IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF KENTUCKY LOUISVILLE DIVISION

EMW WOMEN'S SURGICAL CENTER, P.S.C., on behalf of itself, its staff, and its patients; ERNEST W. MARSHALL, M.D., on behalf of himself and his patients,

Plaintiffs,

v.

ERIC FRIEDLANDER, in his official capacity as Secretary of Kentucky's Cabinet for Health and Family Services; DANIEL CAMERON, in his official capacity as Attorney General of the Commonwealth of Kentucky; MICHAEL S. RODMAN, in his official capacity as Executive Director of the Kentucky Board of Medical Licensure; and THOMAS B. WINE, in his official capacity as Commonwealth's Attorney for the 30th Judicial Circuit of Kentucky,

Defendants.

Case No.: 3:19-cv-00178-DJH-RSE

FIRST SUPPLEMENTAL VERIFIED COMPLAINT

Pursuant to Federal Rule of Civil Procedure 15(d), Plaintiffs bring this First Supplemental Complaint, which alleges facts occurring after the original complaint was filed, and makes claims against the above-named Defendants, their employees, agents, and successors in office, and in support thereof state the following:

INTRODUCTION

1. The Supplemental Complaint incorporates by reference the allegations of the Amended Verified Complaint, Doc. 5, in paragraphs: 4–13, 25–28, 35, 51, 52, 57, 58.

- 2. This Supplemental Complaint raises a constitutional challenge to House Bill 3 (the "Act") on the ground that it bans abortion at 15 weeks in pregnancy, that the other provisions are tantamount to a ban on abortion, and that certain provisions violate patient's informational privacy. While the Act became yesterday, it is impossible to comply with its vast provisions, resulting in an immediate ban on abortion in the Commonwealth absent this Court's intervention.
- 3. The Act is an omnibus law that will immediately and adversely impact one million people of reproductive age throughout Kentucky. The Act consists of over 70 pages of revisions to Kentucky's existing abortion laws and creates new requirements, including an extensive regulatory regime for the provision of abortion-inducing medication, significantly expanded and invasive reporting requirements, and new requirements for cremation or interment of fetal remains. The Act directs the Cabinet for Health and Family Services (the "Cabinet") to promulgate regulations and create forms for compliance with the Act, but those forms and regulations are not yet ready. Accordingly, it is impossible for Plaintiffs to comply with the Act. The Act imposes the immediate potential for criminal penalties, civil liability (including in one instance, potential penalties up to one million dollars), and potential loss of facility and medical licenses due to non-compliance.
- 4. The result is an unconstitutional ban on abortion in Kentucky because Plaintiffs (as well as the other abortion facility in Kentucky) must cease providing abortions immediately. This ban, and the 15-week ban, violate Plaintiffs' and their patients' procedural and substantive due process rights under the Fourteenth Amendment.
- 5. In addition, the Act violates patient privacy by requiring abortion providers to submit to the Commonwealth highly detailed information regarding each abortion. The Act deems these reports "public records," and they will include information that may be used to identify the

individual and would reveal an individual's most sensitive confidential information, including that the individual had an abortion, as well as information such as whether the patient has a sexually transmitted disease.

- 6. A copy of the Act is attached as Exhibit A.
- 7. The Kentucky Legislature passed the Act and delivered it to Governor Beshear on March 30, 2022. Governor Beshear vetoed the bill on April 8, 2022. The governor's veto statement observed that the new administrative burden associated with the Act is an estimated \$1 million, a testament to its complexity and wide-reaching nature, and noted that the Cabinet is under no legal obligation to carry out an unfunded mandate. Yesterday, on April 13, 2022, the legislature voted to override Governor Beshear's veto and the Act became law and took immediate effect.
- 8. Plaintiffs bring this civil rights action, on behalf of themselves, their staff and their patients seeking abortions, under the U.S. Constitution to challenge the constitutionality of the Act and to seek immediate, emergency relief from this Court to enjoin enforcement of the Act.

SUPPLEMENTAL DEFENDANTS²

9. Defendant Michael S. Rodman serves as Executive Director of the Kentucky Board of Medical Licensure ("KBML" or "the Board"), which is located in Jefferson County. Defendant Rodman and the Board possess authority to pursue disciplinary action up to and including license revocation against Kentucky physicians for violating the Act. KRS 311.565; KRS 311.606, KRS 311.782(4). Defendant Rodman is sued in his official capacity.

¹ https://apps.legislature.ky.gov/record/22rs/hb3/veto.pdf

² The Supplemental Defendants were originally named in Plaintiffs' Amended Verified Complaint but were dismissed without prejudice after they agreed to be bound by an injunction against House Bill 5 and Senate Bill 9, the laws challenged in Plaintiffs' original action. Doc. 29, 30.

10. Defendant Thomas B. Wine serves as Commonwealth's Attorney for the 30th Judicial Circuit of Kentucky. In this capacity, Defendant Wine has authority to enforce the Act's criminal penalties in Jefferson County, where Plaintiffs are located. *See* KRS 15.725(1); KRS 23A.010(1). Defendant Wine is sued in his official capacity.

SUPPLEMENTAL FACTUAL ALLEGATIONS

- 11. Medication abortion involves a combination of two pills, mifepristone and misoprostol, which expel the contents of the uterus in a manner similar to a miscarriage, after the patient has left the clinic in a location of the patient's choosing, typically her own home.
- 12. Despite sometimes being referred to as "surgical abortion," procedural abortion is not what is commonly understood to be "surgery," as it involves no incisions. Instead, in a procedural abortion, the provider inserts a thin, flexible tube, and in some instances, other instruments, to empty the contents of the patient's uterus.
- 13. Approximately half of all abortions in the United States and in Kentucky are procedural abortions, and the other half are medication abortions.³
 - 14. Fifteen weeks in pregnancy is a pre-viability point in pregnancy.
- 15. For young people under age 18, Kentucky requires the consent of one parent before she obtains an abortion. Alternatively, a minor may seek judicial authorization for an abortion without parental consent. In Kentucky, almost all abortion patients under 18 years old obtain a parent's consent for their abortion; a small fraction of them obtain a judicial bypass allowing them to end their pregnancies without parental consent.
- 16. People face many obstacles in accessing abortion care in Kentucky. There are only two outpatient abortion providers in the entire Commonwealth. Both are located in Louisville.

³ Kentucky Annual Abortion Report for 2020, Dept. for Public Health, Office of Vital Statistics, at 12.

Both provide medication abortion up to 10 weeks from the patient's last menstrual period ("lmp"). Planned Parenthood Great Northwest, Hawaii, Alaska, Indiana, and Kentucky ("Planned Parenthood") provides procedural abortion until 13 weeks and 6 days lmp. Plaintiff EMW provides abortion up to 21 weeks and 6 days lmp, which is also a pre-viability point in pregnancy.

HOUSE BILL 3

- 17. The Act bans abortion after 15 weeks in pregnancy lmp. Act §§ 27, 32–35. The Board of Medical Licensure shall revoke the medical license if a physician violates the law. KRS 311.782(4). In addition, the Attorney General has the authority to bring an action in law or in equity to enforce the 15-week ban. Act § 35. There is a very limited exception to the 15-week ban, namely that the abortion must be necessary to prevent the death of the pregnant woman or to avoid serious risk of the substantial and irreversible impairment of a major bodily function of the woman, KRS 311.783, and their other limited affirmative defenses, KRS 311.782(2)(b). The Section of the Act that creates the 15-week ban also adds a new requirement for every abortion to be reported on a form to be created by the Cabinet that includes the gestational age of the fetus and the "results of inquiries of the pregnant person and any medical examinations or tests performed." Act § 27(4).
- 18. The Act also creates numerous new, unnecessary requirements for providers of abortion, many of which cannot be complied with immediately.
- 19. New Requirements to Report Detailed Information Regarding Each Abortion.

 Section 4 of the Act requires immediately that abortion providers submit to the Vital Statistics

 Branch reports containing detailed information about each abortion within three (3) days after the end of each month. Act § 4(1), KRS 213.101(1). Reports must include, among other things:
 - The full name and address of the physician who performed the abortion

- The full name and address of the referring physician, agency or service
- The patient's city, county, state, and zip code
- That patient's age, race, and ethnicity
- The age of the "father" of the fetus
- The total number and dates of the patient's previous pregnancies, live births, and abortions
- A list of the patient's pre-existing medical conditions that may complicate the pregnancy
- Whether the patient suffered any complications or adverse events
- The reason for the abortion, if known, including abuse or trafficking, and
- Whether the patient was tested for sexually transmitted diseases and the outcome of those tests.

Act § 4(2), KRS 213.101(2).

- 20. While the Act provides that the report shall not include the name of the patient, the patient's Social Security number or motor vehicle operator's number, and that it shall not include "other information or identifiers that would make it possible to ascertain the patient's identity," Act § 4(3), KRS 213.101(3), it contains no protection for patients whose identities can be determined based on the information required to be included in the report (e.g., zip code, age, race, pre-existing conditions, previous pregnancies).
- a. The Act provides that the reports and/or report forms containing this information shall be public records. Act § 13(3).
 - b. Pursuant to KRS 213.101(10), the Vital Statistics Branch "shall promulgate administrative regulations in accordance with KRS Chapter 13A to assist in compliance with this

section." Regulations addressing new provisions of KRS 213.101 added by the Act have not been promulgated and could take months to promulgate and implement.

- 21. Multiple other provisions of the Act require the same information called for in the above Section 4 to be included in connection with other report forms to be created by the Cabinet, including:
- a. The requirement that health care facilities and physicians file a written report of any complication or adverse event suffered after an abortion, to include "at minimum the information required by Section 4 of this Act." Act § 25(1). The Act contains no protection for patients whose identities can be determined based on the information required to be included in the report (e.g., zip code, age, race, pre-existing conditions, previous pregnancies). Act § 25(2).
- b. The requirement that each prescribing "qualified physician" report "at minimum the information required by Section 4 of this Act." Act §§ 9, 26.
- c. The requirement that for each abortion conducted, the physician additionally "submit a report on a form provided by the cabinet" including the probable gestational age of the fetus and "at a minimum the information required by Section 4 of this Act." Act § 27(4) (KRS 311.783(4)).
 - 22. New Restrictions and Reporting Requirements for Abortions Performed for Minors.

 The Act immediately requires that for a minor seeking an abortion: (a) the attending physician secures written consent for the abortion by the minor and a consenting parent or guardian; (b) 48 hours prior to providing consent, the consenting parent or guardian makes a "reasonable attempt" to notify any other parent with joint or physical custody (absent limited exceptions for parents enjoined or subject to a protective order on account of domestic abuse or convicted of certain criminal offenses); (c) the written consent includes a copy of the minor's government-issued identification, a

copy of the consenting parent or guardian's government issued identification, and documentation of parental or guardian status such as a birth certificate, court-ordered custodial paperwork, or tax return; (d) a notarized certification of consent by the consenting parent or guardian; (e) the physician keeps the notarized written consent in the medical file for at least 5 years after the minor reaches 18, or for 7 years, whichever is longer; and (f) an affidavit by the attending physician certifying, "according to my best information and belief, a reasonable person under similar circumstances would rely on the information presented by both the minor and her parent or legal guardian as sufficient evidence of identity." Act § 1(2)(a)(1-4) (KRS 311.732(2)(a)(1-4)).

- 23. Requirement for Creation of a "Drug Certification Program" and Associated Regulations and Reporting Requirements for Medication Abortions.
- a. Under the Act, medication abortions can now only be provided pursuant to the Kentucky Abortion-Inducing Drug Certification Program by "qualified physicians" and "certified" abortion facilities, pharmacies, manufacturers, and distributors. Act § 15. The Cabinet is tasked with promulgating administrative regulations to create the Drug Certification Program and establish certification requirements for abortion facilities (licensed under KRS 216B.0431), including Plaintiffs' facility, in addition to pharmacies, manufacturers, and distributors of abortion-inducing medication. *Id.* at § 15(1). The Act does not provide a timeframe for the promulgation of the requisite regulations or the creation of the Drug Certification Program.
- b. The Act sets out numerous new procedures a physician must follow to be deemed "qualified" and to register under the Act, including, but not limited to, signing an annual "Dispensing Agreement Form" to be developed and provided by the Cabinet (Act § 17(1)) (the form does not yet exist), and securing admitting privileges or entering into a written associated physician agreement. Act § 17(2); see also Act §§ 7 and 8. There is no process established yet to confirm that a physician is

qualified and registered for purposes of compliance with the law, and there are criminal penalties associated with non-compliance. Act § 28(6) (KRS 315.990(6)); 39(a) (KRS 311.990(39)(a)).

- c. The Act requires that abortion providers obtain written consent from a patient 24-hours prior to dispensing abortion medication to the patient, absent limited exceptions for risk of death or physical impairment or major bodily injury, on "a form created by the Cabinet for Health and Family Services to obtain the consent required prior to providing an abortion-inducing drug" and that they submit the completed form to the Cabinet. Act § 8(1–2). The required consent form does not exist, and there are criminal penalties associated with violations of these provisions. Act § 39(a) (KRS 311.990(39)(a)).
- d. The Act requires that for any adverse event experienced by a patient within 15 days after use of abortion medication, the physician who provided the medication must report such adverse event within three days of the event to the federal Food and Drug Administration. Act § 9(2) *see also* Act §§ 25(1), 26(3) (also requiring submission of report for adverse events and/or complications). Any physician or health care provider who diagnoses or knowingly treats a patient experiencing an adverse event related to the medication abortion must make a report to the Cabinet of such adverse event on a report form provided by the Cabinet within three days after the diagnosis or treatment was provided. *Id.* at § 9(3). Forms have not yet been created for purposes of complying with these requirements.
- e. The Act requires physicians providing medication abortions to a patient to, within three days after providing the medication, report the issuance of the prescription "on a form provided by the cabinet" and signed by the physician. Act § 26(1). It also requires physicians to state in the report of all abortions required by KRS 213.101 whether there were "adverse events" as defined by the Act. *Id.* at §26(3). This report must include all of the personal and identifying information required in

the form to be created by the Cabinet for all abortions under Section 4 of the Act, as well additional information. Act § 26(4).

- f. The Act makes it unlawful for any manufacturer, distributor, physician or any other person to provide abortion inducing drugs to a pregnant person via courier, delivery or mail service. Act § 6(2). There are criminal penalties associated with violations of these provisions. *Id.* at § 3(39)(a).
- g. The Act sets forth the penalties for, *inter alia*, physician noncompliance with the Drug Certification Program, including but not limited to, referral to law enforcement, assessment of a \$100,000 per offense fine on physicians, suspension or revocation of certification, and reporting and recommending sanctions to the Board of Medical Licensure or Board of Pharmacy. Act § 18(1). In addition, it provides that individuals shall have a private right of action to seek restitution and damages for any intentional, knowing or reckless violation of Sections 14–19 of the Act. *Id.* at § 18(2).
 - 24. New Restrictions and Reporting Requirements on Handling of Fetal Tissue Derived from an Abortion.
- a. The Act defines "fetal remains" to mean "the biological remains of a human child resulting from the termination of a pregnancy by a surgical or medication abortion prior to birth or miscarriage." Act § 22(1).
- b. Under the Act, fetal tissue derived from an abortion may no longer be disposed of as medical waste, Act § 22(4)(a), as has consistently been permitted under Kentucky law. *See* 902 K.A.R. § 29:106; 902 K.A.R. § 20:360. With limited exceptions for law enforcement or pathological examination purposes or private interment by the patient, the Act bars transport of such fetal tissue for any purpose other than final disposition by a licensed crematory or funeral establishment. Act §§ 22(4)(d)(1)-(6). Thus, in most instances, products of conception now must be cremated or interred.

c. The Act provides that "[t]he Cabinet shall design forms through administrative regulations that document (a) the age of the parent or parents of the fetal remains"; (b) consent by the parent or guardian of the patient and/or the father if either is a minor; (c) "[t]he status of fetal remains from an abortion for the purpose of cremation that shall meet any requirements for a birth-death, provisional death, or death certificate for transport or cremation;" (d) "[a] designation of how the fetal remains shall be disposed of and who shall be responsible for final disposition;" and (e) "any other information required by the cabinet." Act § 22(3). The forms do not yet exist, and the Act does not specify a timeframe within which the Cabinet is required to make such forms available.

25. Creation and Publication of Report Forms and Promulgation of Regulations.

- a. Pursuant to Section 13 of the Act, "[t]he cabinet shall create and distribute the report forms required in Sections 1, 4, 8, 9, 15, 25, 26, 27 and 29 of this Act within sixty (60) days after the effective date of this Act." Act § 13(1). As stated above, these sections require several different forms required for use in all abortions, abortions by minors, medication abortions, and abortions involving complications or adverse events. The forms have not yet been created for purposes of compliance with these requirements.
- b. Pursuant to Section 13, the reports "shall be deemed public records and shall be provided to the Kentucky Board of Medical Licensure, the Kentucky Board of Pharmacy, state law enforcement offices, and child protective services upon request for use in the performance of their official duties." Act § 13(3).
 - 26. <u>Criminal and Civil Penalties for Violation of the Act</u>. The Act provides that "any person who intentionally, knowingly, or recklessly performs an abortion upon a minor without obtaining the required consent pursuant to Section 1 of this Act shall be guilty of a Class D felony" (Act § 3(12)(a)) and "a person who intentionally, knowingly, or recklessly violates Sections 5 to 11

of [the] Act [restrictions on medication abortions] is guilty of a Class D felony." Act § 3(39)(a). Similarly, it provides that "[a]ny person who intentionally, knowingly, or recklessly violates

Sections 14 to 19 of this Act [abortion Drug Certification Program] is guilty of a Class D felony."

Act § 28(6)(a). And it provides "[a]ny person who intentionally, knowingly, or recklessly violates

Sections 14 to 19 of this Act is guilty of a Class D felony" and "shall be fined not more than one

million (\$1,000,000)." Act §§ 31(2)(a), (b).

- 27. Denial, Suspension or Revocation of License for Violation of the Act. Pursuant to the Act, the board may deny, suspend, limit, restrict or revoke a license (including but not limited to an abortion facility license) upon proof of a failure to comply with the requirements of the Act regarding reporting of all abortions under Section 4 (Act § 4(8)(c)) and regarding abortions by minors under Section 1 of the Act. Act § 2(27) (KRS 311.595). The Attorney General and the Cabinet also may take action against facility licenses for violations of the Act. *See* KRS 216B.990; KRS 15.241
- 28. <u>Civil Liability for Violation of Act</u>. Pursuant to the Act, violations of the restrictions on medication abortions can provide the basis for a civil malpractice action for actual and punitive damages, provide a basis for a professional disciplinary action, and provide a basis for recovery for a patient's survivors for wrongful death. Act § 11(1).
- 29. <u>"Emergency Clause"</u>. The Act took "effect upon its passage and approval by the Governor or upon its otherwise becoming law." Act § 39. The forms and regulations required by the Act do not presently exist.

