

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS**

HODES & NAUSER, MDs, P.A.; HERBERT C.)
HODES, M.D.; and TRACI LYNN NAUSER, M.D.,)

Plaintiffs,)

v.)

ROBERT MOSER, M.D., in his official capacity as)
Secretary of the Kansas Department of Health and)
Environment; STEPHEN HOWE, in his official)
capacity as District Attorney for Johnson County; and)
DEREK SCHMIDT, in his official capacity as)
Attorney General for the State of Kansas,)

Defendants.)

CIVIL ACTION

Case No. 11-2365-RDR-KGS

PLACE OF TRIAL REQUESTED:
KANSAS CITY, KANSAS

COMPLAINT

Plaintiffs, Hodes & Nauser, MDs, P.A. Herbert Hodes, M.D., Traci Nauser, M.D. (collectively “Plaintiffs”), by and through their undersigned attorneys, bring this complaint against above-named Defendants, their employees, agents, and successors in office (“Defendants”) and in support thereof state the following:

I. Preliminary Statement

1. This is an action under the U.S. Constitution and 42 U.S.C. § 1983 brought by a private obstetrics and gynecology practice and the father-daughter team of physicians who own and operate that practice, challenging the constitutionality of the licensing provisions of Kansas Senate Bill No. 36 (2011) (“Act”)¹, Act, at sec. 2, 8, as applied by Defendant Secretary of the Kansas Department of Health and Environment (“KDHE”)² through a sham licensing process, in which KDHE promulgated onerous and medically unnecessary regulations (“Temporary

¹ A true and correct copy of the Act is attached hereto as Exhibit A.

² For the reader’s convenience Secretary Moser is referred to as “KDHE” throughout.

Regulations”) without giving regulated persons and entities notice or an opportunity to be heard, and imposed absurdly short deadlines for compliance with those regulations.³ When the Act and Temporary Regulations take effect on July 1, 2011, Plaintiffs, and other medical practices, will be prohibited from performing virtually all abortions⁴ in their medical offices unless they bring those offices into compliance with the Temporary Regulations, Act, at sec. 1(f), 2(a), which Plaintiffs received just nine business days before the effective date.

2. At every step of the challenged process, KDHE implemented the licensing provisions of the Act in ways that made it impossible for existing medical practices to obtain a license by the effective date: (a) KDHE drafted and finalized Temporary Regulations without giving the facilities to be regulated any opportunity to comment on the regulations, despite the lack of any urgent circumstances necessitating that course of action; (b) KDHE included in the Temporary Regulations medically unnecessary, burdensome and inappropriate requirements, such as rigid specifications as to the number, type and dimensions of rooms in the facility, that cannot possibly be achieved in a matter of weeks; (c) KDHE conditioned licensure upon compliance with the Temporary Regulations, which were not sent to abortion providers until after the close of business on June 17, 2011, less than two weeks before the Act was to take effect; and (d) KDHE refused to consider waiver requests, provisional licensing, or any other accommodations for existing facilities.

³ A true and correct copy of the regulations, which are to be codified at Kan. Admin. Regs. § 28-34-126 - 44 (2011), is attached hereto as Exhibit B.

⁴ The Act applies to any facility that performs five or more first-trimester abortions in a month, or any second or third trimester abortions, excluding abortions performed due to a medical emergency. The Act defines a “medical emergency” as “a condition that, in a reasonable medical judgment [sic], so complicates the medical condition of the pregnant woman as to necessitate the immediate abortion of her pregnancy without first determining gestational age in order to avert her death, or for which a delay necessary to determine gestational age will create serious risk of substantial and irreversible physical impairment of a major bodily function.” Act, at sec. 1(i). The Act specifies that a medical emergency does *not* include a situation in which there is a “claim or diagnosis that the woman will engage in conduct which would result in her death or in substantial and irreversible physical impairment of a major bodily function.” *Id.*

3. For decades, Plaintiffs have provided safe, high-quality obstetrical and gynecological services, including abortion services, in their private medical office. That office meets the needs of their patients, the applicable standards of care, and the existing state regulations governing medical facilities that perform office-based surgeries. Nonetheless, that office cannot meet all of the requirements of the Temporary Regulations, and it is impossible to bring the facility into full compliance by the effective date. Accordingly, in the absence of relief from this Court, beginning on July 1, 2011, Plaintiffs will be forced to stop providing virtually all abortion services in their office, causing irreparable harm to Plaintiffs' medical practice and to the health and well-being of their patients seeking abortions. Plaintiffs seek temporary, preliminary and permanent injunctive relief against the Temporary Regulations and the licensing requirements of the Act as applied by KDHE through its adoption and implementation of the Temporary Regulations (referred to herein as the "Licensing Process"). Such injunctive relief is necessary to prevent irreparable harms and the violation of rights secured to Plaintiffs and their patients by the Due Process Clause of the Fourteenth Amendment to the United States Constitution.

II. Jurisdiction and Venue

4. This court has jurisdiction under 28 U.S.C. §§ 1331 and 1343.

5. Plaintiffs' action for declaratory and injunctive relief is authorized by 28 U.S.C. §§ 2201 and 2202.

6. Venue in this court is proper under 28 U.S.C. 1391(b) because a substantial part of the events giving rise to this action occurred in this district.

III. Parties

A. Plaintiffs

7. Plaintiff Herbert C. Hodes, M.D., is a board-certified obstetrician-gynecologist licensed to practice medicine in Kansas. He is a fellow of the American College of Obstetricians and Gynecologists and holds admitting and clinical privileges at a number of hospitals in the Kansas City area. He has been providing a full range of obstetrical and gynecological services, including first and second-trimester abortions, in his private medical practice for 34 years.

8. Plaintiff Traci Lynn Nauser, M.D., is a board-certified obstetrician-gynecologist licensed to practice medicine in Kansas. She is a fellow of the American College of Obstetricians and Gynecologists and holds admitting and clinical privileges at a number of hospitals in the Kansas City area. She joined the medical practice of her father, Dr. Hodes, 13 years ago, and she has been providing a full range of obstetrical and gynecological services, including first and second-trimester abortions, in that practice ever since.

9. Plaintiff Hodes & Nauser, MDs, P.A. is the private medical practice owned and operated by Dr. Hodes and Dr. Nauser (the “practice”). The practice is located in Overland Park, Kansas, and advertises under the name “Center for Women’s Health.”

10. Plaintiffs Dr. Hodes and Dr. Nauser provide a full range of obstetrical and gynecological services at their practice, including family planning services, pap smears, obstetrical care, gynecological procedures and surgeries, screening for and treatment of sexually transmitted infections, abortion services, treatment of menopausal symptoms, and infertility treatments. The gynecological surgeries performed by Drs. Hodes and Nauser at their office include endometrial ablation, tubal ligation, diagnostic hysteroscopy and surgical completion of miscarriage.

11. Drs. Hodes’ and Nauser’s practice accepts all major forms of health insurance in the area, including private insurance plans, Medicaid, and Medicare.

12. Drs. Hodes and Nauser also provide hospital-based care to their patients who need services in that setting. Their hospital-based services include obstetrical and gynecological surgeries and delivering babies.

13. Drs. Hodes and Nauser regularly provide five or more first-trimester abortions a month, and second trimester abortions, that do not fall under the medical emergency exception contained in the Act. Their practice has offered such abortion services in the same physical facility for over 25 years. That facility meets the applicable standards of care, the existing Kansas regulations governing providers of office-based surgery, Kan. Admin. Regs. § 100-25-1 *et seq.*, and the clinical standards of the National Abortion Federation, a professional association for physicians and facilities providing abortions, of which Plaintiffs are members. The Practice is already subject to oversight and inspections by the Kansas Board of Healing Arts, KDHE (to the extent it administers, in Kansas, the federal Clinic Laboratory Improvement Amendments, governing laboratory testing), and the National Abortion Federation.

14. Plaintiffs perform approximately one-quarter of the total abortions reported in the State annually. *See* Kansas Dep't of Health & Environment – Abortions in Kansas 2010 (Preliminary Report), *available at* http://www.kdheks.gov/hci/abortion_sum/2010itop1.pdf (last visited June 26, 2011) (providing total number of reported abortions performed in the State). The vast majority of these abortions are performed in the first trimester of pregnancy.

15. Plaintiffs perform a significant number of abortions in situations where the woman has been diagnosed with a medical complication or condition and/or where the fetus has been diagnosed with a serious fetal anomaly. Many of the perinatology practices in the region refer their patients who seek terminations after receiving a diagnosis of fetal anomaly to Plaintiffs. Additionally, other outpatient abortion providers in the region also regularly refer

patients to Plaintiffs when the woman has been diagnosed with a medical complication or condition (e.g. hypertension, obesity, fibroids, uterine anomaly, moderately low hemoglobin, placenta previa). Upon information and belief, these referrals are made based on the referring providers' confidence in Dr. Hodes' and Dr. Nauser's ability to provide expert, high-quality care to patients in those circumstances.

16. Plaintiffs bring this action on their own behalf and on the behalf of their patients who seek abortion services presently or in the future.

B. Defendants

17. Defendant Robert Moser, M.D., is the Secretary of KDHE, the agency responsible for promulgating regulations under the Act, enforcing its licensing requirements, and determining violations thereunder. Act, at secs. 9, 6, 2. Secretary Moser is sued in his official capacity, as are his agents and successors.

18. Defendant Stephen Howe is the District Attorney for Johnson County, Kansas, in which the Practice is located. As District Attorney, Defendant Howe has the authority to prosecute violations of the Act occurring in Johnson County. *See* Kan. Stat. Ann. § 22a-104 (district attorney duties); Kan. Stat. Ann. § 22-2602 (place of trial). District Attorney Howe is sued in his official capacity, as are his agents and successors.

19. Defendant Derek Schmidt is the Attorney General for the State of Kansas. As Attorney General, Defendant Schmidt is the "chief law enforcement officer of the state" and "one of the state's prosecuting attorneys." *State v. Rohleder*, 208 Kan. 193, 194 (1971); Kan. Stat. Ann. § 22-2202(17). The Attorney General may assist a county attorney in the prosecution of a case and may take over the prosecution of such a case upon the county attorney's request.

State v. Reynolds, 234 Kan. 574, 578-79 (1984). Defendant Schmidt is sued in his official capacity.

V. Factual Allegations

A. Abortion Services

20. Legal abortion is one of the safest procedures in contemporary medical practice. At earlier gestational ages, abortion is significantly safer than carrying a pregnancy to term. Until the end of the second trimester, abortion is equally safe as carrying a pregnancy to term.

21. Women seek abortions for a variety of reasons, including psychological, emotional, medical, familial, social and economic.

22. The vast majority of abortions in this country, including those in Kansas, are performed in the first trimester of pregnancy.

23. Abortions may be performed by surgical or medical means. Medication abortion involves the administration of medications (in the form of pills) to induce an abortion. Surgical abortion involves the use of instruments to evacuate the contents of the uterus. Surgical abortion is short in duration (a first trimester abortion typically takes about five to eight minutes) and involves no incision into the woman's body.

24. Both surgical abortion and medication abortion are analogous to a number of other outpatient procedures in terms of risks, invasiveness, instrumentation, and duration. For example, first trimester surgical abortion is essentially the same procedure as surgical completion of miscarriage (a procedure performed when a woman has experienced a spontaneous miscarriage but has not completely expelled the contents of the uterus), which is also commonly performed in medical offices and other outpatient settings. Other analogous gynecological procedures performed in such settings include diagnostic dilation and curettage, endometrial

biopsy, and hysteroscopy. Analogous non-gynecological outpatient procedures performed in such settings include vasectomy, sigmoidoscopy and operative colonoscopy.

25. There is no medical basis for requiring that offices and clinics in which abortions are performed meet standards and requirements different from those in which analogous medical procedures are performed.

26. Although abortion is a very safe procedure, the risks of an abortion procedure increase with the duration of the pregnancy. Therefore any delay in obtaining an abortion may cause increased risk of morbidity (major complications) and mortality (death) for the patient.

27. Upon information and belief, there are only three medical facilities in the State of Kansas that regularly provide abortions: the Practice; a medical clinic in Kansas City, which was recently denied a license under the Act by KDHE; and Comprehensive Health Center, an ambulatory surgical center operated by Planned Parenthood of Kansas and Mid-Missouri, which Plaintiffs believe has been inspected but not granted a license by KDHE. The closest out-of-state provider is a Planned Parenthood clinic in Columbia, Missouri that offers only limited first-trimester abortion services. The closest out-of-state provider of second-trimester abortion services is a Planned Parenthood clinic in St. Louis, Missouri. On information and belief, no other physician in Kansas or any neighboring state provides abortions as part of a broader, office-based medical practice.

