IN THE SUPREME COURT OF IOWA

No. 14–1415

Filed June 19, 2015

PLANNED PARENTHOOD OF THE HEARTLAND, INC. and **JILL MEADOWS,**

Appellants,

vs.

IOWA BOARD OF MEDICINE,

Appellee.

Appeal from the Iowa District Court for Polk County, Jeffrey D. Farrell, Judge.

Providers appeal a district court judgment upholding a rule by the Iowa Board of Medicine establishing standards of practice for physicians who prescribe or administer abortion-inducing drugs. **AFFIRMED IN PART AND REVERSED IN PART.**

Alice Clapman of Planned Parenthood Federation of America, Washington, D.C., Sharon K. Malheiro of Davis, Brown, Koehn, Shors & Roberts, P.C., Des Moines, and Roger Evans of Planned Parenthood Federation of America, New York, New York, for appellant.

Thomas J. Miller, Attorney General, Jeffrey S. Thompson, Solicitor General, and Julie J. Bussanmas and Meghan L. Gavin, Assistant Attorneys General, for appellee.

Paige Fiedler of Fiedler & Timmer, P.L.L.C., Urbandale, and Holly A. Harrison, Lynn D. Fleisher, Ph.D., Patrick E. Croke, Daniel C. Craig, and Andrew Chinsky of Sidley Austin LLP, Chicago, Illinois, for amicus curiae American College of Obstetricians and Gynecologists.

Roxanne Barton Conlin of Roxanne Conlin & Associates, P.C., Des Moines, for amici curiae Iowa Coalition Against Sexual Assault, Iowa Coalition Against Domestic Violence, and National Women's Law Center.

Joe Austen of Austen Law Office, PLLC, West Des Moines, and Rita Bettis of ACLU of Iowa, Des Moines, for amicus curiae American Civil Liberties Union of Iowa.

Mailee R. Smith of Americans United for Life, Washington, D.C., and Arthur F. Gilloon of Gilloon, Wright & Hamel PC, Dubuque, for amici curiae Physicians for Life, National Association of Pro Life Nurses, Christian Medical Association, National Association of Catholic Nurses, and The National Catholic Bioethics Center.

Timm Reid of Galligan & Reid, P.C., Des Moines, and Michael J. Norton and Natalie L. Decker of Alliance Defending Freedom, Greenwood Village, Colorado, for amici curiae American Association of Pro-Life Obstetricians & Gynecologists, Donna Harrison, M.D., Iowa Right to Life, and Susan Thayer.

Matthew F. Heffron and Christine F. Delgado of Brown & Brown, P.C., L.L.O., Omaha, Nebraska, Patrick D. Smith of Bradshaw, Fowler, Proctor & Fairgrave, P.C., Des Moines, and Thomas Brejcha of Thomas More Society, Chicago, Illinois, for amici curiae Catholic Medical Association, Catholic Medical Association—Des Moines Guild, Catholic Medical Association—St. Thomas Aquinas Guild of the Quad Cities, Iowans for Life, and Women's Choice Center of the Quad Cities.

WIGGINS, Justice.

In 2013, the Iowa Board of Medicine passed a rule establishing standards of practice for physicians who prescribe or administer abortion-inducing drugs. These standards require the physician to personally perform a physical examination and to be physically present when the abortion-inducing drug is provided. It is not disputed the rule would have the effect of prohibiting telemedicine abortions in Iowa.

Planned Parenthood of the Heartland, Inc. and Dr. Jill Meadows, M.D. (collectively Planned Parenthood) challenge the rule as both improperly enacted and violative of the Iowa Constitution. For purposes of this appeal, we will assume the Board properly enacted the rule and did not violate any of the procedural or rulemaking provisions of Iowa Code chapter 17A (2013), other than Planned Parenthood's claim the rule violates section 17A.19(10)(a), which provides an agency's action is invalid when "substantial rights of the person seeking relief have been prejudiced" and the action is "[u]nconstitutional on its face or as applied." Iowa Code § 17A.19(10)(a). We will therefore focus on the constitutional question.

The Board has conceded the Iowa Constitution provides a right to an abortion that is coextensive with the right available under the United States Constitution. Planned Parenthood argues the Iowa Constitution affords a broader right, and we should therefore apply a strict scrutiny analysis under the Iowa Constitution to the rule. We need not resolve this question because we conclude, for the reasons stated herein, that the Board's rule violates the controlling "undue burden" test announced by the United States Supreme Court as the federal constitutional test. See Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 878–79, 112 S. Ct. 2791, 2821, 120 L. Ed. 2d 674, 715–16 (1992) (plurality opinion)

and Gonzales v. Carhart, 550 U.S. 124, 146, 158, 127 S. Ct. 1610, 1626–27, 1633, 167 L. Ed. 2d 480, 502, 509–10 (2007). Thus, the contested rule violates the Iowa Constitution under the less stringent Iowa constitutional standard advanced by the Board. We therefore reverse the decision of the district court as to the contested portions of the rule.

I. Background Facts and Proceedings.

On our de novo review, we find the following facts.

A. Medication Abortions. In 2000, the United States Food and Drug Administration (FDA) approved the distribution and use of mifepristone in the United States. Mifepristone, also known as RU–486, is a prescription drug that terminates a pregnancy by detaching the gestational sac from the uterine wall. In the clinical trials, the woman returned two to four days later and took a second medication, misoprostol, which induced contractions to complete the medication abortion.

Consistent with the clinical trial documents submitted in support of the application for approval of the drug, the FDA label indicated the appropriate treatment regimen was to administer 600 mg of mifepristone orally, followed two days later by 0.4 mg of misoprostol administered orally. Additionally, the label indicated the patient should take the mifepristone within the first seven weeks of pregnancy.

Once the FDA approves a drug, the FDA does not prohibit physicians from using the drug in a different manner than the label provides—otherwise known as "off-label" use. See U.S. Food & Drug Admin., "Off-Label" and Investigational Use of Marketed Drugs, Biologics, and Medical Devices–Information Sheet, available at www.fda.gov/regulatoryinformation/guidances/ucm126486. Off-label

use means the safety and effectiveness of the dosing regimen has not been established by the FDA.

