IN THE COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO

PLANNED PARENTHOOD SOUTHWEST OHIO REGION, *et al.,* Plaintiffs, v. OHIO DEPARTMENT OF HEALTH, *et al.,* *Defendants.*	Case No. A 2101148 Judge Alison Hatheway **PLAINTIFFS' MOTION FOR LEAVE TO FILE SECOND AMENDED COMPLAINT**

INTRODUCTION

Pursuant to Ohio Civil Rule 15(A), Planned Parenthood Southwest Ohio Region ("PPSWO"), Sharon Liner, M.D., Julia Quinn, Planned Parenthood of Greater Ohio, Preterm-Cleveland, and Women's Med Group Professional Corporation ("WMGPC") (collectively, "Plaintiffs"), by and through their undersigned counsel, hereby move this Honorable Court for leave to file a Second Amended Complaint (attached hereto as Exhibit 1), to (1) challenge additional statutory and regulatory provisions that could be read to give effect to the presently enjoined group of laws that together restrict qualified and skilled advanced practice clinicians ("APCs") from providing medication abortion (the "APC Ban"),[1] (2) account for changes related to Plaintiffs' organizational structures and operations that have occurred since the filing of the Amended Complaint, and (3) update named officeholders for certain official Defendants. Leave

[1] Specifically, Plaintiffs seek to further amend the Amended Complaint to challenge the disciplinary provisions contained in R.C. 4723.28(B)(30) and R.C. 4730.25(B)(24), and the definitional provision in Ohio Adm.Code 3701-47-01, in addition to the statutes and regulations that constitute the APC Ban in the Amended Complaint (*i.e.*, R.C. 2317.56(B), 2919.11, 2919.123, 4723.44(B)(6), 4723.50(B)(1), 4723.151(C), 4730.02(E), 4730.03(F), 4730.39(B)(2), 4730.42(A)(1); Ohio Adm.Code 4723-9-10(K), 4730-2-07(E)). *See* Decision and Order Granting Pls.' Second Mot. for Prelim. Inj., Aug. 29, 2024, at 17–18.

to amend should be granted because Plaintiffs make this request in good faith and without undue delay or undue prejudice to Defendants.

MEMORANDUM IN SUPPORT

In the present action, Plaintiffs seek a determination that certain restrictions on the provision of medication abortion violate Article I, Section 22 (the "Reproductive Freedom Amendment"), the Equal Protection Clause, and/or the Due Process Clause of the Ohio Constitution. Plaintiffs' Proposed Second Amended Complaint seeks to ensure that—should they prevail on their claims—Plaintiffs are able to be afforded comprehensive and meaningful relief. Plaintiffs therefore respectfully request that this Court grant them leave to amend under Ohio Civil Rule 15(A).

I. PROCEDURAL BACKGROUND

Plaintiffs originally brought this action on April 1, 2021. Compl. In the original Complaint, Plaintiffs asserted claims for violations of the Ohio Constitution's equal protection and benefit guarantee under Article I, Section 2, and the Ohio Constitution's protections for individual liberty under Article I, Sections 1, 2, 16, 20, and 21. Compl. ¶¶ 72–87. Plaintiffs also sought and received a preliminary injunction against the Telemedicine Ban.[2] *See* Pls.' Mot. for TRO Followed by Prelim. Inj., Apr. 1, 2021; Entry Granting Pls.' Mot. for a Prelim. Inj., Apr. 20, 2021, at 13. That preliminary injunction is still in effect. Decision and Order Granting Pls.' Second Mot. for Prelim. Inj., Aug. 29, 2024, at 18.

On November 7, 2023, the people of Ohio voted in favor of Ohio's Reproductive Freedom Amendment (the "Amendment"), which amended the Ohio Constitution to explicitly protect the right to abortion. *See* Ohio Const., art. I, § 22. The Amendment went into effect on December 7,

[2] The "Telemedicine Ban" prohibits abortion providers from providing medication abortion via telemedicine. *See* Senate Bill No. 260, 2020 Ohio Laws File 113 (adding R.C. 2919.124).

2023. Based upon the Amendment, Plaintiffs filed a Motion for Leave to File Amended Complaint to add new parties and assert additional claims challenging the APC Ban and Evidence-Based Use Ban.[3] Pls.' Mot. For Leave to File Am. Compl., May 9, 2024. The Court granted Plaintiffs' motion. Order Granting Pls.' Mot. to File Am. Compl., May 14, 2024.

On May 22, 2024, Plaintiffs filed a second motion for a preliminary injunction seeking to enjoin Defendants from enforcing the APC Ban and Evidence-Based Use Ban, as well as "any other Ohio statute or regulation that could be understood to give effect to these provisions." Pls.' Second Mot. for Prelim. Inj., May 22, 2024, at 32. The Court granted Plaintiffs' Second Motion for Preliminary Injunction on August 29, 2024, enjoining the APC Ban and Evidence-Based Use Ban. However, the order enjoining the Bans did not address Plaintiffs' request to enjoin "any other Ohio statute or regulation that could be understood to give effect" to the Bans. Decision and Order Granting Pls.' Second Mot. for Prelim. Inj., Aug. 29, 2024, at 18.

On September 23, 2024, Plaintiffs notified Defendants that they had become aware that certain additional provisions of Ohio law not previously enjoined by this Court's order—notwithstanding the clear purpose of the preliminary injunction—could be read to limit the ability of duly qualified APCs to provide medication abortions. Plaintiffs asked Defendants if they would stipulate not to enforce those provisions. On September 24, 2024, counsel for Defendants informed Plaintiffs that they were working with their office and would inform Plaintiffs of their position on the stipulation. On October 7, 2024, the parties met and conferred to discuss whether Defendants would agree to stipulate not to enforce any other statutes or regulations that would give effect to the APC and Evidence-Based Use Bans. Counsel for Defendants again indicated that

[3] The Evidence-Based Use Ban restricts the use of mifepristone solely with respect to abortion care, by forcing abortion providers to prescribe the drug only in accordance with the U.S. Food and Drug Administration's label for the drug. R.C. 2919.123. The restriction was enacted even though the "off-label" use of mifepristone is common, safe, effective, and well-accepted in medical practice.

Defendants would provide their position shortly. Defendants did not offer a position on the stipulation.

On November 1, 2024, Plaintiffs filed a Motion for Clarification, asking the Court to clarify that "no Ohio statute or regulation may be enforced during the pendency of the Court's preliminary injunction in a way that would give effect to the APC Ban." Pls.' Mot. for Clarification, Nov. 1, 2024, at 5. In the alternative, Plaintiffs requested that the Court enjoin disciplinary provisions contained in R.C. 4723.28(B)(30) and R.C. 4730.25(B)(24) and "[d]efinitional provisions contained in R.C. 2919.11 and Ohio Adm.Code 3701-47-01,[] to the extent they could be construed to prohibit" APCs "from providing medication abortion in a manner permitted by the Court's injunction of the APC Ban." *Id.* On December 17, 2024, the Court granted Plaintiffs' Motion for Clarification with respect to R.C. 2919.11[4] but stated that "[s]hould Plaintiffs wish to preliminarily enjoin additional statutes and regulations, they must file a motion identifying such statutes and regulations, and address[] them under the preliminary injunction standard." Entry on Pls.' Mot. for Clarification, Dec. 17, 2024.

After the issuance of the Court's order, Plaintiffs renewed discussions with Defendants in an attempt to resolve the dispute. For months, Defendants continually indicated that they were open to such a stipulation and indicated they would likely be able to agree to a stipulation of non-enforcement. Defendants claimed that they simply needed more time to discuss internally. Despite these repeated representations, on February 18, 2025, Defendants informed Plaintiffs that they would not agree to any stipulation not to enforce any of these clearly unconstitutional provisions.

[4] In its Entry on Plaintiffs' Motion for Clarification, the Court clarified that the statute was "erroneously excluded from the Court's order," and therefore, enjoined. Entry on Pls.' Mot. for Clarification, Dec. 17, 2024.

In accordance with the Court's order, Plaintiffs now seek to file a Second Amended Complaint to challenge such statutes and regulations.

II. LAW AND ANALYSIS

Ohio Civil Rule 15(A) provides that a party seeking to amend its pleading a second time can do so "with the opposing party's written consent or the court's leave." Civ.R. 15(A). Courts "shall freely give leave" to amend pleadings "when justice so requires." *Id.* "[T]he language of Civ.R. 15(A) favors a liberal amendment policy and a motion for leave to amend should be granted absent a finding of bad faith, undue delay or undue prejudice to the opposing party." *Hoover v. Sumlin*, 12 Ohio St. 3d 1, 6 (1984), *modified on other grounds*, *Jim's Steak House, Inc. v. City of Cleveland*, 81 Ohio St. 3d 18 (1998). Courts consider multiple factors in ruling on a motion for leave to amend, including "whether the movant made a prima facie showing of support for the new matters sought to be pleaded, the timeliness of the motion, and whether the proposed amendment would prejudice the opposing party." *Danopulos v. Am. Trading II, LLC*, 2016-Ohio-5014, ¶ 24 (1st Dist.). Here, each of these factors weighs in favor of granting leave to amend, and thus, Plaintiffs' motion should be granted in the interest of justice.

First, Plaintiffs have made a prima facie showing of support for the new matters they seek to plead. Plaintiffs seek to challenge R.C. 4723.28(B)(30), R.C. 4730.25(B)(24), and Ohio Adm.Code 3701-47-01 on the same grounds as those set forth in the Amended Complaint. *See, e.g.*, Am. Compl. ¶¶ 99–141. The incorporation of these specific provisions into Plaintiffs' claims in the Amended Complaint (and the factual updates that accompany them) only serve to specify the "Ohio statute[s] and regulations[s] that could be understood to give effect" to the APC Ban, as referenced in the Amended Complaint. Am. Compl. at 48. In fact, the Amended Complaint

already references the disciplinary statutes. *Id.* ¶ 29 (citing to R.C. 4723.28(B)(30)[5] and 4730.25(B)(24) to indicate that APCs who provide medication abortion "may be subject to disciplinary action, including the revocation or suspension of their license"). Similarly, the added definitional provision has language that is identical to a provision already enjoined by the Court. *Compare* Ohio Adm.Code 3701-47-01 ("Abortion is the practice of medicine or surgery for the purpose of section 4731.41 of the Revised Code") *with* R.C. 2919.11 ("Abortion is the practice of medicine or surgery for the purposes of section 4731.41 of the Revised Code"). The arguments that support the unconstitutionality of these provisions therefore align with the arguments in favor of enjoining the other provisions identified in the Amended Complaint as constituting the APC Ban, and already preliminarily enjoined by this Court.

Furthermore, the amendments addressing Plaintiffs' ownership and operations that have occurred since the filing of the Amended Complaint are necessary to ensure the factual allegations in the complaint remain accurate. On December 13, 2024, Plaintiff PPSWO took over the ownership and operation of Women's Med Dayton ("WMD") in Kettering, Ohio, now known as the Dayton Surgical Center of Planned Parenthood Southwest Ohio ("DSC"), where PPSWO now provides abortions, including medication abortions. Ex. 1 ¶¶ 9-10. WMGPC, which operated WMD, and PPSWO have submitted a Health Care Facility Change of Ownership Application to the Ohio Department of Health, which would transfer WMD's ambulatory surgical facility ("ASF") license for the former WMD Kettering location to PPSWO for DSC. *Id.* Notwithstanding the sale, PPSWO and WMGPC each remain separate parties in the case, and WMGPC continues to be the license-holder for the facility until PPSWO obtains the ASF license to operate. *See Id.* The change in ownership, while occurring after the filing of the Amended Complaint, does not

[5] Plaintiffs inadvertently referred to R.C. 4723.28(B)(30) as 4623.28(B)(30), which is not an existing statute, in the Amended Complaint. Am. Compl. ¶ 29.

change the claims at issue or relief sought in the case. Plaintiffs merely seek to update their allegations to align with the changed facts in good faith.