B . The Act

28. On May 16, 2011, S.B. 36 was enacted into law. The Act takes effect upon publication in the statute book, which is expected to occur on July 1, 2011. The Act makes it unlawful to operate an “abortion clinic” in the state without possessing a valid license issued by the Department pursuant to the Act. Act, at sec. 8(a). There is no *mens rea* requirement for that

crime. *Id.* Violation of this requirement is a Class A nonperson misdemeanor, Act, at sec. 8(c), punishable by one year of imprisonment and up to \$2,500 in fines, Kan. Stat. Ann. § 21-4502(1)(A); Kan. Stat. Ann. § 21-4503(c)(1). Conviction of a Class A misdemeanor can give rise to the suspension, limitation, or revocation of a medical license by the Kansas Board of Healing Arts. Kan. Stat. Ann. § 65-2836(c). Violation of the Act's licensing provision also constitutes unprofessional conduct under Kan. Stat. Ann. § 65-2837(b), which can lead to suspension, limitation or revocation of a doctor's medical license by the Board of Healing Arts as well. Act, at sec. 8(c); Kan. Stat. Ann. § 65-2836(b).

29. The Act authorizes KDHE to license, inspect, and impose penalties on facilities subject to the Act. Act, at sec. 2-3, 5-6. With respect to licensing, the Act requires KDHE to issue a license to any facility that submits an application and meets all applicable laws and rules and regulations. Act, at sec. 2(c).

30. The Act also requires KDHE to adopt rules and regulations for the licensure of facilities that perform abortions. Act, at sec. 9. The rules and regulations adopted by KDHE under the Act must address "sanitation, housekeeping, maintenance, staff qualifications, emergency equipment and procedures to provide emergency care, medical records and reporting, laboratory, procedure and recovery rooms, physical plant, quality assurance, infection control, information on and access to patient follow-up care and any other areas of medical practice needed to carry out the purpose of [the Act]." *Id.*

31. The Act provides no deadline for when the rules and regulations under the Act must be adopted by KDHE; nor does the Act require or mention the adoption of temporary regulations.

32. Because the Act authorizes licensing on the basis of “applicable” laws, and imposes no deadline for the promulgation of regulations under the Act, KDHE could have provisionally licensed regulated facilities on the basis of their compliance with existing law and waited to apply new regulations until there had been adequate opportunity for notice and comment on them. KDHE could also have imposed flexible minimum standards in the Temporary Regulations especially as to the physical facility requirements.

C. The Licensing Process

33. On May 17, 2011, the day after the Act was signed into law, Plaintiffs, through counsel, wrote a letter to KDHE pointing out that insufficient time existed for the agency to both promulgate regulations and give providers a reasonable opportunity to comply with those regulations prior to the effective day of the Act. The letter therefore suggested that KDHE grant provisional licenses on the basis of compliance with existing law while the agency worked to develop regulations. [A true and correct copy of the letter is attached hereto as Exhibit C].

34. KDHE did not respond to Plaintiffs’ letter until May 26, 2011, at which point the agency informed Plaintiffs that it planned to issue temporary regulations, inspect clinics, and make licensing decisions on or by the July 1st effective date of the bill. [A true and correct copy of the letter is attached hereto as Exhibit D]. At that point, Plaintiffs had not seen any draft of the temporary regulations.

35. On June 9, 2011, KDHE sent Plaintiffs a draft of the temporary regulations (“Draft Regs”) which comprised more than 30 pages, as well as a license application form and cover letter. [A true and correct copy of the letter and enclosures is attached hereto as Exhibit E].

36. KDHE's letter instructed Plaintiffs to complete the application form and return it, along with an application fee and "written verification of compliance with all local codes and ordinances, fire codes and regulations, and arrangements for the removal of biomedical waste and human tissue" by June 17, 2011. The application form included a checklist requiring the facility to indicate that it met the statutory requirements in each of the enumerated areas. Thus, Plaintiffs were given six business days to review the draft regulations for the first time, affirm that they complied with all of the statutory requirements (which had been interpreted in the draft regulations), and gather the required materials, including documentation of their compliance with local codes and ordinances.

37. The June 9th draft of the temporary regulations included extensive requirements for all aspects of the medical facility, including staffing, procedures, equipment, and physical environment. With respect to the physical facility, the June 9th draft specified particular rooms and areas required in the facility, but it did not mandate the dimensions of those rooms and areas or their precise location within the facility. Ex. E, Draft Regs. § 28-4-133(b). With respect to patient recovery time, the June 9th draft required that the facility specify, in accordance with "the usual standards of medical practice," a minimum length of time for a patient to remain in the recovery room based on the type of abortion procedure, gestational age of the pregnancy, and the post-procedure condition of the patient. Ex. E, Draft Regs. § 28-34-139(1).

38. On June 13, 2011, KDHE sent a letter to Plaintiffs informing them that the June 9th draft of the temporary regulations had been changed by the Office of the Kansas Attorney General. KDHE did not at that time provide a copy of the revised regulations, or indicate what changes had been made, but it indicated that it would send them a revised version in the future. [A true and correct copy of the letter is attached hereto as Exhibit F].

39. On Friday, June 17, 2011, after the close of business, KDHE sent Plaintiffs a copy of the revised regulations, indicating that this was the final version of the temporary regulations (“Temporary Regulations”). [A true and correct copy of that correspondence is attached hereto as Exhibit G; *see also*, the Temporary Regulations, at Exhibit B]. Plaintiffs received the Temporary Regulations on the morning of Monday, June 20, 2011.

40. The Temporary Regulations are similar to the June 9th draft in a number of respects; in other respects, they impose far more rigid and onerous requirements.

41. As a whole, the Temporary Regulations impose burdensome and costly requirements that are not medically necessary or appropriate, and that are not imposed on Kansas medical providers performing other comparable procedures.

42. For example, the Temporary Regulations impose numerous physical facility requirements that are difficult or impossible for a medical office to meet, and that are not necessary for the provision of abortion services. These physical facility requirements were made significantly more onerous after the initial draft regulations were changed by the Attorney General’s office. The medically unnecessary physical environment regulations include requirements that the facility have: procedure rooms of at least 150 square feet in size, Kan. Admin. Regs. § 28-34-133(b)(7); janitorial storage space of a size at least equivalent to 50 square feet per procedure room (i.e., a facility with 6 procedure rooms must have 300 sq. ft. of janitorial storage), Kan. Admin. Regs. § 28-34-133(b)(15); designated patient dressing rooms with a toilet, hand-washing station and storage for clothing and valuables, Kan. Admin. Regs. § 28-34-133(b)(2); designated staff dressing rooms with a toilet, hand-washing station and storage for clothing and valuables, Kan. Admin. Regs. § 28-34-133(b)(3); separate sets of toilet facilities specifically designated for use by patients, staff and the public, Kan. Admin. Regs. § 28-34-

133(b)(5); a toilet room that is adjacent to (not just accessible from) the area in which a patient recovers, Kan. Admin. Regs. § 28-34-133(b)(4); “separate facilities” for pre-procedure hand washing (as opposed to hand-washing facilities located in the procedure rooms), Kan. Admin. Regs. § 28-34-133(b)(6); separate soiled and clean workrooms for cleaning and sterilizing used instruments, and two separate sinks in the soiled (rather than just separate clean and soiled areas within one workroom containing one sink), Kan. Admin. Regs. § 28-34-133(b)(13)-(14).

43. The Temporary Regulations also require that every abortion patient remain in the recovery area for at least two hours after her abortion, regardless of the type of abortion procedure, the gestational age of the pregnancy, or the patient’s post-procedure condition. Kan. Admin. Regs. § 28-34-139(1). This rigid and medically inappropriate requirement was added to the regulations after the Attorney General made changes to the first draft.

44. The Temporary Regulations also require regulated facilities to possess unnecessary and inappropriate equipment and supplies, including pediatric-sized ventilation masks, cannulas, pulse oximeter sensors, defibrillator paddles, and EKG electrode skin contacts. Kan. Admin. Regs. § 28-34-135(c)(3), (8), (e)(1), (f) (2), (3), (4). Plaintiffs do not have child-aged patients, do not deliver babies in their office, and only perform abortions there prior to fetal viability.

45. The Temporary Regulations impose a number of ambiguous and unclear requirements, such as requiring Plaintiffs to report “to the appropriate licensing agency” any incident that could “provide possible grounds for disciplinary action by the appropriate licensing agency,” Kan. Admin. Regs. § 28-34-142(f)(1)(d), (f)(2), and to “make all reasonable efforts to ensure that [an abortion patient] returns for a subsequent examination,” Kan. Admin. Regs. § 28-

34-141(d). This latter provision makes no indication of whether the reasonableness of a provider's efforts will be judged by a subjective or objective standard.

46. The Temporary Regulations impose more stringent requirements than those imposed by the State on providers of comparable medical procedures. Moreover, in many respects (including the physical facility requirements), the Temporary Regulations impose more stringent requirements than those imposed on providers that perform much more complex and risky procedures, such as hospitals and ambulatory surgical centers.

47. Despite the fact that it would be extremely costly, if not impossible, for Plaintiffs to bring their facility into compliance with the Temporary Regulations, and thus to continue providing abortions to their patients, KDHE issued an economic impact statement on June 20, 2011, that concluded that the temporary regulations "should not impose any unusual cost on regulated providers or consumers of provider services." [A true and correct copy of the statement is attached hereto as Exhibit H].

48. On June 21, 2011, the day after Plaintiffs received the Temporary Regulations, they received notice from KDHE indicating that their inspection was scheduled for June 27, 2011, six days later. [A true and correct copy of the email is attached hereto as Exhibit I].

49. The notice indicated that any change in that inspection date by Plaintiffs would require 30 days' advance notice.

50. On that same date, Plaintiffs wrote to KDHE, informing KDHE that they could not meet a number of the physical facility regulations that had been added in the revised version of the Temporary Regulations, and asking whether KDHE would entertain requests for waivers of any of those requirements. They further asked KDHE whether it would grant a provisional

license while it considered any such waiver requests. [A true and correct copy of the email is attached hereto as Exhibit J].

51. KDHE responded that same day, stating that it would not consider any waiver requests and would not grant provisional licensing. [A true and correct copy of the email is attached hereto as Exhibit K].

52. At that point, Plaintiffs wrote to KDHE to indicate that, in light of the new requirements, they could not be ready for inspection by June 27, 2011; they therefore requested that their inspection be moved to June 29, 2011. [A true and correct copy of the email is attached hereto as Exhibit L].

53. KDHE agreed to change Plaintiffs inspection date to June 29, 2011, but stated that as a result Plaintiffs might not be able to complete the licensing process by July 1, 2011. [A true and correct copy of the email is attached hereto as Exhibit M].

D. Application of the Temporary Regulations to the Practice

54. Plaintiffs cannot bring their existing office and practice into compliance with the Temporary Regulations prior to July 1, 2011, if ever. They simply do not have additional space in their building to meet the new requirements.

55. Plaintiffs use six procedure rooms in their busy ob-gyn practice; none of those rooms are 150 sq. ft. in size, and a room of that size is not medically necessary for abortions or any of the other procedures Plaintiffs perform.

56. Plaintiffs' office does not have anywhere near the required 300 sq. ft. of janitorial storage, and that amount of space is unnecessary for the safe performance of abortions and the other procedures they perform or the supplies necessary to keep the office clean.

57. Plaintiffs' office does not have designated patient dressing rooms; rather, a patient changes in the privacy of the procedure room in which she will undergo her procedure. The patient's clothes and valuables stay in the same room as the patient throughout the time she is in the facility. There is no medical basis for requiring such dressing rooms in medical practices that perform abortions.

58. Plaintiffs' office does not have designated staff dressing rooms; rather, the staff comes to work dressed, and if a staff member needs to change for any reason, he or she does so in an unoccupied room. There is no medical basis for requiring such dressing rooms in medical practices that perform abortions.

59. Plaintiffs' office patients recover in the privacy of the procedure room in which they underwent their procedures; a patient's recovery is monitored by a member of the staff present in the patient's room. A toilet room is accessible to patients recovering in procedure rooms, but is not located directly adjacent to the procedure rooms. Recovery time after an abortion is short, and patients are ambulatory shortly after the procedure and are able to walk to a bathroom if needed.

60. Plaintiffs' office does not have a separate pre-procedure hand-washing area; rather, Plaintiffs wash their hands in the hand-washing sink in each procedure room. No separate "scrub area" is needed in this setting because an abortion is performed in a clean space, but not a sterile space. This is because surgical abortion, like any other gynecological procedure in which instruments are introduced through the vagina, is not a sterile procedure – the sterile instruments cease to be sterile once they enter the vagina. Thus, the procedure rooms at Plaintiffs' practice are unlike a hospital operating theater, and medical personnel can wash their hands within the procedure rooms.

61. Plaintiffs' office has one workroom, with separate "soiled" and "clean" areas and one sink, for cleaning and sterilizing instruments after use. There is no medical basis for requiring that these areas or functions be contained in separate rooms, or that the workroom contain more than one sink.

