Iowa General Assembly

2015 Legal Updates

Legislative Services Agency – Legal Services Division

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TELEMEDICINE ABORTIONS

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June 19, 2015

Planned Parenthood of the Heartland, Inc. and Jill Meadows vs. Iowa Board of Medicine
No. 14-1415
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Background Facts. In 2000, the United States Food and Drug Administration (FDA) approved the distribution and use of mifepristone, or RU-486, in the United States. Mifepristone is a prescription drug that terminates a pregnancy by detaching the gestational sac from the uterine wall, which is sometimes referred to as a medication abortion. Following the ingesting of mifepristone, a woman subsequently ingests misoprostol, two to four days later, to induce contractions to complete the medication abortion. Initially, the FDA indicated the appropriate regimen was to administer 600 mg of mifepristone, orally, followed two days later by 0.4 mg of misoprostol, administered orally. The label also instructed that the patient should take the mifepristone within the first seven weeks of pregnancy.

Following initial approval, subsequent studies resulted in the development of new protocols for administering the drugs in a manner different than the label provided, also known as “off-label” use. The off-label protocol, not prohibited by nor established by the FDA, but approved as the standard of care to administer these drugs by the American College of Obstetricians and Gynecologists (ACOG), provided for lowering of the dosage amount of mifepristone to 200 mg and increasing the dosage amount of misoprostol to 0.8 mg. The protocol also allowed for an alternative oral administration of misoprostol, and for use within the first nine weeks of pregnancy.

Since 2008, medication abortions performed by Planned Parenthood of the Heartland, Inc. (Planned Parenthood) have utilized the off-label protocol and the same procedures whether the patient was physically present with a physician or if the procedure was performed utilizing telemedicine. At all 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 patient should not undergo a medication abortion. The trained staff member then performs an ultrasound on the patient to check for an ectopic pregnancy, which is a contraindication for a medication abortion, and to obtain the gestational age of the pregnancy. Prior to administering the mifepristone, a physician reviews the lab results, the ultrasound images, and the medical history of the patient. Whether in-person or via telemedicine, the physician does not personally perform a physical exam on the patient. The standard of care developed by ACOG provides that a physical examination by the physician before proceeding with a medical termination of pregnancy is not medically necessary. If there is no medical reason the patient cannot undergo the procedure, the physician informs the patient of the medication regime, potential complications, what to expect after ingesting the misoprostal, and answers the patient’s questions. After receiving informed consent, the physician provides the medication to the patient. If the procedure takes place utilizing telemedicine, the patient-physician communication occurs over a real-time two-way federal Health Insurance Portability and Accountability Act (HIPAA) secured teleconference audio-visual connection, with a staff person in the room with the patient and with the physician at a different location. Under the telemedicine scenario, after receiving informed consent from the patient, the physician releases a secure drawer containing the medications located in the patient’s room. Whether in-person or utilizing telemedicine, both the physician and the staff member watch the patient take the mifepristone. The clinic schedules a follow-up visit within two weeks. The patient subsequently takes the misoprostol 24 to 48 hours later at a location of her choosing. The patient receives a toll-free number to call with any concerns or

questions. If the physician feels the patient needs emergency care, the physician refers the patient to the nearest hospital emergency room.

Administrative Proceedings. On June 25, 2013, the Iowa Board of Medicine (Board) received a petition for rulemaking for the standards of practice for telemedicine medication abortions. The proposed rule included a definition of an abortion-inducing drug, required a physical examination of the patient by a physician prior to providing an abortion-inducing drug, required the physical presence of a physician when the abortion-inducing drug was provided, required a follow-up appointment at the same facility to be provided 12 to 18 days after the use of the abortion-inducing drug, and required that parental notification requirements be followed.

The Board held a public meeting on June 28, 2013, and voted to accept the petition. The Board held a public hearing on the proposed rule on August 28, 2013, and the public was given 35 days to submit written comments on the proposed rule. On August 30, 2013, the Board voted to adopt the rule, announced it would publish the rule on October 2, 2013, and announced the rules would become effective on November 6, 2013. On September 27, 2013, the Board issued a statement regarding the adoption and filing of the rule, including the principal reasons in support of the rule: that the purpose of the rule is to protect the health and safety of patients; that the protocols adopted were inconsistent with the protocols approved by the FDA; that only physicians are, by law, allowed to perform abortions in Iowa; that physical examinations of patients were being delegated to nonphysician persons; and that physicians who prescribe and administer abortion-inducing drugs may never meet with the patient in person or again for follow-up care. The Board also stated reasons for overruling the objections to the rule received from the public, emphasizing the need for protection of the health and safety of patients.