De Facto Ban on Abortion Based on Impossibility of Compliance

- 30. Because the Act is effective immediately, Kentucky abortion providers including Plaintiffs are at immediate risk of committing felonies or incurring serious fines, civil liability or revocation of their licenses if they continue to provide abortions.
- 31. Until the Cabinet publishes the forms required for compliance with the Act and/or promulgates the required administrative regulations, no facility or physician, including Plaintiffs, can provide abortion services in compliance with the Act. Thus, the Act is an unlawful ban on all abortions in Kentucky.
- 32. Within 60 days of its enactment, the Act requires the Cabinet to create at least eight new forms providers must use to comply with its provisions:
 - Section 1 requires a new form for providers to document provision of emergency medical abortion services to minors without consent;
 - Section 4 requires a new form through which abortion providers report *every* abortion they perform within the Commonwealth;
 - Section 8 requires a new form through which abortion providers obtain the informed consent of a patient before providing medication abortion;
 - Section 9 requires a new form through which abortion providers report each provision of medication abortion and any complications or adverse events, as well as any resulting treatment, related to abortion medication;
 - Section 25 requires a new form through which abortion providers report any complications or adverse events related to abortion;
 - Section 26 requires a new form through which abortion providers report each abortion medication prescription issued, each abortion performed, and all adverse events;
 - Section 27 requires abortion providers to report the gestational age of the fetus as well as the results of inquiries of the patient as to gestational age and any medical exams or tests performed; and
 - Section 29 requires a report of each prescription dispensed by a pharmacy for abortion medication.

Act § 13(1). Such forms do not presently exist. Rather, they are "to be developed and provided by

the [C]abinet." Id.

- 33. The Act requires that the Cabinet create additional forms without any deadline for completion and/or the creation of programs and promulgation of regulations to enable compliance, but those forms, regulations, and programs do not presently exist:
 - Section 4, which requires abortion providers to report *every* abortion they perform within the Commonwealth, provides that "[t]he Vital Statistics Branch shall promulgate administrative regulations in accordance with KRS Chapter 13A to assist in compliance with this section";
 - Sections 5 through 9 require that a physician be "registered" as a "nonsurgical abortion provider" in order to lawfully provide abortion medication to a patient;
 - Sections 15 and 17 bar a facility from providing abortion medication to a
 patient unless it is certified under the Kentucky Abortion-Inducing Drug
 Certification Program, pursuant to regulations to be promulgated;
 - Section 17 requires providers to sign a "Dispensing Agreement Form" to register as a "nonsurgical abortion provider," a prerequisite to being legally authorized to prescribe and provide abortion medication to patients;
 - Section 22 directs that the disposition of tissue remains be documented through forms to be created by the Cabinet "through administrative regulations"; and
 - Section 29, which requires a report of each prescription dispensed by a pharmacy for abortion medication, provides that "[t]he Vital Statistics Branch shall promulgate administrative regulations in accordance with KRS Chapter 13A to assist in compliance with this section."
- 34. Plaintiffs also cannot immediately comply with provisions of the Act that require engagement or contracting with third parties for compliance. For example:
- a. It is impossible for Plaintiffs to comply immediately with the provisions regarding handling of fetal tissue because Plaintiffs currently contract with third-party vendors to safely dispose of products of conception as pathological waste, pursuant to Commonwealth regulations for infectious waste. Compliance with the Act with respect to handling of fetal tissue will necessarily

require Plaintiffs to enter into one or more new contracts with a third-party crematorium or funeral establishment, and Plaintiffs will need time to identify such businesses that are willing and able to provide services in compliance with the Act.

- b. With respect to abortions for minors, the Act does not establish processes for convenient access to notaries to carry out the required consent. Act § 1(2)(a)(2)(b). On information and belief, some of Plaintiffs' patients may not have confidential access to a notary in a timely manner, or at all.
 - 35. The Act stands as a substantial obstacle in the path of a woman seeking an abortion because it is tantamount to an abortion ban. It is arbitrary and unconstitutional to enforce penalties for noncompliance while failing to provide a means of immediate compliance. Plaintiffs, in fairness, must be granted time to comply with these sweeping changes to the provision of abortion care. Otherwise, the existence of regulatory requirements uncoupled from the means to comply with them will result in a complete ban on abortion within Kentucky.

Impact of Personal Information Disclosures Required by the Act

- 36. As noted, the Act dramatically increases the personally identifiable and sensitive information that must be reported to the Office of Vital Statistics by abortion providers for each and every abortion (medical and procedural) in Kentucky.
- 37. The Act provides that the reports containing this private medical and personal identifying information about people who undergo abortions shall be "public records." Act § 13.
- 38. These public reports will make sensitive and confidential information related to sexually transmitted diseases, prior pregnancies, current and prior abortions, and pre-existing medical conditions available to the public. Act § 4; see also Act §§ 25, 26, 27, 29.

- 39. On information and belief, the public reports required under the Act will make individually identifiable health information available to the public. For example, reports disclosing the combination of county, zip code, age, and/or race may readily reveal patient identity. Kentucky is comprised of 759 zip codes⁴ and 120 counties.⁵ Hundreds of Kentucky zip codes have a population of less than 1,000⁶. Kentucky is 50.7% female. Per the U.S. Census, Kentucky is 87.5% white, 8.5% black or African American, 1.6% Asian, 2% two or more races, and 3.9% Hispanic or Latino. 54.7% of Kentuckians are between the ages of 18 and 65.⁷ Accordingly, where the patient's zip code, age, race, ethnicity and other personal information such as previous pregnancies, are of public record, there are numerous zip codes where the identity of the patient may be determined.
- 40. Further, once the patient's identity is ascertained, the Act's public record reports may reveal highly sensitive, personal information about a patient, including that she obtained an abortion, as well as whether she has a sexually transmitted disease or a pre-existing medical condition, in addition to whether she sought the abortion because she of abuse.
- 41. By mandating the disclosure of individually identifiable health information of the most sensitive nature (abortions, sexually transmitted infections, whether the patient was seeking the abortion because she was abused), the Act requires the unlawful disclosure of private medical

⁴ https://www.kentucky-demographics.com/zip_codes_by_population (based on U.S. Census Bureau data collected on March 17, 2022).

⁵ "States, Counties, and Statistically Equivalent Entities" U.S. Census Bureau https://www2.census.gov/geo/pdfs/reference/GARM/Ch4GARM.pdf

⁶ <u>https://www.kentucky-demographics.com/zip_codes_by_population</u> (based on U.S. Census Bureau data collected on March 17, 2022).

⁷ https://www.census.gov/quickfacts/fact/table/KY/fips#fips (last accessed April 8, 2022).

information about an individual's sexual life and procreation (among others) in violation of their fundamental right to privacy.

42. The prospect of such disclosures will dissuade some people from seeking an abortion they have decided to have, particularly if they have a need to keep their abortion decision from an abusive parent, partner, or spouse. As such, the Act imposes an undue burden on a woman's right to access abortion in Kentucky.

CLAIMS FOR RELIEF

COUNT I

(Procedural Due Process)

- 43. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 42.
- 44. By taking effect immediately, without providing Plaintiffs and other abortion providers time to comply, and by subjecting Plaintiffs to the Act's penalties when the Cabinet has not yet created the forms Plaintiffs is required to use, or promulgated the required regulations, the Act violates Plaintiffs' right to procedural due process under the Fourteenth Amendment to the United States by depriving it of liberty and/or property without due process of law.

COUNT II

(Substantive Due Process)

- 45. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 42.
- 46. By requiring Plaintiffs to comply with the Act despite compliance being impossible—thereby preventing Plaintiffs from providing abortions and operating its business—the Act is arbitrary and violates Plaintiffs' rights as guaranteed by the Due Process Clause of the

Fourteenth Amendment to the United States Constitution because it is not rationally related to any legitimate state interest.

COUNT III

(Substantive Due Process - Right to Liberty and Privacy)

- 47. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 42.
- 48. By passing a law that takes effect immediately, and making compliance impossible by requiring Plaintiffs to use agency forms and processes not yet available, Plaintiffs will be forced to stop providing abortion immediately, creating a de facto ban on abortion in violation of its patient's rights to liberty and privacy as guaranteed by the Due Process Clause of the Fourteenth Amendment to the United States Constitution.

COUNT IV

(Substantive Due Process – Plaintiffs' Patients' Right to Informational Privacy)

- 49. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 42.
- 50. By requiring involuntary disclosure of Plaintiffs' patients' individually identifiable health information of the most sensitive nature and/or the public disclosure of such information, the Act violates Plaintiffs' patients' rights to privacy as guaranteed by the Fourteenth Amendment to the U.S. Constitution.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs ask this Court:

A. To immediately issue a temporary restraining order and/or preliminary injunction, and a permanent injunction, restraining Defendants, their employees, agents, and successors in

office from enforcing the Act.

- B. To declare that the Act violates the Fourteenth Amendment to the United States

 Constitution by depriving Plaintiffs' patients of their rights to liberty and privacy.
- C. To declare that the Act violates the Fourteenth Amendment to the United States

 Constitution by depriving Plaintiffs of property without due process of law.
 - C. To award Plaintiffs its attorneys' fees and costs pursuant to 42 U.S.C. § 1988.
 - D. To grant such other and further relief as the Court deems just and proper.

Dated: April 14, 2022 Respectfully submitted,

/s/ Brigitte Amiri

jdalven@aclu.org

Brigitte Amiri*
Rachel Reeves*
Jennifer Dalven*
American Civil Liberties Union Foundation
125 Broad Street, 18th Floor
New York, New York 10004
(212) 549-2633
bamiri@aclu.org
rreeves@aclu.org

Heather L. Gatnarek ACLU of Kentucky Foundation 325 West Main Street, Suite 2210 Louisville, Kentucky 40202 (502) 581-9746 heather@aclu-ky.org

Michele Henry Craig Henry PLC 401 West Main Street, Suite 1900 Louisville, Kentucky 40202 (502) 614-5962 mhenry@craighenrylaw.com

Leah Godesky*

O'Melveny & Myers 7 Times Square New York, New York 10036 (212) 326-2000 lgodesky@omm.com

Kendall Turner*
O'Melveny & Myers
1625 Eye St. NW
Washington, D.C. 20006
(202) 383-5300
kendallturner@omm.com

ATTORNEYS FOR PLAINTIFFS

DECLARATION

I declare under penalty of perjury that the statements contained in the First Supplemental Complaint are true and accurate to the best of my knowledge and belief.

s/Ernest W. Marshall, M.D. Ernest W. Marshall, M.D.

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing was filed with the Court using the CM/ECF system on April 14, 2022, which will generate an electronic notice of filing to all counsel registered with that service.

s/Brigitte Amiri
Brigitte Amiri

^{*}pro hac vice motions granted

Exhibit A

1 AN ACT relating to public health and declaring an emergency. 2 WHEREAS, in September 2000, the Food and Drug Administration (FDA) 3 approved the distribution and use of mifepristone (brand name mifeprex), originally 4 referred to as "RU-486", an abortion-inducing drug, subject to distribution restrictions 5 pursuant to 21 C.F.R. 314.520, also referred to as "Subpart H," which allows for post-6 marketing distribution or use restrictions; and 7 WHEREAS, mifepristone is still subject to certain restrictions on its distribution 8 under the Mifepristone REMS Program; and 9 WHEREAS, in September 2000, the FDA prescribed a specific gestation of 49 days 10 from the last menstrual period (LMP), dosage, and administration protocol for 11 mifeprex/mifepristone; and 12 WHEREAS, the approved FDA protocol for mifeprex/mifepristone was modified in 13 March 2016 and maintains that certain distribution restrictions are still necessary because 14 of the drug's potential for serious complications; and 15 WHEREAS, as approved by the FDA, the 2016 administration protocol consists of 16 one 200 mg tablet in a single oral dose of mifeprex/mifepristone followed by four 200 17 mcg tablets misoprostol taken 24 to 48 hours later in the cheek pouch, through 70 days 18 LMP. The patient is to return for a follow-up visit to confirm that a complete abortion has 19 occurred 7 to 14 days after administration of the abortion-inducing drug; and 20 WHEREAS, the 2016 FDA protocol also requires that the distribution and use of 21 mifeprex/mifepristone be under the supervision of a qualified healthcare provider who 22 has the ability to assess the duration of pregnancy, diagnose ectopic pregnancies, and 23 provide surgical intervention or has made plans to provide surgical intervention through 24 another qualified physician; and 25 WHEREAS, on December 16, 2021, the FDA announced that it will no longer 26 require an in-person medical examination, it will permit abortion-inducing drugs to be 27 mailed to the patient, and it will permit pharmacies to fill prescriptions if they are

1	certified by the manufacturers to do so; and		
2	WHEREAS, court testimony by Planned Parenthood and other abortion providers		
3	has demonstrated that providers routinely and intentionally failed to follow the September		
4	2000 FDA-approved protocol for mifeprex/mifepristone (for example, see Planned		
5	Parenthood Cincinnati Region v. Taft, 459 F. Supp. 2d 626, S.D. Oh. 2006); and		
6	WHEREAS, the use of mifeprex/mifepristone presents significant medical risks,		
7	including but not limited to uterine hemorrhage, viral infections, abdominal pain,		
8	cramping, vomiting, headache, fatigue, and pelvic inflammatory disease; and		
9	WHEREAS, health problems usually do not occur during the first pregnancy for an		
10	Rh negative woman with an Rh positive fetus because the body does not have a chance to		
11	develop a large number of antibodies; and		
12	WHEREAS, if the woman is Rh negative and does not receive an injection of Rh		
13	immunoglobulin at the time of an abortion or delivery, she may experience Rh		
14	incompatibility in future pregnancies which can lead to complications and miscarriage.		
15	Therefore, it is critical for a qualified physician to determine blood type and administer		
16	Rh immunoglobulin if a woman is Rh negative; and		
17	WHEREAS, the risk of complications increases with advancing gestational age and		
18	with the failure to either complete the two-step dosage process for the		
19	mifeprex/mifepristone regimen or to receive abortion pill reversal care from a qualified		
20	healthcare professional; and		
21	WHEREAS, studies document that increased rates of complications, including		
22	incomplete abortion, occur even within the FDA-approved gestational limit; and		
23	WHEREAS, as of March 2020, the FDA reported 4,480 adverse events after		
24	women used mifeprex/mifepristone for abortions. Among these events were 24 deaths,		
25	1,183 hospitalizations, 339 blood transfusions, and 256 infections, including 48 severe		
26	infections; and		

WHEREAS, the Adverse Event Reports (AER) systems relied upon by the FDA

27

1 have limitations and typically detect only a small proportion of events that actually occur; 2 and 3 WHEREAS, as of March 31, 2020, 27 women have reportedly died after 4 administration of mifeprex/mifepristone, with 6 deaths attributed to severe bacterial 5 infections. Eight of those women administered the mifeprex/mifepristone regimen in an 6 "off-label" or "evidence-based" manner then-advocated by abortion providers, and the 7 FDA has not been able to determine whether this off-label use led to the deaths; and 8 WHEREAS, medical evidence demonstrates that women who use abortion-inducing 9 drugs risk four times more complications than those who undergo surgical abortions. At 10 least three to eight percent of medical abortions fail to evacuate the pregnancy tissue and 11 require surgical completion. One percent will fail to kill the fetus. If surgical completion 12 is required after a failed medical abortion, the risk of premature delivery in a subsequent 13 pregnancy is more than three times higher. Failure rates increase as gestational age 14 increases. The gestational age range of 63 to 70 days has been inadequately studied. The 15 2016 FDA gestational age extension was based on only one study worldwide of little 16 more than 300 women; and 17 WHEREAS, 2020 marked the state of Arkansas' first full year of data after a new 18 abortion complication reporting law went into effect. Forty-five complications were 19 reported in 2020, of which 40, or 88 percent of all complications, resulted from 20 medication abortions; and 21 WHEREAS, a woman's ability to provide informed consent depends on the extent 22 to which the woman receives information sufficient to make an informed choice; and 23 WHEREAS, the decision to abort "is an important, and often a stressful one, and it 24 is desirable and imperative that it be made with full knowledge of its nature and 25 consequences" as stated in Planned Parenthood v. Danforth, 428 U.S. 52, 67 (1976); and 26 WHEREAS, some women come to regret their decision to abort shortly after 27 ingesting mifeprex/mifepristone; and

WHEREAS, in recent years, physicians have developed a method to potentially reverse the effects of mifeprex/mifepristone. This abortion pill reversal or rescue process has been discussed in a peer-reviewed study and is based on decades of the safe use of progesterone to stabilize and continue pregnancies; and WHEREAS, understanding the science behind the mechanism of action of mifeprex/mifepristone has allowed physicians to design a specific rescue for a woman who has used mifeprex/mifepristone to induce an abortion but has not yet ingested the second drug in the medication abortion regimen. Since physicians know that mifeprex/mifepristone works by blocking progesterone, physicians know that treating a woman with progesterone can displace mifeprex/mifepristone from the progesterone receptors. This allows the woman's body to respond naturally to the progesterone and to effectively fight the effects of the mifeprex/mifepristone-induced blockage; and WHEREAS, it has long been known that mifepristone acts reversibly at the molecular level of receptor binding. Progesterone and mifepristone compete for the binding site of the receptor making the anti-progesterone activity of mifepristone reversible; and WHEREAS, mifeprex/mifepristone floods the progesterone receptors, blocking progesterone. Progesterone reverses the effects of the mifeprex/mifepristone by outcompeting and outnumbering the mifepristone and restoring adequate progesterone to sustain the pregnancy; and WHEREAS, progesterone itself has been used safely during pregnancy for decades. It is used in in-vitro fertilization, infertility treatments, and high-risk pregnancies such as pre-term labor. Using progesterone to reverse the effects of mifeprex/mifepristone is a targeted response that is safe for women; and WHEREAS, statistics show that as of March 2020, more than 1,000 lives have been saved following the progesterone reversal process and that babies born following the reversal process have a rate of birth defects no higher than the general population; and

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

1 WHEREAS, studies show that following the progesterone reversal process or 2 otherwise treating a woman with progesterone during pregnancy does not lead to 3 increased mortality rates; and 4 WHEREAS, to facilitate reliable scientific studies and research on the safety and 5 efficacy of abortion-inducing drugs, it is essential that the medical and public health 6 communities have access to accurate information both on the efficacy and use of 7 abortion-inducing drugs, as well as on resulting complications; and 8 WHEREAS, abortion "record keeping and reporting provisions that are reasonably 9 directed to the preservation of maternal health and that properly respect a patient's 10 confidentiality and privacy are permissible" as stated in Planned Parenthood v. Danforth, 11 428 U.S. 80 at 52, 79-81 (1976); and 12 WHEREAS, abortion and complication reporting provisions do not impose an 13 "undue burden" on a woman's right to choose whether or not to terminate a pregnancy. 14 Specifically, "[t]he collection of information with respect to actual patients is a vital 15 element of medical research, and so it cannot be said that the requirements serve no

17 Casey, 505 U.S. 833 at 900-901 (1992); and

16

18

19

20

21

22

WHEREAS, to promote its interest in maternal health and life, the Commonwealth of Kentucky has an interest in collecting demographic information on all drug-induced abortions performed and all abortion complications from all drug-induced abortions diagnosed or treated and compiling statistical reports based on the information collected for future scientific studies and public health research; and

purpose other than to make abortions more difficult" as stated in Planned Parenthood v.