62. After an abortion at Plaintiffs' office, a patient remains in her private procedure room under the monitoring of a staff member until such time as she meets Plaintiffs' discharge criteria. The patient's recovery time depends on such factors as the length of the pregnancy, the course of the procedure, and the patients' overall health condition. The vast majority of Plaintiffs' abortions patients meet the discharge criteria and are ready to go home well under an hour after the procedure. It is medically unnecessary and burdensome to the patient to try to force her to remain in recovery after she has met appropriate discharge criteria and is ready to go home. Keeping patients in the facility and under staff supervision for this unnecessary length of time will also greatly impair Plaintiffs ability to schedule and see patients, as their rooms will be occupied by patients who do not need them.

63. Had Plaintiffs been afforded the opportunity to comment on the Temporary Regulations, or seek waivers from particular physical facility regulations, they would have explained to KDHE that many of the regulatory requirements are medically unnecessary and unduly rigid; they would have shown KDHE that medical offices can meet the applicable standards of care and provide high-quality, safe health services without complying with these medically unnecessary and rigid requirements; and they would have provided KDHE with evidence of the negative impact that the Temporary Regulations and Licensing Process would have on their patients' health, specifically, and the public health generally.

64. The Temporary Regulations and Licensing Process will force Plaintiffs to cease providing virtually all abortion services in the Practice.

65. On June 28, 2011, Plaintiffs cancelled their inspection because it was apparent that they could not comply with the physical plant requirements as written, and that KDHE would grant no waivers or provisional licenses, or make any accommodations for existing facilities. Taking a further step in KDHE's unconstitutional licensing process would only have resulted in a license denial, which would have tarnished Plaintiffs' reputations and permanent records for purposes of future professional credentialing and licensing. Thus, Plaintiffs' only avenue of recourse for continuing to provide abortion services to their patients and protecting their practice was to file a lawsuit.

66. On information and belief, KDHE adopted and implemented the Temporary Regulations and Licensing Process in the ways described herein because of political pressure from the current State administration to close abortion clinics by any means necessary.

E. Harms Imposed by the Temporary Regulations and Licensing Process

67. Enforcement of the Temporary Regulations and Licensing Process will force Plaintiffs to cease their ongoing provision of abortion services in their practice, thereby unjustifiably delaying Plaintiffs' patients in obtaining abortions.

68. At the present time, these delays are exacerbated by the fact that Plaintiffs do not know of a single licensed abortion provider in the entire State to whom Plaintiffs can refer their patients.

69. The delays caused by the Temporary Regulations and Licensing Process will expose Plaintiffs' patients to unnecessary health risks.

70. Even if one or more of the other abortion providers in the State were able to become licensed, the application of the Temporary Regulations and Licensing Process to Plaintiffs would still cause significant delays for their patients seeking abortion who have complicating medical conditions and/or have received a diagnosis of fetal anomaly. Plaintiffs do not know of any other provider in the surrounding area to whom they can refer these patients.

71. Even if one or more of the other abortion providers in the State were able to become licensed, the application of the Temporary Regulations and Licensing Process to Plaintiffs would still leave Kansas women unable to obtain, or greatly hindered in trying to obtain, abortion services in a private medical office setting. Such a setting is preferred by some patients because it can be less cumbersome and stressful to obtain a medical procedure in that setting than in a hospital or ambulatory surgical center; because the patient already has a relationship with the physician in that setting; or because the patient can more conveniently use her health insurance in that setting. Plaintiffs know of no other physician in the area who provides abortions as part of a private medical practice, and to whom they could refer their patients if injunctive relief is not issued.

72. Enforcement of the Temporary Regulations and Licensing Process will cause immediate and irreparable harms to Plaintiffs' medical practice. These harms include loss of revenues, loss of future patients, and damage to Dr. Hodes' and Dr. Nauser's professional standing among their colleagues, patients, and potential patients.

73. By imposing medically unnecessary burdens on the provision of abortion services, the Temporary Regulations and Licensing Process will cause immediate and irreparable harms to public health.

F. Lack of Harm from Maintaining the Status Quo

74. Delaying enforcement of the Temporary Regulations and Licensing Process during the pendency of this lawsuit will not create any risk of harm to women in Kansas because the Temporary Regulations and Licensing Process are not designed to protect women's health and will not have the effect of protecting women's health; to the contrary, by imposing unnecessary requirements and impeding access to safe and legal abortion services, they will harm women's health.

75. While the Temporary Regulations and Licensing Process are enjoined, Plaintiffs will remain subject to inspections, regulation and oversight by the Kansas Board of Healing Arts, just like other medical offices that provide comparable services.

FIRST CLAIM FOR RELIEF (Patients' Right to Privacy)

76. Plaintiffs hereby re-allege and incorporate by reference paragraphs 1 through 75 above.

77. The Temporary Regulations and Licensing Process have the purpose and the effect of imposing an undue burden on Plaintiffs' patients who seek abortions presently or in the future, in violation of the Fourteenth Amendment to the United States Constitution.

SECOND CLAIM FOR RELIEF (Plaintiffs' Right to Procedural Due Process)

78. Plaintiffs hereby re-allege and incorporate by references paragraphs 1 through 77 above.

79. The Temporary Regulations and Licensing Process violate Plaintiffs' right to procedural due process under the Fourteenth Amendment to the United States Constitution because they deprive Plaintiffs of protected property and liberty interests without providing Plaintiffs with any form of pre-deprivation hearing, including any opportunity to comment on the regulations or request waivers from KDHE.

THIRD CLAIM FOR RELIEF (Plaintiffs' Right to Substantive Due Process)

80. Plaintiffs hereby re-allege and incorporate by references paragraphs 1 through 79 above.

81. The Temporary Regulations and Licensing Process violate Plaintiffs' right to due process of law under the Fourteenth Amendment to the United States Constitution by: depriving them of property (including lost income and future patients) and liberty (including their ability to practice their profession) without serving any compelling, substantial, or legitimate state interest.

FOURTH CLAIM FOR RELIEF (Plaintiffs' Right to Due Process - Vagueness)

82. Plaintiffs hereby re-allege and incorporate by reference paragraphs 1 through 81 above.

83. The Temporary Regulations and Licensing Process violate Plaintiffs' right to due process of law under the Fourteenth Amendment to the United States Constitution by failing to give Plaintiffs fair notice of the requirements they must meet under the Temporary Regulations and encouraging arbitrary and discriminatory enforcement of those regulations.

FIFTH CLAIM FOR RELIEF (Plaintiffs' Right to Equal Protection)

84. Plaintiffs hereby re-allege and incorporate by reference paragraphs 1 through 83 above.

85. The Temporary Regulations and Licensing Process deprive Plaintiffs of equal protection of the laws, as guaranteed by the Fourteenth Amendment to the United States Constitution, by subjecting them to unique burdens not imposed on medical practices that provide comparable services, with no basis for the differential treatment other than animus.

REQUEST FOR RELIEF

WHEREFORE Plaintiffs request that this Court:

1. Issue a declaratory judgment that the Temporary Regulations (to be codified at Kan. Admin. Regs. § 28-34-126 - 44 (2011)) and the licensing requirements of the Act (Senate Bill No. 36 (2011), at sec. 2, 8) as applied by KDHE through its adoption and implementation of the Temporary Regulations violate rights of Plaintiffs and their patients protected by the Fourteenth Amendment to the United States Constitution;

2. Issue preliminary and permanent injunctive relief, without bond, restraining Defendants from: (a) enforcing the Temporary Regulations; and (b) enforcing the licensing requirements of the Act (Senate Bill No. 36 (2011), at sec. 2, 8) until such time as KDHE has implemented constitutionally adequate licensing procedures.

3. Grant Plaintiffs attorney's fees, costs and expenses pursuant to 42 U.S.C. § 1988; and

4. Grant such other and further relief as this Court deems just and proper.

Place of Trial

Plaintiffs respectfully request that the trial of this matter be held in Kansas City, Kansas.

Respectfully submitted, this 28th day of June, 2011,

/s/ Teresa Woody
Teresa Woody, KS Bar #16949
The Woody Law Firm PC
1621 Baltimore Ave.
Kansas City, MO 64108
(816) 421-4246 Phone
(816) 471-4883 Fax
teresa@woodylawfirm.com

Bonnie Scott Jones*
Kara Loewentheil*
Center for Reproductive Rights
120 Wall Street, 14th Floor
New York, NY 10005
(917) 637-3600
(917) 637-3666 Fax
bjones@reprorights.org
kloewentheil@reprorights.org
*Motion for Admission *Pro Hac Vice* to be filed

ATTORNEYS FOR PLAINTIFFS

Exhibit A

House Substitute for SENATE BILL No. 36

AN ACT concerning abortion; relating to licensure of abortion clinics.

Be it enacted by the Legislature of the State of Kansas:

Section 1. As used in sections 1 through 12, and amendments thereto:

(a) "Abortion" means the use or prescription of any instrument, medicine, drug or any other substance or device to terminate the pregnancy of a woman known to be pregnant with an intention other than to increase the probability of a live birth, to preserve the life or health of the child after live birth, or to remove a dead unborn child who died as the result of natural causes in utero, accidental trauma or a criminal assault on the pregnant woman or her unborn child, and which causes the premature termination of the pregnancy.

(b) "Ambulatory surgical center" means an ambulatory surgical center as defined in K.S.A. 65-425, and amendments thereto.

(c) "Clinic" means any facility, other than a hospital or ambulatory surgical center, in which any second or third trimester, or five or more first trimester abortions are performed in a month.

(d) "Department" means the department of health and environment.

(e) "Elective abortion" means an abortion for any reason other than to prevent the death of the mother upon whom the abortion is performed; provided, that an abortion may not be deemed one to prevent the death of the mother based on a claim or diagnosis that she will engage in conduct which would result in her death.

(f) "Facility" means any clinic, hospital or ambulatory surgical center, in which any second or third trimester elective abortion, or five or more first trimester elective abortions are performed in a month, excluding any abortion performed due to a medical emergency as defined in this act, and amendments thereto.

(g) "Gestational age" has the same meaning ascribed thereto in K.S.A. 65-6701, and amendments thereto, and shall be determined pursuant to K.S.A. 65-6703, and amendments thereto.

(h) "Hospital" means a hospital as defined in subsection (a) or (b) of K.S.A. 65-425, and amendments thereto.

(i) "Medical emergency" means a condition that, in a reasonable medical judgment, so complicates the medical condition of the pregnant woman as to necessitate the immediate abortion of her pregnancy without first determining gestational age in order to avert her death, or for which a delay necessary to determine gestational age will create serious risk of substantial and irreversible physical impairment of a major bodily function. No condition shall be deemed a medical emergency if based on a claim or diagnosis that the woman will engage in conduct which would result in her death or in substantial and irreversible physical impairment of a major bodily function.

(j) "Physician" has the same meaning ascribed thereto in K.S.A. 65-6701, and amendments thereto.

(k) "Secretary" means the secretary of the department of health and environment.

Sec. 2. (a) A facility shall be licensed in accordance with sections 1 through 12, and amendments thereto.

(b) Any facility seeking licensure for the performance of abortions shall submit an application for such license to the department on forms and in the manner required by the secretary. Such application shall contain such information as the secretary may reasonably require, including affirmative evidence of the ability of the applicant to comply with such reasonable standards and rules and regulations adopted pursuant to section 9, and amendments thereto.

(c) Upon receipt of such application and verification by the department that the applicant is in compliance with all applicable laws and rules and regulations, the secretary shall issue a license to the applicant.

(d) A license issued under this section shall be posted in a conspicuous place in a public area within the facility. The issuance of a license does not guarantee adequacy of individual care, treatment, personal safety, fire safety or the well-being of any occupant of such facility. A license is not assignable or transferable.

(e) A license shall be effective for one year following the date of issuance. A license issued under this section shall apply only to the premises described in the application and in the license issued thereon, and only one location shall be described in each license.

House Substitute for SENATE BILL No. 36—page 2

(f) At the time application for a license is made the applicant shall pay a license fee in the amount of \$500. Fees paid pursuant to this section shall not be refunded by the secretary.

(g) The secretary may make exceptions to the standards set forth in law or in rules and regulations when it is determined that the health and welfare of the community require the services of the hospital or ambulatory surgical center and that the exceptions, as granted, will have no significant adverse impact on the health, safety or welfare of the patients of such hospital or ambulatory surgical center.

Sec. 3. Applicants for an annual license renewal shall file an application with the department and pay the license fee in accordance with section 2, and amendments thereto. Applicants for an annual license renewal shall also be subject to a licensing inspection in accordance with section 5, and amendments thereto.

Sec. 4. (a) No proposed facility shall be named, nor may any existing facility have its name changed to, the same or similar name as any other facility licensed pursuant to sections 1 through 12, and amendments thereto. If the facility is affiliated with one or more other facilities with the same or similar name, then the facility shall have the geographic area in which it is located as part of its name.

(b) Within 30 days after the occurrence of any of the following, a facility shall apply for an amended license by submitting such application to the department:

- (1) A change of ownership either by purchase or lease; or
- (2) a change in the facility's name or address.

