth in the medication FPL when used for abortion is so completely at odds with the standard that governs the practice of medicine that it can serve no purpose other

than to prevent women from obtaining abortions and to punish and discriminate against those who do").

Defendants contend that the way in which these drugs were approved by the FDA might dictate this statute's requirements. The Ninth Circuit Court of Appeals in *Humble*, 753 F.3d at 907, appears to have addressed this, or a similar argument, and rejected it:

> When the FDA approved mifepristone for use in abortions, it imposed restrictions on mifepristone's marketing and distribution – but not on its use – under the FDA's "Subpart H" regulations. *See* 21 C.F.R. § 314.520. These restrictions require the manufacturer to distribute mifepristone only to doctors who sign an agreement "stating that he or she possesses the necessary qualifications and will adhere to the other requirements." One Subpart H restriction requires doctors to agree to provide each patient "a copy of the Medication Guide and Patient Agreement" and obtain the patient's signature on the Patient Agreement. In the Patient Agreement, the patient attests that she "understand[s]" the steps involved in the on-label regimen. The patient agrees to "follow my provider's advice about when to take each drug." The Subpart H restrictions, Medication Guide, and Patient Agreement do not require doctors to administer mifepristone according to the on-label regimen. *Cline v. Okla. Coal. for Reprod. Justice*, 313 P.3d 253, 261 n. 17 (Okla. 2013) (per curiam).

See also Planned Parenthood Cincinnati Region v. Taft, 444 F.3d 502, 505 (6th Cir. 2006) (discussing FDA requirements and off-label use). The Subpart H approval, upon which defendants focus, does not change this Court's analysis, as it changes nothing about how doctors may use the drug (Dkt. No. 57-2, Fine Rebuttal Decl., ¶¶ 27-28, 33). *See Humble*, 753 F.3d at 907.

There is no record evidence before the Court that the FDA has ever taken steps to restrict the evidence-based regimens for medication abortion. Instead, there is record evidence that the FDA has expressly recognized that the evidence-based use of medications is an appropriate part of medical practice (Dkt. No. 57-2, Fine Rebuttal Decl., ¶¶ 27-34). The FDA confirms that Subpart H approval does not preclude doctors from prescribing a drug off-label. 57 Fed. Reg. 58942 (Dec. 11, 1992). The Supreme Court itself has recognized that off-label use "is an accepted and necessary corollary of the FDA's mission." *Humble*, 753 F.3d at 915 (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001)).

Based on the state of the record before the Court at this stage of the proceeding, the Court for now is persuaded that, even under a deferential standard, some of the legislative findings cited in support of this portion of the Act are inaccurate, incomplete, irrelevant, or outdated (Dkt. No. 2, Fine Decl., ¶¶ 40-49). "Although we review [legislative] factfinding under a deferential standard, . . . [t]he Court retains an independent constitutional duty to review factual findings

when constitutional rights are at stake." *Gonzales*, 550 U.S. at 165.

Tracking certain of these legislative findings, defendants contend that the evidence-based regimens are purportedly responsible for fatal infections in eight women out of the millions of women who have had a medication abortion in the United States. Defendants cite no record evidence for this proposition, aside from an unsupported allegation in Dr. Harrison's affidavit. PPH and Dr. Ho point out that this assertion by Dr. Harrison is contrary to her prior positions on this issue (Dkt. No. 57, at 27 n.19). There is no evidence that any of those eight women used the current evidence-based regimen, and PPH and Dr. Ho have submitted record evidence that in a study of over 700,000 abortions using the current evidence-based regimen, not one death occurred (Dkt. No. 57-2, Fine Rebuttal Decl. ¶ 43); *Humble*, 753 F.3d at 908 (nothing that FDA "found no causal connection between the infections and the use of mifepristone or misoprosol" and that the 2013 study "found no infection-related deaths out of 711,556 medication abortions performed under the current evidence-based regimen").

Defendants also contend that women should be required to take the misoprostol in the health center, instead of at home as the current evidence-based protocol permits. Defendants have failed to put into the record any competent medical evidence supporting this. PPH and Dr. Ho submit record evidence that the ACOG has made its highest (Level A) recommendation, which is made on "good and consistent scientific

evidence," that women "can safely and effectively self-administer misoprostol at home as part of a medical abortion regimen." (Dkt. No. 57-2, Fine Rebuttal Decl. ¶ 51). They argue that requiring women to return to the clinic to take misoprostol is more likely to lead to more, rather than fewer, failures to adhere to the regimen prescribed because of the challenges women face in getting to the clinic (Dkt. No. 57-2, Fine Rebuttal Decl. ¶ 50). Dr. Harrison's argument that women should have to take the misoprostol at the clinic so they can be observed during the expulsion process is not a requirement of the FPL; the FPL regimen actually increases the duration of the expulsion (Dkt. No. 57-2, Fine Rebuttal Decl. ¶ 52, n.43). It is possible that requiring women to begin the expulsion process at the clinic would make it more likely that women would experience the bleeding and cramping of that process when they are on their way home from the clinic, rather than in the comfort of their homes (Dkt. No. 57-2, Fine Rebuttal Decl. ¶ 25). *Humble*, 753 F.3d at 908-09 (noting that the "evidence-based regimen allows women to take misoprostol in their homes, eliminating the risk that they will pass their pregnancies, a process involving heavy bleeding and cramping, during their trip home from the second clinic visit").

Defendants argue, with no record evidence to support the argument, that the risks of medication abortion increase with advancing gestational age and that this fact justifies restricting women to the FPL regimen. Again, the ACOG and other medical organizations have endorsed the use of medication abortion at

the gestational ages that PPH and Dr. Ho provide abortions (Dkt. No. 2, Fine Decl. ¶ 25). The evidence-based regimen is more effective through 63 days LMP than the FPL regimen is to 49 days LMP, which reduces the need for a subsequent surgical procedure to complete the abortion (Dkt. No. 2, Fine Decl. ¶ 24; Dkt. No. 57-2, Fine Rebuttal Decl. ¶¶ 36-37). PPH and Dr. Ho argue that, although surgical abortion is a safe procedure, any medical procedure comes with risks, and the evidence-based regimen used by PPH and Dr. Ho reduces – and they claim nearly eliminates – the need for that additional procedure (Dkt. No. 57-2, Fine Rebuttal Decl. ¶ 37).

Likewise, any argument that the makers of the drugs involved in medication abortion may seek FDA authorization to label and market their drugs for use in medication abortions through the evidence-based regimen is highly improbable (Dkt. No. 2, Fine Decl., ¶ 22). Regardless, the Court's decision must be based on the facts that exist today.

At this point, on the record before it, the Court reaffirms that the record evidence casts doubt as to any benefit gained from the FPL mandate. A careful review and balancing of the existing record evidence suggests that the state's overall interest in the regulation of medication abortions through the FPL mandate, if such an interests exists at all, is low and not compelling. Regardless of whether this Court examines if the Act furthers the legislature's stated purpose, and even if this Court were to accept defendants' argument that this portion of the Act meets rational basis review,

based on the state of the record before the Court at this stage of the proceeding, the Court is persuaded, for now, that PPH and Dr. Ho have carried their burden of demonstrating at this stage of the litigation that they are likely to prevail on the merits and to establish that the Act's FPL mandate creates an undue burden in that this provision has the effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus.

c. Threshold Issues For Undue Burden Analysis

Regardless of whether this Court takes into account defendants' asserted state interests in assessing the burden, this Court concludes that the burden imposed by each of these provisions separately, or when analyzed together, would be undue and, therefore, unconstitutional.