- WHEREAS, based on the findings from scientific studies and public health research, it is the purpose of this Act to:
- 25 1. Protect the health and welfare of every woman considering a drug-induced abortion;
- 27 2. Ensure that a physician examines a woman prior to dispensing an abortion-

1 inducing drug in order to confirm the gestational age of the unborn child, the intrauterine

- 2 location of the unborn child, and that the unborn child is alive, since routine
- 3 administration of mifeprex/mifepristone following spontaneous miscarriage is
- 4 unnecessary and exposes the woman to unnecessary risks associated with both
- 5 mifeprex/mifepristone and misoprostol;
- 6 3. Ensure that a physician does not prescribe or dispense an abortion-inducing
- 7 drug beyond 70 days' gestation;
- 8 4. Reduce "the risk that a woman may elect an abortion, only to discover later,
- 9 with devastating psychological consequences, that her decision was not fully informed."
- 10 Planned Parenthood v. Casey, 505 U.S. 833, 882 (1992);
- 5. Ensure that women considering a drug-induced abortion receives
- 12 comprehensive information on abortion-inducing drugs, including the potential to reverse
- the effects of the drugs should she change her mind, and that women submitting to an
- 14 abortion does so only after giving her voluntary and fully informed consent to the
- 15 procedure; and
- 16 6. Promote the health and safety of women, by adding to the sum of medical and
- 17 public health knowledge through the compilation of relevant data on drug-induced
- 18 abortions performed in the state, as well as on all medical complications and maternal
- 19 deaths resulting from these abortions; and
- WHEREAS, sexually transmitted diseases (STDs) are usually spread by having
- vaginal, oral, or anal sex. More than 9 million women in the United States are diagnosed
- 22 with an STD each year, and women often have more serious health problems associated
- with STDs than men, including infertility; and
- WHEREAS, the primary goal of the Kentucky Sexually Transmitted Disease
- 25 Prevention and Control Program is to prevent the spread and complications of STDs; and
- WHEREAS, local health departments test for chlamydia, gonorrhea, and syphilis,
- and provide treatment for individuals diagnosed with, exposed to, or suspected of having

1 these diseases; and 2 WHEREAS, chlamydia and gonorrhea, left untreated, increase the risk of chronic 3 pelvic pain and life-threatening ectopic pregnancy and untreated syphilis in pregnant 4 women results in infant death up to 40 percent of the time; and 5 WHEREAS, women have a higher risk than men of getting an STD during 6 unprotected sex; and 7 WHEREAS, since women and girls seeking to terminate an unplanned pregnancy 8 may have had limited encounters with a healthcare provider prior to their encounter with 9 an abortion providing facility, it is in the best interest of improving health outcomes for 10 all Kentucky women and girls to ensure women and girls have the opportunity to receive 11 timely and accurate information on women's health risks, especially Rh negative and 12 STDs, that may impact their future health, the health of their partners and future 13 pregnancies, and increase the risk of harmful fetal and child health outcomes; and 14 WHEREAS, despite spending on healthcare in the United States far outpacing other 15 nations, health outcomes are often much worse, particularly for women, because the focus 16 in the United States has been on treating discrete, acute conditions and procedures rather 17 than coordinating care, providing preventive services, and addressing root causes of poor 18 health; 19 NOW, THEREFORE, 20 Be it enacted by the General Assembly of the Commonwealth of Kentucky: 21 → Section 1. KRS 311.732 is amended to read as follows: 22 For purposes of this section the following definitions shall apply: 23 (a) "Minor" means any person under the age of eighteen (18); 24 "Emancipated minor" means any minor who is or has been married or has by (b)

(c) "Abortion" means the use of any instrument, medicine, drug, or any other

court order or otherwise been freed from the care, custody, and control of her

parents; and

25

26

27

1		substance or device with intent to terminate the pregnancy of a woman known
2		to be pregnant with intent other than to increase the probability of a live birth,
3		to preserve the life or health of the child after live birth, or to remove a dead
4		fetus.
5	(2)	No person shall perform an abortion upon a minor unless:
6		(a) The attending physician or his agent has secured the informed written
7		consent of the minor and one (1) parent or legal guardian with joint or
8		physical custody and the consenting parent or legal guardian of the minor
9		has made a reasonable attempt to notify any other parent with joint or
10		physical custody at least forty-eight (48) hours prior to providing the
11		informed written consent.
12		1. Notice shall not be required to be provided to any parent who has:
13		a. Previously been enjoined by a domestic violence order or
14		interpersonal protective order, regardless of whether or not the
15		person to be protected by the order was the minor; or
16		b. Been convicted of, or entered into a diversion program for, a
17		criminal offense against a victim who is a minor as defined in
18		KRS 17.500 or for a violent or sexual criminal offense under
19		KRS Chapter 506, 507, 507A, 508, 509, 510, 529, 530, or 531.
20		2. The informed written consent shall include:
21		a. A copy of the minor's government-issued identification, a copy of
22		the consenting parent's or legal guardian's government-issued
23		identification, and written documentation including but not
24		limited to a birth certificate, court-ordered custodial paperwork,
25		or tax return, establishing that he or she is the lawful parent or
26		<u>legal guardian; and</u>
27		b. The parent's or legal guardian's certification that he or she

Engrossed

I		consents to the abortion. The certification shall be in a signed,
2		dated, and notarized document that has been initialed on each
3		page and that contains the following statement, which shall
4		precede the signature of the parent or legal guardian: "I, (insert
5		name of parent or legal guardian), am the (select ''parent'' or
6		''legal guardian'') of (insert name of minor) and give consent for
7		(insert name of attending physician) to perform an abortion on
8		her. Under penalties of perjury, I declare that I have read the
9		foregoing statement and that the facts stated in it are true."
10		3. The attending physician shall keep a copy of the informed written
11		consent in the medical file of the minor for five (5) years after the
12		minor reaches eighteen (18) years of age or for seven (7) years,
13		whichever is longer.
14		4. The attending physician securing the informed written consent from a
15		parent or legal guardian under this subsection shall execute for
16		inclusion in the medical record of the minor an affidavit stating: "I,
17		(insert name of attending physician), certify that, according to my best
18		information and belief, a reasonable person under similar
19		circumstances would rely on the information presented by both the
20		minor and her parent or legal guardian as sufficient evidence of
21		identity.'';
22	(b)	The minor is emancipated and the attending physician[or his agent] has
23		received the informed written consent of the minor; or
24	(c)	The minor elects to petition any Circuit or District Court of the
25		Commonwealth pursuant to subsection (3) of this section and obtain an order
26		pursuant to subsection (4) of this section granting consent to the abortion and
27		the attending physician[or his agent] has received the informed written

1			consent of the minor.
2	(3)	Eve	ry minor shall have the right to petition any Circuit or District Court of the
3		Con	nmonwealth for an order granting the right to self-consent to an abortion
4		purs	uant to the following procedures:
5		(a)	The minor or her next friend may prepare and file a petition setting forth the
6			request of the minor for an order of consent to an abortion;
7		(b)	The court shall <u>ensure</u> [insure] that the minor prepares or her next friend is
8			given assistance in preparing and filing the petition and shall <u>ensure</u> [insure]
9			that the minor's identity is kept anonymous;
10		(c)	The minor may participate in proceedings in the court on her own behalf or
11			through her next friend and the court shall appoint a guardian ad litem for her.
12			The court shall advise her that she has a right to court-appointed counsel and
13			shall provide her with such counsel upon her request;
14		(d)	All proceedings under this section shall be anonymous and shall be given
15			preference over other matters to ensure [insure] that the court may reach a
16			decision promptly, but in no case shall the court fail to rule within seventy-
17			two (72) hours of the time of application, provided that the seventy-two (72)
18			hour limitation may be extended at the request of the minor; and
19		(e)	The court shall hold a hearing on the merits of the petition before reaching a
20			decision. The court shall hear evidence at the hearing relating to:
21			1. The minor's:
22			a. Age;
23			<u>b.</u> [The]Emotional development <u>and stability; [,]</u>
24			<u>c.</u> Maturity <u>:[,]</u>
25			<u>d.</u> Intellect[, and understanding of the minor];
26			e. Credibility and demeanor as a witness;
27			f. Ability to accept responsibility;

Engrossed

1	g. Ability to assess both the current and future life-impacting[the
2	nature, possible] consequences \underline{of} , and alternatives to, the abortion;
3	<u>and</u>
4	h. Ability to understand and explain the medical risks of the
5	abortion and to apply that understanding to her decision; and
6	2. Whether there may be any undue influence by another on the minor's
7	decision to have an abortion any other evidence that the court may find
8	useful in determining whether the minor should be granted majority
9	rights for the purpose of consenting to the abortion or whether the
10	abortion is in the best interest of the minor].
11	(4) (a) If the court finds by:
12	1. Clear and convincing evidence that the minor is sufficiently mature to
13	decide whether to have an abortion;
14	2. Clear and convincing evidence that the requirements of this section
15	are not in the best interest of the minor; or
16	3. A preponderance of the evidence that the minor is the victim of child
17	abuse or sexual abuse inflicted by one (1) or both of her parents or her
18	<u>legal guardian;</u>
19	the court shall enter a written order, making specific factual findings and legal
20	conclusions supporting its decision to grant the petition for an abortion. [as
21	follows:]
22	(b) If the court does not make any of the findings specified in paragraph (a) of
23	this subsection, the court shall deny the petition [(a) Granting the petition
24	for an abortion if the court finds that the minor is mature and well informed
25	enough to make the abortion decision on her own;
26	(b) Granting consent to the abortion if the court finds that the performance of the
27	abortion would be in the minor's best interest; or

1		(c) Deny the petition, if the court finds that the minor is immature and that
2		performance of the abortion would not be in the minor's best interest].
3		(c) As used in this subsection, "best interest of the minor" shall not include
4		financial best interest, financial considerations, or the potential financial
5		impact on the minor or the minor's family if the minor does not have an
6		abortion.
7	(5)	Any minor shall have the right of anonymous and expedited appeal to the Court of
8		Appeals, and that court shall give precedence over other pending matters.
9	(6)	All hearings under this section, including appeals, shall remain confidential and
10		closed to the public. The hearings shall be held in chambers or in a similarly
11		private and informal setting within the courthouse.
12	<u>(7)</u>	No fees shall be required of any minor who declares she has no sufficient funds to
13		pursue the procedures provided by this section.
14	<u>(8)</u> [((a) The Supreme Court is respectfully requested to promulgate any rules and
15		regulations it feels are necessary to ensure that proceedings under this section
16		are handled in an expeditious and anonymous manner.
17		(b) The Supreme Court, through the Administrative Office of the Courts, shall
18		report by February 1 of each year to the Legislative Research Commission
19		and the cabinet on the number of petitions filed under subsection (3) of this
20		section for the preceding year, and the timing and manner of disposal of the
21		petition by each court. For each approved petition granting an abortion
22		filed under subsection (3) of this section, the specific court finding in
23		subsection (4) of this section shall be included in the report.
24	<u>(9)</u>	The requirements of subsections (2), (3), and (4) of this section shall not
25		apply when, in the best medical judgment of the physician based on the facts
26		of the case before him or her, a medical emergency exists that so complicates
27		the pregnancy as to require an immediate abortion.

1	<u>(b)</u>	If a medical emergency exists, the physician shall make reasonable
2		attempts, whenever possible, and without endangering the minor, to contact
3		the parent or legal guardian of the minor, and may proceed, but must
4		document reasons for the medical necessity in the minor's medical records.
5	<u>(c)</u>	The physician shall inform the parent or legal guardian, in person or by
6		telephone, within twenty-four (24) hours of the abortion, including details
7		of the medical emergency that necessitated the abortion without the parent's
8		or legal guardian's consent. The physician shall also provide this
9		information in writing to the parent or legal guardian at his or her last
10		known address by first-class mail or by certified mail, return receipt
11		requested, with delivery restricted to the parent or legal guardian[A
12		physician who does not comply with subsection (2), (3), or (4) of this section
13		due to the utilization of this exception shall certify in writing the medical
14		indications upon which his judgment was based].
15	<u>(10)</u> [(9)]	A report indicating the basis for any medical judgment that warrants failure to
16	obta	in consent pursuant to this section shall be filed with the Cabinet for Health and
17	Fam	ily Services on a form supplied by the cabinet. This report shall be confidential.
18	<u>(11)</u> [(10)]	Failure to obtain consent pursuant to the requirements of this section is prima
19	facie	evidence of failure to obtain informed consent and of interference with family
20	relat	ions in appropriate civil actions. The law of this state shall not be construed to
21	prec	lude the award of exemplary damages in any appropriate civil action relevant to
22	viola	tions of this section. Nothing in this section shall be construed to limit the
23	com	mon-law rights of parents.
24	(12) A m	inor upon whom an abortion is performed is not guilty of violating this
25	<u>secti</u>	on.
26	→ Se	ection 2. KRS 311.595 is amended to read as follows:
27	If the pov	ver has not been transferred by statute to some other board, commission, or

agency of this state, the board may deny an application or reregistration for a license;

- 2 place a licensee on probation for a period not to exceed five (5) years; suspend a license
- 3 for a period not to exceed five (5) years; limit or restrict a license for an indefinite period;
- 4 or revoke any license heretofore or hereafter issued by the board, upon proof that the
- 5 licensee has:
- 6 (1) Knowingly made or presented, or caused to be made or presented, any false,
- fraudulent, or forged statement, writing, certificate, diploma, or other thing, in
- 8 connection with an application for a license or permit;
- 9 (2) Practiced, or aided or abetted in the practice of fraud, forgery, deception, collusion,
- or conspiracy in connection with an examination for a license;
- 11 (3) Committed, procured, or aided in the procurement of an unlawful abortion,
- including a partial-birth abortion or an abortion in violation of KRS 311.731;
- 13 (4) Entered a guilty or nolo contendere plea, or been convicted, by any court within or
- without the Commonwealth of Kentucky of a crime as defined in KRS 335B.010, if
- in accordance with KRS Chapter 335B;
- 16 (5) Been convicted of a misdemeanor offense under KRS Chapter 510 involving a
- patient, or a felony offense under KRS Chapter 510, 530.064(1)(a), or 531.310, or
- been found by the board to have had sexual contact as defined in KRS 510.010(7)
- with a patient while the patient was under the care of the physician;
- 20 (6) Become addicted to a controlled substance;
- 21 (7) Become a chronic or persistent alcoholic;
- 22 (8) Been unable or is unable to practice medicine according to acceptable and
- prevailing standards of care by reason of mental or physical illness or other
- 24 condition including but not limited to physical deterioration that adversely affects
- cognitive, motor, or perceptive skills, or by reason of an extended absence from the
- active practice of medicine;
- 27 (9) Engaged in dishonorable, unethical, or unprofessional conduct of a character likely

1 to deceive, defraud, or harm the public or any member thereof;

- 2 (10) Knowingly made, or caused to be made, or aided or abetted in the making of, a false
- 3 statement in any document executed in connection with the practice of his
- 4 profession;
- 5 (11) Employed, as a practitioner of medicine or osteopathy in the practice of his
- 6 profession in this state, any person not duly licensed or otherwise aided, assisted, or
- 7 abetted the unlawful practice of medicine or osteopathy or any other healing art;
- 8 (12) Violated or attempted to violate, directly or indirectly, or assisted in or abetted the
- 9 violation of, or conspired to violate any provision or term of any medical practice
- act, including but not limited to the code of conduct promulgated by the board under
- 11 KRS 311.601 or any other valid regulation of the board;
- 12 (13) Violated any agreed order, letter of agreement, final order, or emergency order
- issued by the board;
- 14 (14) Engaged in or attempted to engage in the practice of medicine or osteopathy under a
- 15 false or assumed name, or impersonated another practitioner of a like, similar, or
- different name;
- 17 (15) Obtained a fee or other thing of value on the fraudulent representation that a
- manifestly incurable condition could be cured;
- 19 (16) Willfully violated a confidential communication;
- 20 (17) Had his license to practice medicine or osteopathy in any other state, territory, or
- 21 foreign nation revoked, suspended, restricted, or limited or has been subjected to
- other disciplinary action by the licensing authority thereof. This subsection shall not
- require relitigation of the disciplinary action;
- 24 (18) Failed or refused, without legal justification, to practice medicine in a rural area of
- 25 this state in violation of a valid medical scholarship loan contract with the trustees
- of the rural Kentucky medical scholarship fund;
- 27 (19) Given or received, directly or indirectly, from any person, firm, or corporation, any

fee, commission, rebate, or other form of compensation for sending, referring, or otherwise inducing a person to communicate with a person licensed under KRS 311.530 to 311.620 in his professional capacity or for any professional services not actually and personally rendered; provided, however, that nothing contained in this subsection shall prohibit persons holding valid and current licenses under KRS 311.530 to 311.620 from practicing medicine in partnership or association or in a professional service corporation authorized by KRS Chapter 274, as now or hereinafter amended, or from pooling, sharing, dividing, or apportioning the fees and moneys received by them or by the partnership, corporation, or association in accordance with the partnership agreement or the policies of the board of directors of the corporation or association. Nothing contained in this subsection shall abrogate the right of two (2) or more persons holding valid and current licenses under KRS 311.530 to 311.620 to receive adequate compensation for concurrently rendering professional care to a single patient and divide a fee, if the patient has full knowledge of this division and if the division is made in proportion to the services performed and responsibility assumed by each; (20) Been removed, suspended, expelled, or disciplined by any professional medical association or society when the action was based upon what the association or society found to be unprofessional conduct, professional incompetence, malpractice, or a violation of any provision of KRS Chapter 311. This subsection shall not require relitigation of the disciplinary action; (21) Been disciplined by a licensed hospital or medical staff of the hospital, including removal, suspension, limitation of hospital privileges, failing to renew privileges for cause, resignation of privileges under pressure or investigation, or other disciplinary action if the action was based upon what the hospital or medical staff found to be unprofessional conduct, professional incompetence, malpractice, or a violation of any provisions of KRS Chapter 311. This subsection shall not require relitigation of