Sec. 5. (a) The secretary shall make or cause to be made such inspections and investigations of each facility at least twice each calendar year and at such other times as the secretary determines necessary to protect the public health and safety and to implement and enforce the provisions of sections 1 through 12, and amendments thereto, and rules and regulations adopted pursuant to section 9, and amendments thereto. At least one inspection shall be made each calendar year without providing prior notice to the facility. For that purpose, authorized agents of the secretary shall have access to a facility during regular business hours.

(b) Information received by the secretary through filed reports, inspections or as otherwise authorized under sections 1 through 12, and amendments thereto, shall not be disclosed publicly in such manner as to identify individuals. Under no circumstances shall patient medical or other identifying information be made available to the public, and such information shall always be treated by the department as confidential.

Sec. 6. (a) When the secretary determines that a facility is in violation of any applicable law or rule and regulation relating to the operation or maintenance of such facility, the secretary, upon proper notice, may deny, suspend or revoke the license of such facility, or assess a monetary penalty after notice and an opportunity for hearing has been given to the licensee in accordance with the provisions of the Kansas administrative procedure act.

(b) Either before or after formal charges have been filed, the secretary and the facility may enter into a stipulation which shall be binding upon the secretary and the facility entering into such stipulation, and the secretary may enter its findings of fact and enforcement order based upon such stipulation without the necessity of filing any formal charges or holding hearings in the case. An enforcement order based upon a stipulation may order any disciplinary action authorized by this section against the facility entering into such stipulation.

(c) The secretary may temporarily suspend or temporarily limit the license of any facility in accordance with the emergency adjudicative proceedings under the Kansas administrative procedure act if the secretary determines that there is cause to believe that grounds exist under this section for immediate action authorized by this section against the facility and that the facility's continuation in operation would constitute an imminent danger to the public health and safety.

(d) Violations of sections 1 through 12, and amendments thereto, or of any rules and regulations adopted thereunder shall be deemed one of the following:

- (1) Class I violations are those that the secretary determines to present an imminent danger to the health, safety or welfare of the patients of the

House Substitute for SENATE BILL No. 36—page 3

facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the secretary, is required for correction. Each day such violation shall exist after expiration of such time shall be considered a subsequent violation.

(2) Class II violations are those, other than class I violations, that the secretary determines to have a direct or immediate relationship to the health, safety or welfare of the facility's patients. The citation of a class II violation shall specify the time within which the violation is required to be corrected. Each day such violation shall exist after expiration of such time shall be considered a subsequent violation.

(3) Class III violations are those that are not classified as class I or II, or those that are against the best practices as interpreted by the secretary. The citation of a class III violation shall specify the time within which the violation is required to be corrected. Each day such violation shall exist after expiration of such time shall be considered a subsequent violation.

(e) The secretary shall consider the following factors when determining the severity of a violation:

- (1) Specific conditions and their impact or potential impact on the health, safety or welfare of the facility's patients;
- (2) efforts by the facility to correct the violation;
- (3) overall conditions of the facility;
- (4) the facility's history of compliance; and
- (5) any other pertinent conditions that may be applicable.

(f) Any monetary penalty assessed by the secretary shall be assessed in accordance with the following fine schedule:

(1) For class I violations the following number of violations within a 24-month period shall result in the corresponding fine amount:

- (A) One violation, a fine of not less than \$200 and not more than \$1,000;
- (B) two violations, a fine of not less than \$500 and not more than \$2,000;
- (C) three violations, a fine of not less than \$1,000 and not more than \$5,000; and
- (D) four or more violations, a fine of \$5,000;

(2) for class II violations the following number of violations within a 24-month period shall result in the corresponding fine amount:

- (A) One violation, a fine of not less than \$100 and not more than \$200;
- (B) two violations, a fine of not less than \$200 and not more than \$1,000;
- (C) three violations, a fine of not less than \$500 and not more than \$2,000;
- (D) four violations, a fine of not less than \$1,000 and not more than \$5,000; and
- (E) five or more violations, a fine of \$5,000;

(3) for class III violations the following number of violations within a 24-month period shall result in the corresponding fine amount:

- (A) One violation, there shall be no fine;
- (B) two violations, a fine of not less than \$100 and not more than \$500;
- (C) three violations, a fine of not less than \$200 and not more than \$1,000;
- (D) four violations, a fine of not less than \$500 and not more than \$2,000;
- (E) five violations, a fine of not less than \$1,000 and not more than \$5,000; and
- (F) six or more violations, a fine of \$5,000.

Sec. 7. Except in the case of a medical emergency, as defined in this act, and amendments thereto, an abortion performed when the gestational age of the unborn child is 22 weeks or more shall be performed in a hospital or ambulatory surgical center licensed pursuant to this act. All other abortions shall be performed in a hospital, ambulatory surgical center or facility licensed pursuant to this act. All other abortions shall be performed in a facility licensed pursuant to this act, except that a hospital or ambulatory surgical center that does not meet the definition of a facility under this act

House Substitute for SENATE BILL No. 36—page 4

and that is licensed pursuant to K.S.A. 65-425 et seq., and amendments thereto, may perform abortions.

Sec. 8. (a) It shall be unlawful to operate a facility within Kansas without possessing a valid license issued annually by the secretary pursuant to section 2, and amendments thereto, with no requirement of culpable mental state.

(b) It shall be unlawful for a person to perform or induce an abortion in a facility unless such person is a physician, with clinical privileges at a hospital located within 30 miles of the facility, with no requirement of culpable mental state.

(c) Violation of subsection (a) or (b) is a class A nonperson misdemeanor and shall constitute unprofessional conduct under K.S.A. 65-2837, and amendments thereto.

Sec. 9. (a) The secretary shall adopt rules and regulations for the licensure of facilities for the performance of abortions.

(b) The secretary shall adopt rules and regulations concerning sanitation, housekeeping, maintenance, staff qualifications, emergency equipment and procedures to provide emergency care, medical records and reporting, laboratory, procedure and recovery rooms, physical plant, quality assurance, infection control, information on and access to patient follow-up care and any other areas of medical practice necessary to carry out the purposes of sections 1 through 12, and amendments thereto, for facilities for the performance of abortions. At a minimum these rules and regulations shall prescribe standards for:

- (1) Adequate private space that is specifically designated for interviewing, counseling and medical evaluations;
- (2) dressing rooms for staff and patients;
- (3) appropriate lavatory areas;
- (4) areas for preprocedure hand washing;
- (5) private procedure rooms;
- (6) adequate lighting and ventilation for abortion procedures;
- (7) surgical or gynecologic examination tables and other fixed equipment;
- (8) postprocedure recovery rooms that are supervised, staffed and equipped to meet the patients' needs;
- (9) emergency exits to accommodate a stretcher or gurney;
- (10) areas for cleaning and sterilizing instruments; and
- (11) adequate areas for the secure storage of medical records and necessary equipment and supplies.

(c) The secretary shall adopt rules and regulations to prescribe facility supplies and equipment standards, including supplies and equipment, that are required to be immediately available for use or in an emergency. At a minimum these rules and regulations shall:

- (1) Prescribe required equipment and supplies, including medications, required for the conduct, in an appropriate fashion, of any abortion procedure that the medical staff of the facility anticipates performing and for monitoring the progress of each patient throughout the procedure and recovery period;
- (2) require that the number or amount of equipment and supplies at the facility is adequate at all times to assure sufficient quantities of clean and sterilized durable equipment and supplies to meet the needs of each patient;
- (3) prescribe required equipment, supplies and medications that shall be available and ready for immediate use in an emergency and requirements for written protocols and procedures to be followed by staff in an emergency, such as the loss of electrical power;
- (4) prescribe required equipment and supplies for required laboratory tests and requirements for protocols to calibrate and maintain laboratory equipment at the facility or operated by facility staff;
- (5) require ultrasound equipment in facilities; and
- (6) require that all equipment is safe for the patient and the staff, meets applicable federal standards and is checked annually to ensure safety and appropriate calibration.

(d) The secretary shall adopt rules and regulations relating to facility personnel. At a minimum these rules and regulations shall require that:

- (1) The facility designate a medical director of the facility who is licensed to practice medicine and surgery in Kansas;
- (2) physicians performing surgery in a facility are licensed to practice

House Substitute for SENATE BILL No. 36—page 5

medicine and surgery in Kansas, demonstrate competence in the procedure involved and are acceptable to the medical director of the facility;

(3) a physician with admitting privileges at an accredited hospital located within 30 miles of the facility is available;

(4) another individual is present in the room during a pelvic examination or during the abortion procedure and if the physician is male then the other individual shall be female;

(5) a registered nurse, nurse practitioner, licensed practical nurse or physician assistant is present and remains at the facility when abortions are performed to provide postoperative monitoring and care until each patient who had an abortion that day is discharged;

(6) surgical assistants receive training in the specific responsibilities of the services the surgical assistants provide; and

(7) volunteers receive training in the specific responsibilities of the services the volunteers provide, including counseling and patient advocacy as provided in the rules and regulations adopted by the director for different types of volunteers based on their responsibilities.

(e) The secretary shall adopt rules and regulations relating to the medical screening and evaluation of each facility patient. At a minimum these rules and regulations shall require:

(1) A medical history including the following:

(A) Reported allergies to medications, antiseptic solutions or latex;

(B) obstetric and gynecologic history; and

(C) past surgeries;

(2) a physical examination including a bimanual examination estimating uterine size and palpation of the adnexa;

(3) the appropriate laboratory tests including:

(A) For an abortion in which an ultrasound examination is not performed before the abortion procedure, urine or blood tests for pregnancy performed before the abortion procedure;

(B) a test for anemia as indicated;

(C) Rh typing, unless reliable written documentation of blood type is available; and

(D) other tests as indicated from the physical examination;

(4) an ultrasound evaluation for all patients who elect to have an abortion of an unborn child. The rules shall require that if a person who is not a physician performs an ultrasound examination, that person shall have documented evidence that the person completed a course in the operation of ultrasound equipment as prescribed in rules and regulations. The physician or other health care professional shall review, at the request of the patient, the ultrasound evaluation results with the patient before the abortion procedure is performed, including the probable gestational age of the unborn child; and

(5) that the physician is responsible for estimating the gestational age of the unborn child based on the ultrasound examination and obstetric standards in keeping with established standards of care regarding the estimation of fetal age as defined in rules and regulations and shall verify the estimate in the patient's medical history. The physician shall keep original prints of each ultrasound examination of a patient in the patient's medical history file.

(f) The secretary shall adopt rules and regulations relating to the abortion procedure. At a minimum these rules and regulations shall require:

(1) That medical personnel is available to all patients throughout the abortion procedure;

(2) standards for the safe conduct of abortion procedures that conform to obstetric standards in keeping with established standards of care regarding the estimation of fetal age as defined in rules and regulations;

(3) appropriate use of local anesthesia, analgesia and sedation if ordered by the physician;

(4) the use of appropriate precautions, such as the establishment of intravenous access at least for patients undergoing second or third trimester abortions; and

(5) the use of appropriate monitoring of the vital signs and other defined signs and markers of the patient's status throughout the abortion procedure and during the recovery period until the patient's condition is deemed to be stable in the recovery room.