1. Resolving Disputes Over Legal Standards

As an initial matter, the parties disagree on the legal standard the Court should apply when assessing the burden imposed by these provisions. As explained *supra*, the parties dispute whether the Court should balance the asserted state interest against the purported effects when assessing the burden. The Court concludes that it should engage in balancing to assess whether an undue burden is imposed. Even if the

Court does not engage in this balancing, however, the Court concludes that an undue burden is imposed.

Further, although the parties agree that Supreme Court precedent requires this Court to assess the impact of the Act on those women "for whom it is an actual rather than an irrelevant restriction," *Casey*, 505 U.S. at 895, they dispute what that means here. Defendants argue that this Court should assess the Act's impact on all women of child-bearing age in Arkansas (Dkt. No. 55, at 41, 56-57; Solanky Aff., at 10). PPH and Dr. Ho argue that this Court should assess the Act's impact on women seeking a medication abortion in Arkansas (Dkt. No. 57, at 33).

This Court adopts the position of PPH and Dr. Ho. This Court's analysis begins with the women who chose medication abortion because those are the women upon whom the Act operates. *Casey*, 505 U.S. at 894. In *Casey*, it was estimated that the law that required spousal notification would act as a restriction for only one percent of the women seeking abortion. *Id.* Nonetheless, this was sufficient to support a finding of facial invalidity as to the spousal notification provision. *Id.* at 898. When reviewing challenges similar to those made here, the Ninth Circuit Court of Appeals in *Humble* adopted this same approach. *Humble*, 753 F.3d at 914 ("[W]e address the burden on women who, in the absence of the Arizona law, would receive medication abortions under the evidence-based regimen.").

Defendants argue in part that this is the improper approach because, defendants contend, women do not

have a right to select a particular method of abortion. For this argument, defendants rely on language from *Gonzales* in which the Supreme Court examined a statute banning partial birth abortions during the latter stages of pregnancy. The Supreme Court in *Gonzales* stated as follows: "[T]he State, from the inception of the pregnancy, maintains its own regulatory interest in protecting the life of the fetus that may become a child, cannot be set at naught by interpreting *Casey's* requirement of a health exception so it becomes tantamount to allowing a doctor to choose the abortion method he or she might prefer. Where it has a rational basis to act, and it does not impose an undue burden, the State may use its regulatory power to bar certain procedures and substitute others, all in furtherance of its legitimate interests in regulating the medical profession in order to promote respect for life, including life of the unborn." *Gonzales*, 550 U.S. at 150. As a result, defendants contend that all women of child-bearing age should be considered as the impacted population by this Court when examining whether the Act imposes an undue burden.

This Court determines that this portion of *Gonzales* does not stretch as far as defendants would like here. Part of the core holding in *Casey* was the affirmation that before viability a state may neither prohibit nor impose a substantial obstacle on "the woman's effective right to elect the procedure." *Casey*, 505 U.S. at 846. Based on *Casey*, in this Court's view, the proper measure is to examine the Act's impact on all women who obtained medication abortions. To assess the

burden imposed by the Act, it is necessary to understand the available data regarding abortion in Arkansas and the realities of how abortion is provided in Arkansas.

2. Data Regarding Abortion In Arkansas

There are statistics in the record now before the Court regarding abortion in Arkansas, but it is unclear whether the parties agree on how these statistics should be interpreted. At the hearing, counsel for defendants represented to this Court that although defendants submitted the affidavit of Priya Kakkar, a Health Program Specialist with the Arkansas Department of Health, the information she summarized was provided by the abortion providers. As a result, this Court will consider arguments made by PPH and Dr. Ho as to how the statistics and information upon which Ms. Kakkar relies should be interpreted.

As an initial matter, Ms. Kakkar confirms that there were 4,235 total abortions in the State of Arkansas in 2014 (Dkt. No. 55-8, Kakkar Aff., ¶ 6). Of those, 3,307 abortions were obtained by in-state residents (Dkt. No. 55-8, Kakkar Aff., ¶ 6). Of the total abortions, 608 were medication abortions; the remaining abortions were surgical (Dkt. No. 55-8, Kakkar Aff., ¶ 6). For the reasons explained, this Court will focus on medication abortions.

According to PPH and Dr. Ho, Ms. Kakkar presents in Exhibit C to her affidavit two tables

containing data regarding the gestational ages at which medication abortions were performed in 2014 that must be added together to reach the totals for the year. This does not appear to be a point defendants contest. (*See* Dkt. No. 55-8, Kakkar Aff., at 2) ("In 2014, the Center for Health Statistics split the induced abortion data into two reports: gestation and post-probable fertilization. The reports must be read collectively to obtain totals for the year.") Further, PPH and Dr. Ho maintain that to add the figures presented in the tables, the data in the table "Induced Abortions by Probable Post-Fertilization (PPF) and Type of Procedure Arkansas Occurrences – 2014" must be converted to reflect the gestation age of pregnancies according to the first day of a woman's last menstrual period and that, in order to do this, two weeks must be added to the probable post fertilization age (Dkt. No. 57-2, Fine Rebuttal Decl. ¶ 57) (Dkt. No. 57, at 32, n.22). It is unclear whether defendants agree with this proposition, but the Court has considered the explanation Dr. Fine provides regarding why this is so and finds that explanation compelling, at least at this stage of the proceeding (Dkt. No. 57-2, Fine Rebuttal Decl. ¶ 57).

According to PPH and Dr. Ho, "[c]ombined, these tables show that 402 medication abortions in 2014 were performed in the 7th week of pregnancy or later, in other words, between 49 and 63 days LMP. This is approximately 66% of the medication abortions performed statewide in 2014." (Dkt. No. 57, at 32-33). Of the 303 medication abortions provided at PPH's Fayetteville health center in 2014, 247 of those

abortions, or approximately 81.5%, were provided between 50 and 63 days LMP and could not be provided under the FPL regimen (de Baca Rebuttal Decl., ¶ 9). PPH and Dr. Ho represent that these figures are approximate because medication abortions performed at 49 days LMP are counted as part of the 7th week of pregnancy in these tables and by PPH (Dkt. No. 57, at 33 nn.23, 24).

3. Facilities And Logistics Of Abortion Providers

Arkansas women are currently able to access abortion at three health centers in the state: two in Little Rock and one in Fayetteville (Dkt. No. 2, de Baca Decl., ¶ 3). PPH or predecessor organizations have provided a range of reproductive health services in Arkansas for over 30 years (Dkt. No. 2, de Baca Decl. ¶ 3). PPH operates two of the three abortion-providing health centers in the State of Arkansas, one located in Little Rock, Arkansas, and the other in Fayetteville, Arkansas (Dkt. No. 2, de Baca Decl. ¶ 3). PPH employs two physicians who provide care in Arkansas, one of whom is Dr. Ho. Dr. Ho is a physician licensed by the state of Arkansas who, along with another physician, provides medication abortion services at PPH's health centers (Dkt. No. 2, de Baca Decl. ¶ 4). PPH currently does not provide surgical abortion in Arkansas (Dkt. No. 2, Decl. of Suzanna de Baca in Supp. of Pls.' Mot. For TRO and/or Prelim. Inj. ¶ 4).