Plaintiffs' proposed amendments also update the identities of certain county prosecutors that are named as Defendants.

Second, Plaintiffs' Motion is not unduly delayed. On November 1, 2024, shortly after learning about providers' concerns regarding the threat of disciplinary enforcement, Plaintiffs filed a motion to clarify the scope of injunctive relief. Mot. for Clarification, Nov. 1, 2024. The Court issued its decision on December 17, 2024. Entry on Plaintiffs' Mot. for Clarification, Dec. 17. 2024. Since that time, and over the course of nearly two and a half months, Plaintiffs made repeated, good faith attempts to resolve Plaintiffs' concerns regarding the potential enforcement of R.C. 4723.28(B)(30), R.C. 4730.25(B)(24), and Ohio Adm.Code 3701-47-01 by stipulation with Defendants. During this entire time, Defendants have led Plaintiffs to believe that they were willing to consider stipulating to non-enforcement and likely to agree to such a stipulation. It was not until February 18, 2025, that Defendants finally informed Plaintiffs that they would not agree to any sort of stipulation not to enforce any of these clearly unconstitutional provisions. Similarly, the sale of WMD to PPSWO took place only about two months ago, the transfer of ownership and operations is still in process, and Plaintiffs informed Defendants about the sale of WMD on December 23, 2024 and again on January 21, 2025. *Cf. Shavel v. Shavel*, 2023-Ohio-4876, ¶¶ 42–44 (11th Dist.) (finding no undue delay in moving to amend under Civ.R. 15(A) in part because movant's actions put non-movant on notice of new claims and thus provided counsel with sufficient time to prepare).

Third, Defendants will not be prejudiced by the added provisions or updated factual allegations. Specifically, the Proposed Second Amended Complaint will not trigger additional discovery or affect the scheduling of past or future dispositive motions, especially because Defendants have not moved to dismiss Plaintiffs' Amended Complaint, have not yet produced any documents in discovery, have not yet propounded any discovery requests, and because no depositions have yet been taken. *See Med. Mut. of Ohio v. FrontPath Health Coal.*, 2023-Ohio-243, ¶¶ 82-84, 207 N.E.3d 16, 38–39 (6th Dist.) (finding no prejudice where discovery was ongoing and dispositive motion deadlines were months away); *Blackstone v. Moore*, 2017-Ohio-5704, ¶¶ 24-26, 94 N.E.3d 108, 114–15 (7th Dist.) (finding no prejudice even in midst of discovery and dispositive motion schedule). Moreover, as noted above, Defendants have been on notice for months of the substance of the amendments that Plaintiffs seek to make. Accordingly, the Proposed Second Amended Complaint will not unduly prejudice Defendants.

III. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this motion for leave to file a Second Amend Complaint be granted.

A proposed order will be filed separately.

Respectfully submitted,

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Dated: February 26, 2025

CERTIFICATE OF SERVICE

I hereby certify that on February 26, 2025, the foregoing was electronically filed via the Court's e-filing system. I further certify that a copy of the foregoing was served via electronic mail upon counsel for the following parties:

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Exhibit 1

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Case No. A 2101148

Judge Alison Hatheway

[PROPOSED] SECOND AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

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Defendants.

1. INTRODUCTION

1. On November 7, 2023, Ohioans voted to amend the Ohio Constitution to protect an individual's "right to make and carry out one's own reproductive decisions, including but not limited to decisions on . . . abortion." Ohio Const., art. I, § 22(A) (the "Amendment"). Pursuant to this explicit constitutional right to abortion, the State may not "directly or indirectly, burden, penalize, prohibit, interfere with, or discriminate against" either the exercise of Ohioans' decision to have an abortion or any "person or entity" that assists them in exercising that right, unless the State demonstrates that it is using the "least restrictive means to advance the individual's health in accordance with widely accepted and evidence-based standards of care." Ohio Const., art. I, § 22(B). As Ohio Attorney General Dave Yost acknowledged prior to the Amendment's passage, the Amendment "creates a new, legal standard" that provides greater protection to reproductive freedom than federal precedent predating the U.S. Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215, 142 S. Ct. 2228, 213 L.Ed.2d 545 (2022).[1]

[1] Ohio Atty. Gen., Issue 1 on the November 2023 Ballot: A Legal Analysis by the Ohio Attorney General 3 (Oct 5, 2023), https://www.ohioattorneygeneral.gov/SpecialPages/FINAL-ISSUE-1-ANALYSIS.aspx.

2. Plaintiffs challenge three categories of restrictions on medication abortion that directly and indirectly burden, penalize, interfere with, and discriminate against an individual's exercise of their right to abortion, and health care providers who provide abortion care, without providing any countervailing health benefit: (1) the Telemedicine Ban, (2) the Advanced Practice Clinician ("APC") Ban, and (3) the Evidence-Based Use Ban (collectively, the "Challenged Laws"). With respect to Ohioans for whom medication abortion is the only viable option, the Challenged Laws may also prohibit patients from making and carrying out their reproductive decisions entirely, by pushing them beyond the point in pregnancy when medication abortion is available. This is particularly true given the intersecting burdens the Challenged Laws impose on medication abortion access.

3. Moreover, the Challenged Laws do nothing to advance patient health in accordance with widely accepted and evidence-based standards of care, let alone by employing the least restrictive means of doing so. To the contrary, by delaying and impeding Ohioans' access to time-sensitive, vital abortion care, the Challenged Laws only serve to affirmatively harm patient health and well-being.

4. Consequently, this Court enjoined enforcement of the Challenged Laws, finding that Plaintiffs had shown by clear and convincing evidence that they were substantially likely to prevail on their claims that the Challenged Laws violate the Ohio Constitution. *See* Entry Granting Pls.' Mot. Prelim. Inj., Apr. 19, 2021; *see also* Decision and Order Granting Pls.' Second Mot. Prelim. Inj., Aug. 29, 2024 ("Second PI Order"). This Court's injunction on enforcement of the Telemedicine Ban, along with the injunction on the enforcement of the other Challenged Laws, have led to a sea-change in abortion law and practice in Ohio.

5. **The Telemedicine Ban** prohibits abortion providers from providing medication abortion to Ohioans through telemedicine. *See* Senate Bill No. 260, 2020 Ohio Laws File 113 (adding R.C. 2919.124) ("SB 260"). The Telemedicine Ban restricts access to abortion and threatens draconian felony criminal penalties and civil and professional sanctions for abortion providers who violate it. Telemedicine medication abortion ("TMAB") has been studied extensively and determined to be safe and effective, preferred by many patients, and critical to expanding abortion access to underserved areas and reducing travel and related burdens on patients. Since the Court's order enjoining the Telemedicine Ban, Plaintiffs have worked diligently to adapt their practices to this new legal framework. If not for the Court's injunction, the Telemedicine Ban would prevent practitioners from evaluating and employing new models for offering TMAB, which substantially decreases the distances that many patients must travel to obtain medication abortions. Reducing the necessary travel distance to access care in turn reduces delays and impediments to constitutionally-protected access to abortion, promoting Ohioans' health and well-being.

6. **The APC Ban** is a group of laws that together restrict qualified and skilled advanced practice clinicians ("APCs") from providing medication abortion, regardless of their education, training, and experience, even though Ohio permits them to prescribe the exact same medications for other purposes. *See* R.C. 2317.56(B), 2919.11, 2919.123, 4723.28(B)(30), 4723.44(B)(6), 4723.50(B)(1), 4723.151(C), 4730.02(E), 4730.03(F), 4730.25(B)(24), 4730.39(B)(2), 4730.42(A)(1); Ohio Adm.Code 3701-47-01, 4723-9-10(K), 4730-2-07(E). Abortion providers and APCs, including physician assistants ("PAs"), certified nurse-midwives ("CNMs"),[2] and nurse practitioners ("NPs"), who violate the APC Ban face criminal charges, civil

[2] NPs and CNMs are both types of advanced practice registered nurses ("APRNs").

penalties, civil forfeiture, and professional sanctions. By preventing qualified APCs from providing medication abortion care, the APC Ban restricts the number of available abortion providers throughout Ohio, in turn delaying and impeding access to abortion through the State, risking harm to Ohioans' health and well-being. Even with certain provisions of the APC Ban enjoined, additional restrictions remain in effect which continue to prevent Plaintiffs from commencing APC-provided medication abortion.

7. **The Evidence-Based Use Ban** restricts the evidence-based use of the drug mifepristone solely with respect to abortion care, by forcing abortion providers to prescribe mifepristone only in accordance with the U.S. Food and Drug Administration's ("FDA") label for the drug. R.C. 2919.123. Prescribing an FDA-approved drug for use in a manner not specified by the FDA label (*i.e.*, "evidence-based" or "off-label" use) is extremely common, well accepted in medical practice, safe, and effective. The Evidence-Based Use Ban singles out medication abortion for differential and unfavorable treatment when it comes to mifepristone, because Ohio permits off-label use of mifepristone for other purposes, including miscarriage management. Providers who fail to prescribe mifepristone for abortion in exact conformance with the FDA's final printed labeling face felony criminal penalties, fines, and professional sanctions. R.C. 2919.123. Prior to this Court's injunction of the Evidence-Based Use Ban, mifepristone was only available to Ohio patients for abortion through 70 days from the first day of their last menstrual period ("LMP")—even though research has demonstrated the efficacy and safety of mifepristone for abortion beyond that window. Accordingly, patients beyond 70 days LMP and before the point in pregnancy up to which medication abortion can be provided according to evidence-based standards were left with a difficult choice: seek a procedural abortion, which may be contraindicated, traumatizing, or significantly less manageable for certain patients; travel out of

state for medication abortion care; seek medication abortion care outside the medical system; or in some cases, potentially carry an unwanted pregnancy to term.

8. Plaintiffs, who are reproductive health care providers in Ohio, seek preliminary and permanent injunctive relief to prevent the Challenged Laws' enforcement and a declaratory judgment that the Challenged Laws violate the Ohio Constitution.

PARTIES

A. Plaintiffs

9. **Planned Parenthood Southwest Ohio Region** ("PPSWO") is a nonprofit corporation organized under the laws of the State of Ohio. PPSWO and its predecessor organizations have provided a broad range of high-quality reproductive health care to patients in southwest Ohio since 1929. PPSWO provides abortions, including, because of this Court's decision to enjoin the Evidence-Based Use Ban, medication abortion beyond 70 days LMP, at its ambulatory surgical facility ("ASF") in Cincinnati. On December 13, 2024, PPSWO took over the ownership and operation of Women's Med Dayton ("WMD") in Kettering, Ohio, now known as the Dayton Surgical Center of Planned Parenthood Southwest Ohio ("DSC"), where PPSWO now provides abortions, including medication abortions beyond 70 days LMP. Women's Med Group Professional Corporation ("WMGPC"), which operated WMD, and PPSWO have submitted a Health Care Facility Change of Ownership Application to the Ohio Department of Health. While PPSWO awaits a new license to operate the DSC, WMGPC continues to hold the ASF license for the facility. Even with certain provisions of the APC Ban enjoined, additional restrictions prevent PPSWO APCs from training in and providing medication abortion, as well as prevent PPSWO from hiring additional APCs to provide this care. Absent this Court's injunction, the Evidence-Based Use Ban would prevent PPSWO clinicians from prescribing mifepristone according to evidence-based standards and as clinically indicated, including beyond 70 days LMP,

and the Telemedicine Ban would prevent PPSWO from evaluating potential new models for offering TMAB. Providers at PPSWO are threatened with criminal charges, loss of their licenses, civil penalties, civil forfeiture, and civil suits if they provide care in violation of the Challenged Laws. PPSWO sues on behalf of itself; its current and future physicians, APCs, staff, officers, and agents; and its patients.