Following FDA approval, additional studies led to the development of new protocols for administering these drugs. The new off-label method changed the dosage amounts of the drugs, lowering the amount of mifepristone from 600 mg to 200 mg and increasing the amount of misoprostol from 0.4 mg to 0.8 mg. The new method also changed the administration of misoprostol from oral ingestion to buccally—placing the pill between the cheeks and gums. The studies also showed this method was safe and effective for use within the first nine weeks of pregnancy. The American College of Obstetricians and Gynecologists (ACOG) accepts and approves of this off–label protocol as the standard of care to administer these drugs.

Since 2008, the medication abortions performed by Planned Parenthood in Iowa have involved 200 mg of mifepristone administered orally, followed one to four days later by 0.8 mg of misoprostol taken buccally. The clinic then instructs the patient to return to the clinic within two weeks after taking the misoprostol for a follow-up appointment. Planned Parenthood utilizes the same procedures for medication abortions if the patient is physically present in the doctor's clinic or if the procedure is being performed utilizing telemedicine.

Telemedicine is a method of practicing medicine in which the physician is at one geographical location, the patient is at a different geographical location, and the two communicate through a secure electrical audio-visual connection that complies with the privacy requirements of the Health Insurance Portability and Accountability Act (HIPAA). In Iowa, physicians and hospitals deliver a variety of health care and education services to Iowans living in rural communities

through telemedicine. The Board has adopted a rule effective June 3, 2015, regarding the use of telemedicine by Iowa physicians. The regulations make the following findings:

> 1. The board recognizes that technological advances have made it possible for licensees in one location to provide medical care to patients in another location with or without an intervening health care provider.
>
> 2. Telemedicine is a useful tool that, if applied appropriately, can provide important benefits to patients, including increased access to health care, expanded utilization of specialty expertise, rapid availability of patient records, and potential cost savings.
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> 3. The board advises that licensees using telemedicine will be held to the same standards of care and professional ethics as licensees using traditional in-person medical care.

Iowa Admin. Code r. 653—13.11.

The regulations also state that "[a] licensee who uses telemedicine shall utilize evidence-based telemedicine practice guidelines and standards of practice, to the degree they are available, to ensure patient safety, quality of care, and positive outcomes." Id. r. 653—13.11(2). The regulations further require the licensee to perform "a physical examination, when medically necessary, sufficient for the diagnosis and treatment of the patient." Id. r. 653—13.11(8). They identify nine separate situations in which the licensee need not personally interview, examine, or diagnose the patient, including when "the patient has been examined in person by an advanced registered nurse practitioner or physician assistant or other licensed practitioner with whom the licensee has a supervisory or collaborative relationship." Id. r. 653—13.11(20)(e).

Planned Parenthood has been utilizing telemedicine to perform medication abortions in Iowa since 2008.[1] At all Planned Parenthood

[1]Iowa was the first state in which telemedicine abortions were widely performed.

locations in Iowa, a trained staff member takes a medical history from the patient, checks the patient's vital signs, and gathers the patient's blood for tests to check for any medical reasons the woman should not undergo a medication abortion.

A trained staff member then performs an ultrasound on the woman to check for an ectopic pregnancy and obtain the gestational age of the pregnancy. An ectopic pregnancy occurs when the fertilized egg is implanted somewhere other than the uterus. An ectopic pregnancy is a contraindication for a medication abortion because the drug regimen does not work when the fertilized egg is not located in the uterus. Thus, the doctor uses the ultrasound images to determine if the gestational sac containing the fertilized egg implanted somewhere other than inside the uterus. The ultrasound machine also estimates gestational age.

Prior to administering the mifepristone, the physician reviews the lab results, the ultrasound images, and medical history provided by the patient. After the physician determines there is no medical reason the woman cannot proceed with the procedure, the patient and physician speak to each other. Whether the physician is present in person or communicating remotely through telemedicine, the physician does not personally perform a physical exam on the patient. The standard of care developed by ACOG is that a physical examination by the physician before proceeding with a medical termination of a pregnancy is medically unnecessary.

Next, the physician informs the patient about the medication regime, potential complications, what to expect after ingesting the misoprostol, and answers questions the patient may have. After receiving informed consent from the patient that she wishes to go

forward with the termination, the doctor provides the medications to the patient.

In telemedicine administration, the patient–physician communication occurs over a real-time two-way HIPAA secured teleconference audio-visual connection with a staff person in the room with the patient and the physician at a different clinical location. After receiving informed consent, the physician remotely releases a secure drawer containing the medications located in the patient's room.

Regardless of whether the physician dispenses the medications in person or by telemedicine, both the physician and the staff member watch the patient take the mifepristone (in the telemedicine situation, the physician watches over the two-way video). The clinic schedules a follow-up visit within two weeks. The woman then goes home, or to a location of her choosing, and takes the misoprostol twenty-four to forty-eight hours later.

The woman also receives a toll-free number that she may call to speak with medical staff or the physician regarding any complications or questions, as the actual uterine evacuation occurs while the woman is at home regardless of the location of the initial appointment. In the relatively uncommon case in which the physician feels the patient needs emergency care, the doctor refers the woman to the nearest hospital emergency room.

B. Administrative Proceedings. On June 25, 2013, the Board received a petition for rulemaking regarding the standards of practice for telemedicine medication abortions. The petition proposed the following rule:

653-13.10 – Standards of practice – chemical abortion.
This rule establishes the standards of practice for a physician or osteopathic physician who induces an abortion by an abortion-inducing drug.

13.10(1). Definition. As used in this rule, "abortion-inducing drug" means a drug, medicine, mixture, or preparation, when it is prescribed or administered with the intent to terminate the pregnancy of a woman known to be pregnant.

13.10(2). Physical Examination Required. A physician shall not induce an abortion by providing an abortion-inducing drug unless the physician has first performed a physical examination of the woman to determine, and document in the woman's medical record, the gestational age and intrauterine location of the pregnancy.

13.10(3). Physical Presence Required. When inducing an abortion by providing an abortion-inducing drug, a physician must be physically present with the woman at the time the abortion-inducing drug is provided.