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

- 1 the disciplinary action;
- 2 (22) Failed to comply with the requirements of KRS 213.101, 311.782, or 311.783 or
- failed to submit to the Vital Statistics Branch in accordance with a court order a
- 4 complete report as described in KRS 213.101;
- 5 (23) Failed to comply with any of the requirements regarding making or maintaining
- 6 medical records or documents described in KRS 311.7704 or 311.7707;
- 7 (24) Failed to comply with the requirements of KRS 311.7705 or 311.7706;
- 8 (25) Been convicted of female genital mutilation under KRS 508.125, which shall result
- 9 in mandatory revocation of a license; [or]
- 10 (26) As provided in KRS 311.824(2), been convicted of a violation of KRS 311.823(2);
- 11 <u>or</u>
- 12 (27) Failed to comply with the requirements of Section 1 of this Act.
- → Section 3. KRS 311.990 is amended to read as follows:
- 14 (1) Any person who violates KRS 311.250 shall be guilty of a violation.
- 15 (2) Any college or professor thereof violating the provisions of KRS 311.300 to
- 16 311.350 shall be civilly liable on his bond for a sum not less than one hundred
- dollars (\$100) nor more than one thousand dollars (\$1,000) for each violation,
- which may be recovered by an action in the name of the Commonwealth.
- 19 (3) Any person who presents to the county clerk for the purpose of registration any
- license which has been fraudulently obtained, or obtains any license under KRS
- 21 311.380 to 311.510 by false or fraudulent statement or representation, or practices
- 22 podiatry under a false or assumed name or falsely impersonates another practitioner
- or former practitioner of a like or different name, or aids and abets any person in the
- 24 practice of podiatry within the state without conforming to the requirements of KRS
- 25 311.380 to 311.510, or otherwise violates or neglects to comply with any of the
- provisions of KRS 311.380 to 311.510, shall be guilty of a Class A misdemeanor.
- Each case of practicing podiatry in violation of the provisions of KRS 311.380 to

- 1 311.510 shall be considered a separate offense.
- 2 (4) Each violation of KRS 311.560 shall constitute a Class D felony.
- 3 (5) Each violation of KRS 311.590 shall constitute a Class D felony. Conviction under
- 4 this subsection of a holder of a license or permit shall result automatically in
- 5 permanent revocation of such license or permit.
- 6 (6) Conviction of willfully resisting, preventing, impeding, obstructing, threatening, or
- 7 interfering with the board or any of its members, or of any officer, agent, inspector,
- 8 or investigator of the board or the Cabinet for Health and Family Services, in the
- 9 administration of any of the provisions of KRS 311.550 to 311.620 shall be a Class
- 10 A misdemeanor.
- 11 (7) Each violation of KRS 311.375(1) shall, for the first offense, be a Class B
- misdemeanor, and, for each subsequent offense shall be a Class A misdemeanor.
- 13 (8) Each violation of KRS 311.375(2) shall, for the first offense, be a violation, and, for
- each subsequent offense, be a Class B misdemeanor.
- 15 (9) Each day of violation of either subsection of KRS 311.375 shall constitute a
- separate offense.
- 17 (10) (a) Any person who intentionally or knowingly performs an abortion contrary to
- the requirements of KRS 311.723(1) shall be guilty of a Class D felony; and
- 19 (b) Any person who intentionally, knowingly, or recklessly violates the
- requirements of KRS 311.723(2) shall be guilty of a Class A misdemeanor.
- 21 (11) (a) 1. Any physician who performs a partial-birth abortion in violation of KRS
- 22 311.765 shall be guilty of a Class D felony. However, a physician shall
- 23 not be guilty of the criminal offense if the partial-birth abortion was
- 24 necessary to save the life of the mother whose life was endangered by a
- 25 physical disorder, illness, or injury.
- 26 2. A physician may seek a hearing before the State Board of Medical
- 27 Licensure on whether the physician's conduct was necessary to save the

1		life of the mother whose life was endangered by a physical disorder,
2		illness, or injury. The board's findings, decided by majority vote of a
3		quorum, shall be admissible at the trial of the physician. The board shall
4		promulgate administrative regulations to carry out the provisions of this
5		subparagraph.
6		3. Upon a motion of the physician, the court shall delay the beginning of
7		the trial for not more than thirty (30) days to permit the hearing, referred
8		to in subparagraph 2. of this paragraph, to occur.
9	(b)	Any person other than a physician who performs a partial-birth abortion shall
10		not be prosecuted under this subsection but shall be prosecuted under
11		provisions of law which prohibit any person other than a physician from
12		performing any abortion.
13	(c)	No penalty shall be assessed against the woman upon whom the partial-birth
14		abortion is performed or attempted to be performed.
15	(12) <u>(a)</u>	Except as provided in subsection (12) of Section 1 of this Act, any person
16		who intentionally, knowingly, or recklessly performs an abortion upon a
17		minor without obtaining the required consent pursuant to Section 1 of this
18		Act shall be guilty of a Class D felony.
19	<u>(b)</u>	Except as provided in paragraph (a) of this subsection, any person who
20		intentionally performs an abortion with knowledge that, or with reckless
21		disregard as to whether, the person upon whom the abortion is to be
22		performed is an unemancipated minor, and who] intentionally or knowingly
23		fails to conform to any requirement of KRS 311.732 is guilty of a Class A
24		misdemeanor.
25	<u>(c)</u> [(Any person who negligently releases information or documents which
26		are confidential under KRS 311.732 is guilty of a Class B misdemeanor.
27	<u>(13)</u> [(14)]	Any person who performs an abortion upon a married woman either with

I	knowledge or in reckless disregard of whether KRS 311.735 applies to her and who
2	intentionally, knowingly, or recklessly fails to conform to the requirements of KRS
3	311.735 shall be guilty of a Class D felony.
4	(14)[(15)] Any person convicted of violating KRS 311.750 shall be guilty of a Class B
5	felony.
6	(15) [(16)] Any person who violates KRS 311.760(2) shall be guilty of a Class D felony.
7	(16) [(17)] Any person who violates KRS 311.770 shall be guilty of a Class D felony.
8	(17) [(18)] Except as provided in KRS 311.787(3), any person who intentionally violates
9	KRS 311.787 shall be guilty of a Class D felony.
10	(18) [(19)] A person convicted of violating KRS 311.780 shall be guilty of a Class C
11	felony.
12	(19)[(20)] Except as provided in KRS 311.782(6), any person who intentionally violates
13	KRS 311.782 shall be guilty of a Class D felony.
14	(20)[(21)] Any person who violates KRS 311.783(1) shall be guilty of a Class B
15	misdemeanor.
16	(21) [(22)] Any person who violates KRS 311.7705(1) is guilty of a Class D felony.
17	(22)[(23)] Any person who violates KRS 311.7706(1) is guilty of a Class D felony.
18	(23)[(24)] Except as provided in KRS 311.731(7), any person who violates KRS
19	311.731(2) shall be guilty of a Class D felony.
20	(24)[(25)] Any physician, physician assistant, advanced practice registered nurse, nurse,
21	or other healthcare provider who intentionally violates KRS 311.823(2) shall be
22	guilty of a Class D felony. As used in this subsection, "healthcare provider" has the
23	same meaning as in KRS 311.821.
24	(25)[(26)] Any person who violates KRS 311.810 shall be guilty of a Class A
25	misdemeanor.
26	(26)[(27)] Any professional medical association or society, licensed physician, or
27	hospital or hospital medical staff who shall have violated the provisions of KRS

1	311.6	506 shall be guilty of a Class B misdemeanor.
2	<u>(27)</u> [(28)]	Any administrator, officer, or employee of a publicly owned hospital or
3	publi	cly owned health care facility who performs or permits the performance of
4	abort	ions in violation of KRS 311.800(1) shall be guilty of a Class A misdemeanor.
5	<u>(28)</u> [(29)]	Any person who violates KRS 311.905(3) shall be guilty of a violation.
6	<u>(29)[(30)]</u>	Any person who violates the provisions of KRS 311.820 shall be guilty of a
7	Class	A misdemeanor.
8	<u>(30)</u> [(31)]	(a) Any person who fails to test organs, skin, or other human tissue which is
9		to be transplanted, or violates the confidentiality provisions required by KRS
10		311.281, shall be guilty of a Class A misdemeanor.
11	(b)	Any person who has human immunodeficiency virus infection, who knows he
12		is infected with human immunodeficiency virus, and who has been informed
13		that he may communicate the infection by donating organs, skin, or other
14		human tissue who donates organs, skin, or other human tissue shall be guilty
15		of a Class D felony.
16	<u>(31)</u> [(32)]	Any person who sells or makes a charge for any transplantable organ shall be
17	guilt	y of a Class D felony.
18	<u>(32)</u> [(33)]	Any person who offers remuneration for any transplantable organ for use in
19	trans	plantation into himself shall be fined not less than five thousand dollars
20	(\$5,0	00) nor more than fifty thousand dollars (\$50,000).
21	<u>(33)</u> [(34)]	Any person brokering the sale or transfer of any transplantable organ shall be
22	guilt	y of a Class C felony.
23	<u>(34)</u> [(35)]	Any person charging a fee associated with the transplantation of a
24	trans	plantable organ in excess of the direct and indirect costs of procuring,
25	distri	buting, or transplanting the transplantable organ shall be fined not less than
26	fifty	thousand dollars (\$50,000) nor more than five hundred thousand dollars
27	(\$50	0,000).

1	(35)[(36)] Any hospital performing transplantable organ transplants which knowingly
2	fails to report the possible sale, purchase, or brokering of a transplantable organ
3	shall be fined not less than ten thousand dollars (\$10,000) or more than fifty
4	thousand dollars (\$50,000).
5	(36)[(37)] (a) Any physician or qualified technician who violates KRS 311.727 shall
6	be fined not more than one hundred thousand dollars (\$100,000) for a first
7	offense and not more than two hundred fifty thousand dollars (\$250,000) for
8	each subsequent offense.
9	(b) In addition to the fine, the court shall report the violation of any physician, in
10	writing, to the Kentucky Board of Medical Licensure for such action and
11	discipline as the board deems appropriate.
12	(37)[(38)] Any person who violates KRS 311.691 shall be guilty of a Class B
13	misdemeanor for the first offense, and a Class A misdemeanor for a second or
14	subsequent offense. In addition to any other penalty imposed for that violation, the
15	board may, through the Attorney General, petition a Circuit Court to enjoin the
16	person who is violating KRS 311.691 from practicing genetic counseling in
17	violation of the requirements of KRS 311.690 to 311.700.
18	(38)[(39)] Any person convicted of violating KRS 311.728 shall be guilty of a Class D
19	felony.
20	(39) (a) A person who intentionally, knowingly, or recklessly violates Sections 5 to
21	11 of this Act is guilty of a Class D felony.
22	(b) No criminal penalty may be assessed against a pregnant patient upon whom
23	a drug-induced abortion is attempted, induced, or performed.
24	→ Section 4. KRS 213.101 is amended to read as follows:
25	(1) [(a)] Each abortion as defined in KRS 213.011 which occurs in the
26	Commonwealth, regardless of the length of gestation, shall be reported to the
27	Vital Statistics Branch by the person in charge of the institution within three

1		(3)[fifteen (15)] days after the end of the month in which the abortion
2		occurred. If the abortion was performed outside an institution, the attending
3		physician shall prepare and file the report within three (3)[fifteen (15)] days
4		after the end of the month in which the abortion occurred.
5	<u>(2)[(b)]</u>	The report shall include all the information the physician is required to certify
6	in v	writing or determine under KRS 311.731, 311.7704, 311.7705, 311.7706,
7	311.	7707, 311.774, 311.782, [and]311.783, Sections 1, 8, and 9 of this Act, and at
8	<u>a mi</u>	inimum:
9	<u>(a)</u>	The full name and address of the physician who performed the abortion or
10		provided the abortion-inducing drug as defined in Section 5 of this Act;
11	<u>(b)</u>	The address at which the abortion was performed or the address at which
12		the abortion-inducing drug was provided by a qualified physician, or the
13		method of obtaining the abortion-inducing drug if not provided by a
14		qualified physician, including mail order, internet order, or by a telehealth
15		provider in which case identifying information for the pharmacy, Web site
16		address, or the telemedicine provider shall be included;
17	<u>(c)</u>	The names, serial numbers, National Drug Codes, lot numbers, and
18		expiration dates of the specific abortion-inducing drugs that were provided
19		to the pregnant patient and the dates each were provided;
20	<u>(d)</u>	The full name and address of the referring physician, agency, or service, if
21		any;
22	<u>(e)</u>	The pregnant patient's city or town, county, state, country of residence, and
23		zip code;
24	<u>(f)</u>	The pregnant patient's age, race, and ethnicity;
25	<u>(g)</u>	The age or approximate age of the father, if known;
26	<u>(h)</u>	The total number and dates of each previous pregnancy, live birth, and
27		abortion of the pregnant patient;

1	<u>(i)</u>	The probable gestational and post-fertilization ages of the unborn child, the
2		methods used to confirm the gestational and post-fertilization ages, and the
3		date determined;
4	<u>(j)</u>	A list of any pre-existing medical conditions of the pregnant patient that
5		may complicate her pregnancy, if any, including hemorrhage, infection,
6		uterine perforation, cervical laceration, retained products, or any other
7		condition;
8	<u>(k)</u>	Whether the fetus was delivered alive and the length of time the fetus
9		survived;
10	<u>(l)</u>	Whether the fetus was viable and, if viable, the medical reason for
11		termination;
12	<u>(m)</u>	Whether a pathological examination of the fetus was performed;
13	<u>(n)</u>	Whether the pregnant patient returned for a follow-up examination, the
14		date and results of any such follow-up examination, and what reasonable
15		efforts were made by the qualified physician to encourage the patient to
16		reschedule a follow-up examination if the appointment was missed;
17	<u>(0)</u>	Whether the woman suffered any complications or adverse events as
18		defined in Section 5 of this Act and what specific complications or adverse
19		events occurred, and any follow-up treatment provided as required by
20		Section 26 of this Act;
21	<u>(p)</u>	Whether the pregnant patient was Rh negative and, if so, was provided with
22		an Rh negative information fact sheet and treated with the prevailing
23		medical standard of care to prevent harmful fetal or child outcomes or Rh
24		incompatibility in future pregnancies;
25	<u>(q)</u>	The amount billed to cover the treatment for specific complications or
26		adverse events, including whether the treatment was billed to Medicaid,
27		private insurance, private pay, or other method. This should include ICD-10

1	codes reported and charges for any physician, hospital, emergency room,
2	prescription or other drugs, laboratory tests, and any other costs for
3	treatment rendered;
4	(r) The reason for the abortion, if known, including abuse, coercion,
5	harassment, or trafficking; and
6	(s) Whether the pregnant patient was tested for sexually transmitted diseases
7	when providing the informed consent required in KRS 311.725 and Section
8	8 of this Act twenty-four (24) hours before the abortion procedure or tested
9	at the time of the abortion procedure, and if the pregnant patient tested
10	positive, was treated or referred for treatment and follow-up care [but shall
11	not include information which will identify the physician, woman, or man
12	involved].
13	(3) The report shall not contain:
14	(a) The name of the pregnant patient;
15	(b) Common identifiers such as a Social Security number and motor vehicle
16	operator's license number; and
17	(c) Any other information or identifiers that would make it possible to ascertain
18	the patient's identity.
19	(4) [(c)] If a person other than the physician described in this subsection makes or
20	maintains a record required by Section 1 of this Act, KRS 311.7704, 311.7705,
21	311.7706, or 311.7707 on the physician's behalf or at the physician's direction, that
22	person shall comply with the reporting requirement described in this subsection as if
23	the person were the physician.
24	(5)[(2)] Each prescription issued for <u>an abortion-inducing drug as defined in Section</u>
25	5 of this Act [RU-486, cytotec, pitocin, mifeprex, misoprostol, or any other drug or
26	combination of drugs] for which the primary indication is the induction of abortion
27	as defined in KRS 213.011 shall be reported to the Vital Statistics Branch within

1 three (3)[fifteen (15)] days after the end of the month in which the prescription was 2 issued as required by KRS 311.774, but the report shall not include information 3 which will identify the woman involved or anyone who may be picking up the 4 prescription on behalf of the woman. 5 <u>(6)</u>[(3)] The name of the person completing the report and the reporting institution 6 shall not be subject to disclosure under KRS 61.870 to 61.884. 7 By September 30 of each year, the Vital Statistics Branch shall issue a public <u>(7)</u>[(4)] 8 report that provides statistics on all data collected, including the type of abortion 9 procedure used, for the previous calendar year compiled from all of the reports 10 covering that calendar year submitted to the cabinet in accordance with this section 11 for each of the items listed in [subsections (1) and (2) of]this section. Each annual 12 report shall also provide statistics for all previous calendar years in which this 13 section was in effect, adjusted to reflect any additional information from late or 14 corrected reports. The Vital Statistics Branch shall ensure that none of the 15 information included in the report could reasonably lead to the identification of any 16 pregnant woman upon whom an abortion was performed or attempted. Each annual 17 report shall be made available on the cabinet's Web site. 18 Any person or institution who fails to submit a report by the end of thirty $(8)^{(5)}$ (a) 19 (30) days following the due date set in [subsections (1) and (2) of]this section 20 shall be subject to a late fee of five hundred dollars (\$500) for each additional 21 thirty (30) day period or portion of a thirty (30) day period the report is 22 overdue. 23 Any person or institution who fails to submit a report, or who has submitted (b) 24 only an incomplete report, more than one (1) year following the due date set in 25 [subsections (1) and (2) of]this section, may in a civil action brought by the 26 Vital Statistics Branch be directed by a court of competent jurisdiction to 27 submit a complete report within a time period stated by court order or be