10. **Women's Med Group Professional Corporation** ("WMGPC") owned and operated WMD in Kettering, Ohio until the above-mentioned sale to PPSWO on December 13, 2024. On December 20, 2024, WMGPC and PPSWO submitted a Health Care Facility Change of Ownership Application to the Ohio Department of Health. Until the finalization of the change of ownership process, WMGPC holds the ASF license for the WMD facility now operated by PPSWO as DSC. Prior to the sale, WMGPC and its predecessor organizations had been providing abortions in the Dayton area since 1973, including medication abortions through 70 days LMP. WMGPC is threatened with loss of its ASF license if the care provided at the WMD facility, now operated by PPSWO, is viewed as violating the Challenged Laws. WMGPC sues on behalf of itself.

11. **Sharon Liner, M.D.**, is a physician licensed to practice medicine in Ohio. Dr. Liner is the Medical Director at PPSWO, and she provides abortion at PPSWO's Cincinnati Surgical Center in Hamilton County and at the DSC. Dr. Liner has offered TMAB that would be barred by the Telemedicine Ban if not for the preliminary injunction previously entered in this case. Absent this Court's injunction, the Evidence-Based Use Ban would prevent Dr. Liner from prescribing mifepristone according to evidence-based standards and as clinically indicated, including beyond 70 days LMP. Dr. Liner would face criminal penalties, loss of her medical

license, civil penalties, civil forfeiture, and civil suits if she violated the Telemedicine Ban or the Evidence-Based Use Ban. She sues on her own behalf and on behalf of her patients.

12. **Julia Quinn, MSN, WHNP-BC**, is a board-certified NP, a type of APRN, at PPSWO. Ms. Quinn provides a range of sexual and reproductive health care to her patients, including, for example, prescribing contraception, inserting and removing long-acting contraception (*i.e.*, intrauterine devices and Nexplanon contraceptive implants), and prescribing both pre- and post-exposure prophylaxis to prevent HIV. Absent an injunction of the APC Ban, Ms. Quinn would be prohibited from training in and beginning to provide medication abortion to patients at PPSWO. In addition, absent an injunction of the APC Ban and the Evidence-Based Use Ban, Ms. Quinn would be prevented from prescribing mifepristone according to evidence-based standards and as clinically indicated, including beyond 70 days LMP. Ms. Quinn faces criminal penalties, loss of her nursing license, civil penalties, civil forfeiture, and civil suits if she violates the APC Ban. She sues on behalf of herself and her patients.

13. **Planned Parenthood of Greater Ohio** ("PPGOH") is a nonprofit corporation organized under the laws of the State of Ohio. PPGOH was formed in 2012 through a merger of local and regional Planned Parenthood affiliates that had served patients in Ohio for decades by providing high-quality reproductive health care. PPGOH serves patients in northern, eastern, and central Ohio. In light of this Court's injunction of the Evidence-Based Use Ban, PPGOH now provides medication abortion beyond 70 days LMP at its ASFs in East Columbus and Bedford Heights, and at its health center in Athens, Ohio. Given the new legal landscape created by this Court's injunctions against the Challenged Laws, PPGOH is also evaluating new models for offering TMAB that would otherwise be barred by the Telemedicine Ban if not for the preliminary injunction previously entered in this case. Absent the APC Ban, PPGOH APCs would train in and

begin to provide medication abortion. But for the injunction of the Evidence-Based Use Ban, PPGOH clinicians would be prevented from prescribing mifepristone according to evidence-based standards and as clinically indicated, including beyond 70 days LMP. Providers at PPGOH would be threatened with criminal charges, loss of their licenses, civil forfeiture, civil penalties, and civil suits if they provided care in violation of the Challenged Laws. PPGOH sues on behalf of itself; its current and future physicians, APCs, staff, officers, and agents; and its patients.

14. **Preterm-Cleveland** ("Preterm") is a nonprofit clinic in Cleveland, Ohio, which has been serving patients since 1974. Preterm is an ASF under Ohio law. Preterm provides a range of reproductive and sexual health care services, including abortion. Preterm provides medication abortions through 70 days LMP and is currently working on a protocol to offer it beyond 70 days LMP. Absent the injunction of the APC Ban, Preterm would be prevented from seeking to hire and train APCs to provide medication abortion. Absent the injunction of the Evidence-Based Use Ban, Preterm clinicians would be prohibited from prescribing mifepristone according to evidence-based standards and as clinically indicated, including beyond 70 days LMP. Providers at Preterm would be threatened with criminal penalties, loss of their medical licenses, civil penalties, civil forfeiture, and civil suits if they provided care in violation of the APC Ban or the Evidence-Based Use Ban. Preterm sues on behalf of itself; its current and future physicians, APCs, staff, officers, and agents; and its patients.

B. Defendants

15. **The Ohio Department of Health** ("ODH") is the state agency charged with licensing and overseeing the operation of ASFs, as health care facilities, in the State, including ASFs operated by PPSWO, PPGOH, and Preterm. ODH can suspend, revoke, or decline to renew Plaintiffs' ASF licenses, order Plaintiffs' ASFs to cease operations, and/or impose civil penalties

on Plaintiffs' ASFs for violations of the Challenged Laws. *See* Ohio Adm.Code 3701-83-05, -05.1, -.05.2, -09(A), -03(D).

16. **Bruce Vanderhoff, M.D.**, is the Director of ODH. He can suspend, revoke, or decline to renew Plaintiffs' ASF licenses, order Plaintiffs' ASFs to cease operations, and/or impose civil penalties on Plaintiffs' ASFs for violations of the Challenged Laws. *See* Ohio Adm.Code 3701-83-05, -05.1, -.05.2, -09(A), -03(D). He is sued in his official capacity.

17. **Kim G. Rothermel, M.D.**, is the Secretary of the **State Medical Board of Ohio** (the "Medical Board"), which is charged with enforcing physician and PA licensing. The Medical Board has authority to act against a physician or PA's license based on a commission of an unlawful act, including a violation of the Challenged Laws, through license suspension or revocation. *See* R.C. 4731.22, 4730.25. The Medical Board may also impose civil penalties for violations. R.C. 4731.225(B), 4730.252. She is sued in her official capacity.

18. **Harish Kakarala, M.D.**, is the Supervising Member of the **Medical Board**. The Medical Board has authority to act against a physician or PA's license based on a commission of an unlawful act, including a violation of the Challenged Laws, through license suspension or revocation. *See* R.C. 4731.22, 4730.25. The Medical Board may also impose civil penalties for violations. R.C. 4731.225(B), 4730.252. He is sued in his official capacity.

19. **Erin Keels, DNP, APRN-CNP**, is the Board President of the **Ohio Board of Nursing** (the "Nursing Board"), which is charged with enforcing NP and CNM licensing. The Nursing Board has authority to act against an NP or CNM's license based on commission of an unlawful act, including a violation of the APC Ban, through license suspension or revocation. R.C. 4723.28(B). The Nursing Board may also impose civil penalties for violations. *Id.* She is sued in her official capacity.

20. **Candy Sue Rinehart, DNP, APRN-CNP**, is the Supervising Member for Disciplinary Matters of the **Nursing Board**, which is charged with enforcing NP and CNM licensing. The Nursing Board has authority to act against an NP or CNM's license based on commission of an unlawful act, including a violation of the APC Ban, through license suspension or revocation. R.C. 4723.28(B). The Nursing Board may also impose civil penalties for violations. *Id.* She is sued in her official capacity.

21. **Connie Pillich** is the Hamilton County Prosecuting Attorney. She is responsible for the enforcement of all criminal laws in Hamilton County, where two of PPSWO's health centers, including its Cincinnati Surgical Center, are located; where Dr. Liner and other PPSWO physicians provide abortions, including medication abortions; and where, if not for the APC Ban, Plaintiff Quinn and other PPSWO APCs would train in and begin to provide medication abortion. She is sued in her official capacity.

22. **Shalya D. Favor** is the Franklin County Prosecuting Attorney. She is responsible for the enforcement of all criminal laws in Franklin County, where PPGOH's East Columbus Surgical Center is located; where PPGOH physicians provide abortions, including medication abortions; and where, if not for the APC Ban, PPGOH APCs would train in and begin to provide medication abortion. She is sued in her official capacity.

23. **Michael C. O'Malley** is the Cuyahoga County Prosecutor. He is responsible for the enforcement of all criminal laws in Cuyahoga County, where PPGOH's Bedford Heights ASF and Preterm's ASF are located; where PPGOH and Preterm physicians provide abortion; and where, if not for the APC Ban, PPGOH and Preterm would hire and/or train APCs to begin to provide medication abortion. He is sued in his official capacity.

24. **Mathias H. Heck, Jr.** is the Montgomery County Prosecuting Attorney. He is responsible for the enforcement of all criminal laws in Montgomery County, where PPSWO has two health centers, including the DSC; where PPSWO physicians provide abortions, including medication abortion; and where, if not for the APC Ban, PPSWO would hire and/or train APCs to begin to provide medication abortion. He is sued in his official capacity.

25. **Elliot Kolkovich** is the Summit County Prosecutor. He is responsible for the enforcement of all criminal laws in Summit County, where one of PPGOH's health centers is located, and where, if not for the APC Ban, PPGOH APCs would be able to train in and begin to provide medication abortion. He is sued in his official capacity.

26. **Keller J. Blackburn** is the Athens County Prosecutor. He is responsible for the enforcement of all criminal laws in Athens County, where one of PPGOH's health centers is located; where PPGOH physicians provide medication abortion; and where, if not for the APC Ban, PPGOH APCs would be able to train in and begin to provide medication abortion. He is sued in his official capacity.

27. **Kyle L. Stone** is the Stark County Prosecuting Attorney. He is responsible for the enforcement of all criminal laws in Stark County, where one of PPGOH's health centers is located, and where, if not for the APC Ban, PPGOH APCs would be able to train in and begin to provide medication abortion. He is sued in his official capacity.

28. **Connie J. Lewandowski** is the Portage County Prosecutor. She is responsible for the enforcement of all criminal laws in Portage County, where one of PPGOH's health centers is located, and where, if not for the APC Ban, PPGOH APCs would be able to train in and begin to provide medication abortion. She is sued in her official capacity.

29. **Jodie M. Schumacher** is the Richland County Prosecuting Attorney. She is responsible for the enforcement of all criminal laws in Richland County, where one of PPGOH's health centers is located, and where, if not for the APC Ban, PPGOH APCs would be able to train in and begin to provide medication abortion. She is sued in her official capacity.

30. **Julia R. Bates** is the Lucas County Prosecutor. She is responsible for the enforcement of all criminal laws in Lucas County, where one of PPGOH's health centers is located, and where, if not for the APC Ban, PPGOH APCs would be able to train in and begin to provide medication abortion. She is sued in her official capacity.