(g) The secretary shall adopt rules and regulations that prescribe min-

House Substitute for SENATE BILL No. 36—page 6

imum recovery room standards. At a minimum these rules and regulations shall require that:

- (1) Immediate postprocedure care consists of observation in a supervised recovery room for as long as the patient's condition warrants;
 - (2) the facility arrange hospitalization if any complication beyond the management capability of the staff occurs or is suspected;
 - (3) a licensed health professional who is trained in the management of the recovery area and is capable of providing basic cardiopulmonary resuscitation and related emergency procedures remains on the premises of the facility until all patients are discharged;
 - (4) a physician or a nurse who is advanced cardiovascular life support certified shall remain on the premises of the facility until all patients are discharged and to facilitate the transfer of emergency cases if hospitalization of the patient or viable unborn child is necessary. A physician or nurse shall be readily accessible and available until the last patient is discharged;
 - (5) a physician or trained staff member discusses Rho(d) immune globulin with each patient for whom it is indicated and assures it is offered to the patient in the immediate postoperative period or that it will be available to her within 72 hours after completion of the abortion procedure. If the patient refuses, a refusal form approved by the department shall be signed by the patient and a witness and included in the medical record;
 - (6) written instructions with regard to postabortion coitus, signs of possible problems and general aftercare are given to each patient. Each patient shall have specific instructions regarding access to medical care for complications, including a telephone number to call for medical emergencies;
 - (7) there is a specified minimum length of time that a patient remains in the recovery room by type of abortion procedure and gestational age of the unborn child;
 - (8) the physician assures that a licensed health professional from the facility makes a good faith effort to contact the patient by telephone, with the patient's consent, within 24 hours after surgery to assess the patient's recovery; and
 - (9) equipment and services are located in the recovery room to provide appropriate emergency resuscitative and life support procedures pending the transfer of the patient or viable unborn child to the hospital.
- (h) The secretary shall adopt rules and regulations that prescribe standards for follow-up visits. At a minimum these rules and regulations shall require that:
- (1) A postabortion medical visit is offered and scheduled within four weeks after the abortion, if accepted by the patient, including a medical examination and a review of the results of all laboratory tests;
 - (2) a urine pregnancy test is obtained at the time of the follow-up visit to rule out continuing pregnancy. If a continuing pregnancy is suspected, the patient shall be evaluated and a physician who performs or induces abortions shall be consulted; and
 - (3) the physician performing or inducing the abortion, or a person acting on behalf of the physician performing or inducing the abortion, shall make all reasonable efforts to ensure that the patient returns for a subsequent examination so that the physician can assess the patient's medical condition. A brief description of the efforts made to comply with this requirements, including the date, time and identification by name of the person making such efforts, shall be included in the patient's medical record.
- (i) The secretary shall adopt rules and regulations to prescribe minimum facility incident reporting. At a minimum these rules and regulations shall require that:
- (1) The facility records each incident resulting in a patient's or viable unborn child's serious injury occurring at a facility and shall report them in writing to the department within 10 days after the incident. For the purposes of this paragraph, "serious injury" means an injury that occurs at a facility and that creates a serious risk of substantial impairment of a major body organ;
 - (2) if a patient's death occurs, other than an unborn child's death properly reported pursuant to law, the facility shall report such death to the department of health and environment not later than the next department business day; and
 - (3) incident reports are filed with the department of health and environment and appropriate professional regulatory boards.
- (j) (1) The secretary shall adopt rules and regulations requiring each

House Substitute for SENATE BILL No. 36—page 7

facility to establish and maintain an internal risk management program which, at a minimum, shall consist of:

(A) A system for investigation and analysis of the frequency and causes of reportable incidents within the facility;

(B) measures to minimize the occurrence of reportable incidents and the resulting injuries within the facility; and

(C) a reporting system based upon the duty of all health care providers staffing the facility and all agents and employees of the facility directly involved in the delivery of health care services to report reportable incidents to the chief of the medical staff, chief administrative officer or risk manager of the facility.

(2) As used in this subsection, the term "reportable incident" means an act by a health care provider which:

(A) Is or may be below the applicable standard of care and has a reasonable probability of causing injury to a patient; or

(B) may be grounds for disciplinary action by the appropriate licensing agency.

(k) The rules and regulations adopted by the secretary pursuant to this section do not limit the ability of a physician or other health care professional to advise a patient on any health issue. The secretary periodically shall review and update current practice and technology standards under sections 1 through 12, and amendments thereto, and based on current practice or technology adopt by rules and regulations alternative practice or technology standards found by the secretary to be as effective as those enumerated in sections 1 through 12, and amendments thereto.

(l) The provisions of sections 1 through 12, and amendments thereto, and the rules and regulations adopted pursuant thereto shall be in addition to any other laws and rules and regulations which are applicable to facilities defined as clinics under section 1, and amendments thereto.

(m) In addition to any other penalty provided by law, whenever in the judgment of the secretary of health and environment any person has engaged, or is about to engage, in any acts or practices which constitute, or will constitute, a violation of this section, or any rules and regulations adopted under the provisions of this section, the secretary shall make application to any court of competent jurisdiction for an order enjoining such acts or practices, and upon a showing by the secretary that such person has engaged, or is about to engage, in any such acts or practices, an injunction, restraining order or such other order as may be appropriate shall be granted by such court without bond.

Sec. 10. (a) No abortion shall be performed or induced by any person other than a physician licensed to practice medicine in the state of Kansas. When RU-486 (mifepristone) or any drug is used for the purpose of inducing an abortion, the drug must be administered by or in the same room and in the physical presence of the physician who prescribed, dispensed or otherwise provided the drug to the patient.

(b) The physician inducing the abortion, or a person acting on behalf of the physician inducing the abortion, shall make all reasonable efforts to ensure that the patient returns 12 to 18 days after the administration or use of such drug for a subsequent examination so that the physician can confirm that the pregnancy has been terminated and assess the patient's medical condition. A brief description of the efforts made to comply with this subsection, including the date, time and identification by name of the person making such efforts, shall be included in the patient's medical record.

(c) A violation of this section shall constitute unprofessional conduct under K.S.A. 65-2837, and amendments thereto.

Sec. 11. Nothing in sections 1 through 12, and amendments thereto, shall be construed as creating or recognizing a right to abortion. Notwithstanding any provision of this section, a person shall not perform an abortion that is prohibited by law.

Sec. 12. The provisions of sections 1 through 12, and amendments thereto, are declared to be severable, and if any provision, or the application thereof, to any person shall be held invalid, such invalidity shall not affect the validity of the remaining provisions of sections 1 through 12, and amendments thereto.

House Substitute for SENATE BILL No. 36—page 8

Sec. 13. This act shall take effect and be in force from and after its publication in the statute book.

I hereby certify that the above BILL originated in the
SENATE, and passed that body

SENATE concurred in
HOUSE amendments _____

President of the Senate.

Secretary of the Senate.

Passed the HOUSE
as amended _____

Speaker of the House.

Chief Clerk of the House.

APPROVED _____

Governor.

Exhibit B

K.A.R. 28-34-126. Definitions. For the purposes of K.A.R. 28-34-126 through 28-34-144, the following terms shall have the meanings specified in this regulation. (a) "Admitting privileges" means permission extended by a hospital to a physician to allow the physician to admit a patient to that hospital either as active or courtesy staff.

(b) "Ancillary services" means laboratory, radiology, or pharmacy services.

(c) "Ancillary staff member" means an individual who performs laboratory, radiology, or pharmacy services at a facility.

(d) "Applicant" means a person who has applied for a license but who has not yet been granted a license to operate a facility.

(e) "Clinical privileges" means permission extended by a hospital to a physician to allow the physician to provide treatment to a patient in that hospital.

(f) "Health professional" means an individual, other than a physician, who is one of the following:

(1) A nurse licensed by the Kansas state board of nursing; or

(2) a physician assistant licensed by the Kansas state board of healing arts.

(g) "Licensee" means a person who has been granted a license to operate a facility.

(h) "Medical staff member" means an individual who is one of the following:

(1) A physician licensed by the Kansas state board of healing arts;

(2) a health professional; or

(3) an ancillary staff member.

(i) "Newborn child" means a viable child delivered during an abortion procedure.

ATTORNEY GENERAL

DEPT. OF ADMINISTRATION

JUN 17 2011

JUN 17 2011

APPROVED BY

APPROVED

K.A.R. 28-34-126, page 2

(j) "Person" means any individual, firm, partnership, corporation, company, association, or joint-stock association, and the legal successor thereof.

(k) "Risk manager" means the individual designated by the applicant or licensee to administer the facility's internal risk management program and to receive reports of reportable incidents within the facility.

(l) "Reportable incident" means an act by a medical staff member which:

(1) Is or may be below the applicable standard of care and has a reasonable probability of causing injury to a patient; or

(2) may be grounds for disciplinary action by the appropriate licensing agency.

(m) "Staff member" means an individual who provides services at the facility and who is compensated for those services.

(n) "Unborn child" means a living individual organism of the species homo sapiens, in utero, at any stage of gestation from fertilization to birth.

(o) "Viable" shall have the same meaning ascribed in K.S.A. 65-6701, and amendments thereto.

(p) "Volunteer" means an individual who provides services at the facility and who is not compensated for those services.

This regulation shall be effective on and after July 1, 2011. (Authorized by 2011 House substitute for SB 36, sec. 9; implementing 2011 House substitute for SB 36, sec.1; effective, T-_____, _____.)

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

28-34-127. Application process. (a) Any person desiring to operate a facility shall apply for a license on forms provided by the department.

(b) Each applicant shall submit a fee of \$500 for a license. The applicable fee shall be submitted at the time of license application and shall not be refundable.

(c) Before initial licensing each applicant shall submit to the department the following information:

(1) Written verification from the applicable local authorities showing that the premises are in compliance with all local codes and ordinances, including all building, fire, and zoning requirements;

(2) written verification from the state fire marshal showing that the premises are in compliance with all applicable fire codes and regulations;

(3) documentation of the specific arrangements that have been made for the removal of biomedical waste and human tissue from the premises; and

(4) documentation that the facility is located within 30 miles of an accredited hospital.

(d) The granting of a license to any applicant may be denied by the secretary if the applicant is not in compliance with all applicable laws, rules, and regulations.

This regulation shall be effective on and after July 1, 2011. (Authorized by 2011 House substitute for SB 36, sec. 9; implementing 2011 House substitute for SB 36, secs. 2 and 9; effective, T-_____, _____.)

ATTORNEY GENERAL DEPT. OF ADMINISTRATION

JUN 17 2011

JUN 17 2011

APPROVED BY

APPROVED

K.A.R. 28-34-128. Reserved.

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

28-34-129. Terms of a license. (a) Each license shall be effective for one year following the date of issuance.

(b) Each license shall be valid for the licensee and the address specified on the license. When an initial, renewed, or amended license becomes effective, all licenses previously granted to the applicant or licensee at the same address shall become invalid.

(c) Only one physical location shall be described in each license.

(d) Any applicant may withdraw the application for a license.

(e) Any licensee may submit, at any time, a request to close the facility permanently and to surrender the license.

(f) If a facility is closed, any license granted for that facility shall become void.

This regulation shall be effective on and after July 1, 2011. (Authorized by 2011 House substitute for SB 36, sec. 9; implementing 2011 House substitute for SB 36, sec. 2; effective, T-_____, _____.)

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

28-34-130. Renewals; amendments. (a) No earlier than 90 days before but no later than the renewal date, each licensee wishing to renew the license shall submit the following:

- (1) The nonrefundable license fee of \$500; and
- (2) an application to renew the license on the form provided by the department.

(b) Each licensee shall submit a request for an amended license to the department within 30 days, as set forth in 2011 House substitute for SB 36, sec. 4.

This regulation shall be effective on and after July 1, 2011. (Authorized by 2011 House substitute for SB 36, sec. 9; implementing 2011 House substitute for SB 36, secs. 2, 3, and 4; effective, T-_____, _____.)

ATTORNEY GENERAL

JUN 17 2011

APPROVED L Y

DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

K.A.R. 28-34-131. Operation of the facility. (a) Each applicant and each licensee shall be responsible for the operation of the facility.

(b) Each applicant and each licensee shall:

(1) Ensure compliance with all applicable federal, state, and local laws;

(2) serve as or designate a medical director who is a physician licensed by the Kansas state board of healing arts and who has no limitations to the license that would prohibit the physician's ability to serve in the capacity as a medical director of a facility; and

(3) ensure the following documents are conspicuously posted at the facility:

(A) The current facility license issued by the department; and

(B) the current telephone number and address of the department.

(c) Each applicant and each licensee shall ensure that written policies and procedures are developed and implemented for the operation of the facility. The policies and procedures shall include the following requirements:

(1) An organized recordkeeping system to meet the requirements in K.A.R. 28-34-144;

(2) documentation of personnel qualifications, duties, and responsibilities to meet the requirements in K.A.R. 28-34-132;

(3) that the facility is designed, constructed, equipped, and maintained to protect the health and safety of patients, staff, and visitors to meet the requirements in K.A.R. 28-34-133 through 28-34-136;

(4) ensure proper and adequate medical screening and evaluation of each patient to meet the requirements in K.A.R. 28-34-137;

(5) consent is obtained from each patient before the procedure;

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

K.A.R. 28-34-131, page 2

(6) safe conduct of abortion procedures to meet the requirements in K.A.R. 28-34-138;

(7) the appropriate use of anesthesia, analgesia and sedation to meet the requirements in K.A.R. 28-34-138;

(8) ensure the use of appropriate precautions for any patient undergoing a second or third trimester abortion to meet the requirements in K.A.R. 28-34-138;

(9) post-procedure care of patients to meet the requirements in K.A.R. 28-34-139;

(10) identify and ensure a physician with admitting privileges at an accredited hospital located within 30 miles of the facility is available during facility hours of operation;

(11) if indicated, the transfer of any patient and newborn child to a hospital to meet the requirements in K.A.R. 28-34-140;

(12) follow-up and aftercare for each patient receiving an abortion procedure in the facility to meet the requirements in K.A.R. 28-34-141;

(13) a written plan for risk management to meet the requirements in K.A.R. 28-34-142, including policies and procedures for staff member or volunteer reporting of any clinical care concerns; and

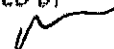
(14) ensure that incidents that require reporting to the department are completed as required in K.A.R. 28-34-143.

This regulation shall be effective on and after July 1, 2011. (Authorized by 2011 House substitute for SB 36, sec. 9; implementing 2011 House substitute for SB 36, secs. 2 and 9; effective, T-_____, _____.)