1		subject to contempt of court.
2	(c)	Failure by any physician to comply with the requirements of this section, other
3		than filing a late report, or to submit a complete report in accordance with a
4		court order shall subject the physician to KRS 311.595.
5	<u>(9)</u> [(6)]	Intentional falsification of any report required under this section is a Class A
6	misc	demeanor.
7	<u>(10)</u> [(7)]	The Vital Statistics Branch shall promulgate administrative regulations in
8	acco	ordance with KRS Chapter 13A to assist in compliance with this section.
9	(11) (a)	The Office of the Inspector General, Cabinet for Health and Family
10		Services, shall annually audit the required reporting of abortion-related
11		information to the Vital Statistics Branch in this section and Section 29 of
12		this Act, and in so doing, shall function as a health oversight agency of the
13		Commonwealth for this specific purpose.
14	<u>(b)</u>	The Office of the Inspector General shall ensure that none of the
15		information included in the audit report could reasonably lead to the
16		identification of any pregnant woman upon whom an abortion was
17		performed or attempted.
18	<u>(c)</u>	If any personally identifiable information is viewed or recorded by the
19		Office of the Inspector General in conducting an audit authorized by this
20		subsection, the information held by the Inspector General shall not be
21		subject to the Kentucky Open Records Act, shall be confidential, and shall
22		only be released upon court order.
23	<u>(d)</u>	The Inspector General shall submit a written report to the General
24		Assembly and the Attorney General by October 1 of each year. The reports
25		shall include findings from:
26		1. The audit required in this subsection, including any identified
27		reporting deficiencies; and

1		2. All abortion facility inspections, including any violations of KKS
2		216B.0431 and 216B.0435.
3		→SECTION 5. A NEW SECTION OF KRS 311.710 TO 311.820 IS CREATED
4	TO	READ AS FOLLOWS:
5	<u>As u</u>	sed in Sections 5 to 11 of this Act unless the context otherwise requires:
6	<u>(1)</u>	"Abortion" has the same meaning as in KRS 311.720;
7	<u>(2)</u>	"Abortion-inducing drug" means a medicine, drug, or any other substance or
8		combination of substances prescribed or dispensed with the intent of terminating
9		the clinically diagnosable pregnancy of a woman, with knowledge that the
10		termination will, with reasonable likelihood, cause the death of the unborn child.
11		This includes the off-label use of drugs known to have abortion-inducing
12		properties, which are prescribed specifically with the intent of causing an
13		abortion, such as mifepristone (mifeprex), misoprostol (cytotec), and
14		methotrexate, or any generic or therapeutic equivalents thereof. The use of such
15		drugs to induce abortion is also known as "medical," "medication," "RU-486,"
16		"mifeprex regimen," or "drug-induced" abortion. This definition does not apply
17		to drugs that may be known to cause an abortion but which are prescribed for
18		other medical indications (e.g., chemotherapeutic agents, diagnostic drugs, etc.);
19	<u>(3)</u>	"Adverse event" means, as defined the Food and Drug Administration (FDA) in
20		21 CFR 312.32, any untoward medical occurrence associated with the use of a
21		drug in humans, whether or not considered drug related. "Adverse event" does
22		not include an adverse event or suspected adverse reaction that, had it occurred
23		in a more severe form, might have caused death;
24	<i>(4)</i>	"Associated physician" means a physician who has entered into an associated
25		physician agreement established in Section 17 of this Act;
26	<u>(5)</u>	"Cabinet" means the Cabinet for Health and Family Services;
27	<u>(6)</u>	"Complication" or "abortion complication" means only the following physical

1		or psychological conditions which, in the reasonable medical judgment of a
2		licensed healthcare professional, arise as a primary or secondary result of an
3		induced abortion: uterine perforation, cervical laceration, infection, vaginal
4		bleeding that qualifies as a Grade 2 or higher adverse event according to the
5		Common Terminology Criteria for Adverse Events, pulmonary embolism, deep
6		vein thrombosis, failure to actually terminate the pregnancy, incomplete abortion
7		(retained tissue), pelvic inflammatory disease, missed ectopic pregnancy, cardiac
8		arrest, respiratory arrest, renal failure, shock, amniotic fluid embolism, coma,
9		death, free fluid in the abdomen, allergic reactions to anesthesia and abortion-
10		inducing drugs, psychological complications as diagnosed that are listed in the
11		current Diagnostic and Statistical Manual of Mental Disorders, and any other
12		"adverse event" as defined by the FDA criteria provided in the MedWatch
13		Reporting System;
14	<u>(7)</u>	"Gestational age" has the same meaning as in KRS 311.7701;
15	<u>(8)</u>	"Hospital" has the same meaning as in KRS 311.720;
16	<u>(9)</u>	"Manufacturer" or "distributor" means an individual or entity that creates,
17		produces, supplies, transports, or sells drugs, including any substances:
18		(a) Recognized by an official pharmacopoeia or formulary;
19		(b) Intended for use in the diagnosis, cure, mitigation, treatment, or prevention
20		of disease;
21		(c) Other than food, intended to affect the structure or any function of the
22		body; and
23		(d) Intended for use as a component of a medicine but not a device or a
24		component, part, or accessory of a device;
25	<u>(10)</u>	"Nonsurgical abortion provider" means a qualified physician who is registered
26		with the Cabinet for Health and Family Services;
27	<i>(11)</i>	"Physician" has the same meaning as in KRS 311.720;

1	(12) "Pregnancy" or "pregnant" has the same meaning as intrauterine pregnancy as
2	<u>defined in KRS 311.7701;</u>
3	(13) "Provide" or "provision" means any act of giving, selling, dispensing,
4	administering, transferring possession, delivering, transporting to, or otherwise
5	providing or prescribing an abortion-inducing drug;
6	(14) "Qualified physician" means a physician who is credentialed and competent to:
7	(a) Identify and document a viable intrauterine pregnancy;
8	(b) Assess the gestational age of pregnancy and to inform the patient of
9	gestational age-specific risks;
10	(c) Diagnose ectopic pregnancy;
11	(d) Determine blood type and administer the prevailing medical standard of
12	care to prevent harmful fetal or child outcomes or Rh incompatibility in
13	future pregnancies if a pregnant patient is Rh negative;
14	(e) Assess for signs of domestic abuse, reproductive control, human trafficking,
15	and other signals of coerced abortion;
16	(f) Provide surgical intervention or has entered into a contract with another
17	qualified physician to provide surgical intervention; and
18	(g) Supervise and bear legal responsibility for any agent, employee, or
19	contractor who is participating in any part of the procedure, including but
20	not limited to pre-procedure evaluation and care; and
21	(15) "Unborn child" has the same meaning as in KRS 311.781.
22	→SECTION 6. A NEW SECTION OF KRS 311.710 TO 311.820 IS CREATED
23	TO READ AS FOLLOWS:
24	(1) Abortion-inducing drugs shall only be provided to a pregnant person by a
25	qualified physician who is registered with the Cabinet for Health and Family
26	Services as a nonsurgical abortion provider by following the procedures
27	established in Sections 7, 8, and 9 of this Act.

1	<u>(2)</u>	It shall be unlawful for any manufacturer, distributor, physician, qualified
2		physician, pharmacy, or any other person to intentionally, knowingly, or
3		recklessly dispense, prescribe, or distribute any abortion-inducing drug as defined
4		in Section 5 of this Act to a pregnant person via courier, delivery, or mail service.
5		→SECTION 7. A NEW SECTION OF KRS 311.710 TO 311.820 IS CREATED
6	TO I	READ AS FOLLOWS:
7	<u>(1)</u>	A qualified physician providing an abortion-inducing drug as defined in Section
8		5 of this Act shall:
9		(a) Be credentialed and competent to handle complication management,
10		including emergency transfer; or
11		(b) Have a signed contract with an associated physician who is credentialed to
12		handle complications and produce that signed contract, including the name
13		and phone number of the associated physician, upon the request of the
14		cabinet and each pregnant patient.
15	<u>(2)</u>	A qualified physician providing an abortion-inducing drug as defined in Section
16		5 of this Act shall examine the patient in person and, prior to providing an
17		abortion-inducing drug, shall:
18		(a) Independently verify that a pregnancy exists;
19		(b) Determine the patient's blood type and, if the patient is Rh negative, provide
20		the patient with an Rh negative information fact sheet and offer to provide
21		treatment with the prevailing medical standard of care to prevent harmful
22		fetal or child outcomes or Rh incompatibility in future pregnancies at the
23		time of the abortion;
24		(c) Inform the patient that the remains of the unborn child may be visible in
25		the process of completing the abortion; and
26		(d) Document, in the patient's medical chart, the gestational age and
27		intrauterine location of the pregnancy, and whether the patient received

1			treatment for Rh negativity, as diagnosed, by the most accurate standard of
2			medical care.
3	<u>(3)</u>	(a)	The qualified physician or an agent of the qualified physician providing any
4			abortion-inducing drug as defined in Section 5 of this Act shall schedule a
5			follow-up visit for the patient for approximately seven (7) to fourteen (14)
6			days after administration of the abortion-inducing drug to confirm that the
7			pregnancy is completely terminated and to assess any degree of bleeding.
8		<u>(b)</u>	The qualified physician shall make all reasonable efforts to ensure that the
9			patient returns for the scheduled appointment.
10		<u>(c)</u>	A brief description of the efforts made to comply with this subsection,
11			including the date, time, and identification by name of the person making
12			such efforts, shall be included in the patient's medical record.
13		→ S	ECTION 8. A NEW SECTION OF KRS 311.710 TO 311.820 IS CREATED
14	TO	REAI	O AS FOLLOWS:
15	<u>(1)</u>	An	abortion-inducing drug as defined in Section 5 of this Act shall not be
16		prov	vided to a pregnant patient without the informed consent of the patient.
17		<u>Info</u>	rmed consent shall be obtained at least twenty-four (24) hours before the
18		<u>aboi</u>	rtion-inducing drug is provided to a pregnant patient, except if, in the
19		<u>reas</u>	onable medical judgment of the qualified physician, compliance with this
20		<u>subs</u>	section would pose a risk of:
21		<u>(a)</u>	The death of the pregnant patient; or
22		<u>(b)</u>	The substantial and irreversible physical impairment of a major bodily
23			function, not including psychological or emotional conditions, of the
24			pregnant patient.
25	<u>(2)</u>	A q	ualified physician shall use a form created by the Cabinet for Health and
26		<u>Fan</u>	nily Services to obtain the consent required prior to providing an abortion-
27		indu	cing drug as defined in Section 5 of this Act and submit the completed form

1	<u>to ti</u>	ne cabinet.
2	(3) A co	onsent form is not valid and consent is not sufficient, unless:
3	<u>(a)</u>	The patient initials each entry, list, description, or declaration required to be
4		on the consent form;
5	<u>(b)</u>	The patient signs the consent statement; and
6	<u>(c)</u>	The qualified physician signs the qualified physician declaration.
7	(4) The	consent form shall include but is not limited to the following:
8	<u>(a)</u>	The probable gestational age of the unborn child as determined by both
9		patient history and by ultrasound results used to confirm gestational age;
10	<u>(b)</u>	A detailed description of the steps to complete the drug-induced abortion;
11	<u>(c)</u>	A detailed list of the risks related to the specific abortion-inducing drug as
12		defined in Section 5 of this Act or drugs to be used, including potential
13		complications and adverse events as defined in Section 5 of this Act;
14	<u>(d)</u>	If the pregnant patient was Rh negative, the pregnant patient was provided
15		with an Rh negative information fact sheet and offered treatment with the
16		prevailing medical standard of care to prevent harmful fetal or child
17		outcomes or Rh incompatibility in future pregnancies;
18	<u>(e)</u>	That the risks of complications from a medication abortion, including
19		incomplete abortion, increase with advancing gestational age;
20	<u>(f)</u>	That it may be possible to reverse the effects of the abortion-inducing drug
21		if desired but that this should be done as soon as possible;
22	<u>(g)</u>	That the patient may see the remains of the unborn child in the process of
23		completing the abortion;
24	<u>(h)</u>	That initial studies suggest that children born after reversing the effects of
25		the abortion-inducing drug mifeprex/mifepristone have no greater risk of
26		birth defects than the general population;
27	(i)	That initial studies suggest that there is no increased risk of maternal

1		mortality after reversing the effects of the abortion-inducing arug
2		mifeprex/mifepristone;
3	<u>(j)</u>	That information on and assistance with reversing the effects of abortion-
4		inducing drugs are available in the state-prepared materials and on the
5		cabinet's Web site;
6	<u>(k)</u>	An ''acknowledgment of risks and consent statement'' which the pregnant
7		patient shall sign. The pregnant patient shall initial by each statement and
8		the statement shall include but is not limited to the following declarations:
9		1. That the pregnant patient understands that the abortion-inducing
10		drug regimen or procedure is intended to end the pregnancy and will
11		result in the death of the unborn child;
12		2. That the pregnant patient is not being forced to have an abortion, has
13		the choice not to have the abortion, and may withdraw consent to the
14		abortion-inducing drug regimen even after it has been provided;
15		3. That the pregnant patient understands that the abortion-inducing
16		drug to be provided has specific risks and may result in specific
17		complications;
18		4. That the pregnant patient has been given the opportunity to ask
19		questions about the pregnancy, the development of the unborn child,
20		alternatives to abortion, the abortion-inducing drug or drugs to be
21		used, and the risks and complications possible when abortion-
22		inducing drugs are provided;
23		5. That the pregnant patient was specifically told that information on the
24		potential ability of qualified medical professionals to reverse the
25		effects of a drug-induced abortion is available and where to obtain
26		information for assistance in locating a medical professional that can
27		aid in the reversal of a drug-induced abortion;

1	6. That the pregnant patient has been provided access to printed
2	materials on informed consent for abortion;
3	7. That the pregnant patient has been given the name and phone number
4	of the associated physician who has agreed to provide medical care
5	and treatment in the event of complications associated with the
6	abortion-inducing drug regimen or procedure;
7	8. That the qualified physician will schedule an in-person follow-up visit
8	for the patient for approximately seven (7) to fourteen (14) days after
9	providing the abortion-inducing drug or drugs to confirm that the
10	pregnancy is completely terminated and to assess any degree of
11	bleeding and other complications;
12	9. That the pregnant patient has received or been given sufficient
13	information to give informed consent to the abortion-inducing drug
14	regimen or procedure; and
15	10. That the patient has a private right of action to sue the qualified
16	physician under the laws of Kentucky if the patient feels coerced or
17	misled prior to obtaining an abortion;
18	(l) A qualified physician's declaration that states that the qualified physician
19	has explained the abortion-inducing drug or drugs to be provided, has
20	provided all of the information required in paragraph (k) of this subsection,
21	and has answered all of the woman's questions, shall be signed by the
22	qualified physician; and
23	(m) If prescribing for the purpose of inducing an abortion, a qualified physician
24	shall include the following on the prescription for an abortion-inducing
25	drug: "For The Purpose of Abortion Inducement".
26	→SECTION 9. A NEW SECTION OF KRS 311.710 TO 311.820 IS CREATED
27	TO READ AS FOLLOWS:

1	<i>(1)</i>	Each abortion-inducing drug as defined in Section 5 of this Act provided to a
2		pregnant patient by a qualified physician shall be reported to the cabinet as
3		required by Section 26 of this Act.
4	<u>(2)</u>	If a qualified physician provides an abortion-inducing drug as defined in Section
5		5 of this Act to a pregnant woman for the purpose of inducing an abortion, and if
6		the qualified physician knows that the woman who uses the abortion-inducing
7		drug for the purpose of inducing an abortion experiences, during or within
8		fifteen (15) days after the use of the abortion-inducing drug, an adverse event as
9		defined in Section 5 of this Act, the qualified physician shall provide a written
10		report of the adverse event within three (3) days of the event to the federal Food
11		and Drug Administration via the MedWatch reporting system, the cabinet, and
12		the board.
13	<u>(3)</u>	Any physician, qualified physician, associated physician, or other healthcare
14		provider who diagnoses or knowingly treats a patient, either contemporaneously
15		to or at any time after a drug-induced abortion, for a complication or adverse
16		event as defined in Section 5 of this Act related to the drug-induced abortion shall
17		make a report of the complication or adverse event to the cabinet on a report form
18		provided by the cabinet. The report shall be completed and signed by the
19		physician, qualified physician, or other healthcare provider who diagnosed or
20		treated the complication or adverse event, and transmitted to the cabinet within
21		three (3) days after the diagnosis or treatment was provided. Each report shall
22		include at minimum the information required by Section 4 of this Act.
23		→SECTION 10. A NEW SECTION OF KRS 311.710 TO 311.820 IS CREATED
24	TO F	READ AS FOLLOWS:
25	<i>(1)</i>	Nothing in Sections 5 to 11 of this Act shall be construed as creating or
26		recognizing a right to abortion.
27	<i>(</i> 2 <i>)</i>	It is not the intention of Sections 5 to 11 of this Act to make lawful an abortion

Engrossed

1	that is otherwise unlawful.
2	(3) Sections 5 to 11 of this Act or any state or federal laws to the contrary, abortion
3	inducing drugs as defined in Section 5 of this Act shall not be provided in any
4	school facility or on state grounds, including but not limited to elementary and
5	secondary schools and institutions of higher education in Kentucky.
6	→SECTION 11. A NEW SECTION OF KRS 311.710 TO 311.820 IS CREATED
7	TO READ AS FOLLOWS:
8	(1) In addition to the remedies available under the laws in this state, failure to
9	comply with Sections 5 to 11 of this Act shall:
10	(a) Provide a basis for a civil malpractice action for actual and punitive
11	damages;
12	(b) Provide a basis for a professional disciplinary action under KRS 411.167
13	<u>and</u>
14	(c) Provide a basis for recovery for a pregnant patient's survivors for the
15	wrongful death of the patient under KRS 411.130.
16	(2) When requested, the court shall allow a patient to proceed using only the
17	patient's initials or a pseudonym and may close any proceedings in the case and
18	enter other protective orders to preserve the privacy of the patient upon whom the
19	drug-induced abortion was attempted, induced, or performed.
20	(3) If judgment is rendered in favor of the plaintiff, the court shall also render
21	judgment for reasonable attorney's fees in favor of the plaintiff against the
22	<u>defendant.</u>
23	(4) If judgment is rendered in favor of the defendant and the court finds that the
24	plaintiff's suit was frivolous and brought in bad faith, the court may render
25	judgment for reasonable attorney's fees in favor of the defendant against the
26	plaintiff.
27	→ SECTION 12. A NEW SECTION OF KRS CHAPTER 213 IS CREATED TO