District Court Proceedings. On September 30, 2013, Planned Parenthood and Jill Meadows, M.D. (collectively Planned Parenthood) filed a petition for judicial review and a motion to stay the enforcement of the rule. The district court granted the motion to stay pending its ruling. On August 18, 2014, the district court denied Planned Parenthood's claims and upheld the rule. Planned Parenthood appealed and asked the Iowa Supreme Court (Court) to stay the enforcement of the rule pending resolution of its appeal. The Court entered the stay and retained the appeal.

Issue on Appeal. Planned Parenthood challenged both the rulemaking process and the constitutionality of the rule as both improperly enacted and violative of the Iowa Constitution. On appeal, however, the Court assumed the Board properly enacted the rule and did not violate any procedural or rulemaking provisions of Iowa Code chapter 17A other than Planned Parenthood's claim that the rule is unconstitutional and violates Iowa Code section 17A.19(10)(a) which provides that the Court may 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." Planned Parenthood did not challenge the ruling of the district court regarding the portion of the rule relating to the definition of abortion-inducing drug or requiring compliance with parental notification requirements, so the Court affirmed the district court judgment regarding those provisions. The only issue remaining was whether the remaining portions of the rule are unconstitutional under the Iowa Constitution. (Hereinafter the remaining portions of the rule are referred to as "rule.")

Arguments. Planned Parenthood argued that the Iowa Constitution affords a broader right to an abortion than the United States Constitution and that a strict scrutiny analysis should be applied by the Court in determining the constitutionality of the rule. The Court noted that it had yet to determine if the Iowa Constitution protects a woman's right to terminate her pregnancy, even though the United States Supreme Court had recognized a woman's constitutionally protected liberty interest in the decision to terminate a pregnancy in *Roe v. Wade,* 410 U.S. 113 (1973) over 40 years earlier, and many states had found their respective state constitution to provide the same right. The Board conceded in its brief and oral arguments that the Iowa Constitution provides a right to an abortion that is coextensive with the right available under the United States Constitution and that the Court should adopt the undue burden standard set forth in *Planned Parenthood of Se. Pa. v. Casey* (505 U.S. 833 (1992)) rather than apply the strict scrutiny standard. The Court, therefore, determined it need not decide whether the Iowa Constitution provides such a right and, if so, whether the regulations must pass a strict scrutiny standard. Instead, the Court applied the less stringent undue burden standard to determine whether the rule was constitutional under the Iowa Constitution.

Analysis.

Undue Burden Test. For a state regulation to meet the undue burden test, 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. The woman's right to terminate a pregnancy, however, is limited. The limitation imposed is the state's important and legitimate interest in preserving and protecting the health of the pregnant woman and in protecting the potentiality of human life. The undue burden test is applied differently depending on the particular interest advanced by the statute or regulation. If the state's interest is to advance fetal life, an undue burden exists if its purpose or effect is to place a substantial obstacle in the path of the woman seeking an abortion before the fetus attains viability. If the state's interest is to further the health or interest of the woman seeking to terminate her pregnancy, unnecessary health regulations that have the purpose or effect of presenting a substantial obstacle to a woman seeking an abortion impose an undue burden.

The Court first noted the substance of the rule is to create a standard of practice for physicians who perform medication abortions, the crux of which is to require greater physician involvement in medication abortions. Second, the Court noted the stated purpose of the rule was not to advance fetal life, but rather to promote the health or interest of a woman

seeking to terminate her pregnancy.

The Court reviewed various United States courts of appeals (circuit courts) decisions in applying the undue burden test to state measures enacted to promote the health or interest of a woman seeking to terminate her pregnancy. In the Fifth and Sixth Circuit Courts, the approach merely determined if the state's justification was sufficient to pass a rational basis review, and did not also consider the strength of the state's justification in its analysis. In the Seventh and Ninth Circuit Courts, however, the courts weighed the strength of the state's justification against the burden placed on a woman seeking to terminate her pregnancy. The Court determined that like the Seventh and Ninth Circuit Courts, the Court was 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.

