Final Analysis

Lisa Baumann *Legislative Service Commission*

Sub. H.B. 126

125th General Assembly
(As Passed by the General Assembly)

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, Jolivette, Aslanides, Calvert, Carmichael, Cates, DePiero, C. Evans, Martin, Schlichter, Schmidt, Setzer, Widener, Wolpert**

Sens. **Jacobsen, Jordan, Wachtmann, Amstutz, Austria, Carey, Harris, Hottinger, Schuler, Schuring, Spada, Mumper, Nein**

Effective date: *

ACT 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 a physician who provides RU-486 to comply with FDA requirements regarding follow-up examinations or care for persons treated with RU-486.

* *The Legislative Service Commission had not received formal notification of the effective date at the time this analysis was prepared. Additionally, the analysis may not reflect action taken by the Governor.*

- Requires a physician who provides RU-486 to make a report to the State Medical Board if the person given the drug experiences any serious medical event 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 regarding RU-486 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-related offenses.

- Subjects a professionally licensed person who violates the prohibitions regarding RU-486 to further sanction by the administrative agency with authority to suspend or revoke the offender's professional license.

- Requires the suspension of a physician's license for at least one year for a second or subsequent violation of the prohibitions regarding RU-486.

- Makes other changes to the law governing discipline of physicians in relation to the violation of the prohibitions regarding RU-486 and extends the provisions governing disciplinary investigations, proceedings, and findings to encompass the prohibitions.

- Requires a prosecutor to notify the State Medical Board if a physician violates any of the prohibitions regarding RU-486.

- Requires prescriptions for RU-486 to be in writing.

CONTENT AND OPERATION

Background

Mifepristone, commonly referred to as RU-486 and marketed in the United States as Mifeprex, is a synthetic steroid used in combination with another drug, misoprostol, to terminate early pregnancy. RU-486, which is the first of the two drugs taken, interferes with a fertilized egg's ability to adhere to the lining of the uterus. Two days later, misoprostol is taken, which prompts uterine contractions.[1]

[1] *U.S. Department of Health and Human Services, "FDA Approves Mifepristone for the Termination of Early Pregnancy," (http://www.fda.gov/bbs/topics/NEWS/*

RU-486 was approved by the United States Food and Drug Administration (FDA) on September 28, 2000. In issuing its approval, the FDA specified that the drug was for use in the termination of early pregnancy, defined as 49 days (seven weeks) or less, counting from the beginning of the last menstrual period.[2] The FDA specified that the drug must be provided by or under the supervision of a physician, listed the qualifications that the physician must meet, and identified other requirements pertaining to the distribution of RU-486.[3]

With respect to the qualifications a physician must meet to distribute RU-486, the FDA provided the following:

(1) The physician must have the ability to assess the duration of pregnancy accurately.

(2) The physician must have the ability to diagnose ectopic pregnancies.[4]

(3) The physician must have the 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 must be able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.

(4) The physician must have read and understood the prescribing information for RU-486.

(5) The physician must fully explain the procedure to each patient, provide her with a copy of the Medication Guide[5] and Patient Agreement,[6] give her an

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NEW00737.html, visited 11/11/03); CNN.Com, "Food and Drug Administration Approves 'Abortion Pill'," September 28, 2000, (http://www.cnn.com/2000/HEALTH/women/09/28/abortion.pill/inden.html, visited 11/11/03).

[2] Id.

[3] FDA Center for Drug Evaluation and Research, "Approval Letter MIFEPREX (mifepristone) Tablets," September 28, 2000, (http://www.fda.gov/cder/foi/appletter/2000/20687appltr.htm).

[4] An "ectopic pregnancy" is gestation that occurs outside the uterus, often in a Fallopian tube (American Heritage Dictionary, 2nd ed.).

[5] This guide provides the information the patient needs, according to the FDA, to be fully informed about the drug.

[6] The agreement contains recitations that inform the patient of the procedure, possible outcomes and complications, and the patient's duties.

opportunity to read and discuss them, obtain her signature on the Patient Agreement, and sign it as well.

(6) The physician must notify the sponsor[7] or its designate in writing as discussed in the package insert under the heading DOSAGE AND ADMINISTRATION in the event of an on-going pregnancy, which is not terminated subsequent to the conclusion of the treatment procedure.

(7) The physician must report any hospitalization, transfusion, or other serious events to the sponsor or its designate.

(8) The physician must record the RU-486 package serial number in each patient's record.

Prohibition regarding the distribution of RU-486

(R.C. 2919.123(A))

The act 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 or enabling the other person to induce abortion, 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 RU-486 for the purpose of inducing an abortion in accordance with all provisions of federal law governing the use of the drug for inducing abortions.[8]

The act 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:

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[7] The sponsor is the Population Council, which is the organization that sought and received FDA approval for the use of RU-486 in the United States.

[8] Current law unchanged by the act defines a "physician" 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 or osteopathic medicine and surgery in Ohio (R.C. 2305.113).