1	REA	AD AS FOLLOWS:
2	<u>(1)</u>	The cabinet shall publish printed material and maintain on its Web site the
3		following statement: "Information on the potential ability of qualified medical
4		professionals to reverse the effects of an abortion obtained through the use of
5		abortion-inducing drugs as defined in Section 5 of this Act is available, and shall
6		also include information for assistance in locating a medical professional who
7		can aid in the reversal of a drug-induced abortion.".
8	<u>(2)</u>	On an annual basis, the cabinet shall review and update, if necessary, the
9		statement required in subsection (1) of this section and shall also include
10		information for assistance in locating a medical professional who can aid in the
11		reversal of a drug-induced abortion.
12		→SECTION 13. A NEW SECTION OF KRS CHAPTER 213 IS CREATED TO
13	REA	AD AS FOLLOWS:
14	<u>(1)</u>	The cabinet shall create and distribute the report forms required in Sections 1, 4,
15		8, 9, 25, 26, 27, and 29 of this Act within sixty (60) days after the effective date of
16		this Act.
17	<u>(2)</u>	The cabinet shall prepare and submit a comprehensive annual statistical report to
18		the General Assembly based upon the data gathered from reports required in
19		Sections 1, 4, 8, 9, 25, 26, 27, and 29 of this Act. The aggregated data shall also
20		be made available to the public by the cabinet in an electronic format.
21	<u>(3)</u>	Reports required in Sections 1, 4, 8, 9, 25, 26, 27, and 29 of this Act shall be
22		deemed public records and shall be provided by the cabinet to the Kentucky
23		Board of Medical Licensure, the Kentucky Board of Pharmacy, state law
24		enforcement offices, and child protective services upon request for use in the
25		performance of their official duties.
26	<u>(4)</u>	Absent a valid court order or judicial subpoena, the cabinet, and any other state
27		department, agency, or office or any employees thereof, shall not compare data

1	concerning drug-induced abortion or drug-induced abortion complications or
2	adverse events as defined in Section 5 of this Act maintained in an electronic or
3	other information system file with data in any other electronic or other
4	information system, the comparison of which could result in identifying, in any
5	manner or under any circumstances, a pregnant patient who is obtaining or
6	seeking to obtain a drug-induced abortion.
7	(5) Statistical information that may reveal the identity of a pregnant person
8	obtaining or seeking to obtain a drug-induced abortion shall not be maintained
9	by the cabinet or any other state department, agency, or office, or any employee
10	or contractor thereof.
11	(6) The cabinet shall communicate the reporting requirements in Sections 1, 4, 8, 9,
12	25, 26, 27, and 29 of this Act to all medical professional organizations, licensed
13	physicians, hospitals, emergency medical service providers, abortion facilities,
14	ambulatory surgical facilities, pharmacies, and other healthcare facilities
15	operating in Kentucky.
16	→ SECTION 14. A NEW SECTION OF KRS CHAPTER 216B IS CREATED
17	TO READ AS FOLLOWS:
18	As used in Sections 14 to 19 of this Act, the following terms have the same meaning as
19	in Section 5 of this Act:
20	(1) "Abortion";
21	(2) ''Abortion-inducing drug'';
22	(3) "Adverse event";
23	(4) "Associated physician";
24	(5) "Complication";
25	(6) ''Distributor'';
26	(7) ''Manufacturer'';
27	(8) ''Nonsurgical abortion provider''; and

1	<u>(9)</u>	"Qualified physician."
2		→SECTION 15. A NEW SECTION OF KRS CHAPTER 216B IS CREATED
3	TO	READ AS FOLLOWS:
4	<u>(1)</u>	The cabinet shall promulgate administrative regulations to create a certification
5		program to oversee and regulate the distribution and dispensing of abortion-
6		inducing drugs. The program shall be known as the Kentucky Abortion-Inducing
7		Drug Certification Program. The program shall establish certification
8		requirements for manufacturers and distributors to transport, supply, or sell
9		abortion-inducing drugs; pharmacies that dispense abortion-inducing drugs; and
10		abortion facilities licensed under KRS 216B.0431.
11	<u>(2)</u>	The certification requirements shall include recognition that abortion-inducing
12		drugs may only be provided to patients by qualified physicians who are registered
13		as nonsurgical abortion providers and that abortion-inducing drugs shall not
14		intentionally, knowingly, or recklessly be provided directly to a patient outside of
15		the parameters of Kentucky's Abortion-Inducing Drug Certification Program.
16		→ SECTION 16. A NEW SECTION OF KRS CHAPTER 216B IS CREATED
17	TO I	READ AS FOLLOWS:
18	<u>(1)</u>	The cabinet, shall, at a minimum:
19		(a) Require completion of the certification process for pharmacies,
20		manufacturers, distributors, and abortion facilities;
21		(b) Notify certified pharmacies, manufacturers, distributors, and abortion
22		facilities which physicians are registered as nonsurgical abortion providers
23		with the cabinet;
24		(c) Prohibit intentionally, knowingly, or recklessly shipping abortion-inducing
25		drugs to physicians who become unregistered;
26		(d) Audit newly certified pharmacies, manufacturers, and distributors within
27		ninety (90) calendar days after certification and annually thereafter, to

1			ensure that all processes and procedures are in place and functioning to
2			support the requirements of the Abortion-Inducing Drug Certification
3			Program;
4		<u>(e)</u>	Suspend immediately a pharmacist's, manufacturer's, or distributor's
5			certification if found to be noncompliant until full compliance is
6			demonstrated;
7		<u>(f)</u>	Enforce compliance and develop a compliance reporting system; and
8		<u>(g)</u>	Prohibit pharmacies from intentionally, knowingly, or recklessly dispensing
9			or distributing abortion-inducing drugs directly to a patient in the
10			Commonwealth;
11		<u>(h)</u>	Require manufacturers and distributors of abortion-inducing drugs to
12			intentionally and knowingly distribute only to certified pharmacies and in-
13			person dispensing clinics, medical offices, and hospitals that are in
14			compliance with the United States Federal Drug Administration's outlined
15			Mifepristone Risk Evaluation and Mitigation Strategy in effect on the
16			effective date of this Act.
17	<u>(2)</u>	To l	be eligible for certification, pharmacies, manufacturers, and distributors of
18		abor	rtion-inducing drugs shall:
19		<u>(a)</u>	Have either obtained a Kentucky license as a distributor, or a Kentucky
20			permit as a pharmacy or manufacturer;
21		<u>(b)</u>	Only distribute to or fulfill prescriptions requested by qualified physicians
22			who are registered as nonsurgical abortion providers with the cabinet;
23		<u>(c)</u>	Abide by all applicable standards of the National Association of Boards of
24			Pharmacy (NABP);
25		<u>(d)</u>	For online sales or orders, hold a current pharmacy or pharma domain and
26			abide by all required standards by NABP to maintain the domain;
27		<u>(e)</u>	Follow all other applicable state or federal laws related to the dispensation,

1	distribution, or delivery of legend drugs, including abortion-inducing drugs;
2	<u>and</u>
3	(f) Follow all acceptable processes and procedures to maintain a dispensation,
4	distribution, or delivery system that is secure, confidential, and follows all
5	processes and procedures, including those for storage, handling, shipping,
6	tracking packages, serial numbers, National Drug Codes, lot numbers,
7	expiration dates, proof of delivery, and controlled returns of abortion-
8	inducing drugs.
9	(3) To be eligible for certification, pharmacies shall:
10	(a) Be certified by the United States Food and Drug Administration (FDA) to
11	dispense abortion-inducing drugs;
12	(b) Submit proof of certification by the abortion-inducing drug manufacturer
13	for the distribution of abortion-inducing drugs; and
14	(c) Only fulfill prescriptions that are accompanied by the required patient
15	consent form.
16	→SECTION 17. A NEW SECTION OF KRS CHAPTER 216B IS CREATED
17	TO READ AS FOLLOWS:
18	(1) To be eligible to register as a nonsurgical abortion provider, the cabinet shall
19	require a qualified physician to:
20	(a) Be licensed to practice medicine and in good standing in Kentucky;
21	(b) Examine any patient in-person prior to providing abortion-inducing drugs;
22	(c) Sign an annual "Dispensing Agreement Form," to be developed and
23	provided by the cabinet, prior to providing abortion-inducing drugs;
24	(d) Inform the patient of gestational age-specific risks of using abortion-
25	inducing drugs;
26	(e) Assess for signs of domestic abuse, reproductive control, human trafficking,
27	and other signals of coerced abortion, per current state guidelines;

1	(j) Inform the patient that studies snow dadies born following the abortion
2	reversal process have a rate of birth defects no higher than the general
3	population;
4	(g) Inform the patient that studies show that following a reversal process or
5	otherwise treating a pregnant patient with progesterone during pregnancy
6	does not lead to increased mortality rates;
7	(h) Refrain from intentionally or knowingly supplying abortion-inducing drugs
8	to patients who present with any of the following:
9	1. Absence of a pregnancy;
10	2. Being post-seventy (70) days gestation or post-ten (10) weeks of
11	pregnancy; or
12	3. Risk factors associated with abortion-inducing drugs, including but
13	not limited to:
14	a. A history of ectopic pregnancies;
15	b. Problems with the adrenal glands near the kidneys;
16	c. Being treated with long-term corticosteroid therapy;
17	d. Allergic reactions to abortion-inducing drugs, mifepristone,
18	misoprostol, or similar drugs;
19	e. Bleeding problems or taking anticoagulant drug products;
20	f. Inherited porphyria;
21	g. An intrauterine device in place; or
22	h. Being Rh negative, requiring treatment with the prevailing
23	medical standard of care to prevent harmful fetal or child
24	outcomes or Rh incompatibility in future pregnancies before
25	providing abortion-inducing drugs;
26	(i) Provide or refer for emergency surgical intervention in cases of incomplete
27	abortion, severe bleeding, or other abortion complications or adverse events,

1			through maintaining hospital admitting privileges or entering into a written
2			agreement with an associated physician;
3		<u>(j)</u>	Ensure patient access to medical facilities equipped to provide blood
4			transfusions and resuscitation or other necessary treatments, if necessary;
5		<u>(k)</u>	Sign, and ensure that the patient signs, all legally required informed-
6			consent material, provide the patient with a copy showing both signatures,
7			and place the original in the patient's medical record and forward to a
8			certified pharmacy, if appropriate;
9		<u>(l)</u>	Record the serial number, National Drug Code, lot number, and expiration
10			date from each package of each abortion-inducing drug given to the patient
11			in the patient's medical record;
12		<u>(m)</u>	Submit a written protocol of how efforts will be made to schedule a follow-
13			up appointment with the patient within fourteen (14) days to ensure a
14			completed abortion;
15		<u>(n)</u>	Submit a written protocol of how complications or adverse events will be
16			handled by the registered physician and submit a copy of a signed contract
17			with an associated physician credentialed to handle certain complications if
18			necessary;
19		<u>(0)</u>	Abide by all applicable state and federal laws regarding medical records
20			retention, confidentiality, and privacy; and
21		<u>(p)</u>	Agree to follow and document compliance with all other legally required
22			conditions for performing an abortion in Kentucky.
23	<u>(2)</u>	The	cabinet shall require the following of registered physicians:
24		<u>(a)</u>	Maintain hospital admitting privileges at one (1) or more hospitals in the
25			county or contiguous county where abortion-inducing drugs will be
26			provided and inform the patient of the hospital or hospitals where the
27			physician holds admitting privileges; or

1	(b) Enter into a written associated physician	agreement as required in Section 7
2	of this Act, with a physician in the co	ounty or contiguous county where
3	abortion-inducing drugs will be provided	d. The written agreement shall meet
4	these conditions:	
5	1. A physician who will be providing	g an abortion-inducing drug shall
6	notify the patient of the location of	the hospital at which the associated
7	physician has admitting privileges;	
8	2. The physician shall keep, at the lo	cation of his or her practice, a copy
9	of the written agreement;	
10	3. The cabinet shall annually submit	t a copy of the written agreement to
11	each hospital located in the count	ty or a county that is contiguous to
12	the county where abortion-inducing	g drugs will be provided;
13	4. The agreement shall be renewed an	nnually; and
14	5. The agreement shall include a req	uirement that the physician provide
15	to the patient, and require the p	atient to sign, all legally required
16	informed- consent material.	
17	→SECTION 18. A NEW SECTION OF K	RS CHAPTER 216B IS CREATED
18	TO READ AS FOLLOWS:	
19	(1) The cabinet shall develop a plan to enforce	e the Kentucky Abortion-Inducing
20	Drug Certification Program that includes the	following conditions:
21	(a) If an individual or entity intentionally,	, knowingly, or recklessly provides
22	abortion-inducing drugs without first	seeking certification, the cabinet
23	<u>shall:</u>	
24	1. Immediately report the act to	local law enforcement or other
25	applicable state and local agencies,	; and
26	2. Impose a fine of no less than fi	ve million dollars (\$5,000,000) for
27	pharmacies, manufacturers, or dist	tributors;

1	<u>(b)</u>	If a certified pharmacy, manufacturer, or distributor is determined to be in
2		noncompliance, suspend any certification until compliance is proven to the
3		satisfaction of the cabinet;
4	<u>(c)</u>	If a current or previously certified pharmacy, manufacturer, or distributor
5		is found to have intentionally, knowingly, or recklessly violated certification
6		requirements, or refuses to bring operations into compliance within ninety
7		(90) calendar days, remove certification and prohibit continued provision of
8		abortion-inducing drugs by the pharmacy, manufacturer, or distributor
9		until compliance is demonstrated to the satisfaction of the cabinet;
10	<u>(d)</u>	If a certified pharmacy, manufacturer, or distributor is in noncompliance,
11		suspend annual recertification until compliance is demonstrated to the
12		satisfaction of the cabinet; and
13	<u>(e)</u>	If a current or previously certified pharmacy, manufacturer, or distributor
14		is found to have intentionally, knowingly, or recklessly violated Sections 14
15		to 19 of this Act, or refuses to bring operations into compliance:
16		1. Immediately suspend the pharmacy's, manufacturer's, or distributor's
17		certification until full compliance is demonstrated;
18		2. For certified pharmacies, manufacturers, or distributors, impose fines
19		of not less than one million dollars (\$1,000,000) per offense;
20		3. For registered physicians, impose fines of not less than one hundred
21		thousand dollars (\$100,000) per offense;
22		4. Permanently revoke the certification of the offender if the offender
23		fails to demonstrate compliance within ninety (90) calendar days;
24		5. Impose remedial actions, which may include additional education,
25		additional reporting, or other actions as required by the cabinet;
26		6. In the case of a pharmacy, manufacturer, or distributor, recommend
27		sanctioning to the appropriate disciplinary committee of the cabinet;

1	7. In the case of a licensed physician, report the violation to the
2	Kentucky Board of Medical Licensure and recommend appropriate
3	sanctioning;
4	8. Publicly report any disciplinary actions, consistent with the practices
5	of the cabinet;
6	9. Permanently revoke the certification of the offender; and
7	10. In the case of a pharmacy, manufacturer, or distributor, report the
8	violation to the Kentucky Board of Pharmacy and recommend
9	appropriate sanctions, including permanent revocation of licensure.
10	(2) Individuals have a private right of action to seek restitution in any court of law
11	with appropriate jurisdiction for any and all damages suffered for intentional,
12	knowing, or reckless violations of Sections 14 to 19 of this Act.
13	→SECTION 19. A NEW SECTION OF KRS CHAPTER 216B IS CREATED
14	TO READ AS FOLLOWS:
15	(1) The cabinet shall develop a complaint portal on its Web site for patients,
16	pharmacy, nursing, and medical professionals, and the public to submit
17	information about potential violations of the Kentucky Abortion-Inducing Drug
18	Certification Program.
19	(2) The portal shall list the names of pharmacies, manufacturers, and distributors
20	that are certified under the program and the physicians registered by the cabinet
21	as nonsurgical abortion providers.
22	(3) An individual shall be allowed to make a complaint anonymously on the portal.
23	(4) The cabinet shall review each complaint and determine a disposition, including
24	referral to another state department, within thirty (30) days.
25	(5) Confidentiality of the originator of the complaint shall be protected at all times
26	except for intrastate referrals for investigation.
27	→ Section 20. KRS 213.081 is amended to read as follows:

Engrossed

1	(1)	No person shall cremate or cause to be transported for the purpose of cremation the
2		body of any person whose death occurs in the Commonwealth, without first
3		obtaining from the coroner of the county in which the death occurred, a permit
4		stating the cause of death and authorizing the cremation or transportation for
5		cremation of the body. The permit shall be filed immediately following cremation
6		with the local registrar of vital statistics.
7	(2)	[The provisions of this section shall not apply to the cremation of]Fetal death
8		remains shall require the same permit required by subsection (1) of this section [in
9		the absence of any indication of a criminal act].
10	<u>(3)</u>	Notwithstanding KRS 367.97514, fetuses may be cremated by simultaneous
11		<u>cremation.</u>
12		→ Section 21. KRS 213.096 is amended to read as follows:
13	(1)	Each fetal death of twenty (20) completed weeks' gestation or more, calculated from
14		the date last normal menstrual period began to the date of delivery or in which the
15		fetus weighs three hundred fifty (350) grams or more, which occurs in the
16		Commonwealth, shall be reported on a combination birth-death or stillbirth
17		certificate in accordance with applicable provisions of KRS 213.046 and KRS
18		213.076. If the fetal death occurs in a hospital, the person in charge of the institution
19		or the person's designated representative shall complete the stillbirth certificate,
20		obtain the medical certification, and file the certificate with the state registrar.
21	(2)	The name of the father shall be entered on the stillbirth certificate in accordance
22		with the provisions of KRS 213.046.
23	(3)	All abortions shall be reported in the manner prescribed in KRS 213.101 and shall
24		not be reported as stillbirths.
25	<u>(4)</u>	If requested by the patient to whom an abortion is provided, the person in charge
26		of the institution or the person's designated representative, shall complete the
27		form created by the cabinet under subsection (3) of this section, obtain the

