



H.B. 126

125th General Assembly
(As Reported by H. Health)

Reps. Brinkman, Blasdel, Buehrer, Callender, Clancy, Collier, Daniels, DeWine, Distel, Driehaus, Faber, Fessler, Flowers, Gibbs, Gilb, Grendell, Hagan, Hughes, Husted, McGregor, Niehaus, T. Patton, Raga, Raussen, Reidelbach, Reinhard, Schneider, Seaver, Wagner, Schaffer, Seitz, Sferra, Taylor, Widowfield, Willamowski, Williams, White, Young, Kearns, Hoops, Jolivet

BILL SUMMARY

- Prohibits the use of RU-486 (mifepristone) to cause an abortion unless it is administered, provided, or prescribed by a physician in compliance with U.S. Food and Drug Administration (FDA) restrictions.
- Exempts from the prohibition a pregnant woman who obtains or possesses RU-486 for the purpose of terminating her own pregnancy, the legal transport of RU-486, and the distribution, provision, or sale of RU-486 by a legal manufacturer or distributor of the drug.
- Requires physicians who provide RU-486 to cause an abortion to comply with FDA requirements regarding follow-up care and examinations for persons treated with RU-486.
- Requires physicians who provide RU-486 to cause an abortion to make a report to the State Medical Board regarding any serious events or complications related to the use of the drug.
- Requires the State Medical Board to compile and retain all physician reports of complications related to use of RU-486.
- Makes violation of any of the prohibitions a fourth degree felony on the first offense and a third degree felony if the offender previously has been convicted of or pleaded guilty to violation of the offenses or certain other abortion offenses.

- Subjects a professionally licensed person who violates the prohibitions to further sanction by the regulatory or licensing board that has the authority to suspend or revoke the offender's professional license.
- Requires the suspension of the license of a physician, practitioner of a limited branch of medicine, or podiatrist for at least one year for a second or subsequent violation of the prohibitions.
- Makes other changes to the law governing discipline of physicians, practitioners of a limited branch of medicine, and podiatrists in relation to the violation of any of the prohibitions and extends the provisions governing disciplinary investigations, proceedings, and findings to encompass the new prohibitions.
- Requires a prosecutor to notify the State Medical Board if a physician, practitioner of a limited branch of medicine, or podiatrist violates any of the prohibitions or a trial court dismisses the charge for the violation on technical or procedural grounds.
- Requires prescriptions for RU-486 to be in writing.

CONTENT AND OPERATION

Criminal prohibitions regarding the use of RU-486

(sec. 2919.123)

Prohibition against knowingly providing, prescribing, or administering

The bill provides that no person shall knowingly give, sell, dispense, administer, otherwise provide, or prescribe RU-486 to another for the purpose of inducing an abortion in any person or enabling the other person to induce abortion in any person, unless the person who gives, sells, dispenses, administers, or otherwise provides or prescribes the RU-486 is a physician; the physician satisfies all the criteria established by federal law that a physician must satisfy in order to provide or supervise the provision of RU-486 for inducing abortions; and the physician provides or supervises its provision to the other person for the purpose

of inducing an abortion in accordance with all provisions of federal law governing the drug (see **COMMENT 1, 2, and 3**).¹

The bill also provides that a person who gives, sells, dispenses, administers, otherwise provides, or prescribes RU-486 to another in accordance with the criteria described above cannot be prosecuted based on a violation of those criteria unless one or more of the following applies:

- The person knows that the person is not a physician;
- The person did not satisfy all the criteria established by federal law;
- The person did not provide the RU-486 in accordance with the federal law.

Exceptions

The bill provides that the prohibition does not apply to any of the following:

(1) A pregnant woman who obtains or possesses RU-486 for the purpose of inducing an abortion to terminate her own pregnancy;

(2) The legal transport and delivery of RU-486 by any person or entity;

(3) The distribution, provision, or sale of RU-486 by any legal manufacturer or distributor of the drug, provided that the manufacturer or distributor made a good faith effort to comply with any applicable requirements of federal law regarding the distribution, provision, or sale.

Prohibition against failure to comply with FDA restrictions

The bill provides that no physician who provides RU-486 to another for the purpose of inducing an abortion as permitted by the bill shall knowingly fail to comply with the applicable requirements of federal law that pertain to follow-up examinations or care for persons to whom or for whom the drug is provided for the purpose of inducing abortion.