13.10(4). Follow-Up Appointment Required. If an abortion is induced by an abortion-inducing drug, the physician inducing the abortion must schedule a follow-up visit with the woman at the same facility where the abortion-inducing drug was provided, 12 to 18 days after the use of an abortion-inducing drug to confirm the termination of the pregnancy and evaluate the woman's medical condition. The physician shall use all reasonable efforts to ensure that the woman is aware of the follow-up appointment and that she returns for the appointment.

13.10(5). Parental Notification regarding Pregnant Minors. A physician shall not induce an abortion by providing an abortion-inducing drug to a pregnant minor prior to compliance with the requirements of chapter 135L of the Iowa Code and Rules 641-89.12 and 641-89.21 adopted by the Public Health Department.

On June 28, the Board held a public meeting and discussed the proposed rule. Three members of the public spoke at the meeting, Daniel McConchie, Vice President of Government Affairs for Americans United for Life, spoke in favor of the rule; Tom Ross, M.D., a doctor at Planned

Parenthood, spoke against the rule; and Kelly Larson, a registered nurse at InnerVisions HealthCare, spoke in favor of the rule. After hearing the public comments, board member Allison Schoenfelder, M.D., moved to accept the petition and begin the rulemaking process. The Board voted eight to two to accept the petition.

The Board held a public hearing on the proposed rule on August 28, and the public had thirty-five days to submit written comments on the proposed rule. The Board heard testimony from twenty-eight individuals at the public hearing and received 244 written comments from both individuals and organizations. The Board heard from many doctors both for and against the rule.

Dr. Sean Kenney, a practicing obstetrician and gynecologist from Lincoln, Nebraska, spoke in favor of the rule. Dr. Daniel Grossman, an obstetrician and gynecologist from Oakland, California, spoke against the rule. The Board also received public comment from the Iowa Medical Society and the Iowa Osteopathic Medical Association, both of which expressed concern regarding the procedures used to implement the rule and opposed the rule itself. Other physicians also testified the Planned Parenthood clinics follow the standard of care used for medication abortions, whether the physician performs the procedure at an in-clinic visit or by telemedicine.

On August 30, the Board held a meeting to determine whether it should adopt the rule. The Board passed the rule, again with an eight to two vote. The Board announced it would publish the adopted rule on October 2, and it would become effective November 6.

On September 27, the Board issued a statement regarding the adoption and filing of the rule. The Board listed its principal reasons in support of the rule as follows:

1. To protect the health and safety of patients, standards of practice are needed for physicians who prescribe and administer abortion-inducing drugs to terminate a pregnancy.

2. The practices used by physicians who prescribe and administer abortion-inducing drugs using telemedicine are inconsistent with the protocols approved by the U.S. Food and Drug Administration (FDA) and the manufacturer of the drugs.

3. Iowa Code Section 707.7(3) only allows physicians to perform abortions in Iowa.

4. A physical examination of the patient in telemedicine settings is not being performed by the physician who prescribes and administers the abortion-inducing drugs, but is delegated to non-physician persons who do not have appropriate training to confirm or discover contraindications or to perform an ultrasound to determine the age and location of the embryo.

5. Physicians who prescribe and administer abortion-inducing drugs using telemedicine may never meet with the patient in person and may never see the patient again for a follow-up appointment.

The Board also provided its reasons for overruling the objections to the rule.

1. The rule would limit rural Iowa women's access to medical abortions. The new rule does not restrict where medical abortion services may be provided. The emphasis of the rule is on the patient's health and safety and the responsibility of physicians who perform medical abortions. The Board believes that all Iowans are entitled to the same high level of health care, regardless of whether they live in rural or urban areas. The Board believes that the physician's decision that the patient should have a medical or surgical abortion should depend on multiple factors including patient preference, medical and psychological status of the patient, and the patient's access to emergency medical services.

2. The rule is politically motivated and is not sound public policy. While issues such as abortion have been politicized, the Board does not have authority to react politically to any issue. The Board is only authorized to adopt all necessary and proper rules for the licensure and

standards of practice for health care providers licensed pursuant to Iowa Code Chapters 148 (physicians) and 148E (acupuncturists). The Board is motivated to adopt this administrative rule by its mandate to protect the health and safety of Iowans.

3. The rule is an attempt to ban access to a procedure that is legal. It deprives Iowa women of their constitutionally protected right to obtain a pre-viability abortion. Abortion is legal in Iowa and the goal of the new rule is to protect the health and safety of patients who seek medical abortions. Federal court decisions have set the guidelines for the availability of abortion. Nothing in the rule bans medical abortion. Rather, the rule sets forth the standards of practice that must be followed by physicians who perform medical abortions.

4. The Board previously addressed this matter in 2010 when it reviewed Planned Parenthood of the Heartland's medical abortion services using telemedicine and concluded they were safe. The membership of the Board has changed completely over the past three years. The Board has not previously promulgated any rules addressing medical abortion services using telemedicine. This is the first rulemaking proceeding which has given licensed physicians and the public an opportunity to comment on the use of telemedicine in this context. Because there was no rule in place addressing this particular procedure, the Board determined a rule was necessary to protect the health and safety of Iowans.

5. The Board promulgated rulemaking without a thorough study or analysis of the matter under regulatory consideration and the Board did not take into consideration the impact the rule may potentially have on expectations and requirements for telemedicine delivery of other medical services. After accepting a petition on June 28, 2013, to promulgate rulemaking on the standards of practice for physicians who perform medical abortions, Board members studied the matter and reviewed medical research papers and a significant amount of public comments received on a broad spectrum of issues regarding medical abortions. The Board determined that the new rule is narrowly focused on the standards of practice for physicians who perform medical abortions. The Board may determine in the future to more broadly address the standards of practice for other medical services using telemedicine.