31. **Lynn Maro** is the Mahoning County Prosecutor. She is responsible for the enforcement of all criminal laws in Mahoning County, where one of PPGOH's health centers is located, and where, if not for the APC Ban, PPGOH APCs would be able to train in and begin to provide medication abortion. She is sued in her official capacity.

32. **Michael T. Gmoser** is the Butler County Prosecuting Attorney. He is responsible for the enforcement of all criminal laws in Butler County, where one of PPSWO's health centers is located, and where, if not for the APC Ban, PPSWO APCs would train in and begin to provide medication abortion. He is sued in his official capacity.

33. **Daniel P. Driscoll** is the Clark County Prosecutor. He is responsible for the enforcement of all criminal laws in Clark County, where one of PPSWO's health centers is located, and where, if not for the APC Ban, PPSWO APCs would train in and begin to provide medication abortion. He is sued in his official capacity.

PROCEDURAL BACKGROUND

34. On April 1, 2021, PPSWO, Dr. Liner, and PPGOH brought this action seeking a temporary restraining order followed by a preliminary injunction, as well as a declaratory judgment and permanent injunctive relief, against the Telemedicine Ban. The Complaint asserted

claims for violations of the Ohio Constitution's equal protection and benefit guarantee under Article I, Section 2, and the Ohio Constitution's protections for individual liberty under Article I, Sections 1, 2, 16, 20, and 21.

35. On April 7, 2021, this Court issued a temporary restraining order. Following an expedited briefing schedule and oral argument, the Court issued a preliminary injunction enjoining enforcement of the Telemedicine Ban, finding that, absent relief, Ohioans would have suffered irreparable deprivation of their constitutional rights and serious, irreparable harm to their physical, psychological, and emotional well-being. That preliminary injunction is still in effect.

36. On July 13, 2022, the Court granted the original Plaintiffs' Motion to Stay Proceedings pending resolution of *State ex rel. Preterm-Cleveland v. Yost*, No. 2022-0803 (Ohio June 29, 2022).

37. Since this Court's grant of the original Plaintiffs' Motion to Stay, the people of Ohio voted to amend the Ohio Constitution to explicitly protect the right to abortion. Ohio Const., art. I, § 22. The Amendment took effect on December 7, 2023.

38. On December 15, 2023, the Ohio Supreme Court dismissed the appeal in *State ex rel. Preterm-Cleveland v. Yost*, No. 2023-0004 (Ohio Dec. 15, 2023). This Court thereafter lifted the stay in this case.

39. On August 29, 2024, this Court issued a preliminary injunction enjoining enforcement of the APC Ban and Evidence-Based Use Ban, finding that Plaintiffs had shown by clear and convincing evidence that they were substantially likely to prevail on their claims that these Bans violate the Ohio Constitution. *See* Second PI Order. That preliminary injunction is still in effect.

JURISDICTION AND VENUE

40. The Court has jurisdiction over this Second Amended Complaint pursuant to R.C. 2721.02, 2727.02, and 2727.03.

41. Venue is proper in this Court pursuant to Civ.R. 3(C)(4) because Defendant Pillich maintains her principal office in Hamilton County.

42. Venue is further proper in this Court pursuant to Civ.R 3(C)(3) because Defendant Pillich initiates prosecutions in Hamilton County.

43. Venue is further proper in this Court pursuant to Civ.R. 3(C)(6) because Plaintiffs PPSWO, Dr. Liner, and Ms. Quinn provide reproductive health care services in Hamilton County, so the business, professional and other injuries caused by the Challenged Laws with respect to them occur in Hamilton County, and Defendant Pillich would bring any resulting prosecutions against Dr. Liner, Ms. Quinn, or other PPSWO physicians or APCs in Hamilton County. In addition, judicial proceedings to adjudicate ODH enforcement action over violations of the Challenged Laws would occur in Hamilton County. *See* R.C. 119.12(B)(2).

ALLEGATIONS

A. Abortion is an Essential Component of Health Care

44. Abortion is extremely common in the United States. Approximately one in four women in this country will have had an abortion by age 45.

45. Two types of abortion are available in Ohio: medication and procedural abortion. This case concerns restrictions on medication abortion.

46. The most common regimen of medication abortion involves a combination of two medications: mifepristone and misoprostol. Medication abortion patients first take mifepristone orally, which blocks the hormone progesterone. Progesterone is necessary to maintain pregnancy.

Then, typically 24 to 48 hours later, patients take misoprostol, which causes the uterus to contract and expel its contents, in a process similar to miscarriage.

47. The decision to terminate a pregnancy is an incredibly personal decision that is informed by a combination of diverse, complex, and interrelated factors that are intimately related to an individual's values, beliefs, culture, religion, health status, reproductive history, familial situation, resources, and economic stability.

48. Most people who seek abortion have already given birth at least once, and many pregnant people seek an abortion because they feel they cannot adequately care for another child; because they want to prioritize the needs of their existing children; or because of other caretaking responsibilities. For some, an additional child can place significant economic and emotional strain on a family. A significant majority of people seeking abortions in the United States are either poor or low-income.

49. Some people seek abortions because they simply do not want to become a parent at that point in their lives, or ever. For some people, having a child will make it too difficult for them to pursue educational, career, or other life goals and support themselves and their families going forward.

50. People experiencing intimate partner violence may seek abortion to escape the dangers posed by their relationships, which can be amplified by pregnancy and parenting.

51. Survivors of sexual assault or incest may choose abortion to avoid the ongoing emotional distress and trauma associated with carrying a pregnancy resulting from their assault, regain control over their bodies and reproductive choices, facilitate their healing process, and/or prevent further ties to their assailant through parenthood.

52. Others seek an abortion because continuing their pregnancies would threaten their health or life due to pre-existing medical conditions or complications that arise during pregnancy.

53. Individual circumstances vary greatly, and the reasons outlined above are not exhaustive but rather examples of the diverse factors that may influence someone's decision to seek abortion. People seeking abortion often base their decision on multiple interconnected factors and considerations.

54. Whatever a person's reasons, accessing abortion is essential to their autonomy, dignity, and ability to care for themselves and their families. Forcing a person to continue a pregnancy against their will jeopardizes their physical, mental, and emotional health, as well as the stability and well-being of their family and existing children.

55. Patients generally seek abortion as soon as they are able to, but many face logistical obstacles that can delay access to abortion. Patients need to schedule an appointment, gather the resources to pay for the abortion and related costs, arrange transportation to a clinic, take time off work (often unpaid, due to a lack of paid time off or sick leave), and possibly arrange for child care during appointments. The delay caused by these barriers and others posed by the Challenged Laws results in higher financial, physical, and emotional costs to the patient. These burdens fall most heavily on patients with low incomes, patients who live far from health centers, patients of color, patients with children, patients under the age of 18, and patients experiencing interpersonal violence.[3]

[3] These barriers are further exacerbated by the fact that Ohio law requires patients to receive certain state-mandated information at least 24 hours before their abortion, forcing most patients to make at least two trips to a health center for care. *See infra* ¶ 69.

C. Abortion Is Extremely Safe

56. Legal abortion is very safe. Complications from both medication and procedural abortions are extremely rare. In the rare cases where complications from medication abortion occur, they can typically be managed in an outpatient clinic setting.

57. Medication abortion is one of the safest treatments in contemporary medical practice. Current medical evidence demonstrates that medication abortion is safe and effective through at least 84 days LMP.

58. Despite this evidence, absent this Court's injunction, the Evidence-Based Use Ban would prevent patients after 70 days LMP from obtaining medication abortion. *See infra* ¶¶ 143–50; R.C. 2919.123.

59. For some patients, medication abortion may be safer than procedural abortion due to complications of the patient's reproductive and genital tract, such as large uterine fibroids, that make accessing the pregnancy inside the uterus as part of a procedural abortion difficult or impossible.

60. Many patients also prefer medication abortion because they can end their pregnancy at home and at a time more suitable for them and because it allows them more privacy and autonomy. Victims of rape, sexual abuse, or molestation may choose medication abortion to feel more in control of the experience and to avoid trauma from having instruments inserted through their vaginas.

61. Regardless of the method of abortion, abortion is substantially safer than continuing a pregnancy through childbirth. The national risk of maternal mortality associated with live birth is approximately 14 times higher than the risk of death associated with induced abortion. The maternal mortality rate is significantly higher for Black women in Ohio, where they are 1.5 to 2.5

times more likely than white women to die of causes related to pregnancy.[4] Indigenous women also face higher maternal mortality rates than white women.

62. Even for the healthiest patients, pregnancy poses extraordinary physical challenges and significant health risks. Pregnancy places significant stress on most major organs and results in profound and long-lasting physiological changes.

63. Pregnancy complications are also extremely common. Some of the more common complications include preeclampsia, gestational diabetes, and maternal cardiac disease. All of these conditions can result in serious, permanent harm to an individual's health, up to and including death.

64. Pregnancy may also cause or exacerbate certain health conditions, such as diabetes, hypertension, asthma, heart disease, an autoimmune disorder, or renal disease. People with such conditions face an even greater risk of experiencing medical complications during pregnancy.

65. Forcing someone to continue a pregnancy against their will poses severe risks to their physical, mental, and emotional health, as well as to the stability and well-being of their family, including their existing children.

66. While abortion is always very safe, the risks associated with it do increase as pregnancy progresses. Accordingly, when patients seeking abortion are unnecessarily delayed in accessing that care, they are subjected not only to the harms associated with being forced to remain

[4] According to Ohio statistics from 2008–2016, non-Hispanic Black women were more than 2.5 times as likely to die from pregnancy-related causes than their white counterparts. Ohio Dept. of Health, *A Report on Pregnancy-Associated Deaths in Ohio 2008–2016*, at 19 (2019), https://bit.ly/3uZraej (accessed Feb. 26, 2025). However, in 2017–2018, due to the adoption of new criteria employed by ODH "to determine the pregnancy-relatedness of unintentional overdose deaths, an increased number of unintentional overdose deaths were determined to be pregnancy related in 2017 and 2018," and the majority of those occurred among non-Hispanic white women. Ohio Dept. of Health, *A Report on Pregnancy-Related Deaths in Ohio 2017–2018*, at 4, 28 (2022), http://bit.ly/4b1iSXx (accessed Feb. 26, 2025). However, "pregnancy-related deaths due to causes other than overdose occurred disproportionately among non-Hispanic Black women." *Id.* at 4, 28.

pregnant for longer, but also to increased risks from abortion, if and when they eventually obtain their desired care.

D. Plaintiffs' Abortion Services

67. PPSWO, PPGOH, and Preterm provide a broad range of sexual and reproductive health services throughout Ohio.

68. PPSWO operates six clinics in southwest Ohio, and PPGOH operates another 15 clinics throughout the rest of the State. Preterm is a clinic in Cleveland, Ohio.

69. Ohio law requires clinics that offer procedural abortion (sometimes called surgical abortion) to be ASFs. Five of these clinics offer procedural abortion: PPSWO's Cincinnati ASF and DSC, PPGOH's East Columbus and Bedford Heights ASFs, and Preterm. Each of the ASFs has one or more physicians at the facility each day it offers services.

70. The remaining health centers operated by PPSWO and PPGOH (*i.e.*, the non-ASF centers) have one or more APCs on site. Other medical professionals, such as registered nurses, licensed practical nurses, and/or medical assistants, also staff each center.