As long as patients are no more than nine weeks pregnant, they currently have the option of choosing between a surgical procedure in Little Rock at a center operated by an entity other than PPH and a procedure using medications alone offered in both Little Rock and Fayetteville (Dkt. No. 3, at 2). If PPH's Fayetteville health center stops providing abortions all together due to an inability to meet the contracted physician requirement, women in the area will have to make a 380-mile round trip to Little Rock to access surgical abortion services (Dkt. No. 2, Fine Decl., ¶ 52; de Baca Decl., ¶ 18).

Because of a different Arkansas abortion restriction that requires all women seeking abortions – medication or surgical – to receive certain state-mandated information in person at least 48 hours prior to the abortion, all women seeking abortions will have to make that trip more than once. *See* Ark. Code Ann. § 20-16-1703. Arkansas law provides no exceptions to this requirement based on distance traveled for the procedure. *Cf. Cole*, 790 F.3d at 594 (noting that Texas's requirement that a woman wait 24 hours after receiving state-mandated information is shortened to a two-hour wait when a woman certifies that she lives 100 miles or more from the nearest abortion provider); Tex Health & Safety Code Ann. § 171.012(a)(4). It is unclear to this Court whether, when providing an average for how many miles Arkansas women would have to travel to obtain an abortion, defendants' expert Tumulesh K.S. Solanky considered the necessity of repeat trips to the nearest clinic (Solanky Aff., ¶¶ 9, 12). For a

surgical abortion in Arkansas, there are two round trips required, one for informed consent and one for the procedure. For a medication abortion at 49 days LMP or fewer, there are four round trips required, one for informed consent, two for the procedure, and one for confirmation and follow-up care. This likely will alter the percentages Mr. Solanky reports, if he has not accounted for the repeat trips. It also is unclear to the Court to what group Mr. Solanky refers when he uses the phrase "Arkansas women" – all Arkansas women, all Arkansas women of child bearing age, or those women who have had a medication abortion. The Court acknowledges that, at various points, Mr. Solanky more precisely defines the group of women he studied and about whom he is relaying information. He does not clarify whether he considers the necessity of repeat trips.

If the FPL mandate portion of the Act goes into effect, women with gestational ages of 49 days LMP or fewer for whom medication abortion remains an option would have to undergo the FPL procedure. Further, these women would be required to make an additional trip to the clinic for completion of the FPL regimen because unlike the evidence-based regimen it requires an additional clinic visit, increasing the expenses and other burdens associated with medication abortion (Fine Rebuttal Decl., ¶ 38). There is an additional increased cost with the FPL regimen aside from an additional trip to the clinic, as the evidence-based regimen requires only 200 mg of mifepristone while the FPL regimen requires 600 mg; there is record evidence that

mifepristone is an expensive medicine (Fine Rebuttal Decl., ¶ 38).

On the record before the Court, the Court determines that, if the FPL mandate portion of the Act only goes into effect, women with gestational ages between 50 and 63 days LMP would not be able to access medication abortions, causing all of those women to have to travel to Little Rock to obtain a surgical abortion (Dkt. No. 2, Fine Decl., ¶ 25). For those women with gestational ages between 50 and 63 days LMP who would have to travel to Little Rock to obtain a surgical abortion, they would face the same increased travel distances and consequent burdens and a riskier surgical procedure. PPH and Dr. Ho argue that, although complications from abortion are rare, risks increase as the pregnancy advances (Fine Decl. ¶ 54).

In regard to traveling to the clinic or clinics to receive certain state-mandated information, to obtain the procedure, and to make the additional clinic visit required if the FPL mandate takes effect for women with gestation ages of 49 days LMP or fewer, each time these women travel, they will have to arrange the necessary funds, transportation, child care, and time off work required to travel (*See* Dkt. No. 2, Fine Decl., ¶¶ 53, 56). Some women forced to make the trips will be unable to do so because of these obstacles (Dkt. No. 2, Fine Decl., ¶ 55). There is evidence in the record before the Court that increased travel distances and costs – both monetary and otherwise – for those who must travel to a clinic multiple times to obtain an abortion may cause women who otherwise would have

obtained an abortion not to obtain one at all (Henshaw Decl. ¶ 11 (citing studies that show an increased travel burden of 100 miles or more will cause 20-25% of women who would have otherwise obtained an abortion not to obtain one and that longer distances will cause an even higher proportion of women not to obtain an abortion)). Others will be delayed by the increased travel distances and increases in costs, forcing these women into later abortions that are both riskier and more expensive, if they can obtain them at all (*Id.*, ¶¶ 53-54). There is evidence in the record supporting this (Henshaw Decl. ¶ 20; Fine Decl. ¶ 54). Inability to travel to the sole remaining clinic in the state will lead some women to take desperate measures, such as attempting to self-abort or seeking care from unsafe providers, which would further put their health at risk (*Id.*, ¶ 55).

d. Undue Burden Analysis As To Contracted Physician Requirement

The burden on abortion imposed by the contracted physician requirement under the Act as applied to PPH and Dr. Ho, at least based on the record before the Court at this stage of the proceeding, appears greater than in the cases in which the Fourth and Fifth Circuits have upheld similar admitting privileges requirements because the plaintiffs in those cases failed to satisfy the courts that the challenged statutes would lead to a substantial decline in the availability of abortion. In both *Abbott I*, 734 F.3d 406, and *Greenville Women's Clinic v. Bryant*, 222 F.3d 157, 162, 170 (4th

Cir. 2000), the courts decided that the evidence compelled the conclusion that the clinics forced to close due to the regulation performed only a small proportion of each state's abortions. That is not the case here when the Court considers medication abortions.

Further, the burden imposed here appears, at least on this record, to be greater than the burden at issue in *Casey* regarding the informed consent provision. Accounting for Arkansas's informed consent requirement and the travel distance to Little Rock required for women to obtain surgical abortions, the distances traveled and associated costs – both monetary and otherwise – appear greater here. A woman from Fayetteville who could no longer obtain a medication abortion but would instead be required to travel to Little Rock for a surgical abortion would have to make the 380-mile round trip twice, resulting in over approximately ten hours of travel time alone. *See Abbott II*, 748 F.3d at 598 ("the district court in *Casey* made a finding that, under the Pennsylvania law, women in 62 of Pennsylvania's 67 counties were required to 'travel for at least one hour and sometimes longer than three hours, to obtain an abortion from the nearest provider.' . . . Upholding the law, the Supreme Court recognized that the 24-hour waiting period would require some women to make two trips over these distances."). Further, the specific issue in *Casey* that had the Court conducting this analysis was informed consent, not the threat of eliminating a specific method of abortion, otherwise medically recognized as safe and effective, or forcing clinics to stop providing abortion services all together

due to the regulation. At this stage, the Court views these distinctions as meaningful.