1	med	dical certification, and file the certificate with the state registrar.
2	→5	SECTION 22. A NEW SECTION OF KRS CHAPTER 213 IS CREATED TO
3	READ A	S FOLLOWS:
4	(1) For	the purposes of this section, ''fetal remains'' means the biological remains of
5	<u>a h</u>	uman child resulting from the termination of a pregnancy by a surgical or
6	<u>mec</u>	dication abortion prior to birth or miscarriage.
7	(2) (a)	Within twenty-four (24) hours before a surgical or medication abortion or
8		within twenty-four (24) hours of a miscarriage, the healthcare facility or
9		abortion clinic shall disclose to the parent or parents of the fetus, both
10		orally and in writing, the parents' right to determine if they will take
11		responsibility for the final disposition of the fetal remains or relinquish the
12		responsibility for final disposition to the healthcare facility or abortion
13		<u>clinic.</u>
14	<u>(b)</u>	If the procedure is a medication induced abortion, the mother:
15		1. Shall be informed that she will expel a fetus after leaving the
16		healthcare facility or abortion clinic;
17		2. May choose to return the fetal remains to the healthcare facility or
18		abortion clinic for final disposition;
19		3. Shall be exempted from the requirements of Section 20 of this Act that
20		require a permit for the purpose of transporting the fetal remains back
21		to the healthcare facility or abortion clinic for final disposition; and
22		4. Shall be exempted from the requirements of Section 21 of this Act that
23		require an abortion to be reported on a combination birth-death or
24		stillbirth certificate.
25	<u>(c)</u>	After receiving the information required by paragraphs (a) and (b) of this
26		subsection, the parent or parents of the fetus shall inform the healthcare
27		facility or abortion clinic of their choice for the disposition of the fetal

1		<u>remains by electing to either:</u>
2		1. Relinquish the guardianship of the fetal remains and the
3		responsibility for final disposition of those remains to the
4		guardianship of the healthcare facility or abortion clinic which shall
5		dispose of those remains as they would any other human remains; or
6		2. Retain the guardianship for the fetal remains and designate that fetal
7		remains shall be released to the parent or parents for disposition.
8		(d) The healthcare facility or abortion clinic shall document the parent's or
9		parents' choice for the disposition of the fetal remains in the medical
10		<u>record.</u>
11	<u>(3)</u>	The cabinet shall design forms through administrative regulations that
12		document:
13		(a) The age of the parent or parents of the fetal remains;
14		(b) In the event that the parents are under eighteen (18) years of age, have not
15		been emancipated by court order, or have not obtained a court order
16		granting the right to self-consent, a consent by their parent or guardian;
17		(c) The status of fetal remains resulting from an abortion for the purpose of
18		cremation that shall meet any requirements for a birth-death, provisional
19		death, or death certificate for transport or cremation;
20		(d) A designation of how the fetal remains shall be disposed of and who shall
21		be responsible for the final disposition; and
22		(e) Any other information required by the cabinet.
23	<u>(4)</u>	A person or entity shall not:
24		(a) Dispose of a fetus or fetal remains as medical or infectious waste;
25		(b) Offer money or anything of value for an aborted fetus or fetal remains;
26		(c) Accept money or anything of value for an aborted fetus or fetal remains; or
27		(d) Transport, or arrange for the transportation of, fetal remains for any

1		purpose other than:
2		1. Final disposition by a crematory licensed under KRS Chapter 367;
3		2. Interment by a funeral establishment licensed under KRS Chapter
4		<u>316;</u>
5		3. Interment by the parent or parents privately in conformance with KRS
6		381.697 and administrative regulations promulgated by the Cabinet
7		for Health and Family Services;
8		4. Delivery of the fetal remains to the healthcare facility or abortion
9		clinic for final disposition;
10		5. For law enforcement in the context of a criminal investigation with
11		the consent of the parent; or
12		6. To a pathology laboratory for examination of the fetal remains with
13		the consent of the parent.
14		→ Section 23. KRS 367.97501 is amended to read as follows:
15	As u	ised in KRS 367.97501 to 367.97537, unless the context requires otherwise:
16	(1)	"Authorizing agent" means the person legally entitled to order the cremation of the
17		human remains.
18	(2)	"Casket" means a rigid container which is designed for the encasement of human
19		remains constructed of wood, metal, or other material.
20	(3)	"Closed container" means a sealed container or urn in which cremated remains are
21		placed and enclosed in a manner that prevents leakage or spillage of cremated
22		remains or the entrance of foreign material.
23	(4)	"Cremated remains" means the fragments remaining after the cremation process has
24		been completed.
25	(5)	"Cremation" means the heating process that reduces human remains to bone
26		fragments through combustion and evaporation.
27	(6)	"Cremation authorization form" means a form promulgated by administrative

regulation of the Attorney General that expresses consent to the decedent's cremation. The form shall include information concerning the parties' rights and

- 3 responsibilities.
- 4 (7) "Cremation chamber" means an enclosed space designed and manufactured for the
- 5 purpose of cremating human remains.
- 6 (8) "Cremation container" means a container in which human remains may be delivered
- 7 to a crematory for cremation that is:
- 8 (a) Rigid enough to support the weight of the corpse, closed, and leakproof;
- 9 (b) Composed of a combustible material or other material approved by the crematory authority; and
- 11 (c) A proper and dignified covering for the human remains.
- 12 (9) "Crematory authority" means the legal entity which is licensed by the Attorney
- General to operate a crematory and conduct cremations. Crematory authority does
- not include state university health science centers.
- 15 (10) "Crematory" means a fixed building or structure that contains one (1) or more
- 16 cremation chambers for the reduction of bodies of deceased persons to cremated
- remains. "Crematory" includes crematorium.
- 18 (11) "Crematory operator" means the person in charge of a licensed crematory authority.
- 19 (12) "Declaration" has the same meaning as in KRS 367.93101.
- 20 (13) "Holding facility" means an area designated for the retention of human remains
- 21 prior to cremation.
- 22 (14) "Human remains" means the body of a deceased person or part of a body or limb
- 23 that has been removed from a living person, in any state of decomposition, prior to
- cremation.
- 25 (15) "Pathological waste" means human tissues, organs, and blood or body fluids, in
- liquid or semiliquid form that are removed from a person for medical purposes.
- 27 "Pathological waste" does not include amputations or fetal remains as defined in

1 <u>Section 22 of this Act</u>.

- 2 (16) "Processed remains" means the end result of pulverization, by which the residual from the cremation process is reduced and cleaned leaving only fragments reduced
- 4 to unidentified dimensions.
- 5 (17) "Retort operator" means a person operating a cremation chamber.
- 6 (18) "Scattering area or garden" means an area which may be designated by a cemetery
- and located on a dedicated cemetery property where cremated remains which have
- 8 been removed from their container can be mixed with or placed on top of the soil or
- 9 ground cover.
- 10 (19) "Temporary container" means a receptacle for cremated remains, usually made of
- plastic, cardboard, ceramics, plastic film, wood, or metal, designed to prevent the
- leakage of processed remains or the entrance of foreign materials which will hold
- the cremated remains until an urn or other permanent container is acquired.
- → Section 24. KRS 311.715 is amended to read as follows:
- 15 (1) As used in this section, "public agency funds" means any money, regardless of
- the original source of the money, of a public agency.
- 17 (2) Public agency funds shall not be used for the purpose of obtaining an abortion or
- paying for the performance of an abortion. Public medical facilities may be used for
- the purpose of conducting research into or the performance of in-vitro fertilization
- as long as such procedures do not result in the intentional destruction of a human
- embryo.
- 22 (3) Public agency funds shall not be directly or indirectly used, granted, paid, or
- 23 <u>distributed to any entity, organization, or individual that performs, induces, refers</u>
- 24 for, or counsels in favor of abortions. This subsection shall not apply to funding
- 25 available through KRS 205.510 to 205.560 to the minimum extent necessary to
- 26 comply with federal conditions for the state's participation in the program
- 27 <u>established by KRS 205.510 to 205.560 or to funding that is used to provide</u>

abstinence education in schools.

1

9

10

11

12

13

14

15

16

17

18

19

20

- 2 Public agency funds shall not be directly or indirectly used, granted, <u>(4)</u>[(2)] (a) 3 paid, or distributed to any nonpublic entity or organization described in 4 paragraph (b)3. of this subsection. This paragraph shall not apply to funding 5 available through KRS 205.510 to 205.560 to the minimum extent necessary 6 to comply with federal conditions for the state's participation in the program 7 established by KRS 205.510 to 205.560 or to funding that is used to provide 8 abstinence education in schools.
 - (b) Notwithstanding any other state law to the contrary, all federal family planning funds shall be awarded to eligible individuals, organizations, or entities applying to be family planning contractors in the following order of descending priority:
 - Public agencies that directly provide family planning services, including state, county, and local community health clinics and federally qualified health centers;
 - 2. Nonpublic entities that directly provide basic health services, as described in 42 U.S.C. sec. 254b(b)(1)(A), including family planning services; and
 - 3. Nonpublic entities that directly provide only family planning services but do not provide all basic health services as described in 42 U.S.C. sec. 254b(b)(1)(A).
- 22 (c) This subsection shall be effective upon repeal of federal regulations 23 prohibiting states from prioritizing recipients of federal Public Health Service 24 Act, Title X Family Planning Program funds.
- 25 (5)[(3)] Nothing in this section shall be deemed to deprive a woman of all appropriate medical care necessary to prevent her physical death.
- 27 (6)[(4)] Nothing in this section shall be construed to allow public funds to pay for in-

1 vitro fertilization procedures performed on any individual patient. 2 → SECTION 25. A NEW SECTION OF KRS 311.710 TO 311.820 IS CREATED 3 TO READ AS FOLLOWS: 4 A hospital, healthcare facility, or individual physician shall file a written report with the cabinet regarding each patient who comes under the hospital's, 5 6 healthcare facility's, or physician's care and reports any complication or adverse 7 event as defined under Section 5 of this Act, requires medical treatment, or suffers a death that the attending physician, hospital staff, or facility staff has 8 9 reason to believe is a primary or secondary result of an abortion. The reports 10 shall be completed by the hospital, healthcare facility, or attending physician who 11 treated the patient, signed by the attending physician, and transmitted to the 12 cabinet within thirty (30) days of the discharge or death of the patient treated for 13 the complication or adverse event. 14 Each report of a complication or adverse event as defined in Section 5 of this Act, 15 medical treatment, or death following abortion required under this section shall 16 contain at minimum the information required by Section 4 of this Act. 17 Reports required under this section shall not contain: 18 (a) The name of the patient; 19 (b) Common identifiers such as Social Security number or motor vehicle 20 operator's license number; or 21 (c) Other information or identifiers that would make it possible to identify, in 22 any manner or under any circumstances, a patient who has obtained an 23 abortion and subsequently suffered an abortion complication or adverse 24 event as defined in Section 5 of this Act. 25 → Section 26. KRS 311.774 is amended to read as follows: Each prescription issued for an abortion-inducing drug as defined in Section 5 of 26 (1) 27 this Act[RU-486, cytotec, pitocin, mifeprex, misoprostol, or any other drug or

	combination of drugs] for which the primary indication is the induction of abortion
	as defined in KRS 311.720 shall be reported on a report form provided by the
	cabinet within three (3)[fifteen (15)] days after [the end of the month in which] the
	prescription was issued. The report form shall be signed by the qualified physician
	who provided the abortion-inducing drug and transmitted to the cabinet within
	three (3) days after the drug was provided. Each report shall include at minimum
	the information required by Section 4 of this Act.
(2)	Information on the potential ability of a physician to reverse the effects of <u>abortion-</u>
	inducing [prescription]drugs as defined in Section 5 of this Act for which the
	primary indication is the induction of abortion, including where additional
	information about this possibility may be obtained and contact information for
	assistance in locating a physician who may aid in the reversal, shall be provided
	with each prescription issued for an abortion-inducing drug[RU-486, cytotec,
	pitocin, mifeprex, misoprostol, or any other drug or combination of drugs] for
	which the primary indication is the induction of abortion as defined in KRS
	311.720.
(3)	For each abortion reported to the Vital Statistics Branch as required by KRS
	213.101, the report shall also state whether any abortion complication or adverse
	event as defined in Section 5 of this Act or medical treatment was known to the
	provider as a result of the abortion. The report shall be completed and signed by
	the physician, qualified physician, or other healthcare provider who diagnosed or
	treated the complication or adverse event.
<u>(4)</u>	The report shall include at a minimum the information required by Section 4 of
	this Act and:
	(a) Whether a complication or adverse event as defined in Section 5 of this Act
	occurred during the abortion procedure or while the pregnant patient was
	still at the facility where the abortion was performed and the level of

1		intervention required to attend to the complication or adverse event:
2		1. Emergency medical services;
3		2. Stabilization on site;
4		3. Transport to another medical facility;
5		4. Urgent care follow-up; and
6		5. Primary care provider;
7	<u>(b)</u>	The date the pregnant patient presented for diagnosis or treatment for the
8		complication or adverse event;
9	<u>(c)</u>	Whether the complication or adverse event was previously managed by the
10		qualified physician who provided the abortion-inducing drug as defined in
11		Section 5 of this Act or a backup qualified physician;
12	<u>(d)</u>	The amount billed to cover the treatment for specific complications,
13		including whether the treatment was billed to Medicaid, private insurance,
14		private pay, or other method. This should include the ICD-10 codes reported
15		and charges for any physician, hospital, emergency room, prescription or
16		other drugs, laboratory tests, and any other costs for treatment rendered;
17		<u>and</u>
18	<u>(e)</u>	A list of complications, adverse events, or treatments that occurred, a list of
19		any emergency transfers, and any follow-up treatment provided including
20		whether any additional drugs were provided in order to complete the drug-
21		induced abortion. [Abortion complications to be reported shall include only
22		the following physical or psychological conditions arising from the induction
23		or performance of an abortion:
24	(a)	Uterine laceration;
25	(b)	Cervical laceration;
26	(c)	-Infection;
27	(d)	heavy bleeding that causes symptoms of hypovolemia or the need for a blood

1	transfusion;
2	(e) Pulmonary embolism;
3	(f) Deep vein thrombosis;
4	(g) Failure to terminate the pregnancy;
5	(h) Incomplete abortion or retained tissue;
6	(i) Pelvic inflammatory disease;
7	(j) Missed ectopic pregnancy;
8	(k) Cardiac arrest;
9	(1) Respiratory arrest;
10	(m) Renal failure;
11	(n) Shock;
12	(o) Amniotic fluid embolism;
13	(p) Coma;
14	(q) Placenta Previa in subsequent pregnancies;
15	(r) Pre term delivery in subsequent pregnancies;
16	(s) Free fluid in the abdomen;
17	(t) Hemolytic reaction due to the administration of ABO-incompatible blood or
18	blood products;
19	(u) Hypoglycemia occurring while the patient is being treated at the abortion
20	facility;
21	(v) allergic reaction to anesthesia or abortion-inducing drugs;
22	(w) Psychological complications, including depression, suicidal ideation, anxiety,
23	and sleeping disorders;
24	(x) Death; and
25	(y) Any other adverse event as defined by criteria provided in the Food and Drug
26	Administration Safety Information and Adverse Event Reporting Program.]
2.7	Section 27 KRS 311 783 is amended to read as follows:

Engrossed

(1)	Except in a medical emergency that prevents compliance with this section, no
	physician shall intentionally perform or induce or intentionally attempt to perform
	or induce an abortion on a pregnant woman unless, prior to the performance or
	inducement of the abortion or the attempt to perform or induce the abortion, the
	physician determines, in the physician's reasonable medical judgment, the unborr
	child's probable <i>gestational</i> [post fertilization] age. The physician shall make that
	determination after making inquiries of the pregnant woman and performing any
	medical examinations or tests of the pregnant woman the physician considers
	necessary as a reasonably prudent physician, knowledgeable about the case and
	medical conditions involved, would consider necessary to determine the unborn
	child's probable <i>gestational</i> [post-fertilization] age.
(2)	Except in a medical emergency that prevents compliance with this section, no
	physician shall intentionally perform or induce or intentionally attempt to perform
	or induce an abortion on a pregnant woman after the unborn child reaches the
	probable gestational[post fertilization] age of fifteen (15)[twenty (20)] weeks
	without first entering the determination made in subsection (1) of this section and
	the associated findings of the medical examination and tests in the medical record
	of the pregnant woman.
(3)	The state Board of Medical Licensure shall suspend a physician's license to practice
	medicine in this state for a period of not less than six (6) months if the physician
	violates this section.
<u>(4)</u>	The physician shall submit a report on a form provided by the cabinet that
	includes at a minimum the information required by Section 4 of this Act and:
	(a) The unborn child's probable gestational age determined by the physician;
	<u>and</u>
	(b) The results of inquiries of the pregnant woman and any medical
	examinations or tests performed.

1		→ Section 28. KRS 315.990 is amended to read as follows:
2	(1)	Except for the provisions of KRS 315.320, any person violating any provision of
3		KRS Chapter 315 shall be fined for each offense not less than one hundred dollars
4		(\$100) nor more than one thousand dollars (\$1,000) or imprisoned in the county jai
5		for not more than six (6) months, or both. Each week that any provision of KRS
6		315.020, 315.030, or 315.035 is violated shall also constitute a separate offense.
7	(2)	Any person convicted of willfully resisting, preventing, impeding, obstructing
8		threatening, or interfering with the officers, agents, or inspectors of the board in the
9		administration of the provisions of this chapter shall be guilty of a Class A
10		misdemeanor.
11	(3)	The board may levy an administrative fine not to exceed five thousand dollars
12		(\$5,000) for each offense, for any violation of KRS 315.121. All such fines shall be
13		deposited to the credit of the licensing board to be used by the board in carrying our
14		the provisions of this chapter.
15	(4)	The board may refuse to issue or renew a permit, or may suspend, temporarily
16		suspend, revoke, fine, or reasonably restrict any permit holder for any violation of
17		KRS 315.0351. Any administrative fine levied by the board shall not exceed five
18		thousand dollars (\$5,000) for any violation of KRS 315.0351. All such fines shall
19		be deposited to the credit of the licensing board to be used by the Board of
20		Pharmacy in carrying out the provisions of this chapter.
21	(5)	For a violation of KRS 315.320, the Board of Pharmacy may, in addition to any
22		other civil or criminal penalty, levy an administrative fine not exceeding one
23		hundred thousand dollars (\$100,000). All such fines shall be deposited to the credit
24		of the Board of Pharmacy in carrying out the provisions of this chapter.
25	<u>(6)</u>	(a) Any person who intentionally, knowingly, or recklessly violates Sections 14

to 19 of this Act is guilty of a Class D felony.