¹ "Physician" is defined as a person who is licensed to practice medicine and surgery or osteopathic medicine and surgery by the State Medical Board or a person who otherwise is authorized to practice medicine and surgery in Ohio.

"Federal law" is defined as any law, rule, or regulation of the United States or any drug approval letter of the Food and Drug Administration that governs or regulates the use of RU-486 for use in inducing abortions.

Report to State Medical Board

The bill requires a physician who provides RU-486 for the purpose of inducing an abortion in accordance with the bill and knows that the person who uses the drug experiences during or after the use an incomplete abortion, severe bleeding, or an adverse reaction to the drug or is hospitalized, receives a transfusion, or experiences any other serious event, to promptly provide a written report to the State Medical Board. The Board is required to compile and retain all reports it receives. The bill provides that in no case may the Board release to any person the name or any other personal identifying information regarding a person who uses RU-486 for the purpose of inducing an abortion and is the subject of a report the Board receives as required by the bill.² Except for the prohibition against releasing identifying information, all reports the Board receives under the bill are public records open to public inspection under Ohio's Public Records Law.

The bill also provides that no physician who provides RU-486 for the purpose of inducing an abortion is permitted to fail to file a report as described above.

Penalties for violation

The bill provides that whoever violates the above-described prohibitions is guilty of unlawful distribution of an abortion-inducing drug, a felony of the fourth degree. If the offender previously has been convicted of or pled guilty to a violation of any of the prohibitions or another abortion-related offense is a third degree felony.³

Under the bill, if the offender is a professionally licensed person, in addition to any other sanction imposed by law for the offense, the offender is subject to sanctioning as provided by law by the regulatory or licensing board or agency that has the administrative authority to suspend or revoke the offender's professional license, including the sanctioning that may be exercised by the State

² *"Personal identifying information" includes the name, address, telephone number, driver's license or license number, commercial driver's license or license number, state identification card or card number, social security card or number, place of employment, employee identification number, mother's maiden name, demand deposit, savings, money market, mutual fund, or other financial account number, personal identification number, password, or credit card number of a living or dead individual.*

³ *The offenses are unlawful abortion, performing or inducing unlawful abortion on a minor, abortion manslaughter, abortion trafficking, partial birth feticide, terminating or attempting to terminate human pregnancy after viability, or failure to perform viability testing, unlawful distribution of an abortion-inducing drug.*

Medical Board (as described below) for offenders who have a certificate to practice or certificate of registration issued by the Board.⁴

Discipline of physicians

(sec. 4731.22)

Under current law, the State Medical Board, with respect to the practice of medicine or surgery, osteopathic medicine or surgery, a limited branch of medicine, or podiatry, may limit, revoke, or suspend an individual's certificate, refuse to register an individual, refuse to reinstate a certificate or reprimand or place on probation the certificate holder for various reasons including, for example, (1) a plea of guilty to, a judicial finding of guilt of, or a judicial finding of eligibility for intervention in lieu of conviction for, a felony, or (2) commission of an act that constitutes a felony in this state, regardless of the jurisdiction in which the act was committed.⁵

⁴ "Professionally licensed person" means a person who is registered, licensed, or certified, or holds a permit, as applicable, to be a manufacturer or wholesaler of controlled substances; certified public accountant or accountant; architect or landscape architect; auctioneer, apprentice auctioneer, or auction company operator; barber; a person engaged in the business of a debt pooling company; cosmetologist, manicurist, esthetician, managing cosmetologist, manicurist, or esthetician, cosmetologist, manicurist, or esthetician instructor, or a person operating a tanning facility; dentist, person administering general anesthesia or conscious intravenous sedation, limited resident, limited teacher, dental hygienist, or dental hygienist teacher; embalmer or apprentice, funeral director or apprentice, funeral home operator, or crematory operator; registered nurse, licensed practical nurse, or nurse midwife; optometrist or optical dispenser; pawnbroker; pharmacist, pharmacy intern, wholesale distributor of dangerous drugs, or terminal distributor of dangerous drugs; physician assistant; physician, practitioner of a limited branch of medicine, or podiatrist; psychologist or school psychologist; professional engineer or surveyor; chiropractor; real estate broker or sales person; sanitarian; junk yard operator; motor vehicle salvage dealer; steam engineer; veterinarian or graduate animal technician; hearing aid dealer and fitter or trainee; private investigator, security service provider, or security guard employee; nursing home administrator; speech-language pathologist or audiologist; occupational or physical therapist; professional clinical counselor, professional counselor, social worker, independent social worker, or social worker assistant; dietician; respiratory therapist; and real estate appraiser.