This Court finds on the record before it at this stage of the proceeding that, despite trying to find a contracted physician, PPH and Dr. Ho cannot comply with the contracted physician requirement (Dkt. No. 2, de Baca Decl., ¶ 12). *See Schimel*, 806 F.3d at 917 (noting the "vilification, threats, and sometimes violence directed against abortion clinics and their personnel in states . . . in which there is intense opposition to abortion."); *Williamson*, 120 F.Supp.3d at, 1318-19 (discussing possible violence, harassment, and stigma abortion providers face); *Strange*, 33 F.Supp.3d at 1349-53 (describing the anti-abortion harassment and stigma that prevents physicians from associating with abortion providers, including protestors who "threaten economic destruction for any doctor who enable[s] the provision of abortion").

If the contracted physician requirement of the Act goes into effect, PPH and Dr. Ho represent that only one health center in the state – located in Little Rock – will provide abortions (Dkt. No. 2, de Baca Decl., ¶ 13). They also represent that these abortions will only be surgical. There is record evidence that if the Act takes effect, all three Arkansas health centers will no longer offer medication abortion (Dkt. No. 2, Fine Decl., ¶ 52). Only one provider statewide will be available and will offer only surgical abortion (*Id.*). The inability to provide medication abortion at PPH's centers likely will stretch the capacity of the only one health center in the state in Little Rock that will provide

surgical abortions. It is unclear on this record whether that sole remaining clinic will be able to absorb such an increase in the number of procedures or whether that remaining clinic will be able to cover fully the needs of women who might have sought care at PPH. Further, removing medication abortion as an option for women will result in negative consequences for those women for whom medication abortion is medically indicated (Dkt. No. 2, Fine Decl., ¶ 13). It is unclear from this record what percentage of the patient population that may be. On the record before the Court, the Court concludes PPH and Dr. Ho meet their burden at this stage of the proceeding.

e. Undue Burden Analysis As To FPL Mandate

On the record before the Court, the Court determines that, if the FPL mandate portion of the Act goes into effect, women for whom medication abortion remains an option, meaning those with gestation ages under 49 days LMP, would be required to receive critical medical care through an inferior regimen that likely is inconsistent with the current standard of care (Dkt. No. 2, Fine Decl., ¶ 25). These women would be required to make an additional trip to the clinic for completion of the FPL regimen because, unlike the evidence-based regimen, it requires an additional clinic visit, increasing the expenses and other burdens associated with medication abortion (Fine Rebuttal Decl., ¶ 38). The cost of a medication abortion would increase further under the FPL mandate because of the

increased dose of mifepristone and the accompanying increased cost of the drug (Dkt. No. 2, de Baca Decl., ¶ 17; Fine Rebuttal Decl., ¶ 38).

Given the higher cost due to the extra clinic visit to take the misoprostol and increased dose of mifepristone, the FPL mandate could result in some women not being able to access abortion at all (Dkt. No. 3, at 9). The Court has before it record evidence that "42.4% of abortion patients [nationally] have incomes below the poverty line" and that "cost is a significant barrier to access" (Fine Rebuttal Decl., ¶ 38). There is evidence in the record that far fewer women choose medication abortion – or can access medication abortion – in states that restrict doctors to the FPL regimen (Fine Rebuttal Decl., ¶ 38).

Further, because many women do not discover they are pregnant until 49 days LMP, which is the last day the FPL regimen is available under the Act, the Act may ban effectively medication abortions for some women. Defendants argue that "where – as here – a law has a valid purpose, any incidental effect making it more expensive to procure an abortion cannot be enough to invalidate the law." *Dempsey*, 167 F.3d at 464 (quoting *Casey*, 505 U.S. at 874). It is not all together clear to this Court that the law has a valid purpose, based on the scientific evidence of record. Even when the Court puts that issue aside and examines only the effects, the Court concludes PPH and Dr. Ho meet their burden.

There is evidence in the record that approximately 66% of medication abortions performed statewide in 2014 were performed between 49 and 63 days LMP. Further, there is record evidence that approximately 81.5% of PPH and Dr. Ho's medication abortion patients in 2014 were between 50 and 63 days LMP (Dkt. No. 2, de Baca Decl., ¶ 16). Under the FPL mandate, these women will not be able to obtain a medication abortion, despite such an option being medically safe and otherwise available to them. Arkansas law will prohibit it.

If PPH is required to follow the FPL regimen, record evidence indicates PPH likely would stop providing abortion at both Arkansas health centers (de Baca Rebuttal Decl., ¶ 9). PPH and Dr. Ho claim that the vast majority of PPH patients seeking abortions obtain abortions between 50 and 63 days LMP. If required to perform medication abortion according to the FPL regimen only, the number of medication abortions would decrease while the cost of medication abortion would increase. The FPL regimen requires women to make an additional trip to the clinic, which means the clinic may need increased staffing. Further, the cost of mifepristone would increase as the required dose increases under the FPL regimen. Given these factors, PPH represents that "it would not be possible for us to retain our physicians to provide abortion to such a small number of patients who will be left able to access this service" (de Baca Rebuttal Decl., ¶ 9). In other words, there is record evidence that these clinics likely will

likely stop providing abortion services if the Act takes effect.

The Court notes, as part of the undue burden analysis at this stage, that this provision has no stated exception for cases where the procedure, in the considered judgment of the patient's physician, is necessary to preserve a woman's life or health. The ban applies equally to victims of rape, incest, other forms of sexual abuse, and domestic violence. The FPL mandate has no stated exception for cases where the procedure, in the considered judgment of the patient's physician, is necessary to preserve a woman's life or health. The ban applies equally to victims of rape, incest, other forms of sexual abuse, and domestic violence, who may choose medication abortion to feel more in control of the experience and to avoid trauma from having instruments placed in their vagina (Dkt. No. 2, Fine Decl., ¶ 12). The ban also applies to women with medical reasons why medication abortion is better for them than surgical abortion, including but not limited to certain medical conditions identified in the record that make medication abortion a safer option with a lower risk of complications and failure than surgical abortion (Dkt. No. 2, Fine Decl., ¶ 13).