6. An appropriate physical examination, including an ultrasound to determine age and location of the embryo, is performed by appropriately trained staff in the telemedicine setting and this information is provided to an off-site physician who remotely prescribes and administers the abortion-inducing drugs. The Board considers a thorough medical history and physical examination to be the cornerstone of good medical care. On this foundation an accurate diagnosis can be made and the most appropriate treatment plan offered to the patient. The Board is concerned about the quality and sufficiency of the physical examination being performed prior to a medical abortion. The first area of concern is the lack of opportunity for a physician to perform a basic physical examination of the patient to screen for conditions that would be contraindications to medical abortion. The drugs used in a medical abortion are mifepristone and misoprostol. As listed in the FDA literature the contraindications to these medications include "confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass; an intrauterine device (IUD) in place; chronic adrenal failure; concurrent long-term corticosteroid therapy; history of allergy to mifepristone, misoprostol, or other prostaglandins; hemorrhagic disorders or concurrent anticoagulant therapy; and inherited porphyrias." As stated in the FDA literature on abortion-inducing drugs, "There are no data on the safety and efficacy of mifepristone in women with chronic medical conditions such as cardiovascular, hypertensive, hepatic, respiratory, or renal disease; insulin-dependent diabetes mellitus; severe anemia or heavy smoking. Women who are more than 35 years of age and who also smoke 10 or more cigarettes per day should be treated with caution because such patients were generally excluded from clinical trials of mifepristone." The Board believes that a basic physical examination of a patient is necessary to exclude this narrower list of contraindications and essential to exclude the list of exclusionary conditions that were not part of the clinical studies. The second area of concern is the quality of the ultrasound that is being performed prior to a medical abortion. Without the option of a clinical pelvic examination of the patient to confirm dating of the embryo, these remote clinics are relying primarily on ultrasound to date the embryo and rule out ectopic pregnancy, which occurs when an embryo implants somewhere other than the uterus. The Board is concerned about the uncertainty of whether clinic staff members providing the ultrasounds are actually qualified to produce useful images to sufficiently rely upon for diagnostic purposes. If an ectopic pregnancy was missed the medications may not expel the

embryo and may lead to delayed diagnosis and treatment of this dangerous condition. In the FDA reports of deaths from mifepristone and misoprostol two of the 14 deaths were related to ruptured ectopic pregnancies, and 58 other women suffered morbidity from failed diagnosis of ectopic pregnancy. The Board believes that a basic physical examination for every patient will help to exclude the conditions that are contraindications to the medications. The Board believes that a pelvic examination may be necessary in some cases to correlate with ultrasound findings and should be available to all women presenting for a medical abortion. The Board believes that adequate ultrasound services and interpretation are necessary if a clinical pelvic examination is not being used to date the embryo. For all these reasons the Board believes that a physician should be present to conduct this physical examination before proceeding with a medical abortion.

7. The treatment and consultation recommendations made by the physician in the telemedicine setting are the same standards of appropriate practice as those in face-to-face settings. The physician does not have to be present to perform a medical abortion. Iowa Code section 707.7(3) requires that abortions in Iowa be performed by physicians. The Board believes that the prescribing physician must be physically present with the patient to administer the abortion-inducing drug. This physician-patient relationship is fundamental to the provision of a safe medical abortion. It is the expectation of the Board that physicians recognize the obligations, responsibilities and patient rights associated with establishing and maintaining an appropriate physician-patient relationship in the specific context of prescribing and administering abortion-inducing drugs.

8. Patients are already receiving appropriate follow-up care to their medical abortions in remote clinics where a physician is not physically present. The Board believes that follow-up care of the patient is critical after providing a medical abortion. The new rule requires the physician who prescribes and performs a medical abortion to make all reasonable efforts to ensure that the patient is aware of the importance of follow-up care and that she returns for an appointment with the prescribing physician. The Board believes that the physician's in-person interview to collect the patient's medical history and an in-person physical examination will strengthen the physician-patient relationship and result in improved and increased follow-up care of the patient.

The final rule adopted by the Board reads:

653—13.10 Standards of practice–physicians who prescribe or administer abortion-inducing drugs.

13.10(1) Definition. As used in this rule:

"Abortion-inducing drug" means a drug, medicine, mixture, or preparation, when it is prescribed or administered with the intent to terminate the pregnancy of a woman known to be pregnant.

13.10(2) Physical examination required. A physician shall not induce an abortion by providing an abortion-inducing drug unless the physician has first performed a physical examination of the woman to determine, and document in the woman's medical record, the gestational age and intrauterine location of the pregnancy.

13.10(3) Physician's physical presence required. When inducing an abortion by providing an abortion-inducing drug, a physician must be physically present with the woman at the time the abortion-inducing drug is provided.

13.10(4) Follow-up appointment required. If an abortion is induced by an abortion-inducing drug, the physician inducing the abortion must schedule a follow-up appointment with the woman at the same facility where the abortion-inducing drug was provided, 12 to 18 days after the woman's use of an abortion-inducing drug to confirm the termination of the pregnancy and evaluate the woman's medical condition. The physician shall use all reasonable efforts to ensure that the woman is aware of the follow-up appointment and that she returns for the appointment.

13.10(5) Parental notification regarding pregnant minors. A physician shall not induce an abortion by providing an abortion-inducing drug to a pregnant minor prior to compliance with the requirements of Iowa Code chapter 135L and rules 641—89.12(135L) and 641—89.21(135L) adopted by the public health department.

Iowa Admin. Code r. 653—13.10.

C. District Court Proceedings. On September 30, Planned Parenthood filed a petition for judicial review and a motion to stay the enforcement of the rule. The district court granted Planned Parenthood's

motion to stay the enforcement of the rule pending its ruling. On August 18, 2014, the district court denied Planned Parenthood's claims and upheld the rule addressing each of Planned Parenthood's challenges.

Planned Parenthood appealed and asked us to stay the enforcement of the rule pending the resolution of its appeal. We entered a stay and retained the appeal.

II. Issues.

Planned Parenthood raised a number of issues before the district court challenging both the rulemaking process and the constitutionality of the rule. For purposes of this appeal, we will assume the Board properly enacted the rule and did not violate any of the procedural or rulemaking provisions of Iowa Code chapter 17A other than Planned Parenthood's claim the rule is unconstitutional and violates Iowa Code section 17A.19(10)(a). Under the Code, we can provide appropriate relief when the agency action is "[u]nconstitutional on its face or as applied or is based upon a provision of law that is unconstitutional on its face or as applied." Iowa Code § 17A.19(10)(a).