⁵ "Limited branches of medicine" refers to massage therapy, cosmetic therapy, and, under certain circumstances, narapathy and mechanotherapy. (Sec. 4731.15.)

See sec. 4731.22 for the rest of the acts for which a certificate can be suspended.

Disciplinary actions must be taken in compliance with the adjudication requirements under the Administrative Procedure Act (R.C. Chapter 119.), except that in lieu of compliance with the adjudication requirements, the Board may enter into a consent agreement with an individual to resolve an allegation of a violation.

Under the bill, if the Board takes disciplinary action against an individual for a second or subsequent plea of guilty to, or judicial finding of guilt of, a violation of the criminal prohibitions established by the bill, the disciplinary action must consist of a suspension of the individual's certificate to practice for a period of at least one year or, if determined appropriate by the Board, a more serious sanction involving the individual's certificate to practice. Any consent agreement entered into with an individual that pertains to the second or subsequent violation must provide for a suspension of the individual's certificate to practice for a period of at least one year or, if determined appropriate by the Board, a more serious sanction involving the individual's certificate to practice.

The bill also provides that the certificate to practice issued to an individual and the individual's practice in the state are automatically suspended as of the date of the individual's second or subsequent plea of guilty to, or judicial finding of guilt of, a violation of the criminal prohibitions established by the bill. The Board must notify the individual subject to the suspension by certified mail or in person in accordance with the Administrative Procedure Act's requirements. If an individual whose certificate is automatically suspended fails to make a timely request for an adjudication under the Administrative Procedure Act, the Board must enter an order suspending the individual's certificate to practice for a period of at least one year or, if determined appropriate by the Board, imposing a more serious sanction involving the individual's certificate to practice.

Prosecutorial notification

(sec. 4731.223)

Under the bill, whenever a person holding a certificate to practice medicine, osteopathic medicine, a limited branch of medicine, or podiatry for a second or subsequent time pleads guilty to, or is subject to a judicial finding of guilt of, a violation of the criminal prohibitions established by the bill, the prosecutor in the case, on forms prescribed and provided by the Board, must promptly notify the Board of the conviction or guilty plea. The bill also requires the prosecutor, in any case against a certificate holder, on forms prescribed and provided by the Board, to notify the Board of a plea of guilty to, a finding of guilt by a jury or court of, or judicial finding of eligibility for intervention in lieu of conviction for a felony, or a case in which the trial court issues an order of dismissal on technical or procedural grounds of a charge that the person violated the criminal prohibitions established by the bill. The report must include the name and address of the certificate holder,

the nature of the offense for which the action was taken, and the certified court documents recording the action.

Prescription requirement

(sec. 3719.06)

The bill requires a licensed health professional authorized to prescribe drugs, when prescribing authorized drugs in the course of the professional's practice and in accordance with the laws regulating that practice and the State Pharmacy Board's rules, to comply with the prohibitions established by the bill.⁶ The bill also requires that prescriptions for RU-486 be in writing.

COMMENT

1. Mifepristone, or RU-486 as it is most commonly known, is a drug that, when taken in early pregnancy along with another drug, misoprostol, will cause abortion. RU-486 is a synthetic steroid that interferes with a fertilized egg's ability to adhere to the lining of the uterus. Misoprostol prompts uterine contractions to expel the fertilized egg or embryo. Studies have shown that the drug is 92% to 95.5% effective in causing abortion when used within the first seven weeks of pregnancy. A small percentage of patients need additional surgery or blood transfusions. For most women, the process takes as little time as a few hours to as long as a week. Side effects include uterine bleeding.⁷