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

K.A.R. 28-34-132. Staff requirements. (a) Each applicant and each licensee shall ensure that each physician performing surgery in a facility is approved by the medical director, licensed to practice medicine and surgery in the state of Kansas, and demonstrates competence in the procedure involved in the physician's duties at the facility. Competence shall be demonstrated through both of the following means and methods:

- (1) Documentation of education and experience; and
- (2) observation by or interaction with the medical director.

(b) Each applicant and each licensee shall ensure the following:

- (1) A physician with admitting privileges at an accredited hospital located within 30 miles of the facility is available.
- (2) Any physician performing or inducing abortion procedures in the facility has clinical privileges at a hospital located within 30 miles of the facility.

(c) Each applicant and each licensee shall ensure that each individual who performs an ultrasound is one of the following:

- (1) A physician licensed in the state of Kansas who has completed a course for the type of ultrasound examination the physician performs; or
- (2) an individual who performs ultrasounds under the supervision of a physician and who meets all of the following requirements:
 - (A) Has completed a course in performing ultrasounds;
 - (B) has completed a training for the specific type of ultrasound examination the individual performs; and
 - (C) is not otherwise precluded by law from performing ultrasound examinations.

ATTORNEY GENERAL

DEPT. OF ADMINISTRATION

JUN 17 2011

JUN 17 2011

APPROVED BY



APPROVED

K.A.R. 28-34-132, page 2

(d) Each applicant and each licensee shall ensure that each physician assistant, each nursing, and each ancillary staff member employed by or contracted with the facility are licensed, if required by state law, are qualified, and provide services to patients consistent with the scope of practice of the individual's training and experience.

(e) Each applicant and each licensee shall ensure that each surgical assistant employed by or contracted with the facility receives training in the specific responsibilities of the services the surgical assistant provides in the facility.

(f) Each applicant and each licensee shall ensure that each volunteer receives training as identified by the medical director in the specific responsibilities the volunteer provides at the facility.

(g) Each applicant and each licensee shall ensure that at least one physician or registered nurse is certified in advanced cardiovascular life support and is present at the facility when any patient is present.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

K.A.R. 28-34-133. Facility environmental standards. (a) Each applicant and each licensee shall ensure that the facility is designed, constructed, equipped, and maintained to protect the health and safety of patients, staff members, volunteers, and visitors.

(b) Each facility shall include the following rooms and areas:

- (1) At least one room with private space consisting of at least 80 square feet, designated for patient interviews, counseling, and medical examinations;
- (2) designated dressing rooms for patients only, including a toilet, hand washing station, and storage for clothing and valuables;
- (3) designated dressing rooms for staff members only, including a toilet, hand washing station, and storage for clothing and valuables;
- (4) a toilet room adjacent to the recovery area, designated for patients only;
- (5) a toilet room designated for the public only;
- (6) separate facilities for pre-procedure handwashing by staff members;
- (7) private procedure rooms consisting of at least 150 square feet, excluding fixed cabinet areas;
- (8) a recovery area consisting of at least 80 square feet per patient in the area;
- (9) a nurse station with visual observation of each patient in the recovery area;
- (10) privacy for each patient in the recovery area with at least cubicle curtains around each patient gurney or bed;
- (11) a waiting area for patients and visitors;
- (12) an administrative area, including office space for the secure filing and storage of facility patient records;

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

K.A.R. 28-34-133, page 2

(13) a soiled workroom exclusive to the procedure rooms, including the following:

(A) A hand washing station;

(B) a work counter;

(C) a clinical sink; and

(D) receptacles for waste and soiled items;

(14) a clean workroom including the following:

(A) A hand washing station;

(B) counter space;

(C) storage space for clean and sterile supplies;

(D) and an area for cleaning and sterilizing instruments; and

(E) physically separated from the soiled workroom; and

(15) a storage area designated for janitorial supplies and equipment consisting of at least 50 square feet per procedure room.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



K.A.R. 28-34-134, Health and safety requirements. (a) Each applicant and each licensee shall ensure that the facility meets the following health and safety requirements:

(1) The room temperature in each procedure room shall be between 68 and 73 degrees Fahrenheit during each abortion procedure.

(2) The room temperature in each patient recovery area shall be between 70 and 75 degrees Fahrenheit at all times.

(3) Fixed or portable lighting units shall be present in each examination, procedure, and recovery room or area, in addition to general lighting.

(4) Each emergency exit shall accommodate a stretcher or a gurney.

(5) The facility shall be maintained in a clean condition.

(6) The facility shall not be infested by insects and vermin.

(7) A warning notice shall be placed at the entrance to any room or area where oxygen is in use.

(8) Soiled linen and clothing shall be kept in covered containers in a separate area from clean linen and clothing.

(b) A written emergency plan shall be developed and implemented, including procedures for protecting the health and safety of patients and other individuals in any of the following circumstances:

(1) A fire;

(2) a natural disaster;

(3) loss of electrical power; or

(4) threat or incidence of violence.

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

K.A.R. 28-34-134, page 2

(c) An evacuation drill shall be conducted at least once every six months, including participation by all individuals in the facility at the time of the drill. Documentation shall be maintained at the facility for one year from the date of the drill and shall include the date and time of the drill.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

DEPT. OF ADMINISTRATION

ATTORNEY GENERAL

JUN 17 2011

JUN 17 2011

APPROVED

APPROVED BY 

K.A.R. 28-34-135. Equipment; supplies; drugs and medications. (a) Each applicant and each licensee shall ensure that supplies, equipment, drugs, and medications are immediately available for use or in an emergency.

(b) Equipment and supplies shall be maintained in the amount required to assure sufficient quantities of clean and sterilized durable equipment to meet the needs of each patient during any abortion procedure and for monitoring each patient throughout the procedure and recovery period.

(c) Each applicant and each licensee shall ensure that the following equipment and supplies are maintained in the facility for airway management:

- (1) An oxygen source with flowmeter;
- (2) simple face masks, in sizes for infants, children, and adults;
- (3) pediatric and adult masks for assisting ventilation;
- (4) self-inflating bag with reservoir, 500 cc and 1000 cc;
- (5) suction, either wall or machine;
- (6) suction catheters, Yankauer, 8, 10, and 14F;
- (7) oral airways, infant to adult sizes;
- (8) nasal cannulas in infant, child, and adult sizes 1-3;
- (9) options for intubation, if needed;
- (10) laryngoscope handle with batteries;
- (11) miller blades, 0, 1, 2, and 3;
- (12) endotracheal tubes, uncuffed, 3.0, 3.5, 4.0, 4.5, 5.0, 6.0, 7.0, and 8.0;
- (13) stylets, small and large; and

ATTORNEY GENERAL

DEPT. OF ADMINISTRATION

JUN 17 2011

JUN 17 2011

APPROVED BY

APPROVED

K.A.R. 28-34-135, page 2

(14) adhesive tape to secure airway.

(d) Each applicant and each licensee shall ensure that the following supplies are maintained in the facility for fluid management:

- (1) Intraosseous needles, 15 or 18 gauge;
- (2) intravenous catheters, 18, 20, 22, and 24 gauge;
- (3) butterfly needles, 23 gauge;
- (4) intravenous boards, tape, alcohol swabs, and tourniquets;
- (5) pediatric drip chambers and tubing;
- (6) D5 ½ normal saline; and
- (7) isotonic fluids, either normal saline or lactated Ringer's solution.

(e) Each applicant and each licensee shall ensure that the following miscellaneous equipment and supplies are maintained in the facility:

- (1) Blood pressure cuffs, preemie, infant, child, and adult;
- (2) nasogastric tubes, 8, 10, and 14F; and
- (3) sphygmomanometer manual.

(f) Each applicant and each licensee may maintain the following optional equipment and supplies in the facility:

- (1) Portable monitor/defibrillator, with settings less than 10;
- (2) pediatric defibrillation paddles;
- (3) pediatric electrocardiogram (EKG) skin electrode contacts, peel and stick;

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

K.A.R. 28-34-135, page 3

(4) pulse oximeter with reusable sensors for older children and non-reusable sensors for small children;

(5) device to check serum glucose;

(6) strips to check urine for glucose and blood; and

(7) central lines over guidewire catheters, 3, 4, and 5F.

(g) Each applicant and each licensee shall ensure that all equipment is safe for each patient and for the staff.

(h) Each applicant and each licensee shall ensure that each item of equipment is installed and used according to the manufacturer's recommendations for use.

(i) Each applicant and each licensee shall ensure that each item of equipment is checked annually to ensure safety and appropriate calibration.

(j) Each applicant and each licensee shall ensure that equipment and supplies are clean and sterile, if applicable, before each use.

(k) Each applicant and each licensee shall ensure that the facility meets the following requirements for equipment:

(1) All equipment shall be clean, functional, and maintained in accordance with the manufacturer's instructions.

(2) The following equipment shall be available at all times:

(A) Ultrasound equipment;

(B) intravenous equipment;

(C) laboratory equipment;

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

K.A.R. 28-34-135, page 4

(D) patient resuscitation and suction equipment;

(E) equipment to monitor vital signs in each room in which an abortion is performed;

(F) a surgical or gynecologic examination table;

(G) equipment to measure blood pressure;

(H) a stethoscope;

(I) a scale for weighing a patient; and

(J) additional equipment for any abortion procedure performed after the first trimester, including ultrasound equipment, drugs to support cardiopulmonary function, and equipment to monitor cardiopulmonary status.

(I) Each applicant and each licensee shall ensure that equipment and appropriate medications are located in the recovery area as needed for the provision of appropriate emergency resuscitative and life support procedures pending the transfer to a hospital of a patient or a newborn child.

(1) Each applicant and each licensee shall maintain an emergency kit or a stock supply of drugs and medications for the use of the physician in treating the emergency needs of patients, as required in subsection (m) of this regulation.

(2) The emergency kit or medication shall be stored in such a manner as to prohibit access by unauthorized personnel.

(3) Contents of the emergency kit or stock supplies of medications shall be regularly reviewed to ensure proper inventory control with removal or replacement of expired drugs and medications.

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

K.A.R. 28-34-135, page 5


(4) Drugs and equipment shall be available within the facility to treat the following conditions consistent with standards of care:

- (A) Cardiac arrest;
- (B) a seizure;
- (C) an asthma attack;
- (D) allergic reaction;
- (E) narcotic or sedative toxicity;
- (F) hypovolemic shock;
- (G) vasovagal shock; and
- (H) anesthetic reactions.

(m) The following medications shall be maintained at the facility:

(1) Aqueous epinephrine – 1:1000 and 1:10,000 {1:1000 = 1 gram/1000 cc or 1 mg/cc and is available as both 1 cc glass vials which must be cracked and 30 cc multiple dose vials} {1:10,000 = 1 gram/10,000 cc or 0.1 mg/cc comes as a 10 cc bristojet};

- (2) atropine sulfate;
- (3) dextrose in water – 50%;
- (4) sodium bicarbonate – 1 meg/cc (approximately);
- (5) lorazepam or diazepam;
- (6) phenobarbital;
- (7) antibiotics, parenteral, including ampicillin, gentamycin, and ceftriaxone;
- (8) methylprednisolone or dexamethasone;

DEPT. OF ADMINISTRATION
ATTORNEY GENERAL
JUN 17 2011
JUN 17 2011
APPROVED BY

APPROVED

K.A.R. 28-34-135, page 6

(9) naloxone (1 mg/cc);

(10) activated charcoal;

(11) albuterol concentrated for inhalation (5 mg/cc) {also supplied premixed with 2.5 mg/2.5 cc};

(12) lidocaine 2% (20 mg/cc); and

(13) Benadryl (50 mg/cc).

(n) Drugs and medications shall be administered to individual patients only by a facility physician or a facility health professional.

(o) If a stock of controlled drugs is to be maintained at the facility, the applicant or licensee shall ensure that the facility is registered by the Kansas board of pharmacy. Each applicant and each licensee shall ensure the proper safeguarding and handling of controlled substances within the facility, and shall ensure that all possible control measures are observed and that any suspected diversion or mishandling of controlled substances is reported immediately.

(p) Records shall be kept of all stock supplies of controlled substances giving an accounting of all items received or administered.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

DEPT. OF ADMINISTRATION

ATTORNEY GENERAL

JUN 17 2011

JUN 17 2011

APPROVED

APPROVED BY



K.A.R. 28-34-136. Ancillary services. (a) Each applicant and each licensee shall document that the facility maintains a certificate of compliance from the centers for medicare and medicaid services pursuant to section 353 of the public health services act, 42 U.S.C. 263a, as revised by the clinical laboratory and current clinical laboratory improvement amendments for the purpose of performing examinations or procedures.

(b) Each applicant and each licensee shall ensure that the facility meets the following requirements for radiology services:

(1) Allow only trained and qualified individuals to operate radiology equipment;

(2) document annual checks and calibration of radiology equipment and maintain records of the annual checks and calibrations;

(3) ensure that all radiology and diagnostic procedures are provided only on the order of a physician; and

(4) maintain signed and dated clinical reports of the radiological findings in each patient's record.