The Court is aware of the language in *Casey* stating that "the incidental effect of making it more difficult or more expensive to procure an abortion" is in and of itself not enough to meet the substantial obstacle requirement. 505 U.S. at 874. However, on the record currently developed before the Court, all of the other factors, in conjunction with the increased cost, effort,

time, extra dosage of the medication, and threat of clinics not providing abortion services if the Act takes effect alone are enough, and especially if weighed against the potential that women would be required to receive critical medical care through an inferior regimen that likely is inconsistent with the current standard of care for PPH and Dr. Ho to meet their burden at this stage of the proceeding. *See*, *e.g.*, *Schimel*, 806 F.3d at 920 ("[T]he abridgment challenged in this case would actually endanger women's health. It would do that by reducing the number of abortion doctors in Wisconsin, thereby increasing the waiting time for obtaining an abortion, and that increase would in turn compel some women to defer abortion to the second trimester of their pregnancy – which the studies we cited earlier find to be riskier than a first-trimester abortion."); *Williamson*, 120 F.Supp. 3d. 1296, 1310 ("[R]egulations such as the one at issue here, which purportedly enhance women's health, cause delays which increase the risk of complications if the woman is able to eventually obtain the procedure."); *Strange*, 33 F.Supp.3d at 1363 (finding that privileges requirement would result in "obstacles related to reduced capacity, namely delay and outright inability to secure abortion services . . . compounded by the threat that women who desperately seek to exercise their ability to decide whether to have a child would take unsafe measures to end their pregnancies"); *but see Cole*, 790 F.3d 563; *Abbott II*, 748 F.3d 583, 590 (5th Cir. 2014). *See also Gonzales*, 550 U.S. at 161 (recognizing that the "prohibition in the Act would be unconstitutional,

under precedents we here assume to be controlling, if it "subject[ed] [women] to significant health risks' ").

f. Other Considerations Regarding The Undue Burden Analysis

The Court rejects defendants' arguments that plaintiffs have caused these impacts by failing to locate a contracted physician and by choosing not to provide surgical abortions in Fayetteville and Little Rock, Arkansas (Response Brief, at 52-56). *Casey* requires a contextualized inquiry into how an abortion restriction interacts with facts on the ground, not only on the law's direct effects. *See*, *e.g.*, *Casey*, 505 U.S. at 887-895; *Humble*, 753 F.3d at 915.

Defendants claim that PPH has not made a serious effort to locate a contracted physician. PPH and Dr. Ho maintain that they have exhausted their limited network of friendly physician contacts throughout Arkansas by reaching out to certain obstetricians and gynecologists in the state in an effort to locate a contracted physician (Dkt. No. 29, Ho. Decl., ¶¶ 6-10). In January, PPH sent a letter to approximately 225 obstetricians and gynecologists in the state, asking if these individuals would be willing to be the contracted physician (Dkt. No. 29, Ho Decl., ¶ 10; Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 10). To date, PPH has received no positive response (Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 10). As for PPH and Dr. Ho's efforts to comply prior to filing suit, the Court does not share defendants' view of PPH and Dr. Ho's decision to exclude

medical providers affiliated with religious institutions. Dr. Ho explained her reasoning on this point, as she believes "hospitals' religious affiliations would prevent a physician on staff from working with PPH." (Dkt. No. 29, Ho. Decl., ¶ 6). Further, she eliminated physicians affiliated with the University of Arkansas for Medical Sciences ("UAMS") system, as she understood the chair of the obstetrics and gynecology department there communicated to PPH that UAMS physicians would not be permitted to work with PPH (Dkt. No. 29, Ho Decl., ¶ 6). Dr. Ho also explained her reasons for eliminating physicians affiliated with Sparks Health System (Ho Decl., ¶ 6). In addition, she admits she eliminated physicians working in small towns because, in her view, those "areas tend to be very conservative" and practicing physicians in those areas "would have difficulty publicly associating with PPH." (Dkt. No. 29, Ho Decl., ¶ 6). Even if the Court accepted defendants' invitation to criticize PPH and Dr. Ho's efforts to comply, the fact remains, and no party disputes, that despite these efforts PPH and Dr. Ho have been unable to comply with this provision. Given the record evidence before the Court, the Court rejects defendants' argument on this point.

There is evidence in the record that physicians who provide abortions or associate with physicians who provide abortions risk being ostracized from their communities and face harassment and violence toward themselves, their family, and their private practices (Dkt. No. 30, Stulberg Decl., ¶¶ 13-17). Even if a physician is willing to take on these risks, there is evidence

in the record that many private practice groups, hospitals, HMOs, and health networks will not permit physicians working for them to associate with abortion providers (Dkt. No. 30, Stulberg Decl., ¶¶ 9-12). There is specific evidence that Arkansas's urban medical facility, the UAMS system, did not want to risk association with PPH or permitting its physicians to work with PPH (Dkt. No. 29, Ho. Decl., ¶ 6). Defendants have presented no information to the contrary on these points. *See Schimel*, 806 F.3d at 917 (finding it is difficult for abortion providers to recruit physicians "because of the vilification, threats, and sometimes violence directed against abortion clinics and their personnel in states such as Wisconsin, in which there is intense opposition to abortion"); *Strange*, 33 F.Supp.3d at 1348-49 (finding it is difficult for abortion providers to recruit physicians "due to the severe professional consequences of [association with abortion] and the lingering threat of violence against abortion doctors, particularly in Alabama").

As for defendants' claim about surgical abortions, to begin to provide surgical abortions in Fayetteville or Little Rock, the record evidence indicates that PPH's current health centers do not have sufficient space to accommodate surgical abortion services, so that PPH would need to relocate its current health centers and renovate the new location to meet its needs, as well as the state regulatory requirements for surgical abortion providers (Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 8); Ark. Code R. 007.05.2-12(G). PPH represents in the record that it does not have a sufficient budget to make

these moves (de Baca Rebuttal Decl., ¶ 8). Further, PPH maintains that the stigma against abortion providers in Arkansas makes it extremely difficult for PPH to locate and secure real estate, as landlords and sellers are unwilling to work with PPH (Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 8; Dkt. No. 30, Stulberg Decl., ¶ 14). Even if PPH had the necessary office space to provide surgical abortions, it does not currently have physicians who are trained and available to provide surgical abortions in Arkansas.

Further, at this stage of the proceeding, this Court adopts the view that it may not factor into its analysis that neighboring states provide opportunities across state lines for Arkansas residents to obtain an abortion, despite Mr. Jegley and Mr. Durrett's urging this Court to do so. As the Supreme Court explained in *Missouri ex rel. Gaines v. Canada*, 305 U.S. 337, 350 (1938):

> the obligation of the State to give the protection of equal laws can be performed only where its laws operate, that is, within its own jurisdiction. It is there that the equality of legal right must be maintained. That obligation is imposed by the Constitution upon the States severally as governmental entities-each responsible for its own laws establishing the rights and duties of persons within its borders. It is an obligation the burden of which cannot be cast by one State upon another, and no State can be excused from performance by what another State may do or fail to do.

See also Schimel, 806 F.3d at 918-19; *Jackson Women's Health Organization v. Currier*, 760 F.3d 448, 457 (5th Cir. 2014) (holding that "the proper formulation of the undue burden analysis focuses solely on the effects within the regulating state."). The Court, at least at this stage, finds this reasoning persuasive, and defendants cite no controlling law to the contrary.