2. On September 28, 2000, the Food and Drug Administration (FDA), pursuant to the Federal Food, Drug, and Cosmetic Act, approved RU-486, for use in the United States to induce abortion. The FDA approval was conditioned on the application of numerous restrictions focused on ensuring safe and effective use of the drug.⁸ Those restrictions provide that the drug may be used only for the

⁶ "Licensed health professional authorized to prescribe drugs" means an individual who is authorized by law to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice, including only the following: (1) dentists, (2) until January 17, 2004, advanced practice nurses approved to prescribe drugs and therapeutic devices, (3) clinical nurse specialists, certified nurse-midwives, and certified nurse practitioners who hold a certificate to prescribe, (4) optometrists licensed to practice optometry under a therapeutic pharmaceutical agents certificate, (5) physicians, and (6) veterinarians (sec. 4729.01, not in the bill).

⁷ CNN.com website report September 28, 2000.

⁸ FDA new Drug Approval letter 20-867 to Population Council, September 28, 2000. Office Memorandum to Population Council, September 28, 2000.

medical termination of intrauterine pregnancy through 49 days (seven weeks) pregnancy and only if the following conditions are met:⁹

- **RU-486 must be provided by or under the supervision of a physician who meets the following qualifications:** (1) ability to assess the duration of pregnancy accurately, (2) ability to diagnose ectopic pregnancies, (3) ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through other qualified physicians, and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary, (4) has read and understood the prescribing information for RU-486, (5) must provide each patient with a Medication Guide¹⁰ and must fully explain the procedure to each patient, provide her with a copy of the Medication Guide and Patient Agreement,¹¹ given her an opportunity to read and discuss them, obtain her signature on the Patient Agreement, and sign it as well, (6) Must notify the sponsor¹² or its designate in writing as discussed in the package insert under the heading of DOSAGE AND ADMINISTRATION in the event of an on-going pregnancy, which is not terminated subsequent to the conclusion of the treatment procedure, (7) must report any hospitalization, transfusion, or other serious events to the sponsor or its designate, and (8) must record the RU-486 package serial number in each patient's record.
- **RU-486 must be subject to the following distribution restrictions:** (1) secure manufacturing, receiving, and holding areas for the drug, (2) secure shipping procedures, including tamper-proof seals, (3) Controlled returns procedures, (4) tracking system ability to trace individual packages to the patient level, while maintaining patient confidentiality, (5) use of authorized distributors and agents with necessary expertise to handle distribution requirements for the drug, and (6) provision of drug

⁹ Id.

¹⁰ *This guide provides all the information the patient needs, according to the FDA, to be fully informed about the drug.*

¹¹ *The agreement contains recitations that inform the patient of the procedure, possible outcomes and complications, and the patient's duties.*

¹² *The sponsor is the Population Council. That organization is the one that sought and received FDA approval for the use of RU-486 in the United States. FDA New Drug Application 20-687; FDA New Drug Approval letter 20-867 to Population Council.*

through a direct, confidential physician distribution system that ensures only qualified physicians will receive the drug for patient dispensing.

3. A pregnant woman, under the Federal Constitution, has a right to choose to terminate her pregnancy prior to fetal viability. A law designed to further the state's interest in fetal life that imposes an undue burden on the woman's decision before fetal viability is unconstitutional. "Undue burden" is shorthand for the conclusion that a state regulation has the purpose and effect of placing a substantial obstacle in the path of a woman seeking an abortion.¹³ And with respect to a pre-viable fetus, it has been held that a state creates an undue burden if it acts to ban a method of abortion that may be medically safer for the woman.¹⁴ After viability, the state, in promoting its interest in the potentiality of human life may, if it chooses, regulate, and even prohibit, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother.¹⁵ If a court views the regulation of RU-486 as an undue burden on a woman's right to choose to terminate her pregnancy, the bill could be held unconstitutional.

HISTORY

ACTION	DATE	JOURNAL ENTRY
Introduced	03-13-03	p. 253
Reported, H. Health	06-18-03	p. 609

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¹³ *Stenberg v. Carhart*, 530 U.S. 914, 921 (2000).

¹⁴ *Women's Medical Professional Corporation v. Taft*, ___F.Supp.2d___, 2001 WL 1097813 (2001), (U.S. Dist. Ct., S. D. Ohio).

¹⁵ *Stenberg*, 530 U.S. at 921.