1	more than one million dollars (\$1,000,000).
2	(c) Notwithstanding KRS 440.200, the Attorney General may demand from the
3	Governor of any other state the surrender of any person found in the other
4	state who is charged in Kentucky with the crime of violating Sections 14 to
5	19 of this Act. The provisions for extradition under this subsection shall
6	apply to any such demand even if the person whose surrender is demanded
7	was not in Kentucky at the time of the commission of the crime. Neither the
8	demand, the oath, nor any proceedings for extradition pursuant to this
9	section need state or show that the person whose surrender is demanded has
10	fled from justice, or at the time of the commission of the crime was in
11	Kentucky or the other state.
12	→SECTION 29. A NEW SECTION OF KRS CHAPTER 213 IS CREATED TO
13	READ AS FOLLOWS:
14	(1) Each prescription dispensed by a pharmacy for RU-486, cytotec, pitocin,
15	mifeprex, misoprostol, or any other drug or combination of drugs for which the
16	primary indication is the induction of abortion as defined in KRS 213.011 shall
17	be reported to the Vital Statistics Branch within three (3) days after the end of the
18	month in which the prescription was dispensed, but the report shall not include
19	information which will identify the pregnant patient involved or anyone who may
20	have picked up the dispensed prescription on behalf of the woman.
21	(2) The report shall include at a minimum:
22	(a) The full name and address of the pharmacist or pharmacy dispensing the
23	prescription;
24	(b) The names, serial numbers, National Drug Codes, lot numbers, and
25	expiration dates of the specific abortion-inducing drugs that were
26	<u>dispensed;</u>
27	(c) The full name and address of the referring physician, agency, or service, if

1			any;
2		<u>(d)</u>	The pregnant patient's city or town, county, state, country of residence, and
3			zip code;
4		<u>(e)</u>	The pregnant patient's age, race, and ethnicity;
5		<u>(f)</u>	The age or approximate age of the father, if known;
6		<u>(g)</u>	A list of any pre-existing medical conditions of the pregnant patient that
7			may complicate her pregnancy, if any, including hemorrhage, infection,
8			uterine perforation, cervical laceration, retained products, or any other
9			condition;
10		<u>(h)</u>	Whether the pregnant patient was Rh negative and, if so, was provided with
11			an Rh negative information fact sheet and treated with the prevailing
12			medical standard of care to prevent harmful fetal or child outcomes or Rh
13			incompatibility in future pregnancies; and
14		<u>(i)</u>	The reason for the abortion, if known, including abuse, coercion,
15			harassment, or trafficking.
16	<u>(3)</u>	The	report shall not contain:
17		<u>(a)</u>	The name of the pregnant patient;
18		<u>(b)</u>	Common identifiers such as a Social Security number and motor vehicle
19			operator's license number; and
20		<u>(c)</u>	Any other information or identifiers that would make it possible to ascertain
21			the patient's identity.
22	<u>(4)</u>	The	name of the person completing the report and the reporting institution shall
23		<u>not l</u>	be subject to disclosure under KRS 61.870 to 61.884.
24	<u>(5)</u>	(a)	Any person or institution who fails to submit a report by the end of thirty
25			(30) days following the due date set in subsection (1) of this section shall be
26			subject to a late fee of five hundred dollars (\$500) for each additional thirty
27			(30) day period or portion of a thirty (30) day period the report is overdue.

1	(b) Any person or institution who fails to submit a report, or who has submitted
2	only an incomplete report, more than one (1) year following the due date set
3	in subsection (1) of this section, may in a civil action brought by the Vital
4	Statistics Branch be directed by a court of competent jurisdiction to submit
5	a complete report within a time period stated by court order or be subject to
6	contempt of court.
7	(c) Failure by any pharmacist or pharmacy to comply with the requirements of
8	this section, other than filing a late report, or to submit a complete report in
9	accordance with a court order shall subject the pharmacist or pharmacy to
10	<u>KRS 315.121.</u>
11	(6) Intentional falsification of any report required under this section is a Class A
12	misdemeanor.
13	(7) The Vital Statistics Branch shall promulgate administrative regulations in
14	accordance with KRS Chapter 13A to assist in compliance with this section.
15	→ SECTION 30. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO
16	READ AS FOLLOWS:
17	Any prescription or medical order for a drug that is known to possibly cause an
18	abortion shall be presumed by a pharmacy to be for indications other than for the
19	termination of a pregnancy. A pharmacy dispensing such prescription or medical order
20	shall not be required to verify that the prescription or medical order does not violate
21	any provision of this chapter or KRS Chapter 216B.
22	→SECTION 31. A NEW SECTION OF KRS 311.710 TO 311.820 IS CREATED
23	TO READ AS FOLLOWS:
24	(1) The Attorney General may bring an action to enforce compliance with the
25	Humanity in Healthcare Act of 2022 or intervene as a matter of right in any case
26	in which the constitutionality of any section of the Act is challenged.
27	(2) (a) Any person who intentionally, knowingly, or recklessly violates Sections 14

1	to 19 of this Act is guilty of a Class D felony.
2	(b) Any person who violates Sections 14 to 19 of this Act shall be fined not
3	more than one million dollars (\$1,000,000).
4	(c) Notwithstanding KRS 440.200, the Attorney General may demand from the
5	Governor of any other state the surrender of any person found in the other
6	state who is charged in Kentucky with the crime of violating Sections 14 to
7	19 of this Act. The provisions for extradition under this subsection shall
8	apply to any such demand even if the person whose surrender is demanded
9	was not in Kentucky at the time of the commission of the crime. Neither the
10	demand, the oath, nor any proceedings for extradition pursuant to this
11	section need state or show that the person whose surrender is demanded has
12	fled from justice, or at the time of the commission of the crime was in
13	Kentucky or the other state.
14	→SECTION 32. A NEW SECTION OF KRS 311.781 TO 311.786 IS CREATED
15	TO READ AS FOLLOWS:
16	The General Assembly finds and declares, according to contemporary medical
17	research, all of the following:
18	(1) Medical and other authorities now know more about human prenatal
19	development than ever before, including:
20	(a) Between five (5) and six (6) weeks' gestation, an unborn child's heart begins
21	beating;
22	(b) At approximately eight (8) weeks' gestation, an unborn child begins to move
23	about in the womb;
24	(c) At nine (9) weeks' gestation, all basic physiological functions are present,
25	including teeth, eyes, and external genitalia;
26	(d) At ten (10) weeks' gestation, an unborn child's vital organs begin to
27	function, and hair, fingernails, and toenails begin to form;

1		(e) At eleven (11) weeks' gestation, an unborn child's diaphragm is developing,
2		he or she may even hiccup, and he or she is beginning to move about freely
3		in the womb; and
4		(f) At twelve (12) weeks' gestation, an unborn child can open and close his or
5		her fingers, starts to make sucking motions, senses stimulation from the
6		world outside the womb, and has taken on "the human form" in all
7		relevant aspects under Gonzales v. Carhart, 550 U.S. 124, 160 (2007);
8	<u>(2)</u>	The United States Supreme Court has long recognized that the state has an
9		"important and legitimate interest in protecting the potentiality of human life,"
10		Roe v. Wade, 410 U.S. 113, 162 (1973), and specifically that "the state has an
11		interest in protecting the life of the unborn". Planned Parenthood of
12		Southeastern Pennsylvania v. Casey, 505 U.S. 833, 873 (1992);
13	<u>(3)</u>	The majority of abortion procedures performed after fifteen (15) weeks' gestation
14		are dilation and evacuation procedures which involve the use of surgical
15		instruments to crush and tear the unborn child apart before removing the pieces
16		of the dead child from the womb, procedures prohibited under Section 36 of this
17		Act, and the General Assembly finds that the intentional commitment of such
18		acts for nontherapeutic or elective reasons is a barbaric practice, dangerous for
19		the maternal patient, and demeaning to the medical profession;
20	<u>(4)</u>	Abortion carries significant physical and psychological risks to the maternal
21		patient, and these physical and psychological risks increase with gestational age;
22	<u>(5)</u>	As the second trimester progresses, in the vast majority of uncomplicated
23		pregnancies, the maternal health risks of undergoing an abortion are greater
24		than the risks of carrying a pregnancy to term;
25	<u>(6)</u>	Seventy-five percent (75%) of all the nations in the world do not permit abortion
26		after twelve (12) weeks' gestation except, in most instances, to save the life and
27		preserve the physical health of the mother; and

1 The Commonwealth of Kentucky has legitimate interests from the outset of the 2 pregnancy in protecting both the health of the woman and the life of an unborn 3 human individual who may be born. 4 → Section 33. KRS 311.781 is amended to read as follows: 5 As used in KRS 311.781 to 311.786: 6 As used in KRS 311.781 to 311.786: 7 (1) "Fertilization" means the fusion of a human spermatozoon with a human ovum; 8 (2) "Gestational age" has the same meaning as in KRS 311.7701; 9 "Medical emergency" means a condition that in the physician's reasonable medical *(3)* 10 judgment, based upon the facts known to the physician at that time, so complicates 11 the woman's pregnancy as to necessitate the immediate performance or inducement 12 of an abortion in order to prevent the death of the pregnant woman or to avoid a 13 serious risk of the substantial and irreversible impairment of a major bodily function 14 of the pregnant woman that delay in the performance or inducement of the abortion would create; 15 16 <u>(4)[(3)]</u> "Pain-capable unborn child" means an unborn child of a probable 17 gestational[post-fertilization] age of fifteen (15)[twenty (20)] weeks or more; 18 <u>(5)</u>[(4)] "Physician" has the same meaning as in KRS 311.720; 19 "Probable gestational age" has the same meaning as in KRS 311.720; 20 [(5) "Post-fertilization age" means the age of the unborn child as calculated from the 21 fusion of a human spermatozoon with a human ovum; 22 (6) "Probable post-fertilization age" means, in reasonable medical judgment and with 23 reasonable probability, the age of the unborn child, as calculated from fertilization, 24 at the time the abortion is performed or induced or attempted to be performed or 25 induced; 26 (7) "Reasonable medical judgment" means a medical judgment that would be made by

a reasonably prudent physician, knowledgeable about the case and the treatment

1 possibilities with respect to the medical conditions involved;

2

3

4

5

6

7

8

9

21

22

23

24

25

26

- (8) "Serious risk of the substantial and irreversible impairment of a major bodily function" means any medically diagnosed condition that so complicates the pregnancy of the woman as to directly or indirectly cause the substantial and irreversible impairment of a major bodily function. A medically diagnosed condition that constitutes a "serious risk of the substantial and irreversible impairment of a major bodily function" includes pre-eclampsia, inevitable abortion, and premature rupture of the membranes, but does not include a condition related to the woman's mental health; and
- 10 (9) "Unborn child" means an individual organism of the species homo sapiens from fertilization until live birth.
- → Section 34. KRS 311.782 is amended to read as follows:
- 13 (1) No person shall intentionally perform or induce or intentionally attempt to perform
 14 or induce an abortion on a pregnant woman when the probable *gestational*[post15 <u>fertilization</u>] age of the unborn child is *fifteen* (15)[twenty (20)] weeks or greater.
- 16 (2) It shall be an affirmative defense to a charge under subsection (1) of this section that
 17 the abortion was intentionally performed or induced or intentionally attempted to be
 18 performed or induced by a physician and that the physician determined, in the
 19 physician's reasonable medical judgment, based on the facts known to the physician
 20 at that time, that either of the following applied:
 - (a) The probable *gestational*[post-fertilization] age of the unborn child was less than *fifteen* (15)[twenty (20)] weeks; or
 - (b) The abortion was necessary to prevent the death of the pregnant woman or to avoid a serious risk of the substantial and irreversible impairment of a major bodily function of the pregnant woman. No abortion shall be necessary if it is based on a claim or diagnosis that the pregnant woman will engage in conduct that would result in her death or in substantial and irreversible impairment of a

1 major bodily function or if it is based on any reason related to her mental 2 health.

- (3) (a) Except when a medical emergency exists that prevents compliance with KRS 311.783, the affirmative defense set forth in subsection (2)(a) of this section does not apply unless the physician who intentionally performs or induces or intentionally attempts to perform or induce the abortion makes a determination of the probable *gestational*[post fertilization] age of the unborn child as required by KRS 311.783(1) or relied upon such a determination made by another physician and certifies in writing, based on the results of the tests performed, that in the physician's reasonable medical judgment the unborn child's probable *gestational*[post fertilization] age is less than *fifteen* (15)[twenty (20)] weeks.
 - (b) Except when a medical emergency exists that prevents compliance with one
 (1) or more of the following conditions, the affirmative defense set forth in subsection (2)(b) of this section does not apply unless the physician who intentionally performs or induces or intentionally attempts to perform or induce the abortion complies with all of the following conditions:
 - 1. The physician who intentionally performs or induces or intentionally attempts to perform or induce the abortion certifies in writing that, in the physician's reasonable medical judgment, based on the facts known to the physician at that time, the abortion is necessary to prevent the death of the pregnant woman or to avoid a serious risk of the substantial and irreversible impairment of a major bodily function of the pregnant woman;
 - 2. A different physician not professionally related to the physician described in subparagraph 1. of this paragraph certifies in writing that, in that different physician's reasonable medical judgment, based on the

UNOFFICIAL COPY 22 RS HB 3/EN

facts known to that different physician at that time, the abortion is necessary to prevent the death of the pregnant woman or to avoid a serious risk of the substantial and irreversible impairment of a major bodily function of the pregnant woman;

The physician intentionally performs or induces or intentionally attempts.

- 3. The physician intentionally performs or induces or intentionally attempts to perform or induce the abortion in a hospital or other health care facility that has appropriate neonatal services for premature infants;
- 4. The physician who intentionally performs or induces or intentionally attempts to perform or induce the abortion terminates or attempts to terminate the pregnancy in the manner that provides the best opportunity for the unborn child to survive, unless that physician determines, in the physician's reasonable medical judgment, based on the facts known to the physician at that time, that the termination of the pregnancy in that manner poses a greater risk of death of the pregnant woman or a greater risk of the substantial and irreversible impairment of a major bodily function of the pregnant woman than would other available methods of abortion;
- The physician certifies in writing the available method or techniques considered and the reasons for choosing the method or technique employed; and
- 6. The physician who intentionally performs or induces or intentionally attempts to perform or induce the abortion has arranged for the attendance in the same room in which the abortion is to be performed or induced or attempted to be performed or induced at least one (1) other physician who is to take control of, provide immediate medical care for, and take all reasonable steps necessary to preserve the life and health of the unborn child immediately upon the child's complete expulsion or

1 extraction from the pregnant woman.

- 2 (4) The state Board of Medical Licensure shall revoke a physician's license to practice
- medicine in this state if the physician violates or fails to comply with this section.
- 4 (5) Any physician who intentionally performs or induces or intentionally attempts to
- 5 perform or induce an abortion on a pregnant woman with actual knowledge that
- 6 neither of the affirmative defenses set forth in subsection (2) of this section applies,
- or with a heedless indifference as to whether either affirmative defense applies, is
- 8 liable in a civil action for compensatory and punitive damages and reasonable
- 9 attorney's fees to any person, or the representative of the estate of any person
- including but not limited to an unborn child, who sustains injury, death, or loss to
- person or property as the result of the performance or inducement or the attempted
- performance or inducement of the abortion. In any action under this subsection, the
- court also may award any injunctive or other equitable relief that the court considers
- appropriate.
- 15 (6) A pregnant woman on whom an abortion is intentionally performed or induced or
- intentionally attempted to be performed or induced in violation of subsection (1) of
- this section is not guilty of violating subsection (1) of this section or of attempting
- 18 to commit, conspiring to commit, or complicity in committing a violation of
- subsection (1) of this section.
- 20 → SECTION 35. A NEW SECTION OF KRS 311.781 TO 311.786 IS CREATED
- 21 TO READ AS FOLLOWS:
- 22 The Attorney General shall have authority to bring an action in law or equity to
- 23 enforce any provisions of KRS 311.781 to 311.786 on behalf of the Commonwealth of
- 24 Kentucky. The state Board of Medical Licensure shall also have authority to bring an
- 25 action on its own behalf.
- **→** Section 36. KRS 311.787 is amended to read as follows:
- 27 (1) As used in this section:

Engrossed

1		(a)	"Bodily dismemberment, crushing, or human vivisection" means a procedure
2			in which a person, with the purpose of causing the death of an unborn child,
3			dismembers the living unborn child and extracts portions, pieces, or limbs of
4			the unborn child from the uterus through the use of clamps, grasping forceps,
5			tongs, scissors, or a similar instrument that, through the convergence of two
6			(2) rigid levers, slices, crushes, or grasps, or performs any combination of
7			those actions on, any portion, piece, or limb of the unborn child's body to cut
8			or separate the portion, piece, or limb from the body. The term includes a
9			procedure that is used to cause the death of an unborn child and in which
10			suction is subsequently used to extract portions, pieces, or limbs of the unborn
11			child after the unborn child's death;
12		(b)	"Medical emergency" has the same meaning as in KRS 311.720;
13		(c)	"Probable <u>gestational</u> [post-fertilization] age" has the same meaning as in KRS
14			<u>311.720</u> [311.781]; and
15		(d)	"Unborn child" has the same meaning as in KRS 311.781.
16	(2)	No j	person shall intentionally perform or induce or attempt to perform or induce an
17		abor	tion on a pregnant woman:
18		(a)	That will result in the bodily dismemberment, crushing, or human vivisection
19			of the unborn child; and
20		(b)	When the probable gestational [post-fertilization] age of the unborn child is
21			eleven (11) weeks or greater;
22		exce	ept in the case of a medical emergency.
23	(3)	A pı	regnant woman on whom an abortion is performed or induced or attempted to be
24		perf	ormed or induced in violation of subsection (2) of this section is not guilty of
25		viol	ating subsection (2) of this section or of attempting to commit, conspiring to

commit, or complicity in committing a violation of subsection (2) of this section.

→ Section 37. (1) If any provision of this Act or the application thereof to any

26

- 1 person or circumstance is held invalid, the invalidity shall not affect the other provisions
- 2 or applications of this Act that can be given effect without the invalid provision or
- 3 application, and to this end the provisions of this Act are severable.
- 4 (2) Nothing in this Act shall be construed as creating or recognizing a right to
- 5 abortion.
- 6 (3) Nothing in Section 27 or Sections 32 to 36 of this Act shall be construed as
- 7 altering generally accepted medical standards.
- Section 38. Sections 1 to 31 of this Act may be cited as the Humanity in
- 9 Healthcare Act of 2022.
- → Section 39. Whereas the Commonwealth of Kentucky has a paramount interest
- in protecting all human life, an emergency is declared to exist, and this Act take effect
- upon its passage and approval by the Governor or its otherwise becoming a law.