Planned Parenthood did not challenge the ruling regarding provisions (1) and (5) of rule 653—13.10. Therefore, we will affirm the district court judgment regarding rule 653—13.10(1) and 13.10(5).

III. Standard of Review.

We review Planned Parenthood's constitutional claims de novo. Gartner v. Iowa Dep't of Pub. Health, 830 N.W.2d 335, 344 (Iowa 2013).

IV. Analysis.

A. The Right of a Woman to an Abortion Under the Iowa Constitution. On appeal, Planned Parenthood asks us to declare the rule unconstitutional under the Iowa Constitution. We have yet to determine if the Iowa Constitution protects a woman's right to terminate

her pregnancy. Over forty years ago, the United States Supreme Court recognized a woman has a constitutionally protected liberty interest in the decision to terminate a pregnancy. Roe v. Wade, 410 U.S. 113, 153–54, 93 S. Ct. 705, 727, 35 L. Ed. 2d 147, 177–78 (1973). The Supreme Court reaffirmed the "constitutional liberty of the woman to have some freedom to terminate her pregnancy" in 1992. Casey, 505 U.S. at 869, 112 S. Ct. at 2816, 120 L. Ed. 2d at 709.

Many states considering this issue under their state constitutions have found their state constitutions provide such a right. See, e.g., Valley Hosp. Ass'n, Inc. v. Mat-Su Coal. for Choice, 948 P.2d 963, 967–69 (Alaska 1997); Comm. to Defend Reprod. Rights v. Myers, 625 P.2d 779, 784 (Cal. 1981); In re T.W., 551 So. 2d 1186, 1192–93 (Fla. 1989); Hope Clinic for Women, Ltd. v. Flores, 991 N.E.2d 745, 760 (Ill. 2013); Moe v. Sec'y of Admin. & Fin., 417 N.E.2d 387, 398–99 (Mass. 1981); Women of the State of Minn. by Doe v. Gomez, 542 N.W.2d 17, 27 (Minn. 1995); Pro-Choice Miss. v. Fordice, 716 So. 2d 645, 653 (Miss. 1998); Reprod. Health Servs. of Planned Parenthood of St. Louis Region, Inc. v. Nixon, 185 S.W.3d 685, 692 (Mo. 2006) (en banc) (per curiam); Armstrong v. State, 989 P.2d 364, 374–75 (Mont. 1999); Hope v. Perales, 634 N.E.2d 183, 186 (N.Y. 1994); Planned Parenthood of Middle Tenn. v. Sundquist, 38 S.W.3d 1, 15 (Tenn. 2000). But cf. Taylor v. Kurapati, 600 N.W.2d 670, 687 (Mich. Ct. App. 1999) ("This Court has held that the Michigan Constitution does not provide a right to end a pregnancy."); Mahaffey v. Att'y Gen., 564 N.W.2d 104, 111 (Mich. Ct. App. 1997) ("We merely hold that the Michigan Constitution does not guarantee a right to abortion that is separate and distinct from the federal right."); MKB Mgmt. Corp. v. Burdick, 855 N.W.2d 31, 31–32, 52, 64, 89, 91, 98 (N.D. 2014) (per curiam) (upholding the constitutionality of amendments to the state

abortion control act that limited medication abortions where two justices determined the law violated the North Dakota Constitution, two justices concluded the law did not violate the state constitution, three justices determined the statute violated the Federal Constitution, one justice concluded the law did not violate the Federal Constitution, and one justice concluded the federal constitutional issue was not properly before the court because there was not a sufficient majority of the court that agreed the law was unconstitutional). However, in this case, we need not decide whether the Iowa Constitution provides such a right, and if so, whether regulations affecting that right must pass strict scrutiny.[2] The Board in its brief and in its oral argument conceded a woman has a right to terminate her pregnancy protected by the Iowa Constitution that is coextensive with the federal right.[3] For the reasons discussed herein, we

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[2]As previously noted, Planned Parenthood urges that the Iowa Constitution provides greater protection than the Federal Constitution for a woman's right to terminate her pregnancy. It urges us to adopt a strict scrutiny standard under the Iowa Constitution. Several state courts have previously reached this conclusion. See Valley Hosp. Ass'n, 948 P.2d at 968–69 (applying a strict scrutiny analysis to abortion regulations under its state constitution while noting that Alaska's constitution has a privacy provision and "provides more protection of individual privacy rights than the United States Constitution"); In re T.W., 551 So. 2d at 1191, 1195–96 (applying a strict scrutiny analysis under the Florida Constitution, which provides that "[e]very natural person has the right to be let alone and free from governmental intrusion into his private life except as otherwise provided herein"); Women of the State of Minn., 542 N.W.2d at 31 (applying strict scrutiny under the Minnesota Constitution which has no separate privacy provision); Armstrong, 989 P.2d at 372, 373–74 (applying strict scrutiny under the Montana Constitution which provides that "[t]he right of individual privacy is essential to the well-being of a free society and shall not be infringed without the showing of a compelling state interest"); Planned Parenthood of Middle Tenn., 38 S.W.3d at 14–15 (applying strict scrutiny under the Tennessee Constitution which has no separate privacy provision). Other courts have found a state constitutional right that is coextensive with the federal right. See, e.g., Hope Clinic, 991 N.E.2d at 760; Reprod. Health Servs., 185 S.W.3d at 692 ("There is no reason, within the context of this case, to construe this language from the Missouri constitution more broadly than the language used in the United States constitution."); Pro-Choice Miss., 716 So. 2d at 655.

[3]In its brief, the Board asserts, "[T]his Court should adopt [under the Iowa Constitution] the undue burden standard set forth in Casey."

find the challenged rule fails to meet the federal undue burden test for constitutionality.

B. The Federal Undue Burden Test. In a plurality decision, the Supreme Court developed the undue burden test to reconcile the state's interest with the constitutionally protected interest of the woman. Casey, 505 U.S. at 876–80, 112 S. Ct. at 2820–22, 120 L. Ed. 2d at 714–17. Generally, under the undue burden test for a state regulation to place an undue burden on a woman's right to terminate a pregnancy, the state regulation must have "the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus." Id. at 877, 112 S. Ct. at 2820, 120 L. Ed. 2d at 714.