This Court acknowledges the Fifth Circuit's 2015 decision in *Cole*, 790 F.3d 563. That decision has been stayed pending review by the Supreme Court. In *Cole*, the Fifth Circuit followed the prior *Abbott* decision that considered the same law at issue in *Cole* and held that 150 miles categorically does not present a substantial obstacle. In doing so, the Fifth Circuit also found that the 235 mile distance women in McAllen, Texas, would have to travel only once to reach a provider in San Antonio did present a substantial obstacle. *Cole*, 790 F.3d at 594. Further, unlike Texas law, there is no exception from Arkansas's 48-hour waiting period, requiring women in Arkansas to make the trip twice. *Cf.* Tex. Health & Safety Code Ann. § 171.012(a)(4). Likewise, defendants here cannot argue that considering abortion providers across state lines is reasonable, given the so-called metropolitan areas involved. *Cf. Cole*, 790 F.3d at 597 (considering the availability of an abortion provider in Santa Teresa, New Mexico, to women living in the El Paso area, since the two cities "are part of the same metropolitan area, though separated by a state line, and that people regularly go between the two cities for commerce, work, and medical care"). None of the out-of-state abortion providers defendants cite are

within the same metropolitan area as the current Arkansas provider; these out-of-state options are at least 113 miles and up to 262 miles from a current Arkansas provider (Dkt. No. 57, at 38 n.27). PPH and Dr. Ho represent that one of the out-of-state providers relied upon by defendants, the provider in Jackson, Mississippi, is only able to operate currently because of an injunction against an abortion restriction, and many of the other out-of-state providers upon which defendants rely are in states in which abortion restrictions have been passed in recent years (Dkt. No. 57, at 38 n.28).

2. Threat Of Irreparable Harm

A plaintiff seeking temporary injunctive relief must establish that the claimant is "likely to suffer irreparable harm in the absence of preliminary relief." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). A threat of irreparable harm exists when a party alleges a harm that may not be compensated by money damages in an action at law. *See Kroupa*, 731 F.3d at 820; *Glenwood Bridge, Inc. v. City of Minneapolis*, 940 F.2d 367, 371-72 (8th Cir. 1991). Accordingly, "[l]oss of intangible assets such as reputation and goodwill can constitute irreparable injury." *United Healthcare Ins. Co. v. Advance PCS*, 316 F.3d 737, 741 (8th Cir. 2002). Furthermore, a threat of irreparable harm may exist when relief through money damages in an action at law will not fully compensate a claimant's economic loss. *See Glenwood Bridge*, 940 F.2d at 367. The deprivation of constitutional rights

"unquestionably constitutes irreparable injury." *Elrod v. Burns*, 427 U.S. 347, 373 (1976); *Planned Parenthood of Minn., Inc. v. Citizens for Cmty. Action*, 558 F.2d 861, 867 (8th Cir. 1977).

PPH and Dr. Ho allege that the Act threatens irreparable harm because the contracted physician requirement eliminates abortions in Fayetteville, making abortions available only in Little Rock, and making only surgical abortions available causing women in Arkansas to travel to Little Rock to obtain a surgical abortion (Dkt. No. 3, at 19). Even without the contracted physician requirement, PPH and Dr. Ho maintain that the FPL mandate would cause irreparable injury in that medication abortion will be unavailable after 49 days LMP, causing all women between 50 and 63 days LMP to travel to Little Rock for a surgical abortion (*Id.*). They also contend that, even for those women for whom medication abortion would remain an option under the FPL mandate, those women would face increased travel, increased cost, and clinics that would stop providing abortion services all together is the Act takes effect, along with the requirement that these women receive critical medical care through an inferior regimen that likely is inconsistent with the current standard of care (*Id.*). Further, record evidence indicates that if the FPL mandate takes effect, PPH's clinics in Arkansas likely will stop providing abortion services (Dkt. No. 57-1, de Baca Rebuttal Decl., ¶ 9). Mr. Jegley and Mr. Durrett contest these representations and claim no irreparable harm has been shown. This Court concludes that, given the undue burden

analysis the Court has conducted, PPH and Dr. Ho have sustained their burden of demonstrating the threat of irreparable harm based on the current record evidence.

3. Balance Of Equities And Public Interest

PPH and Dr. Ho argue that the aforementioned threats of injury to them outweigh any harm caused to Mr. Jegley and Mr. Durrett. In fact, PPH and Dr. Ho contend that defendants will not be harmed because the issuance of a preliminary injunction will merely preserve the *status quo* and that PPH and Dr. Ho have been providing medication abortions to women for years (Dkt. No. 3, at 20-21). PPH and Dr. Ho also argue that the public interest weighs in favor of entering a preliminary injunction because the public interest "is not served by burdening women without any medical benefit" (Dkt. No. 3, at 22).

The Court must examine its case in the context of the relative injuries to the parties and to the public. *Dataphase*, 640 F.2d at 114. After balancing the relative injuries and the equities, while evaluating the limited record before it, the Court finds that because enforcement of the Act would result in the threat of irreparable harm to PPH and Dr. Ho, as well as the patients of PPH and Dr. Ho, the resulting harm to PPH and Dr. Ho is greater than the potential harm to the state. On this record, there is evidence medication abortion has been provided in the state since at least

2008. At this stage of the proceedings, the Court finds that the threat of irreparable harm to PPH and Dr. Ho, and the public interest, outweighs the immediate interests and potential injuries to the state.

IV. Security

Under Federal Rule of Civil Procedure 65(c), a district court may grant a preliminary injunction "only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." Fed. R. Civ. P. 65(c). In these proceedings, Mr. Jegley and Mr. Durrett have neither requested security in the event this Court grants a preliminary injunction nor presented any evidence that they will be financially harmed if they were wrongfully enjoined. For these reasons, the Court declines to require security from PPH or Dr. Ho.

V. Conclusion

For the foregoing reasons, the Court determines that PPH and Dr. Ho have met their burden for the issuance of a preliminary injunction. Therefore, the Court grants PPH and Dr. Ho's motion for preliminary injunction. The Court hereby orders that Mr. Jegley and Mr. Durrett, and all those acting in concert with them, are temporarily enjoined from enforcing the requirements of Sections 1504(a) and 1504(d) of Arkansas Act 577, Reg. Sess. (2015). Further, Mr. Jegley and Mr. Durrett are enjoined from failing to notify

immediately all state officials responsible for enforcing the requirements of Sections 1504(a) and 1504(d) of Arkansas Act 577, Reg. Sess. (2015), about the existence and requirements of this preliminary injunction. This preliminary injunction remains in effect until further order from this Court.

So ordered this 14th day of March, 2016 at 4:33 p.m.

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

No: 16-2234

Planned Parenthood of Arkansas & Eastern Oklahoma, on behalf of itself and its patients, doing business as Planned Parenthood Great Plains and Stephanie Ho, MD, on behalf of herself and her patients

Appellees

v.

Larry Jegley, Prosecuting Attorney for Pulaski County, in his official capacity, his agents and successors and Matt Durrett, Prosecuting Attorney for Washington County, in his official capacity, his agents and successors

Appellants

American Public Health Association and American College of Obstetricians and Gynecologists

Amici on Behalf of Appellee(s)

Appeal from U.S. District Court for the Eastern District of Arkansas – Little Rock (4:15-cv-00784-KGB)

ORDER

Before GRUENDER and KELLY*, Circuit Judges, and GRITZNER, District Judge.

Planned Parenthood's motion to stay issuance of the mandate is granted.

Judge Gruender voted to deny the motion.

October 13, 2017

Order Entered at the Direction of the Court:
Clerk, U.S. Court of Appeals, Eighth Circuit.