Board Justification for Rule. The Court assumed the Board had a rational basis to act, but analyzed the strength of the Board's justification for the rule. The Board's first justification was to ensure competent medical care by requiring the woman to undergo a physical examination by a physician. However, the weight of the record of evidence indicated that an examination does not provide any measureable gain in patient safety. The physician provided the medically necessary information by reviewing the patient's medical history, blood work, vital signs, and ultrasound images. The second justification for the presence of a physician was the off-label use of the medications. However, the method used by Planned Parenthood conformed to the present medical standard of care for administering the drug. An additional justification was that a patient may never meet with the physician face-to-face. However, an increasing number of medical procedures are being performed by telemedicine. Studies have shown that medical termination of pregnancies can be provided safely and effectively by nonphysician clinicians and that they pose no further risk of complications to a woman than those performed with a physician present. The rule requires the physician to be present when the physician provides the drug to terminate the pregnancy, yet the record did not show the necessity of this provision to promote the woman's health. The rule also requires the physician to schedule a follow-up visit at the same facility. The record established that a clinic equipped to detect and examine the woman for signs of pregnancy could make that determination.

Undue Burden on Woman Seeking Abortion. The Court next analyzed the burden on the woman seeking to terminate her pregnancy. Planned Parenthood argued the rule imposed a substantial burden on a woman seeking to terminate her pregnancy because the woman would potentially have to drive hundreds of miles, miss more days of work, and be subject to a greater possibility of an abusive spouse, partner, or relative finding out her plans and causing her to lose her ability to make the abortion decision privately and discretely. The Board countered that in *Casey*, the 24-hour waiting period was upheld even though it resulted in additional trips and additional driving. The Board noted that under *Casey,* if the law serves a valid purpose, but had an incidental effect of making it more difficult or more expensive to procure an abortion, that alone cannot be enough to invalidate the law. Additionally in *Casey*, a requirement that the physician provide the consent form to the patient was upheld, the Board asserted, so a physician could also be required to perform a physical exam. The Board further asserted that an undue burden should not be determined by the decisions and circumstances of a single provider, and that since Iowa had had telemedicine abortions since 2008 but telemedicine abortions did not exist in a majority of states, compared with the rule or the situation before 2008, the rule does not have a significant adverse effect.

Justification vs. Undue Burden. The Court then weighed the comparative strength of the Board's justification for its rule against the burden placed on the woman seeking to terminate her pregnancy by weighing the health benefits of the rule against the burdens imposed on the woman. The Court surmised the record evidence showed very limited health benefits. The record also provided almost no medical support for the necessity of a pelvic exam prior to dispensing the medication, but did indicate the rule would make it more challenging for a woman to exercise her constitutional right to terminate a pregnancy. The Court was concerned that the Board's arguments were not context-specific, whereas the Court in *Casey* indicated the undue burden test is context-specific. In *Casey*, the evidence and record included recognition that the informed consent requirement served a substantial government interest including the psychological well-being of the woman. The Court found only minimal medical justification in the record for the challenged portion of the rule. The Court noted the Board had adopted rules for telemedicine in general, effective June 3, 2015, that recognized telemedicine as a technological advance to provide medical care with or without an intervening health care provider, authorized the use of telemedicine in accordance with evidence-based guidelines, and provided exceptions to a required examination, personal interview, or diagnosis of the patient. However, under the rule in question, the Board appeared to hold abortion to different medical standards than other procedures, making it difficult for the Court to avoid the conclusion that the Board's concerns were selectively limited to abortions.

Holding. The Court held the rule at issue places 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 agreed that the Iowa Constitution protects a woman's right to terminate her pregnancy to the same extent as the United States Constitution, the Court held the rule violates the Iowa Constitution.

Disposition. The Court found the rule at issue unconstitutional and reversed the district court's judgment as to the rule. The Court affirmed the district court's judgment regarding the uncontested portions of the rule relating to the definition of an abortion-inducing drug and the requirements relating to parental notification, and lifted the stay with regard to these

affirmed portions of the rule.
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