(c) Each applicant and each licensee shall ensure that written policies and procedures are developed and implemented relating to drugs, including the following:

(1) Storage of drugs;

(2) security of drugs;

(3) labeling and preparation of drugs;

(4) administration of drugs; and

(5) disposal of drugs.

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

K.A.R. 28-34-136, page 2

(d) Each applicant and each licensee shall ensure that all drugs and medications shall be ordered pursuant to a written order from a facility physician or a facility health professional.

(e) Each applicant and each licensee shall ensure that each adverse drug reaction is reported to the physician responsible for the patient and is documented in the patient record.

(f) Each applicant and each licensee shall ensure that each drug and each medication requiring refrigeration is stored in a refrigerator that is used only for drug and medication storage.

(g) Each applicant and each licensee shall ensure that there is a mechanism for the ongoing review and evaluation of the quality and scope of laboratory, radiology, and pharmaceutical services.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

K.A.R. 28-34-137. Patient screening and evaluation. (a) Each applicant and each licensee shall ensure written policies and procedures are developed and implemented for the medical screening and evaluation of patients. A medical screening and evaluation shall be completed on each patient before an abortion procedure is performed.

(b) The medical screening and evaluation shall consist of the following:

(1) A medical history shall be completed, including the following:

(A) Reported allergies to medications, antiseptic solution, or latex;

(B) obstetric and gynecologic history;

(C) past surgeries;

(D) medication currently being taken by the patient; and

(E) any other medical conditions.

(2) A physical examination shall be performed by a physician, including a bimanual examination to estimate uterine size and palpation of the adnexa.

(3) An ultrasound evaluation shall be completed for any patient who elects to have an abortion of an unborn child. The physician shall estimate the gestational age of the unborn child based on the ultrasound examination and obstetric standards in keeping with established standards of care regarding the estimation of the age of the unborn child and shall verify the estimate in the patient's medical history. The physician shall keep the original prints of each ultrasound examination for each patient in the patient's medical history file.

(4) The appropriate laboratory tests shall be completed, including the following:

(A) For an abortion performed in a medical emergency and in which an ultrasound examination is not performed before the abortion procedure, urine or blood tests for pregnancy,

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

K.A.R. 28-34-137, page 2

which shall be completed before the abortion procedure;

(B) a test for anemia as indicated;

(C) determination of Rh factor or Rh typing, unless the patient provides written documentation of blood type acceptable to the physician; and

(D) other tests recommended by the physician or the medical director on the basis of the physical examination, which may include tests for chlamydia and gonorrhea and other cultures, syphilis serology, and a papanicolaou procedure.

(c) Each licensee shall ensure that another individual is present in the room during a pelvic examination or an abortion procedure. If the physician conducting the examination or the procedure is male, the other individual in the room shall be female.

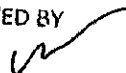
(d) The physician or health care professional shall review, at the request of the patient, the ultrasound evaluation results with the patient before the abortion procedure is performed, including the probable gestational age of the unborn child.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

K.A.R. 28-34-138. Abortion procedure. (a) Each applicant and each licensee shall ensure that written policies and procedures are developed and implemented for the following procedures:

(1) Safe conduct of abortion procedures that conform to obstetric standards in keeping with established standards of care regarding the estimation of the gestational age of the unborn child;

(2) the appropriate use of local anesthesia, analgesia, and sedation if ordered by the physician; and

(3) the use of appropriate precautions, including the establishment of intravenous access for any patient undergoing a second or third trimester abortion, unless the physician determines that establishing intravenous access is not appropriate for the patient and documents that fact in the medical record of the patient.

(b) Each licensee shall ensure that the following procedures are followed for each patient before performance of an abortion:

(1) Information is provided to the patient on the abortion procedure, including alternatives, risks, and potential complications.

(2) Written consent is signed and dated by the patient.

(c) Each licensee shall ensure that a physician and at least one health professional is available to each patient throughout the abortion procedure.

(d) Each licensee shall ensure that an infection control program is established which includes the following:

(1) Measures for surveillance, prevention, and control of infections;

(2) policies and procedures outlining infection control and aseptic techniques to be

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

K.A.R. 28-34-138, page 2

followed by staff members and volunteers; and

(3) training on infection control and aseptic techniques for all staff members and volunteers.

(e) Each licensee shall ensure that each abortion is performed according to the facility's policies and procedures and in compliance with all applicable laws, rules, and regulations.

(f) Each licensee shall ensure that health professionals monitor each patient's vital signs throughout the abortion procedure to ensure the health and safety of the patient.

(g) Each licensee shall ensure that the following steps are performed if an abortion procedure results in the delivery of a newborn child:

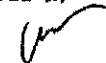
- (1) Resuscitative measures are used to support life;
- (2) the newborn child is transferred to a hospital; and
- (3) resuscitative measures and the transfer to a hospital are documented.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____,
_____.)

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

K.A.R. 28-34-139. Recovery procedures; discharge. (a) Each applicant and each licensee shall ensure written policies and procedures are developed and implemented for the post-procedure care of patients, which shall include the following:

(1) Each patient shall remain in the recovery area at least two hours following the abortion procedure and as necessary based on the physician's evaluation of the patient's medical condition.

(2) Immediate post-procedure care for each patient shall consist of observation in a supervised recovery area.

(3) The vital signs and bleeding of each patient shall be monitored by a physician or a health professional.

(b) Each licensee shall ensure that a physician or an individual designated by a physician shall discuss Rho(d) immune globulin with each patient for whom it is indicated and assure that it is offered to the patient in the immediate post-procedure period or that it will be available to the patient within 72 hours after completion of the abortion procedure. If the patient refuses the Rho(d) immune globulin, the refusal shall be documented on a form approved by the department, signed by the patient and a witness, and filed in the medical record of the patient.

(c) At the time of discharge from the facility, each patient shall receive the following written information:

- (1) Signs of possible complications;
- (2) when to access medical care in response to complications;
- (3) the telephone number to call in an emergency;
- (4) instructions and precautions for resuming vaginal intercourse; and

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

K.A.R. 28-34-139, page 3

(5) any other instructions specific to a patient's abortion or condition.

(d) Each licensee shall ensure that a physician signs the discharge order for each patient.

This regulation shall be effective on and after July 1, 2011. (Authorized by and
implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____ ,

_____.)

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

K.A.R. 28-34-140. Transfers. (a) Each applicant and each licensee shall ensure that written policies and procedures are developed and implemented for the transfer of patients and newborn children to a hospital.

(b) Each licensee shall ensure that a physician arranges the transfer of a patient to a hospital if any complications beyond the medical capability of the health professionals occurs or is suspected.

(c) Each licensee shall ensure that a physician arranges the transfer of a newborn child to a hospital if the child requires emergency care.

(d) A physician or a nurse who is certified in advanced cardiovascular life support shall remain on the premises of the facility to facilitate the transfer of an emergency case if hospitalization of a patient or a newborn child is required.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

K.A.R. 28-34-141. Follow-up contact and care. Each applicant and each licensee shall ensure that written policies and procedures are developed and implemented for follow-up and aftercare for each patient receiving an abortion procedure in the facility, including the following: (a) With the consent of the patient, a health professional from the facility shall contact the patient by telephone within 24 hours after the procedure to assess the patient's recovery.

(b) Each patient shall be offered a follow-up visit and, if requested by the patient, shall be scheduled no more than four weeks after completion of the procedure. The follow-up visit shall include the following:

(1) A physical examination; and

(2) a review of all laboratory tests performed as required in K.A.R. 28-34-137.

(c) A urine pregnancy test shall be obtained. If a continuing pregnancy is suspected, a physician who performs abortion procedures shall be consulted.

(d) The physician who performs or induces the abortion, or an individual designated by the physician, shall make all reasonable efforts to ensure that the patient returns for a subsequent examination so the physician can assess the patient's medical condition. A description of the efforts made to comply with this regulation, including the date, time, and name of the individual making the efforts, shall be included in the patient's medical record.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

K.A.R. 28-34-142. Risk management. (a) Each applicant and each licensee shall develop and implement a written risk management plan.

(b) The risk management plan shall be reviewed and approved annually by the licensee.

(c) Findings, conclusions, recommendations, actions taken, and results of actions taken shall be documented and reported through procedures established within the risk management plan.

(d) All patient services, including those services provided by outside contractors or consultants, shall be periodically reviewed and evaluated in accordance with the risk management plan.

(e) Each risk management plan shall include the following:

(1) Section I. A description of the system implemented by the facility for investigation and analysis of the frequency and causes of reportable incidents within the facility;

(2) Section II. A description of the measures used by the facility to minimize the occurrence of reportable incidents and the resulting injuries within the facility;

(3) Section III. A description of the facility's implementation of a reporting system based upon the duty of all medical staff members staffing the facility and all agents and staff members of the facility directly involved in the delivery of health care services to report reportable incidents; and

(4) Section IV. A description of the organizational elements of the plan, including the following:

(A) Name and address of the facility;

(B) name and title of the facility's risk manager; and

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY

DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED



K.A.R. 28-34-142, page 2

(C) description of involvement and organizational structure of medical staff members as related to the risk management program, including names and titles of medical staff members involved in investigation and review of reportable incidents.

(f) The standards-of-care determinations shall include the following:

(1) Each facility shall assure that analysis of patient care incidents complies with the definition of a "reportable incident". Each facility shall use categories to record its analysis of each incident, and those categories shall be in substantially the following form:

(A) Standards of care met;

(B) standards of care not met, but with no reasonable probability of causing injury;

(C) standards of care not met, with injury occurring or reasonably probable; or

(D) possible grounds for disciplinary action by the appropriate licensing agency.

(2) Each reported incident shall be assigned an appropriate standard-of-care determination. Separate standard-of-care determinations shall be made for each involved medical staff member and each clinical issue reasonably presented by the facts. Any incident determined to meet paragraph (f)(1)(C) or (D) of this regulation shall be reported to the appropriate licensing agency.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

K.A.R. 28-34-143. Reporting requirements. In addition to the reporting requirements for risk management required in K.A.R. 28-34-142, each licensee shall ensure that the following incidents are reported to the department, on a form provided by the department:

(a) Each incident resulting in serious injury of a patient or a viable unborn child shall be reported to the department within 10 days after the incident.

(b) The death of a patient, other than the death of an unborn child, shall be reported to the department not later than the next department business day.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

K.A.R. 28-34-144. Records. (a) Each applicant and each licensee shall maintain an organized recordkeeping system that provides for identification, security, confidentiality, control, retrieval, and preservation of all staff member and volunteer records, patient medical records, and facility information.

(b) Each applicant and each licensee shall ensure that only individuals authorized by the applicant or licensee have access to patient medical records.

(c) All records shall be available at the facility for review by the secretary or the authorized agent of the secretary.

(d) For staff member and volunteer records, each applicant and each licensee shall ensure that an individual record is maintained at the facility. The record shall include all of the following information:

(1) The employee's or volunteer's name, position, title, and the first and last date of employment or volunteer service;

(2) verification of qualifications, training, or licensure, if applicable;

(3) documentation of cardiopulmonary resuscitation certification, if applicable;

(4) if a physician, documentation of verification of competence, as required in K.A.R.

28-34-132, signed and dated by the medical director;

(5) documentation of ultrasound training required in K.A.R. 28-34-132;

(6) if a surgical assistant, documentation of training required in K.A.R. 28-34-132; and

(7) if a volunteer, documentation of training required in K.A.R. 28-34-132.

(e) For patient records, each licensee shall ensure that an individual record is maintained at the facility for each patient. The record shall include all of the following information:

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

K.A.R. 28-34-144, page 2

(1) Patient identification, including the following:

(A) Name, address, and date of birth; and

(B) name and telephone number of an individual to contact in an emergency;

(2) medical history as required in K.A.R. 28-34-137;

(3) the physical examination required in K.A.R. 28-34-137;

(4) laboratory test results required in K.A.R. 28-34-137;

(5) ultrasound results required in K.A.R. 28-34-137;

(6) the physician's estimated gestational age of the unborn child as required in K.A.R.

28-34-137;

(7) Each consent form signed by the patient;

(8) a record of all orders issued by a physician, physician assistant, or nurse practitioner;

(9) a record of all medical, nursing, and health-related services provided to the patient;

(10) a record of all adverse drug reactions as required in K.A.R. 28-34-136; and

(11) documentation of the efforts to contact the patient within 24-hours of the procedure

and offer and schedule a follow-up visit no more than four weeks after the procedure, as required in K.A.R. 28-34-141.

(c) For facility records, each applicant and each licensee shall ensure that a record is maintained for the documentation of the following:

(1) All facility, equipment, and supply requirements specified in K.A.R. 28-34-133 through 28-34-136;

(2) ancillary services documentation required in K.A.R. 28-34-136;

DEPT. OF ADMINISTRATION

JUN 17 2011

ATTORNEY GENERAL

APPROVED

JUN 17 2011

APPROVED BY



K.A.R. 28-34-144, page 3

(3) risk management activities required in K.A.R. 28-34-142; and

(4) submission of all reports required in K.A.R. 28-34-143.