In adopting the test, the Supreme Court recognized that even though a woman has a liberty interest in deciding whether to terminate a pregnancy, the right to do so is limited. Id. at 869, 112 S. Ct. at 2816, 120 L. Ed. 2d at 709–10. The limitation imposed by the Supreme Court is the state's "important and legitimate interests in preserving and in protecting the health of the pregnant woman" and "in protecting the potentiality of human life." Roe, 410 U.S. at 162, 93 S. Ct. at 731, 35 L. Ed. 2d at 182. The Court balanced a woman's right to terminate her pregnancy against the legitimate interests of the state by developing the undue burden test. Casey, 505 U.S. at 876, 112 S. Ct. at 2820, 120 L. Ed. 2d at 714.

In the most recent case, Gonzales v. Carhart, the Court—considering a ban on late term abortions—stated the undue burden test as

> [w]here it has a rational basis to act, and it does not impose an undue burden, the State may use its regulatory power to bar certain procedures and substitute others, all in the furtherance of its legitimate interests in regulating the

> medical profession in order to promote respect for life, including life of the unborn.

Carhart, 550 U.S. at 158, 127 S. Ct. at 1633, 167 L. Ed. 2d at 509–10.

The Court applies the undue burden test differently depending on the state's interest advanced by a statute or regulation. If the state's interest is to advance fetal life, "[a]n undue burden exists, and therefore a provision of law is invalid, if its purpose or effect is to place a substantial obstacle in the path of a woman seeking an abortion before the fetus attains viability." Casey, 505 U.S. at 878, 112 S. Ct. at 2821, 120 L. Ed. 2d at 715.

On the other hand, if the state's interest is to further the health or interest of a woman seeking to terminate her pregnancy, "[u]nnecessary health regulations that have the purpose or effect of presenting a substantial obstacle to a woman seeking an abortion impose an undue burden on the right." Id. at 878, 112 S. Ct. at 2821, 120 L. Ed. 2d at 716. Some federal courts applying this test have interpreted it to mean "[t]he feebler the medical grounds, the likelier the burden, even if slight, to be 'undue' in the sense of disproportionate or gratuitous." Planned Parenthood of Wis., Inc. v. Van Hollen, 738 F.3d 786, 798 (7th Cir. 2013); see also Planned Parenthood Ariz., Inc. v. Humble, 753 F.3d 905, 912–14 (9th Cir. 2014). Under this approach, we are required "to weigh the extent of the burden against the strength of the state's justification in the context of each individual statute or regulation." Planned Parenthood Ariz., 753 F.3d at 914.

In contrast to the Seventh and Ninth Circuits, the Fifth and Sixth Circuit Courts of Appeals have applied Casey differently to measures passed by their state to promote the health or interest of a woman seeking to terminate her pregnancy. The Fifth and Sixth Circuits do not

weigh the strength of the state's justifications against the burden placed on women. Under the Fifth Circuit's approach, once the state sets forth a justification for an abortion regulation sufficient to pass rational basis review, it is not necessary to consider the strength of the state's justification in its analysis. Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott, 748 F.3d 583, 593–99 (5th Cir. 2014). The Sixth Circuit took the same approach as the Fifth Circuit when it decided its case without considering the strength of the state's justification in its analysis. See Planned Parenthood Sw. Ohio Region v. DeWine, 696 F.3d 490, 513–18 (6th Cir. 2012).

Like the Seventh and Ninth Circuits, we believe the "unnecessary health regulations" language used in Casey requires us to weigh the strength of the state's justification for a statute against the burden placed on a woman seeking to terminate her pregnancy when the stated purpose of a statute limiting a woman's right to terminate a pregnancy is to promote the health of the woman.

C. Applying the Federal Undue Burden Test to this Case. We will assume for purposes of this appeal that the Board has a rational basis to act under the federal constitutional test. Therefore, we will analyze the rule under the undue burden prong of the test.

1. Substance of Iowa Administrative Code rule 653—13.10. The rule creates a standard of practice for physicians who perform medication abortions. Planned Parenthood is challenging rule 653—13.10(2) through 13.10(4). The crux of this rule is to require greater physician involvement in the termination of a pregnancy than is now provided by Planned Parenthood for medical terminations of pregnancies.

Rule 653—13.10(2) requires a physician to perform a physical examination of the woman for the purposes of determining the

gestational age and intrauterine location of the pregnancy. Iowa Admin. Code r. 653—13.10(2). Rule 653—13.10(3) requires the physician to be physically present in the room and give the medications to the woman. Id. r. 653—13.10(3). Finally, rule 653—13.10(4) requires the physician to schedule a follow-up visit with the woman at the same facility where the physician dispensed the medication to confirm the termination of the pregnancy and to evaluate the woman's medical condition. Id. r. 653—13.10(4). Planned Parenthood challenges the rule as applied to medication abortions done with the physician present or by telemedicine.

2. Purpose of Iowa Administrative Code rule 653—13.10. The Board did not pass this rule to advance the state's interest in advancing fetal life. Rather, the Board passed this rule to promote the health or interest of a woman seeking to terminate her pregnancy. The first reason given by the Board for the enactment of the rule is "[t]o protect the health and safety of patients." The reasons given by the Board also state the rule is necessary because "physicians who prescribe and administer abortion-inducing drugs using telemedicine are inconsistent with the protocols approved by the U.S. Food and Drug Administration (FDA) and the manufacturer of the drugs." Additionally, in its explanations for overruling the reasons presented in opposition to the rule, the Board stated, "[t]he Board is motivated to adopt this administrative rule by its mandate to protect the health and safety of Iowans." Finally, "[p]hysicians who prescribe and administer abortion-inducing drugs using telemedicine may never meet with the patient in person and may never see the patient again for a follow-up appointment." Under the undue burden test, we "weigh the extent of the burden against the strength of the state's justification in the context of each individual statute or regulation." Planned Parenthood Ariz., 753 F.3d at 914.

3. The strength of the Board's justification of the rule. The underpinning of the Board's rule is that competent medical care to promote the health of a woman seeking to terminate her pregnancy requires a physician to do a physical examination. In its explanations for overruling the reasons presented in opposition to the rule, the Board said:

> The Board considers a thorough medical history and physical examination to be the cornerstone of good medical care. On this foundation an accurate diagnosis can be made and the most appropriate treatment plan offered to the patient. The Board is concerned about the quality and sufficiency of the physical examination being performed prior to a medical abortion.