71. Regardless of the method of abortion, abortion patients in Ohio are required by law to travel to a clinic or health center to receive certain state-mandated information in person at least 24 hours prior to obtaining abortion care. *See* R.C. 2317.56(B)(1), 2919.192-94. As written, Ohio law requires patients to make at least two trips to a clinic or health center in order to obtain an abortion: the first to receive the state-mandated information (the "Day 1" visit) and the second—at least 24 hours later, if not much longer—to obtain their abortion (the "Day 2" visit).

72. Enforcement of these statutes is currently enjoined pursuant to a preliminary injunction in *Preterm-Cleveland v. Yost* (the "24-Hour PI").[5] *See* Decision, *Preterm-Cleveland v. Yost*, Franklin C.P. No. 24 CV 2634 (Aug. 23, 2024). Absent the 24-Hour PI, Ohio law would require the Day 1 mandatory, in-person information session to be completed by a physician. *See* R.C. 2317.56(B)(1). Thus, PPGOH and PPSWO could offer Day 1 visits only at their four ASFs (*i.e.*, their surgical centers in Cincinnati, Dayon, East Columbus, and Bedford Heights), where physicians are regularly on site. It would not be operationally feasible for PPGOH or PPSWO to place physicians in their non-ASFs to provide Day 1 visits.

E. The Challenged Laws

1. Telemedicine Ban

73. The Telemedicine Ban prohibits abortion providers from providing medication abortion to Ohioans through telemedicine. This prohibition directly and indirectly burdens, penalizes, interferes with, discriminates against and, in some cases, may prohibit patients' exercise of their right to abortion and inhibits Plaintiffs from assisting patients in exercising this right.

74. The Ohio General Assembly passed the Telemedicine Ban on December 17, 2020, and Governor DeWine signed it into law on January 9, 2021. While the Telemedicine Ban was slated to take effect on April 12, 2021, this Court issued a temporary restraining order followed by a preliminary injunction blocking its enforcement.

75. Had the Telemedicine Ban not been enjoined by this Court, R.C. 2919.124(B) would have barred a clinician from providing an "abortion-inducing drug" to a pregnant person

[5] *See* Am. Compl., *Preterm-Cleveland v. Yost*, Franklin C.P. No. 24 CV 2634 (Apr. 5, 2024). Prior to the 24-Hour PI, a small minority of medication abortion patients in Ohio were able to obtain a medication abortion with one in-person visit to a clinic followed by a virtual visit at least 24 hours later. However, these patients still had to schedule two separate appointments—and delay their care for at least 24 hours. *See id.* ¶ 84.

unless the clinician is "physically present at the location where the initial dose of the drug or regimen of drugs is consumed at the time" the patient consumes that dose. SB 260, § 1 (adding R.C. 2919.124(A)(l), (B)).

76. The Telemedicine Ban would also make it illegal for a clinician to "knowingly fail to comply with division (B) of this section" when the clinician provides "an abortion-inducing drug to another" for "the purpose of inducing an abortion." SB 260, § 1 (adding R.C. 2919.124(C)).

77. The Telemedicine Ban defines "abortion-inducing drug" to include mifepristone, the first medication in the most common medication abortion regimen. SB 260, § 1 (adding R.C. 2919.124(A)(l)). However, it also sweeps in any other "drug or regimen of drugs that causes the termination of a clinically diagnosable pregnancy." *Id.* (adding R.C. 2919.124(A)(l)).

78. A violation of the Telemedicine Ban is a fourth-degree felony, which carries a potential prison term of between six and eighteen months in Ohio. SB 260, § 1 (adding R.C. 2919.124(E)); *see* R.C. 2929.14(A)(4)). Licensed physicians are also "subject to sanctioning" by the Medical Board for violations of the Telemedicine Ban. SB 260, § 1 (adding R.C. 2919.124(E), which cross-references R.C. 4731.22); *see also* R.C. 2925.01(W)(l7).

79. For a second or subsequent violation of the Telemedicine Ban, a physician is subject to mandatory and automatic medical license suspension for at least one year. SB 260, § 1 (amending R.C. 4731.22(I)(1)). That is so even though Ohio law otherwise reserves this automatic suspension penalty to several far more serious crimes, such as aggravated murder, felonious assault, kidnapping, and rape. R.C. 4731.22(I).

a. Benefits of Telemedicine Care

80. Telemedicine is a common and effective way to provide health care. Telemedicine refers to traditional clinical diagnosis and monitoring that a health care provider delivers live to

patients via secure audio and/or video. Telemedicine allows patients to interact in real-time with health care providers who are physically distant.

81. Telemedicine is used for a wide range of services, from emergency care to psychotherapy, and in many different settings, including in general medical practices, urgent care clinics, hospitals, and specialists' offices. The need for telemedicine in reproductive and sexual health care is particularly acute given provider shortages.

82. Although some obstetric and gynecological care can only be done in person, telemedicine can be used to provide a range of medical interventions and treatments, including some that carry far greater medical risks than medication abortion.

83. Ohio and federal government officials alike have recognized telemedicine's benefits. For example, Governor DeWine has stated that Ohio policymakers now "realize[ ] that when you need healthcare and behavioral health services, a virtual visit can save time and money." and he has touted a law to permanently expand insurance coverage of telehealth.[6] In 2017, then-Attorney General DeWine criticized "bureaucracy" standing in the "way of innovative programs like telemedicine and remote prescribing."[7]

84. The U.S. Department of Health and Human Services acknowledges numerous benefits to telemedicine, including that it can reduce travel time, obviate the need to take time off from work or the need to find child care; shorten wait times to meet with a provider; and increase

[6] Governor Mike DeWine, As Prepared State of the State Address 3 (Mar. 23, 2022), https://governor.ohio.gov/wps/wcm/connect/gov/27cd3f50-5604-4a35-a531-32914135ec0b/As+Prepared+2022+Governor+Mike+DeWine+State+of+the+State+Remarks.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=ROOTWORKSPACE.Z18_M1HGGIK0N0JO00QO9DDDDM3000-27cd3f50-5604-4a35-a531-32914135ec0b-n-Z8q2E.

[7] Press Release, Mike DeWine, Statement from Ohio Attorney General Mike DeWine Following the President's Declaration of National Public Health Emergency on Opioids (Oct. 26, 2017), https://www.ohioattorneygeneral.gov/Media/News-Releases/October-2017/Statement-from-Ohio-Attorney-General-Mike-DeWine-F.

patients' access to specialists who live farther away.[8] After the COVID-19 public health emergency, many of the Department's telehealth policies implemented during that time have been made permanent, while others have been extended through March 31, 2025.[9]

85. Recognizing these valuable benefits of telemedicine, Ohio has taken steps to reduce legal and regulatory barriers to telemedicine. These aspects of Ohio law are consistent with efforts in many other states to reduce impediments to telemedicine and thereby increase availability of health care. For example, Ohio has adopted flexible licensing rules to facilitate telemedicine. State law permits the creation of a physician-patient relationship without an in-person medical evaluation, provided the standard of care is met. Ohio Adm.Code 4731-11-09(C)–(F); R.C. 4731.74(B). Physicians may prescribe non-controlled substances on that basis. R.C. 473l.74(B)(1). They can also decide whether prescription of a *controlled* substance is appropriate for a patient via telehealth under some circumstances. R.C. 473l.74(B)(2).

b. PPSWO and PPGOH's Telemedicine Medication Abortion Procedures

86. PPSWO and PPGOH strive to make their services as accessible as possible, particularly for patients in underserved communities. Consistent with this mission, PPSWO and PPGOH offer many services via telemedicine.

87. Before the introduction of TMAB, all Day 1 (in-person pre-abortion information) and Day 2 (abortion provision) visits occurred at PPSWO and PPGOH's ASFs in Cincinnati, East Columbus, and Bedford Heights. As explained above, Plaintiffs cannot legally perform procedural abortions anywhere other than those ASFs. *See* R.C. 3702.30(A)(l), (E)(l). And although state

[8] Health Resources & Servs. Administration, *Why Use Telehealth?* (updated Feb. 29, 2024), https://telehealth.hhs.gov/patients/why-use-telehealth#what-are-the-benefits-of-telehealth.

[9] Health Resources & Servs. Administration, *Telehealth Policy Updates* (updated Jan. 17, 2025), https://telehealth.hhs.gov/providers/telehealth-policy/telehealth-policy-updates.

law does not expressly bar the provision of medication abortion at non-ASFs, it provides that only physicians may provide these abortions. Because PPSWO and PPGOH's physicians are based at ASFs, and they cannot feasibly be regularly distributed to other health centers, patients obtaining medication abortion from PPSWO and PPGOH traditionally had to complete their Day 2 visit at one of PPSWO and PPGOH's ASFs as well.

88. Starting in 2018 and 2019, respectively, PPGOH and PPSWO allowed some qualified patients to have their second day medication abortion appointment via site-to-site telemedicine. For operational reasons, PPSWO and PPGOH discontinued this practice, and, prior to the 24-Hour PI, both had been piloting a new telemedicine practice that allowed some qualified patients to complete their second medication abortion appointment via telemedicine. After having their Day 1 appointment at one of the ASFs, patients in the TMAB pilot programs were provided with a combination-coded secure lockbox containing their doses of mifepristone and misoprostol, as well as nausea medication and ibuprofen to take home. After the required 24-hour waiting period had passed, the patient could have their Day 2 appointment via telemedicine from their home or another location of their choosing. During this appointment, the physician confirmed the patient's decision to proceed, confirmed the patient had not had a change in symptoms, answered any questions the patients may have had, and finally, gave the patient the combination code to the lockbox. The physician then observed the patient ingesting the mifepristone. The patient then took the misoprostol 24 to 48 hours later. However, this Court's injunctions enjoining enforcement of the Challenged Laws, in combination with the 24-Hour PI, have rendered this model unnecessary, and Plaintiffs have instead been evaluating alternative models for offering TMAB.

89. PPGOH and PPSWO's experiences with TMAB have been very positive. TMAB services are equivalent in quality to those provided in-person on Day 2 at those clinics' ASFs, and

for many patients, the TMAB option is superior in meeting their preferences and needs. The TMAB process also helps reduce patients' travel burden and related delays.

c. Impact of the Telemedicine Ban on Patients and Providers

90. If allowed to go into effect, the Telemedicine Ban would burden, penalize, interfere with, and, in some cases, may prohibit patients' exercise of their right to abortion, and providers' efforts to assist them in doing so. Indeed, PPSWO, PPGOH, and Dr. Liner would be prevented from offering TMAB entirely.

91. The Telemedicine Ban also discriminates against abortion care compared to all other forms of health care. For example, it does not affect the provision by telemedicine of medication used to manage miscarriage, even though such medication is often identical to that used for medication abortion.

92. The Telemedicine Ban also does nothing to advance patient health in accordance with widely accepted and evidence-based standards of care. According to the National Academies of Sciences, Engineering, and Medicine ("NASEM"), "[t]here is no evidence that the dispensing or taking of mifepristone tablets requires the physical presence of a clinician . . . to ensure safety or quality. The effects of mifepristone occur after women leave the clinic, and extensive research shows that serious complications are rare."[10] Similarly, the American College of Obstetricians and Gynecologists ("ACOG") has concluded that patients can "safely and effectively" use mifepristone and misoprostol at home for medication abortion.[11]

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[10] Nat'l Academies of Sciences, Eng. & Medicine, The Safety & Quality of Abortion Care in the United States 79 (2018).

[11] ACOG, *Medication Abortion Up to 70 Days of Gestation*, Practice Bulletin No. 225 (Oct. 2020), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation#:~:text=Patients%20can%20safely%20and%20effectively,who%20undergo%20a%20medication%20abortion. ACOG is a professional membership organization for obstetrician–gynecologists.