/s/ Michael E. Gans

* Judge Jane Kelly has been substituted for Judge William Jay Riley, who retired on August 31, 2017. See 8th Cir. R. 47E.

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Appellants

American Public Health Association and American College of Obstetricians and Gynecologists

Amici on Behalf of Appellee(s)

Appeal from U.S. District Court for the Eastern District of Arkansas – Little Rock (4:15-cv-00784-KGB)

ORDER

The petition for rehearing *en banc* is denied. The petition for panel rehearing is also denied.

September 27, 2017

Order Entered at the Direction of the Court:
Clerk, U.S. Court of Appeals, Eighth Circuit.

/s/ Michael E. Gans

A.C.A. § 20-16-1501. Title

This subchapter may be known and cited as the "Abortion-Inducing Drugs Safety Act".

A.C.A. § 20-16-1502.
Legislative findings and purpose

(a) The General Assembly finds that:

(1) The United States Food and Drug Administration approved the drug mifepristone, a first-generation progesterone receptor modulator, as an abortion-inducing drug with a specific gestation, dosage, and administration protocol;

(2) The United States Food and Drug Administration approved mifepristone under the rubric of 21 C.F.R. § 314.520, also referred to as "Subpart H", which is the only United States Food and Drug Administration approval process that allows for postmarketing restrictions and provides for accelerated approval of certain drugs that are shown to be effective but "can be safely used only if distribution or use is restricted";

(3) The United States Food and Drug Administration does not treat Subpart H drugs in the same manner as drugs that undergo the typical approval process;

(4) As approved by the United States Food and Drug Administration and as outlined in the final printed labeling of mifepristone, an abortion by mifepristone consists of three (3) two-hundred-milligram tablets of mifepristone taken orally,

followed by two (2) two-hundred-microgram tablets of misoprostol taken orally, through forty-nine (49) days from the first day of the woman's last menstrual period;

(5) The patient is to return for a follow-up visit in order to confirm that a complete termination of pregnancy has occurred;

(6) This United States Food and Drug Administration-approved protocol is referred to as the "Mifeprex regimen";

(7) This treatment requires three (3) office visits by the patient, and the dosages may only be administered in a clinic, medical office, or hospital and under supervision of a physician;

(8) The final printed labeling of Mifeprex outlines the United States Food and Drug Administration-approved dosage and administration of both drugs in the Mifeprex regimen, namely mifepristone and misoprostol;

(9) When the United States Food and Drug Administration approved the Mifeprex regimen under Subpart H, it did so with certain restrictions such as the requirement that the distribution and use of the Mifeprex regimen must be under the supervision of a physician who has the ability to assess the duration of pregnancy, diagnose ectopic pregnancies, and provide surgical intervention or has made plans to provide surgical intervention through other qualified physicians;

(10) One (1) of the restrictions imposed by the United States Food and Drug Administration as part of its Subpart H approval is a written

agreement that must be signed by both the physician and patient;

(11) In that agreement, the woman, along with the physician, attests to the following, among other statements:

(A) "I believe I am no more than 49 days (7 weeks) pregnant";

(B) "I understand that I will take misoprostol in my provider's office two days after I take Mifeprex (Day 3)"; and

(C) "I will do the following: return to my provider's office in 2 days (Day 3) to check if my pregnancy has ended. My provider will give me misoprostol if I am still pregnant";

(12) The United States Food and Drug Administration concluded that available medical data did not support the safety of home use of misoprostol, and it specifically rejected information in the Mifeprex final printed labeling on self-administering misoprostol at home;

(13) Court testimony in Planned Parenthood Cincinnati Region v. Taft, 459 F. Supp. 2d 626 (S.D. Oh. 2006), by Planned Parenthood and other abortion providers demonstrates that providers routinely fail to follow the United States Food and Drug Administration-approved protocol for the Mifeprex regimen as it is outlined in the Mifeprex final printed labeling and that providers are administering a single oral dose of two-hundred milligrams (200 mg) of mifepristone, followed by a single vaginal or buccal dose of eight-tenths milligram (.8 mg) of misoprostol, through sixty-three

(63) days of the woman's last menstrual period, without medical supervision and without follow-up care;

(14) The use of mifepristone presents significant medical risks to women, including without limitation abdominal pain, cramping, vomiting, headache, fatigue, uterine hemorrhage, viral infections, and pelvic inflammatory disease;

(15) Abortion-inducing drugs are associated with an increased risk of complications relative to surgical abortion, and the risk of complications increases with advancing gestational age and, in the instance of the Mifeprex regimen, with failure to complete the two-step dosage process;

(16)(A) In July 2011, the United States Food and Drug Administration reported two thousand two hundred seven (2,207) adverse events in the United States of America after women used the Mifeprex regimen for the termination of pregnancy.

(B) Among those were fourteen (14) deaths, six hundred twelve (612) hospitalizations, three hundred thirty-nine (339) blood transfusions, and two hundred fifty-six (256) infections, including forty-eight (48) severe infections;

(17)(A) Off-label or so-called evidence-based use of the Mifeprex regimen may be deadly.

(B) To date, fourteen (14) women have reportedly died after administration of the Mifeprex regimen, with eight (8) deaths attributed to severe bacterial infection.

(C) All eight (8) of those women administered the regimen in an off-label or evidence-based manner advocated by abortion providers.

(D) The United States Food and Drug Administration has not been able to conclude whether off-label use led to the eight (8) deaths; and

(18) Medical evidence demonstrates that women who use abortion-inducing drugs incur more complications than those who have surgical abortions.

(b) Based on the findings in subsection (a) of this section, it is the purpose of this subchapter to:

(1) Protect women from the dangerous and potentially deadly off-label use of abortion-inducing drugs such as, but not limited to, the Mifeprex regimen; and

(2) Ensure that physicians abide by the protocol tested and approved by the United States Food and Drug Administration for such abortion-inducing drugs, as outlined in the drug labels.

A.C.A. § 20-16-1503. Definitions

As used in this subchapter:

(1)(A) "Abortion" means the act of using or prescribing any instrument, medicine, drug, or any other substance, device, or means with the intent to terminate the clinically diagnosable pregnancy of a woman, with knowledge that the termination by those means will

with reasonable likelihood cause the death of the unborn child.

(B) An act under subdivision (1)(A) of this section is not an abortion if the act is performed with the intent to:

(i) Save the life or preserve the health of the unborn child;

(ii) Remove a dead unborn child caused by spontaneous abortion;

(iii) Remove an ectopic pregnancy; or

(iv) Treat a maternal disease or illness for which the prescribed drug is indicated;

(2)(A) "Abortion-inducing drug" means a medicine, drug, or any other substance prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman, with knowledge that the termination will with reasonable likelihood cause the death of the unborn child.

(B) "Abortion-inducing drugs" includes off-label use of drugs known to have abortion-inducing properties, which are prescribed specifically with the intent of causing an abortion, such as misoprostol, Cytotec, and methotrexate.

(C) This definition does not apply to drugs that may be known to cause an abortion, but which are prescribed for other medical indications such as chemotherapeutic agents or diagnostic drugs.