However, the weight of the record evidence indicates that a pelvic examination prior to administering the mifepristone does not provide any measurable gain in patient safety.

Dr. Kenney was the only actively practicing doctor who opined that a doctor should give a patient seeking a medical termination of a pregnancy a physical exam that includes a pelvic exam before proceeding with the termination.[4] This opinion was contrary to the opinions of the other board certified obstetricians and gynecologists. This opinion was also contrary to the standards of practice developed by ACOG. In their view, the medically necessary information a physician needs to determine whether to proceed with a medication abortion is contained in the patient's history, blood work, vital signs, and ultrasound images—which can be accessed by reviewing the patient's records remotely or in person.

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[4]He testified the ultrasound would not be sufficient to diagnose an ectopic pregnancy and that a pelvic exam is also needed. All other actively practicing physicians who testified on that issue disagreed.

The physician reads the ultrasound images before giving the patient the medication. The physician uses the ultrasound images to determine the location of the gestational sac. If the ultrasound images are of poor quality or do not clearly show the gestational sac, the physician does not dispense the medication to the woman. If the gestational sac is located outside the uterus, the woman may have an ectopic pregnancy. The physician will not dispense the medication if the patient is experiencing an ectopic pregnancy. The physician only dispenses the medication if the gestational sac is in the uterus.

The physician also reviews the patient's medical history, blood work, and vital signs. The physician reviews the history taken by the medical provider who takes the history in-person and asks further questions of the patient as needed. A person other than a physician draws the patient's blood and a lab processes it. These results are reviewed by the physician, who can order further blood work if necessary. Finally, the physician reviews the vital signs, which a person other than the physician normally takes. If the doctor has any questions regarding a patient's vital signs, the physician can have a vital sign retaken.

The next justification for the presence of a physician was the off-label use of the medications by Planned Parenthood. However, studies have shown that the off-label protocol is safer and more effective than the FDA approved protocol for administering the drugs. The method presently used by Planned Parenthood conforms to the present medical standard of care for administering the drug.

An additional reason for the rule prohibiting telemedicine abortions is that a patient may never meet face-to-face with the physician prescribing the medication. The Board determined a face-to-face meeting

was important in promoting the health or interest of a woman seeking to terminate her pregnancy. However, an increasing number of medical procedures are being performed today by telemedicine. Studies have shown medical termination of pregnancies can be "provided safely and effectively by nonphysician clinicians." Medical Management of First-Trimester Abortion, Practice Bulletin No. 143 (Am. Coll. of Obstetricians & Gynecologists, Wash., D.C.) Mar. 2014, at 11 (hereinafter ACOG Bulletin). Second, studies have shown that telemedicine abortions pose no further risk of complications to the woman than medication abortions done with the physician present. Daniel Grossman, et al., Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine, 118 Obstetrics & Gynecology 296, 302 (2011).[5]

Based on these studies, ACOG issued a practice bulletin. A practice bulletin is

> designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care. These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

ACOG Bulletin at 1. The ACOG Bulletin recommends that the off-label use of mifepristone and misoprostol are superior to the FDA protocol. Id. at 11. In addition, the bulletin recommends that "[m]edical abortion can be provided safely and effectively via telemedicine with a high level of patient satisfaction; moreover, the model appears to improve access to early abortion in areas that lack a physician health care provider." Id. at 12.

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[5]The record indicates there has been no increase in complications reported since telemedicine abortions began being performed in Iowa in 2008.

The rule also requires the physician's physical presence with the woman at the time the physician provides the drug to terminate the pregnancy. The record does not show the necessity of this part of the rule to promote the woman's health. In fact, when a speaker asked a physician board member whether it was her practice to be present when she dispensed drugs, the board member did not answer. Planned Parenthood has a health care professional in the room when the patient ingests the drug to make sure the patient swallows the pill.

The final part of the Board's rule requires the physician to schedule a follow-up visit with the woman at the same facility where the physician dispensed the medication to confirm the termination of the pregnancy and to evaluate the woman's medical condition. The purpose of the follow-up visit is to make sure the termination of the pregnancy was complete. The record, however, established that a clinic equipped to detect and examine women for signs of pregnancy could make this determination.

4. The burden on a woman seeking to terminate her pregnancy. Planned Parenthood urges that the telemedicine rule imposes a substantial burden on a woman seeking to terminate her pregnancy because it only has physicians at its clinics in Des Moines, Iowa City, and Ames. This means that a woman seeking a medication abortion in Iowa potentially would have to drive hundreds of miles. Additionally, requiring two visits to the same clinic would cause a working mother to potentially miss two to four days of work and incur additional childcare expense. Planned Parenthood claims these additional costs are a significant financial strain on low-income women and their families, and for some individuals these costs are prohibitive. Finally, it asserts that increased travel means a greater possibility that an abusive spouse,

partner, or relative could find out the woman is terminating her pregnancy. This may cause the woman to lose the ability to make the abortion decision privately and discretely. See Casey, 505 U.S. at 887–98, 112 S. Ct. at 2826–31, 120 L. Ed. 2d at 721–28 (striking down a spousal notification requirement as an undue burden because it was "likely to prevent a significant number of women from obtaining an abortion").

There is no question the rule imposes some burdens that would not otherwise exist and did not exist before the rule was adopted. Planned Parenthood provides telemedicine abortions at clinics in Burlington, Cedar Falls, Council Bluffs, Dubuque, the Quad Cities, and Sioux City. Clearly, those services would end and women in those communities would have to travel—in many cases hundreds of miles—to obtain abortions from Planned Parenthood if the rule took final effect.[6]

Even opponents did not dispute the rule would impose some burdens on women seeking abortion services. Their contention was that a woman who wants an abortion, even if she was indigent, would overcome these burdens.[7]

The Board has several responses to Planned Parenthood's position regarding burden. First, it points out that the twenty-four-hour waiting period in Casey resulted in additional trips and therefore additional driving, but was upheld. See id. at 885–87, 112 S. Ct. at 2825–26, 120

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[6]After the adoption of the rule, Planned Parenthood for a period of time provided in-person physician services in the Quad Cities and Sioux City but claims it did so at a financial loss and ceased providing that service at those locations when it could no longer sustain the loss.