93. Complications from medication abortion are exceedingly rare, and when such complications arise, it would not matter whether the patient obtained a medication abortion in person or through telemedicine because such events most commonly occur only after the patient has taken the second medication, misoprostol, which occurs at least 24 hours after they have left the clinic.

94. Absent the 24-Hour PI and this Court's injunction on enforcement of the Telemedicine Ban, the Telemedicine Ban would force abortion patients in Ohio to make at least two trips to the clinic. Forcing more abortion patients to make at least two separate visits to the clinic for care imposes tangible burdens and costs on them and creates significant logistical barriers to accessing time-sensitive abortion care.

95. Without the 24-Hour PI and this Court's injunction on enforcement of the Telemedicine Ban, the Telemedicine Ban would force abortion patients who could have otherwise made only one visit to the clinic to take more time off from work or away from school, arrange and pay for additional child care, arrange and pay for additional transportation to and from the clinic on different days, and/or find and pay for overnight accommodations near the clinic, particularly for those traveling from further distances. In many cases, patients would have to overcome all of these obstacles to return to the clinic simply so their physician can hand them medication.

96. These financial and logistical barriers would be particularly burdensome and harmful for already vulnerable groups, including poor or low-income patients who constitute a majority of people seeking abortion. These patients often have particular difficulty getting time off work due to inflexible scheduling at low-wage jobs, and even if they are able to get days off, they often work in jobs that do not provide paid leave and therefore may forgo wages for time

away from work. Low-income patients would possibly also need to delay their second appointment to save up enough money to afford the expense of additional child care and costs.

97. Patients whose access to abortion would be delayed by the Telemedicine Ban may also suffer increased medical risks associated with delaying their abortion or continuing pregnancy—because, as noted above, while abortion is very safe, its risks increase as pregnancy progresses. And, absent this Court's injunction on the Evidence-Based Use Ban, some patients could lose the ability to access medication abortion altogether if the pregnancy extended beyond Ohio's 70-day LMP limit.

98. Without the 24-Hour PI and this Court's injunction on enforcement of the Telemedicine Ban, the Telemedicine Ban may create barriers that, for some patients, would so delay their access that they cannot have an abortion at all.

99. If allowed to go into effect, the Telemedicine Ban would cause irreparable harm to both patients and to PPSWO, PPGOH, and Dr. Liner, who would be forced to stop providing constitutionally protected health care to their patients and be threatened with criminal and civil penalties.

100. In sum, the Telemedicine Ban burdens, penalizes, interferes with, discriminates against and, in some cases, may prohibit patients' voluntary exercise of their right to make and carry out their own reproductive decisions, including the decision to obtain medication abortion, and inhibits PPSWO, PPGOH, and Dr. Liner from assisting patients in exercising this right, without any countervailing benefit to patient health.

2. APC Ban

101. The APC Ban prevents health care providers who are not physicians from providing medication abortion. R.C. 2317.56(B), 2919.11, 2919.123, 4723.28(B)(30), 4723.44(B)(6), 4723.50(B)(1), 4723.151(C), 4730.02(E), 4730.03(F), 4730.25(B)(24), 4730.39(B)(2),

4730.42(A)(1); Ohio Adm.Code 3701-47-01, 4723-9-10(K), 4730-2-07(E). Even with certain provisions of the APC Ban enjoined, additional restrictions remain in effect which continue to prevent Plaintiffs from commencing APC-provided medication abortion. Without an injunction on the enforcement of the APC Ban, advanced practice clinicians cannot prescribe "any drug or device to perform or induce an abortion, or otherwise perform or induce an abortion." R.C. 4723.44(B)(6) (advanced practice registered nurses ("APRNs" [12])), 4730.02(E) (PAs); *see also* Ohio Adm.Code 4723-9-10(K) (APRNs), 4730-2-07(E) (PAs). Any APC who does so may be subject to disciplinary action, including the revocation or suspension of their license to practice as an APC. *See* R.C. 4723.28(B)(30) (APRNs); 4730.25(B)(24) (PAs). Ohio law further restricts APCs by preventing any person from providing, selling, dispensing, or administering mifepristone "for the purpose of inducing an abortion in any person or enabling the other person to induce an abortion in any person," unless that person is a physician. R.C. 2919.123(A).

102. Ohio law also provides that abortion constitutes the practice of medicine or surgery, *see* R.C. 2919.11, Ohio Adm.Code 3701-47-01, and that medicine or surgery may only be practiced or performed by a person licensed by the Medical Board, *see* R.C. 4731.41(A).

103. Lastly, as explained above, absent the 24-Hour PI, Ohio law would require the Day 1, mandatory, in-person information session to be completed by a physician. *See* R.C. 2317.56(B)(1). Thus, APCs could not obtain informed consent from abortion patients. In conjunction, these provisions would establish the requirement that only physicians may provide abortions in Ohio.

104. The APC Ban burdens, penalizes, interferes with, and discriminates against patients' right to abortion, and prohibits APCs from assisting such patients by providing

[12] NPs and CNMs are two types of APRNs.

medication abortions. Even with the Court's preliminary injunction of certain aspects of the APC Ban, Plaintiffs are prevented from training currently employed APCs and/or seeking to hire APCs to provide medication abortions due to additional restrictions that remain in effect.

a. APCs' Scope of Practice in Ohio

105. APCs are health care professionals who have completed advanced education in a specific area of health care. APCs include NPs, CNMs, and PAs. In Ohio, APCs' scope of practice is highly regulated. Even so, APCs are delegated broad authority by the Medical Board, in the case of PAs, and the Nursing Board, in the case of NPs and CNMs.

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

107. With appropriate education and training, APCs are highly qualified to provide medication abortions.

108. Ohio APCs currently perform a variety of reproductive health interventions of greater technical complexity that require more advanced skills than administering a medication abortion. For example, consistent with their training and experience, APCs can insert and remove intrauterine devices ("IUDs") and contraceptive implants; and perform colposcopies.

109. APCs are subject to Ohio's generally applicable professional licensure, health, and tort laws and regulations. For instance, the Medical Board has the power to place PAs on probation, impose sanctions or civil penalties, or suspend or revoke their licenses or prescriber number for a variety of acts or conduct. R.C. 4730.25, 4730.252. The Nursing Board has the same power to discipline NPs and CNMs. R.C. 4723.28.

110. APCs also face criminal penalties for violating the APC Ban. *See* R.C. 2919.123(E), 4723.99(A) (APRNs), 4730.99 (PAs).

i. Nurse Practitioners

111. NPs are regulated by the Nursing Board, and in order to practice, must be a registered nurse, be certified by an approved national certification organization, hold a master's or higher degree in nursing or a related field, and have completed a graduate-level NP education program. R.C. 4723.41, 4723.482(A)–(B). NPs are required to renew their license to practice nursing every two years and complete continuing nursing education credits, of which at least twelve hours must be in advanced pharmacology from an accredited institution. *See* R.C. 4723.24(A)(1)(c), (C)(2)(c).

112. NPs have a broad scope of practice by virtue of their advanced education and training. Under Ohio law, NPs' scope of practice includes performing medical procedures and prescribing controlled substances, appropriate to their education and experience. R.C. 4723.43(C).

113. By virtue of their skill and competency, NPs are authorized under Ohio law to practice with a high degree of independence, so long as they have entered into a standard care arrangement with a primary supervising physician. *See* R.C. 4723.43, 4723.431; Ohio Adm.Code 4723-8-04. While physicians can enter into standard care arrangements with more than five nurses, physicians cannot collaborate at the same time with over five nurses "in the prescribing component[s] of their practices." R.C. 4723.431(A)(1). Additionally, while the supervising physician must be "continuously available to communicate" with the NP "either in person, or by electronic communication," the physician is not required to be physically present when the NP is practicing. Ohio Adm.Code 4723-8-01(B)(1).

ii. Certified Nurse-Midwives

114. Like NPs, CNMs are regulated by the Nursing Board. In order to practice, CNMs must obtain a master's or doctoral degree with a major in nursing specialty or in a related field and pass a national CNM certification examination. R.C. 4723.41(A). CNMs must renew their license

to practice nursing every two years and complete continuing nursing education credits, of which at least twelve hours must be in advanced pharmacology from an accredited institution. R.C. 4723.24(A)(1)(c), (C)(2)(c).

115. It is within CNMs' scope of practice in Ohio to manage preventive and primary care services necessary to provide health care to women during pregnancy, labor, and birth, attend to normal vaginal deliveries, and repair vaginal tears. As part of their practice, CNMs regularly treat and monitor maternal risks, including vaginal tears, postpartum hemorrhage, and more—all of which are routine and carry higher risks to patient health than the risks associated with medication abortion.

116. Ohio statutes expressly permit CNMs to prescribe medications, attend patients in uncomplicated labor, and perform procedures associated with childbirth (*i.e.*, episiotomies and repair of vaginal tearing). R.C. 4723.43(A). In emergencies, CNMs can "perform version, deliver breech or face presentation, use forceps, do any obstetric operation, or treat any other abnormal condition." *Id.*

117. By virtue of their skill and competency, CNMs are authorized under Ohio law to practice with a high degree of independence, so long as they have entered into a standard care agreement with a primary supervising physician. Ohio Adm.Code 4723-8-04. Although physicians may enter in standard care arrangements with more than five nurses, they are limited to collaborating with no more than five nurses at the same time "in the prescribing component[s] of their practices." R.C. 4723.431(A)(1). Additionally, while the primary or back-up supervising physician must be "continuously available to communicate" with the CNM "either in person, or by electronic communication," the physician is not required to be physically present when the CNM is practicing. Ohio Adm.Code 4723-8-01(B)(2).

iii. Physician Assistants

118. PAs are regulated by the Medical Board, must be licensed, must generally complete a master's or higher degree from an accredited organization or program, and must complete 12 hours of continuing medical education every two years. R.C. 4730.11, 4730.14, 4730.49(A)(1).

119. A PA may perform "services authorized by the supervising physician" that are within the "supervising physician's normal course of practice and expertise." R.C. 4730.20(A).

120. PAs can also see patients in ways similar to physicians. Within their scope of practice, and consistent with their training and qualifications, PAs can perform comprehensive physical exams, order and interpret diagnostic tests, diagnose and initiate treatment, assist physicians in surgery, and perform bedside procedures, among other forms of care.

121. By virtue of their skill and competency, PAs are authorized by Ohio law to practice with a high degree of independence, so long as they practice under a "supervising physician." R.C. 4730.02. As in the case of NPs and CNMs, this does not require the supervising physician's physical presence, provided the physician is "continuously available for direct communication" with the PA through other means. R.C. 4730.21(A)(1). Physicians are not allowed to supervise over five PAs at a time, but a PA may enter into supervision agreements "with any number of supervising physicians." R.C. 4730.21(B).

122. PAs can order, prescribe, personally furnish, and administer drugs and medical devices, including controlled substances, so long as the PA "holds a valid prescriber number issued by the state medical board and has been granted physician-delegated prescriptive authority." R.C. 4730.20(A)(7), 4730.41.

b. Ohio Law Bars APCs from Providing Medication Abortions Even When Doing So Would Be Within Their Scope of Practice

123. Although this Court has enjoined certain aspects of the APC Ban, Ohio law as drafted prohibits APCs from providing medication abortion despite their qualifications, training, and experience. The APC Ban is out of step with Ohio's scope of practice regulations, as evidenced by the fact that APCs may legally provide the same medications used in medication abortion—mifepristone and misoprostol—for other purposes, such as miscarriage management. There is no medical basis for prohibiting APCs from prescribing and overseeing the use of these same medications for a medication abortion, consistent with their training and experience.