The act defines "federal law" 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 the purpose of inducing abortions (R.C. 2919.123(F)).

- The person knows that the other 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

(R.C. 2919.123(D))

The act 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 of RU-486 by any person or entity and the legal delivery of the RU-486. The act specifies that this exception does not apply regarding any conduct related to the RU-486 other than its transport and delivery to the recipient.

(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 regarding failure to provide follow-up care

(R.C. 2919.123(B))

The act provides that no physician who provides RU-486 to another for the purpose of inducing an abortion as permitted by the act 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.

Prohibition regarding failure to report complications

(R.C. 2919.123(C))

Under the act, a physician who provides RU-486 for the purpose of inducing an abortion must promptly provide a written report to the State Medical Board if the physician knows that the person who uses the drug experiences an incomplete abortion, severe bleeding, or an adverse reaction to the drug or is hospitalized, receives a transfusion, or experiences any other serious event. The

Board is required to compile and retain all reports it receives. The act 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 act.[9] Except for the prohibition against releasing identifying information, all reports the Board receives under the act are public records open to public inspection under Ohio's public records law.

The act provides that no physician who provides RU-486 for the purpose of inducing an abortion shall knowingly fail to file a report as described above.

Penalties for violations

(R.C. 2919.123(E))

The act 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 pleaded guilty to a violation of any of the prohibitions or another abortion-related offense, the violation is a third degree felony.[10]

Under the act, if the offender is a professionally licensed person, the offender is also 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 Medical Board (as described below) for offenders who have a certificate to practice or certificate of registration issued by the Board.

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[9] *Current law unchanged by the act defines "personal identifying information" as 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, birth certificate, 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 (R.C. 2919.123(F)(2)).*

[10] *The other abortion-related offenses specified in the act 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, and failure to perform viability testing.*

Discipline of physicians

(R.C. 4731.22)

Under current law, the State Medical Board, with respect to the practice of medicine and surgery or osteopathic medicine and surgery, 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.

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 act, if the Board takes disciplinary action against a physician for a second or subsequent plea of guilty to, or judicial finding of guilt of, unlawful distribution of an abortion-inducing drug, the disciplinary action must consist of a suspension of the physician'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 physician's certificate to practice. Any consent agreement entered into with a physician that pertains to the second or subsequent offense must provide for a suspension of the physician'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 physician's certificate to practice.

The act also provides that the certificate to practice issued to a physician and the physician's practice in Ohio are automatically suspended as of the date of the physician's second or subsequent plea of guilty to, or judicial finding of guilt of, unlawful distribution of an abortion-inducing drug. The Board must notify the physician by certified mail or in person in accordance with the Administrative Procedure Act's requirements. If the physician fails to make a timely request for an adjudication under the Administrative Procedure Act, the Board must enter an order suspending the physician'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 physician's certificate to practice.

Prosecutorial notification

(R.C. 4731.223)

Under the act, whenever a physician for a second or subsequent time pleads guilty to, or is subject to a judicial finding of guilt of, unlawful distribution of an abortion-inducing drug, the prosecutor in the case must promptly notify the Board of the conviction or guilty plea. The report must be made on forms prescribed by the Board, and within 30 days, the Board must initiate action to determine whether to suspend or revoke the physician's certificate to practice.

Although not expressly required by the act, a report involving a first violation of the act's criminal prohibitions would be made pursuant to existing laws that require reports when any felony is involved. Such a report must include the name and address of the physician, the nature of the offense for which the action was taken, and the certified court documents recording the action.

Prescription requirement

(R.C. 4729.29)

Current law provides limitations on the provisions in the pharmacy law regulating the practice of pharmacy and prohibiting a person who is not a pharmacist or a supervised pharmacy intern from compounding, dispensing, or selling dangerous drugs or otherwise engaging in the practice of pharmacy. One limitation is that these provisions do not apply to a licensed health professional authorized to prescribe drugs or prevent a prescriber from personally furnishing the prescriber's patients with drugs within the prescriber's scope of professional practice that seem proper to the prescriber. When a prescriber personally furnishes drugs to a patient pursuant to this provision, the prescriber must ensure that the drugs are labeled and packaged in accordance with state and federal drug laws and any rules and regulations adopted pursuant to those laws. The prescriber also must maintain records of purchase and disposition of all drugs personally furnished to patients in accordance with those laws and rules.

The act subjects a prescriber to the prohibitions established by the act when personally furnishing to a patient RU-486. The prescription must be in writing and in accordance with those prohibitions.

HISTORY

ACTION	DATE	JOURNAL ENTRY
Introduced	03-13-03	p. 253
Reported, H. Health	06-18-03	p. 609
Passed House (79-20)	06-25-03	pp. 968-969
Reported, S. Health, Human Services & Aging	12-04-03	p. 1239
Passed Senate (22-10)	05-19-04	pp. 1975-1981
House concurred in Senate amendments (83-16)	05-25-04	pp. 1949-1950

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