[7]Planned Parenthood witnesses testified that the introduction of telemedicine abortions has not increased the number of abortions in Iowa, but has resulted in their occurring, on average, earlier in the pregnancy.

L. Ed. 2d at 720–21.[8] Second, the Board relies on the following language from Casey:

> The fact that a law which serves a valid purpose, one not designed to strike at the right itself, has the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate it.

Id. at 874, 112 S. Ct. at 2819, 120 L. Ed. 2d at 712. Third, the Board notes that in Casey, the Supreme Court upheld a requirement that a physician provide the informed consent form to the patient. It argues that if a physician can be required to obtain informed consent, a physician also can be required to perform a physical exam. The Board directs us to this passage from Casey:

> The Pennsylvania statute also requires us to reconsider the holding in [City of Akron v. Akron Center for Reproductive Health, Inc., 462 U.S. 416, 103 S. Ct. 2481, 76 L. Ed. 2d 687 (1983)] that the State may not require that a physician, as opposed to a qualified assistant, provide information relevant to a woman's informed consent. Since there is no evidence on this record that requiring a doctor to give the information as provided by the statute would amount in practical terms to a substantial obstacle to a woman seeking an abortion, we conclude that it is not an undue burden. Our cases reflect the fact that the Constitution gives the States broad latitude to decide that particular functions may be performed only by licensed professionals, even if an objective assessment might suggest that those same tasks could be performed by others.

Id. at 884–85, 112 S. Ct. at 2824, 120 L. Ed. 2d at 719–20 (citation omitted).

Lastly, the Board argues that undue burden should not be determined by the decisions and circumstances of a single provider. The rule does not mandate that Planned Parenthood close clinics. If Planned Parenthood could deploy physicians in more communities, its clients

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[8]The Board also notes that Iowa, unlike a majority of states, does not have a mandatory waiting period and thus does not automatically require two visits.

would not have to travel as far. An additional noteworthy point is that telemedicine abortions have existed in Iowa only since 2008 and do not exist in the vast majority of states. Thus, as compared to the situation before 2008 or in many other states, the Board's rule does not have a significant adverse effect.

5. Weighing the strength of the Board's justification for its rule against the burden placed on a woman seeking to terminate a pregnancy. Consistent with United States Supreme Court precedent, we must now weigh the health benefits of rule 653—13.10(2) through 13.10(4) against the burdens they impose on a woman who wishes to terminate a pregnancy. As the foregoing indicates, the record evidence showed very limited health benefits. While undoubtedly at an abstract level everyone would prefer to see a doctor in person every time they have a medical issue, the reality of modern medicine is otherwise. In this case, the record indicates the physician plays an important role in reviewing the ultrasound images and dispensing the prescribed medications, but those roles can be performed without the physician being personally present. The record also provides almost no medical support for the necessity of a pelvic exam prior to dispensing the medication. At the same time, the record indicates that the telemedicine rule would make it more challenging for many women who wish to exercise their constitutional right to terminate a pregnancy in Iowa to do so.

A general concern we have with the Board's appellate arguments is that they are not "context-specific." See Planned Parenthood Ariz., 753 F.3d at 914 (indicating "the undue burden test is context-specific, and . . . both the severity of a burden and the strength of the state's justification can vary depending on the circumstances"). Rather, the Board argues broadly that because travel burdens and physician presence

requirements were acceptable in Casey, they must be acceptable here. But as we read Casey, it turned on the evidence and record in that case, including a recognition that the informed consent requirement served a "substantial government interest," including the "psychological well-being" of the woman. Casey, 505 U.S. at 882, 112 S. Ct. at 2823, 120 L. Ed. 2d at 718. As we have discussed already, this record, which is based on 2013 medical standards and practices in Iowa, reveals only minimal medical justification for the challenged aspects of the rule.

Given the strongly held beliefs on both sides of the issue, it is not surprising that the Board received many thoughtful comments expressing a variety of viewpoints. While the commenters vigorously disagree as to the extent of the burden imposed by the rule, there was little discussion in medical terms as to how the rule was medically necessary to protect a woman's health. Whenever telemedicine occurs, the physician at the remote location does not perform a physical examination of the patient. It is difficult to avoid the conclusion that the Board's medical concerns about telemedicine are selectively limited to abortion.

Most significantly, as noted above, the Board has adopted a rule that generally approves of the use of telemedicine, recognizing the existence of "technological advances [that] have made it possible for licensees in one location to provide medical care to patients in another location with or without an intervening health care provider." Iowa Admin. Code r. 653—13.11. The rule authorizes the use of telemedicine in accordance with "evidence-based" guidelines and standards. Id. r. 653—11(2). As the Seventh Circuit observed in the somewhat different circumstances presented in Van Hollen, "An issue of equal protection of

the laws is lurking in this case." 738 F.3d at 790. The Board appears to hold abortion to a different medical standard than other procedures.[9]

After careful consideration, we hold that rule 653—13.10(2) through 13.10(4) place an undue burden on a woman's right to terminate her pregnancy as defined by the United States Supreme Court in its federal constitutional precedents. Because the Board agrees the Iowa Constitution protects a woman's right to terminate her pregnancy to the same extent as the United States Constitution, we find the rule violates the Iowa Constitution.

V. Disposition.

For the foregoing reasons, we find Iowa Administrative Code rule 653—13.10(2) through 13.10(4) is unconstitutional. Therefore, we reverse that part of the district court's judgment finding rule 653—13.10(2) through 13.10(4) constitutional. We affirm the district court's judgment as to rule 653—13.10(1) and 13.10(5). We also lift our stay as to the Board's enforcement of rule 653—13.10(1) and 13.10(5).

AFFIRMED IN PART AND REVERSED IN PART.

Zager, J., takes no part.

[9]The Board's recent rule endorsing evidence-based telemedicine in other contexts exempt abortion. See Iowa Admin. Code r. 653—13.11(22).