124. Preventing APCs from prescribing certain medications solely in the abortion context is particularly burdensome and discriminatory, as Ohio law does not categorically prevent APCs from handling pre- and post-medication abortion patient care. APCs may, for example, perform an ultrasound, pregnancy test, and/or other lab tests for the patient. In addition, APCs are trained to recognize circumstances when they would need to refer a patient to a physician, should the patient need a higher level of care.

c. Evidence Demonstrates APCs Can Safely and Effectively Provide Medication Abortion

125. There is no medical basis for the APC Ban, because widely accepted, evidence-based standards of care support appropriately trained APCs providing medication abortion.

126. APCs are capable of providing medication abortion safely and effectively. NASEM concluded in their 2018 consensus report that "[b]oth trained physicians . . . and APCs (physician assistants, certified nurse-midwives, and nurse practitioners) can provide medication .

. . abortions safely and effectively," citing an "extensive body of research documenting the safety of abortion care in the United States."[13]

127. Leading medical authorities, including ACOG, the American Public Health Association, the World Health Organization, and Physicians for Reproductive Health have concluded that laws prohibiting qualified APCs from providing medication abortion services prevent access to safe abortion care.

128. Indeed, the FDA has contemplated APC prescription of mifepristone since its approval in 2000. The 2000 label allowed APCs to prescribe mifepristone without a physician's physical presence, provided the APC was supervised by a physician. The 2016 label removed all restrictions on APC prescription, allowing them to prescribe mifepristone fully independently.

129. Of the states in which abortion is legal, twenty-one states and the District of Columbia allow APCs to provide medication abortion care.

130. PPSWO currently employs APCs, including NPs and CNMs. Absent injunctive relief, PPSWO is prevented from training its current APCs to provide medication abortion, and seeking to hire additional APCs as needed.

131. PPGOH currently employs APCs, including NPs. Absent injunctive relief, PPGOH is prevented from training its current APCs to provide medication abortion.

132. Preterm is not currently staffed with APCs but, absent injunctive relief, Preterm is prevented from seeking to hire and train APCs to provide medication abortion.

[13] Nat'l Academies of Sciences, Eng. & Medicine, The Safety & Quality of Abortion Care in the United States 14 (2018).

133. While certain aspects of the APC Ban have been enjoined, certain restrictions remain in place that are preventing the APC provision of medication abortion at PPSWO, PPGOH, and Preterm.

134. APCs at PPSWO and PPGOH, including Plaintiff Quinn, perform procedures, including IUD and contraceptive implants insertion and removal, that are either comparable in complexity and risk to medication abortion, or are even more complex and risky than medication abortion.

135. APCs at PPSWO and PPGOH, including Plaintiff Quinn, are highly qualified and trained clinicians who, but for the APC Ban, would be trained to provide safe medication abortion care through the appropriate collaborative practice and supervisory arrangements with physicians.

d. The APC Ban Harms Patients and Providers

136. By unnecessarily limiting the pool of available medication abortion providers in Ohio, absent an injunction, the APC Ban significantly restricts and delays access to abortion and contradicts widely accepted and evidence-based standards of care, thereby jeopardizing (rather than advancing) patient health and safety and imposing significant financial and logistical burdens on clinics and patients.

137. The APC Ban burdens, penalizes, discriminates against, and interferes with Ohioans' fundamental constitutional right to abortion because it subjects medication abortion patients to unnecessary delays in accessing care, which increases risks to patient health and adds to the financial and logistical burdens of obtaining an abortion.

138. The APC Ban also burdens, penalizes, discriminates against, and interferes with providers' ability to assist Ohioans seeking to exercise this fundamental right to make reproductive decisions. APCs are expressly prohibited from providing medication abortions, forcing patients

to rely on physicians at ASFs and effectively limiting the number of patients that can access medication abortions.

139. There is a nationwide shortage of reproductive health care providers, and Ohio is no exception. Absent injunctive relief, Plaintiffs are prevented from expanding the pool of qualified professionals able to provide medication abortion care in Ohio to include APCs. This means Ohioans have a smaller pool of providers and fewer appointments from which to obtain medication abortion care, decreasing schedule flexibility for both Plaintiffs and their patients and increasing delays and travel burdens.

140. Having a limited pool of medication abortion providers does not advance patient health and instead causes medically unnecessary delays that may harm patients' health in a number of ways. Delays subject patients to the risks associated with pregnancy for a longer period of time and force patients to obtain care later in pregnancy, which increases the associated risks of an abortion, despite its overall safety. In some cases, delaying access to care can push a patient past the point in pregnancy when medication abortion is available.

141. If the APC Ban were fully enjoined, PPSWO and PPGOH could provide medication abortion at their non-ASF health centers, rather than just at their ASFs. This would reduce the distance traveled by some patients to receive medication abortion care.

142. If the APC Ban were fully enjoined, the Plaintiff clinics could hire and train APCs to provide medication abortion care, expanding access.

143. In sum, absent injunction, the APC Ban burdens, penalizes, interferes with, discriminates against and, in some cases, may prohibit patients' voluntary exercise of their right to make and carry out their own reproductive decisions, including the decision to obtain medication

abortion, and inhibits Plaintiffs from assisting patients in exercising this right, without any countervailing benefit to patient health.

3. Evidence-Based Use Ban

144. Although currently enjoined, the Evidence-Based Use Ban would otherwise restrict the use of mifepristone solely for abortion care, despite best medical evidence, by mandating that providers use the drug for abortion only in accordance with the FDA's final printed label. This prohibition on other uses of mifepristone not expressly included in the label, also known as "evidence based" or "off-label use," would burden, penalize, interfere with, discriminate against and, in some cases, possibly prohibit patients' access to abortion and would inhibit Plaintiffs from assisting patients in exercising their right to abortion.

145. In 2004, the Ohio General Assembly enacted R.C. 2919.123—the Evidence-Based Use Ban—a first-of-its-kind restriction on the off-label use of mifepristone.

146. The Evidence-Based Use Ban criminalizes providing mifepristone for abortion care except "in accordance with all provisions of federal law that govern the use of RU-486 (mifepristone) for inducing abortions." R.C. 2919.123(A), 2919.123(F)(1).

147. The Supreme Court of Ohio has interpreted the Evidence-Based Use Ban to mean that a physician providing mifepristone for the purpose of inducing an abortion may do so "only by using the dosage indications and treatment protocols expressly approved by the FDA in the drug's final printed labeling as incorporated by the drug approval letter." *Cordray v. Planned Parenthood Cincinnati Region*, 122 Ohio St.3d 361, 2009-Ohio-2972, 911 N.E.2d 871, ¶ 35 (Ohio 2009).

148. The FDA's approved drug regimen is the result of a lengthy review process. In order to obtain FDA approval to market a drug product in the United States, a manufacturer submits an application containing evidence that the drug is safe and effective for its intended use.

If the FDA determines that the drug's health benefits outweigh its known risks for that particular use, the FDA approves the drug for sale along with its proposed label.

149. To ensure the drug's benefits outweigh its risks, the FDA may require a Risk Evaluation and Mitigation Strategy ("REMS"). 21 U.S.C. § 355-1(a)(1). In 2011, the FDA approved a REMS for mifepristone that incorporated the same conditions of use the agency had imposed when first approving mifepristone in 2000.[14] Despite the proven safety of mifepristone in the two decades since its approval, and despite broad calls from the medical community to eliminate it based on mifepristone's safety record, FDA has kept a REMS in place.[15]

150. The current FDA-approved mifepristone regimen, which was established in 2016, includes 200 mg of mifepristone taken orally, followed 24 to 48 hours later by 800 µg of misoprostol taken buccally, through 70 days LMP.

151. Absent the Evidence-Based Use Ban injunction, if a provider prescribed mifepristone to terminate a pregnancy in a way that differed from this regimen—in other words, if they prescribed mifepristone "off-label"—they would be "guilty of unlawful distribution of an abortion-inducing drug, a felony of the fourth degree" under Ohio law, and also subjected to administrative penalties, including revocation of professional licenses. R.C. 2919.123(E). For a second violation, the provider would be guilty of a felony in the third degree. *Id.*

a. Evolution and Benefits of Off-Label Use

152. Off-label use of medications pursuant to evidence-based protocols is an essential part of medical practice. In clinical practice, new uses or dosing regimens often become widely adopted and well accepted long before they are reflected in the drug's final printed labeling. Off-

[14] The FDA implemented restrictions for mifepristone when first approving its use, under a provision then known as "subpart H," 21 C.F.R. §§ 314.500–560, and later under a REMS.

[15] On March 29, 2016, the FDA approved changes to mifepristone's label, including its REMS.

label protocols are supported by evidence-based medical practices and providers' exercise of their professional judgment in caring for their patients.

153. Examples of common off-label protocols abound and include prescribing aspirin to prevent heart attacks, Wellbutrin, approved by the FDA as an antidepressant, for smoking cessation, laxatives for children with constipation,[16] and Lidocaine to treat complications from shingles.[17]

154. Ohio does not restrict off-label use of the vast majority of drugs. Upon information and belief, such restrictions are only in effect for mifepristone for abortion and certain Schedule III anabolic steroids, *see* R.C. 3719.06(B), which exhibit significantly higher rates of adverse effects than mifepristone.

155. In Ohio, off-label protocols are even protected in certain areas. For example, as long as a drug has been recognized as safe and effective for treatment, R.C. 1751.66(A) prohibits insurance providers from "exclud[ing] coverage for any drug approved by the [FDA] on the basis that the drug has not been approved by the [FDA] for the treatment of the particular indication for which the drug has been prescribed."

156. The Evidence-Based Use Ban singles out patients and abortion providers using mifepristone for abortion care for differential and unfavorable treatment because Ohio law does not impose similar restrictions on the off-label use of mifepristone for other purposes, including miscarriage management.

157. Mifepristone is a case in point of how off-label use can become the standard of medical care well before the FDA formally approves the protocol.

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[16] Divya Hoon et al., *Trends in Off-Label Drug Use in Ambulatory Settings: 2006–2015*, 144(4) Pediatrics 5–6 (2019).

[17] Christopher M. Wittich et al., *Ten Common Questions (and Their Answers) About Off-Label Drug Use*, 87(10) Mayo Clinic Proc. 982 (2012).

158. The FDA originally approved mifepristone for use in the United States for abortion care in 2000 using 600 mg of mifepristone, followed two days later by 400 μg of misoprostol, through 49 days LMP.

159. Even before the FDA's approval of mifepristone, newer research had been conducted showing that a lower dosage (200 mg) of mifepristone combined with a different dosage and manner of administering misoprostol was equally safe and effective through 63 days LMP. This research also showed that reducing the mifepristone dose decreased side effects. As a result, for almost two decades after mifepristone was first approved for use by the FDA, the regimen most commonly used across the country was a regimen that differed from that detailed in the approved label at the time.

160. In 2016, the FDA approved several changes to mifepristone's label, including its REMS, expressly relying on this evidence-based regimen, which had become the standard of care in clinical practice. This update resulted in the current label outlining a regimen of 200 mg of mifepristone taken orally, followed 24 to 48 hours later by 800 μg of misoprostol taken buccally, through 70 days LMP.