(D) Use of drugs to induce abortion is also known as a medical, drug-induced, or chemical abortion;

(3) "Adverse event" means an undesirable experience associated with the use of a medical product in a patient, including without limitation an event that causes:

(A) Death;

(B) Threat to life;

(C) Hospitalization;

(D) Disability or permanent damage;

(E) Congenital anomaly or birth defect, or both;

(F) Required intervention to prevent permanent impairment or damage; or

(G) Other serious important medical events, including without limitation:

(i) Allergic bronchospasm requiring treatment in an emergency room;

(ii) Serious blood dyscrasias;

(iii) Seizures or convulsions that do not result in hospitalization; and

(iv) The development of drug dependence or drug abuse;

(4) "Final printed labeling" means the United States Food and Drug Administration-approved informational document for an abortion-inducing drug that outlines the protocol authorized by the United States Food and Drug Administration and agreed upon by the drug company applying for United States Food and Drug Administration authorization of that drug;

(5) "Gestational age" means the time that has elapsed since the first day of the woman's last menstrual period;

(6) "Mifeprex regimen" means the abortion-inducing drug regimen that involves administration of mifepristone or the brand name "Mifeprex" and misoprostol, which is the only abortion-inducing drug regimen approved by the United States Food and Drug Administration and is also known as the RU-486 regimen or simply RU-486;

(7) "Mifepristone" means the first drug used in the Mifeprex regimen;

(8) "Misoprostol" means the second drug used in the Mifeprex regimen;

(9) "Physician" means any person licensed to practice medicine in this state, including medical doctors and doctors of osteopathy; and

(10) "Unborn child" means the offspring of human beings from conception until birth.

A.C.A. § 20-16-1504.
Unlawful distribution of abortion-inducing drug

(a)(1) It shall be unlawful to knowingly give, sell, dispense, administer, or otherwise provide or prescribe an abortion-inducing drug to a pregnant woman to induce an abortion or enable another person to induce an abortion unless the person who gives, sells, dispenses,

administers, or otherwise provides or prescribes the abortion-inducing drug is a physician and the provision or prescription of the abortion-inducing drug satisfies the protocol authorized by the United States Food and Drug Administration, as outlined in the final printed labeling for the drug or drug regimen.

(2) In the case of the Mifeprex regimen, the final printed labeling for Mifeprex includes the United States Food and Drug Administration-approved dosage and administration instructions for both mifepristone and misoprostol.

(b) Because the failure and complication rates from medical abortion increase with advancing gestational age, because the physical symptoms of medical abortion can be identical to the symptoms of ectopic pregnancy, and because abortion-inducing drugs do not treat ectopic pregnancies but rather are contraindicated in ectopic pregnancies, the physician giving, selling, dispensing, administering, or otherwise providing or prescribing the abortion-inducing drug shall first examine the woman and document in the woman's medical chart prior to giving, selling, dispensing, administering, or otherwise providing or prescribing the abortion-inducing drug the following information without limitation:

(1) Gestational age; and

(2) Intrauterine location of the pregnancy.

(c) Every pregnant woman to whom a physician gives, sells, dispenses, administers, or otherwise provides or

prescribes any abortion-inducing drug shall be provided with a copy of the drug's label.

(d)(1) The physician who gives, sells, dispenses, administers, or otherwise provides or prescribes the abortion-inducing drug shall have a signed contract with a physician who agrees to handle complications and be able to produce that signed contract on demand by the patient or by the Department of Health.

(2) The physician who contracts to handle emergencies shall have active admitting privileges and gynecological/surgical privileges at a hospital designated to handle any emergencies associated with the use or ingestion of the abortion-inducing drug.

(3) Every pregnant woman to whom a physician gives, sells, dispenses, administers, or otherwise provides or prescribes any abortion-inducing drug shall receive the name and phone number of the contracted physician and the hospital at which that physician maintains admitting privileges and which can handle any emergencies.

(e)(1) The physician who gives, sells, dispenses, administers, or otherwise provides or prescribes any abortion-inducing drug, or an agent of the physician, shall schedule a follow-up visit for the woman for approximately fourteen (14) days after administration of the abortion-inducing drug to confirm that the pregnancy is completely terminated and to assess the degree of bleeding.

(2) The physician or agent of physician shall make all reasonable efforts to ensure that the woman returns for the scheduled appointment.

(3) A brief description of the efforts made to comply with this subsection, including without limitation the date, time, and identification by name of the person making such efforts, shall be included in the woman's medical record.

A.C.A. § 20-16-1505. Reporting

(a) If a physician provides an abortion-inducing drug to another for the purpose of inducing an abortion as authorized in § 20-16-1504 and if the physician knows that the woman who uses the abortion-inducing drug for the purpose of inducing an abortion experiences an adverse event, the physician shall provide a written report of the adverse event within three (3) days of the event to the United States Food and Drug Administration via the Medwatch program reporting system and to the Arkansas State Medical Board.

(b)(1) The board shall compile and retain all reports it receives under this section.

(2)(A) All reports received by the board are public records open to inspection under the Arkansas Freedom of Information Act of 1967, § 25-19-101 et seq.

(B) The board shall not release to any person or entity the name or any other personal identifying information regarding a person who:

(i) Uses an abortion-inducing drug to induce an abortion; and

(ii) Is the subject of a report received by the board under this section.

A.C.A. § 20-16-1506. Criminal penalties

(a) A person who intentionally, knowingly, or recklessly violates a provision of this subchapter is guilty of a Class A misdemeanor.

(b) A criminal penalty may not be assessed against the pregnant woman upon whom the drug-induced abortion is performed.

A.C.A. § 20-16-1507.
Civil remedies and professional sanctions

(a) In addition to whatever remedies are available under the common or statutory law of this state, failure to comply with the requirements of this subchapter shall provide a basis for:

(1) A civil malpractice action for actual and punitive damages;

(2) A professional disciplinary action under § 16-114-201 et seq.; and

(3) Recovery for the woman's survivors for the wrongful death of the woman under § 16-62-102.

(b) A civil liability may not be assessed against the pregnant woman upon whom the drug-induced abortion is performed.

(c) When requested, the court shall allow a woman to proceed using solely her initials or a pseudonym and may close any proceedings in the case and enter other protective orders to preserve the privacy of the woman upon whom the drug-induced abortion was performed.

(d) If judgment is rendered in favor of the plaintiff, the court shall also render judgment for a reasonable attorney's fee in favor of the plaintiff against the defendant.

(e) If judgment is rendered in favor of the defendant and the court finds that the plaintiff's suit was frivolous and brought in bad faith, the court shall also render judgment for a reasonable attorney's fee in favor of the defendant against the plaintiff.

A.C.A. § 20-16-1508. Construction

(a) This subchapter does not create or recognize a right to abortion.

(b) It is not the intention of this subchapter to make lawful an abortion that is currently unlawful.

A.C.A. § 20-16-1509. Right of intervention

The General Assembly, by joint resolution, may appoint one (1) or more of its members who sponsored or cosponsored this subchapter in his or her official capacity to intervene as a matter of right in any case in which the constitutionality of this law is challenged.

A.C.A. § 20-16-1510. Effective date

This subchapter takes effect on January 1, 2016.