161. Additional safe, validated off-label uses of mifepristone have made, and will likely continue to make, abortion safer and more accessible.

162. For example, subsequent research shows that a regimen of mifepristone and misoprostol is safe and effective beyond 70 days LMP.[18]

163. Although currently enjoined, the Evidence-Based Use Ban would also restrict the prescription of misoprostol when it is prescribed as part of a medication abortion regimen that

[18] *See, e.g.*, Ilana G. Dzuba et al., *A Repeat Dose of Misoprostol 800 mcg Following Mifepristone for Outpatient Medical Abortion at 64–70 and 71–77 Days of Gestation: A Retrospective Chart Review*, 102(2) Contraception 104, 106 (2020); Nathalie Kapp et al., *Medical Abortion in the Late First Trimester: A Systematic Review*, 99(2) Contraception 77, 77–86 (Feb. 2019).

includes mifepristone. For example, while some patients prefer to take misoprostol orally or vaginally, the FDA label specifies that it should be taken buccally, so providers could not employ these alternative routes of administration for misoprostol when the drug is being used in tandem with mifepristone for abortion, even though they have been shown to be safe and effective.

b. The Evidence-Based Use Ban's Impact on Patients and Providers

164. By prohibiting off-label uses of mifepristone for abortion care, the Evidence-Based Use Ban violates Ohioans' right to make and carry out their own reproductive decisions and interferes with Plaintiffs' ability to assist them in doing so.

165. For many patients, including some of Plaintiffs' patients, an evidence-based, off-label mifepristone regimen is the safest and most effective way to obtain an abortion. Many patients also strongly prefer medication abortions over procedural abortions.

166. Prohibiting off-label use of mifepristone for abortion care would impede access by, among other things, prohibiting these patients from obtaining medication abortion, exacerbating the psychological and emotional toll for those who find a more invasive procedural abortion to be uncomfortable or traumatic; and erecting barriers in the form of travel and its associated costs, such as lost wages and expenses for child care, transportation, and accommodations.

167. Further, patients who would otherwise be unable to undergo a procedural abortion, whether because of medical indications, trauma, or concerns around bodily control, would be left either to attempt to travel out of state to access medication abortion, obtain a medication abortion outside the medical system, or in some cases, potentially even to carry an unwanted pregnancy to term.[19]

[19] These harms are only exacerbated by the Day 1 and Day 2 visit requirement because the delays resulting from that requirement can push a patient beyond 70 days LMP before the patient is able to access medication abortion services. *See supra* ¶¶ 71–72.

168. But for the injunction of the Evidence-Based Use Ban, Plaintiffs would be prohibited from prescribing mifepristone for the termination of pregnancies beyond 70 days LMP based on the best available medical evidence.

169. As research continues to progress, additional validated, effective off-label uses of mifepristone for abortion care may be identified, which will continue to make abortion safer and more accessible. But, by prohibiting off-label use of mifepristone for abortions, the Evidence-Based Use Ban would prevent patients from benefiting from such advances.

170. Restricting off-label use of mifepristone for abortions does not advance patient health in accordance with widely accepted and evidenced-based standards of care. To the contrary, it risks harming patient health by restricting Plaintiffs' discretion to use the most appropriate, safest, and evidenced-based treatment for their patients and thereby preventing some patients from obtaining their preferred method of abortion; delaying their care while they attempt to travel out of state for medication abortion; or putting them in the position of having to try to obtain a medication abortion outside the medical system or carry an unwanted pregnancy to term.

171. As demonstrated through historical practice and clinical research, evidence-based, off-label protocols for mifepristone are safe and effective, and providers outside of Ohio routinely prescribe mifepristone, as with many drugs, off-label in accordance with evidence-based standards of care, their best medical judgment, and patients' wishes and best interest.

172. The Evidence-Based Use Ban's discriminatory nature and failure to advance patient health is further evidenced by the law's selective restrictions on mifepristone "for the purpose of inducing an abortion" without comparable restrictions on mifepristone in other contexts, including for managing miscarriages. There is simply no medical justification for restricting one and not the other.

173. In sum, absent this Court's injunction, the Evidence-Based Use Ban would burden, penalize, interfere with, discriminate against and, in some cases, possibly prohibit patients' voluntary exercise of their right to make and carry out their own reproductive decisions, including the decision to obtain medication abortion, and would inhibit Plaintiffs from assisting patients in exercising this right, without any countervailing benefit to patient health.

2. CLAIMS FOR RELIEF

COUNT I – Right to Reproductive Freedom

174. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171.

175. Under the Ohio Constitution, "[e]very individual has a right to make and carry out one's own reproductive decisions" including the decision to obtain an abortion, and the State "shall not, directly or indirectly, burden, penalize, prohibit, interfere with, or discriminate against" any "individual's voluntary exercise of" the right to abortion, or "[a] person or entity that assists an individual exercising this right, unless the State demonstrates that it is using the least restrictive means to advance the individual's health in accordance with widely accepted and evidence-based standards of care." Ohio Const., art. I, § 22(A)–(B).

176. The Challenged Laws impose onerous and unnecessary requirements that delay, impede, and, in some cases, may prevent access to abortion, create financial and logistical obstacles to obtaining an abortion, undermine patient self-determination, and discriminate against abortion patients and providers, singling them out for differential and unfavorable treatment. In doing so, the Challenged Laws—the Telemedicine Ban[20], the APC Ban, and the Evidence-Based Use Ban—each individually and in combination, directly and indirectly burden, penalize, prohibit,

[20] WMGPC and Preterm are not challenging the Telemedicine Ban.

interfere with, and discriminate against both Ohioans' right to make and carry out the decision to have an abortion, including a medication abortion, and Plaintiffs in assisting their patients in exercising that right.

177. The Challenged Laws are not "the least restrictive means to advance the individual's health in accordance with widely accepted and evidence-based standards of care." The Challenged Laws have no legitimate medical justification, contradict evidence-based best medical practice, the standard of care, and mainstream medical consensus, and serve only to harm patients' health and well-being.

178. Accordingly, the Challenged Laws violate Article I, Section 22 of the Ohio Constitution.

179. Plaintiffs and their patients have no adequate remedy at law to address these harms.

COUNT II – Substantive Due Process

180. PPGOH, PPSWO, and Dr. Liner reallege and incorporate by reference the allegations contained in paragraphs 1 through 171.

181. By prohibiting access to safe and effective TMAB, the Telemedicine Ban infringes on the right to pre-viability abortion, privacy, bodily autonomy, and free choice of health care guaranteed under the Ohio Constitution, Article I, Sections 1, 2, 16, and 20, without adequate justification.

182. If the Telemedicine Ban is allowed to take effect, PPGOH, PPSWO, and Dr. Liner and their patients will be unable to offer and use TMAB in Ohio, thereby causing them to suffer significant constitutional, medical, emotional, financial, and other harm. PPGOH, PPSWO, and Dr. Liner have no adequate remedy at law to address these harms.

COUNT III – Patients' Equal Protection

183. PPGOH, PPSWO, and Dr. Liner reallege and incorporate by reference the allegations contained in paragraphs 1 through 171.

184. The Telemedicine Ban denies PPGOH, PPSWO, and Dr. Liner's patients their right to the enjoyment of equal protection and benefit under the Ohio Constitution, Article I, Section 2, by singling out medication abortion for worse treatment than comparable types of health care freely offered via telemedicine, including forms of health care sought by men, without adequate justification.

185. If the Telemedicine Ban is allowed to take effect, PPGOH, PPSWO, and Dr. Liner's patients will be deprived of equal protection of the laws under the Ohio Constitution, thereby causing them to suffer significant constitutional, medical, emotional, financial, and other harm. PPGOH, PPSWO, and Dr. Liner have no adequate remedy at law to address these harms.

COUNT IV – Abortion Providers' Equal Protection

186. PPGOH, PPSWO, and Dr. Liner reallege and incorporate by reference the allegations contained in paragraphs 1 through 171.

187. The Telemedicine Ban denies PPGOH, PPSWO, and Dr. Liner their right to the enjoyment of equal protection and benefit under the Ohio Constitution, Article I, Section 2, by targeting abortion providers with criminal penalties and professional sanctions for providing medication abortion using telemedicine, while leaving unrestricted other medical providers, including those who treat miscarriage using the exact same medications as in medication abortion, without adequate justification.

188. If the Telemedicine Ban is allowed to take effect, PPGOH, PPSWO, and Dr. Liner will be subject to irreparable harm by depriving them of equal protection of the laws under the Ohio Constitution, thereby causing them to suffer significant constitutional, business, and

professional harm and threatening them with civil and criminal penalties. PPGOH, PPSWO, and Dr. Liner have no adequate remedy at law to address these harms.

COUNT V – Declaratory Judgment

189. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 171.

190. A real controversy exists between the parties, the controversy is justiciable, and speedy relief is necessary to preserve the rights of the parties. Plaintiffs and their patients are adversely affected by the Challenged Laws, as set forth herein.

191. The rights, status, and other legal relations of Plaintiffs are uncertain and insecure, and the entry of a declaratory judgment by this Court will terminate the uncertainty and controversy that has given rise to the action.

192. Pursuant to R.C. 2721.01, et seq., Plaintiffs request that the Court find and issue a declaration that:

a. The Challenged Laws violate Article I, Section 22 of the Ohio Constitution because they burden, penalize, prohibit, interfere with, and discriminate against Ohioans in exercising their constitutional right to abortion and those who assist them in doing so;

b. The Telemedicine Ban violates Article I, Sections 1, 2, 16, and 20 of the Ohio Constitution by denying PPGOH, PPSWO, and Dr. Liner and their patients substantive due process rights to previability abortion, privacy, bodily autonomy, and free choice in health care;

c. The Telemedicine Ban violates Article I, Section 2 of the Ohio Constitution by denying PPGOH, PPSWO, and Dr. Liner's patients the equal protection and benefit of the law, in that it singles out medication abortion via telemedicine from all other comparable forms of care, including care obtained by men and miscarriage management, without adequate justification; and

d. The Telemedicine Ban violates Article I, Section 2 of the Ohio Constitution by denying PPGOH, PPSWO, and Dr. Liner the equal protection and benefit of the law, in that it singles out abortion providers for criminal and civil sanctions while leaving unregulated other health care providers offering comparable services without adequate justification.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs ask this Court:

A. To keep in place and modify the preliminary injunction, and later enter a permanent injunction, restraining Defendants, their employees, agents, servants, and successors, and any persons in active concert or participation with them, from enforcing the APC Ban (R.C. 2317.56(B), 2919.11, 2919.123, 4723.28(B)(30), 4723.44(B)(6), 4723.50(B)(1), 4723.151(C), 4730.02(E), 4730.03(F), 4730.25(B)(24), 4730.39(B)(2), 4730.42(A)(1); Ohio Adm.Code 3701-47-01, 4723-9-10(K), 4730-2-07(E)), the Evidence-Based Use Ban (R.C. 2919.123), and any other Ohio statute or regulation that could be understood to give effect to those provisions, including through any future enforcement actions based on conduct that occurred during the pendency of an injunction;

B. To keep in place the preliminary injunction, and later enter a permanent injunction, restraining Defendants, their employees, agents, servants and successors, and any persons in active concert or participation with them, from enforcing the Telemedicine Ban (R.C. 2919.124), and any other Ohio statute or regulation that could be understood to give effect to that provision, including through any future enforcement actions based on conduct that occurred during the pendency of an injunction; and

C. To grant such other and further relief as the Court deems just and proper.

Respectfully submitted,

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