This regulation shall be effective on and after July 1, 2011. (Authorized by 2011 House substitute for SB 36, sec 9; implementing 2011 House substitute for SB 36, secs. 5 and 9; effective, T-_____, _____.)

ATTORNEY GENERAL

JUN 17 2011

APPROVED BY



DEPT. OF ADMINISTRATION

JUN 17 2011

APPROVED

Exhibit C



VIA FEDERAL EXPRESS

May 17, 2011

Robert Moser, MD
Kansas Department of Health and Environment
Curtis State Office Building
1000 SW Jackson
Topeka, KS 66612

Dear Doctor Moser,

We write on behalf of our clients, the Center for Women's Health, Herbert C. Hodes, MD, and Traci L. Nauser, MD, regarding KDHE's implementation of Senate Bill 36 (the "Act"). The Act, which takes effect July 1, 2011, requires the licensing of medical facilities in which abortions are performed, and requires KDHE to promulgate regulations for those facilities. Our clients provide abortions in their private obstetrics and gynecology practice. Once the Act takes effect on July 1, 2011, the operation of our clients' current medical practice will constitute a crime unless they have obtained a facility license from KDHE.

We write to you because KDHE has not yet publicly announced any plan for granting licenses to abortion providers on the basis of compliance with existing laws (as KDHE could do under the Act § 2(c)), nor has KDHE publicly announced a timeline for promulgating regulations. Moreover, given that facilities must become licensed in the next month and a half, there does not appear to be time for KDHE to both promulgate regulations (even temporary regulations) *and* give the facilities subject to these regulations a reasonable opportunity to come into compliance. Thus, it appears possible that the Act may end up operating as a temporary ban on the performance of abortions at medical facilities such as our clients'. That result would obviously not be in the interests of our clients or their patients, and we are confident that it is not KDHE's intended outcome.

Accordingly, we wish to suggest a solution to avoid such a problem. Specifically, we suggest that KDHE promptly begin accepting licensing applications from Kansas abortion providers and grant those facilities provisional licenses on the basis of existing, applicable laws and regulations. We believe that this approach would best serve all of the interests involved by: (a) giving KDHE time to develop appropriate regulations; (b) giving facilities newly-regulated by KDHE a reasonable amount of time to bring their facilities into compliance with new regulations; and (c) preventing the violation of constitutional rights and the potential for litigation to protect those rights.

May 17, 2011

Page 2 of 2

We request your prompt attention to this matter, and would appreciate a response within a week so that we may assess the need for more formal action on our clients' behalf. We welcome the opportunity to speak with you about this matter, and you may feel free to contact either of us by phone or email at your convenience.

Sincerely,

Teresa Woody
The Woody Law Firm
1044 Main Street Suite 500
Kansas City, MO 64105
816-421-4246
teresa@woodylawfirm.com

Bonnie Scott Jones*
Center for Reproductive Rights
120 Wall Street, 14th Floor
New York, NY 10005
917-637-3679
bjones@reprorights.org

**Admitted to bars of New York & Massachusetts*

Exhibit D

Division of Health
Curtis State Office Building
1000 SW Jackson St., Suite 300
Topeka, KS 66612-1368



Phone: 785-296-1086
Fax: 785-296-1562
www.kdheks.gov

Robert Moser, MD, Secretary

Department of Health & Environment

Sam Brownback, Governor

May 26, 2011

The Woody Law Firm
Teresa Woody
1621 Baltimore Ave.
Kansas City, MO 64108

On May 16, 2011, Governor Brownback signed into law House Substitute for Senate Bill 36, legislation establishing a process for facilities seeking licensure to perform abortions. This letter is intended to outline the process and timeline for issuing and complying with regulations under the new law.

The law's effective date is upon publication in the statute book, which will be published July 1, 2011. All provisions will be effective on that date.

Therefore, in order to ensure facilities have the opportunity to comply with the law, the Kansas Department of Health and Environment (KDHE) will prepare final draft regulations for distribution to clinics on or before June 13, 2011. Those regulations will be sent with application packets to interested facilities. The purpose of this action is not to solicit comment on the draft regulations, but rather to allow facilities to make a good faith effort to comply with the new regulations in order for KDHE to comply with its obligation to implement SB 36 and issue licenses by July 1. This procedure was selected by KDHE in order to provide clinics with a full and fair opportunity to *not* experience any break in services. Facilities seeking licensure on July 1 will be asked to return applications by June 17. KDHE will review applications and conduct any necessary inspections between June 20 and June 30.

It is our intent to issue temporary regulations simultaneous with initiating the process for permanent regulations. The process for adopting permanent regulations will include a public comment period and hearing. These regulations will be identical to or substantially similar to the draft regulations provided by June 13, 2011. Pending approval of the temporary regulations by the State Rules and Regulations Board, licenses will be issued to facilities in compliance on July 1.

In the meantime, KDHE urges potentially affected facilities to review the language of the enrolled legislation, which itself sets forth the minimum necessary requirements that will be included in the regulations.

Sincerely,

Joseph F. Kroll, Director
Bureau of Child Care and Health Facilities
Topeka, Kansas 66612-1365
Phone: 785-296-1240
Fax: 785-296-3075
jkroll@kdheks.gov

cc: Caleb Stégaill, KDHE General Counsel
Jeff Chanay, Deputy Attorney General for Civil Litigation
Dennis Taylor, Secretary of Administration
Kris Kobach, Secretary of State

Exhibit E

Division of Health
Curtis State Office Building
1000 SW Jackson St., Suite 300
Topeka, KS 66612-1368



Phone: 785-296-1086
Fax: 785-296-1562
www.kdheks.gov

Robert Moser, MD, Secretary

Department of Health & Environment

Sam Brownback, Governor

June 9, 2011

The Woody Law Firm
Teresa Woody
1621 Baltimore Ave.
Kansas City, MO 64108

Please find enclosed the application form and instructions for the purpose of applying to be licensed as an abortion facility pursuant to 2011 House Substitute for Senate Bill 36.

Also enclosed is a copy of the draft regulations as of this date.

In order to be scheduled for an inspection prior to June 30 we are asking that you return the completed application by June 17. You may fax the completed application and related material to 785-291-3419.

Upon review and approval of the application the state survey manager will call your facility and notify you of the date your inspection will commence.

Please note in the legislation and proposed regulations the requirements you must meet prior to being licensed. These include written verification of compliance with all local codes and ordinances, fire codes and regulations, and arrangements for the removal of biomedical waste and human tissue. These verifications should be sent with your application to the same address referenced below.

A survey inspection tool has been developed which identifies statutory and regulation requirements. A met, not met or not applicable check off will be used, accompanied by notes of explanation if appropriate. At the conclusion of the inspection the surveyors will present the document to you at an exit conference.

Approval or denial of a license will be made by officials in KDHE, not the surveyors. You will be notified of our decision to approve or deny your facility for licensing on or before July 1, 2011.

Please send your completed application and any related materials to:

Greg Reser, Director of Health Facilities, Bureau of Child Care and Health Facilities, Curtis State Office Building, Suite 200, Topeka, Kansas 66612-1365. You may fax the same to 785-291-3419 Attention Greg Reser.

If you have questions regarding your application or the process please contact Mr. Reser at 785-296-1240.

Sincerely,

Joseph F. Kroll, Director
Bureau of Child Care and Health Facilities
Topeka Kansas 66612-1365

cc: Greg Reser, Director of Health Facilities

**INSTRUCTIONS FOR COMPLETING APPLICATION FOR
KANSAS ABORTION FACILITY LICENSE**

I. IDENTIFICATION

A facility means any clinic, hospital, or ambulatory surgical center, in which any second or third trimester elective abortion, or five or more first trimester abortions are performed in a month, and is required to be licensed by the Kansas Department of Health and Environment under the provisions of 2011 House Substitute for Senate Bill No. 36.

Provide the full legal name of the facility and an e-mail address.

Provide the physical address of the facility including the nine-digit zip code. Include the telephone number, fax number, and e-mail address.

Identify the person designated by the governing authority to be responsible for the daily management of the facility. This person is usually referred to as the administrator/chief executive officer. Include telephone and fax numbers and e-mail address.

Identify the individual designated as the medical director of the facility who is licensed to practice medicine and surgery in Kansas. Include the individual's physician license number, street address and city, including the nine digit zip code. Also list a telephone and fax number and e-mail address.

II. OWNER INFORMATION

Give the legal name of the organization that owns and controls the abortion facility. List the ownership's street address, city, and nine digit zip code. Also include a telephone and fax number and e-mail address and web address, if applicable.

Provide the name and title of the principle contact person for the organization owning and operating the facility.

III. ORGANIZATIONAL INFORMATION

Identify the type of structure which describes the organizational structure of the entity which owns and operates the facility. Check the appropriate box and include on a separate, attached sheet the requested information for the organization checked.

IV. GENERAL INFORMATION

A. Provide the name and license number of each physician who will be performing abortions at the facility and identify the accredited hospital(s) within 30 miles of the facility at which each physician has clinical privileges. Provide the name and address of the hospital(s).

B. Provide the name and license number of a physician who will be available to patients of the facility and who has admitting privileges at an accredited hospital within 30 miles of the facility. Provide the name and address of the hospital(s).

Provide the number of health professionals, other than physicians, the facility plans to have on staff at the time of application. Indicate if the staff positions will be full time or part time.

V. CLINICAL LABORATORY IMPROVEMENT ACT (CLIA) CERTIFICATION

Indicate the facility's CLIA status and submit a copy of the certificate of registration or waiver.

VI. STATUTORY REQUIREMENTS

Indicate that each of the physical environment requirements specified by law is available at the facility. A check by each standard affirms presence of the requirement at the facility.

(OVER)

A non refundable license fee of \$500 must accompany the license application. A check or money order shall be submitted for payment to: **Kansas Department of Health and Environment**. A license, once issued shall be effective for one year following the date of issuance and shall apply only to the premises described in Section I. B. **The applicant must submit an application for an amended license to the Department within 30 days of a change of ownership by purchase or lease; or a change in the facility's name or address.**

KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT
DIVISION OF HEALTH
Bureau of Child Care & Health Facilities

LICENSE APPLICATION FOR ABORTION FACILITY

- ☐ Initial

☐ Renewal

☐ Amended (Change of Ownership or Address)

The undersigned affirms that the facility named herein has the ability to comply with the requirements for licensure as an abortion facility under the provisions of 2011 House Substitute for Senate Bill No. 36 and provide the following information.

I. Facility Identifying Information

Name of Facility: _____

Street Address: _____

City: _____ Zip: _____

Telephone: _____ Fax: _____ E-mail: _____

Chief Executive Officer: _____

Telephone: _____ Fax: _____ E-mail: _____

Medical Director: _____ License Number: _____

Street Address: _____

City: _____ Zip: _____

Telephone: _____ Fax: _____ E-mail: _____

II. Owner Information

Name of Owner: _____

Street Address: _____

City: _____ Zip: _____

Telephone: _____ Fax: _____ E-mail: _____

Name and Title of Contact: _____

Do Not Write in this Box

License ID No.: _____

Effective Date: _____

Approved By: _____

Renewal Date: _____

III. Organizational Information

Identify the structure under which the Owner is organized.

- ☐ **Sole Proprietorship** [On a separate, attached sheet please provide the name, address, telephone number, fax number and e-mail address for the sole proprietor, if different from the Owner Information.]
- ☐ **Partnership** [On a separate attached sheet please provide the name, address, telephone number, fax number and e-mail address for each partner.]
- ☐ **Joint Venture** [On a separate, attached sheet please provide the name, address, telephone number, fax number and e-mail address for each participant in the joint venture.]
- ☐ **Limited Liability Company** [On a separate, attached sheet please provide the name, address, telephone number, fax number and e-mail address for each member of the LLC and identify the managing member.]
- ☐ **Corporation (for profit)** [On a separate, attached sheet please provide the name, address, telephone number, fax number and e-mail address for each officer and director of the corporation.]
- ☐ **Corporation (not for profit)** [On a separate, attached sheet please provide the name, address, telephone number, fax number and e-mail address for each officer and director of the corporation.]
- ☐ **Other** [On a separate, attached sheet please explain the organizational structure and provide the name, address, telephone number, fax number and e-mail address for all participants in the facility ownership.]

IV. General Information

- A. Provide the name and license number of each physician who will be performing abortions at the facility and identify the accredited hospital(s) at which the physician has clinical privileges within 30 miles of the facility. (If necessary use additional sheet.)
-
-

- B. Provide the name and license number of a physician who has admitting privileges at an accredited hospital within 30 miles of the facility and identify the hospital. (If necessary use additional sheet.)
-
-

What is the planned number of health professional staff other than physicians:

Nurse Practitioner:	Full time _____	Part time _____
Registered Nurse:	Full time _____	Part time _____
Physician Assistant:	Full time _____	Part time _____
Licensed Practical Nurse:	Full time _____	Part time _____
CRNA:	Full time _____	Part time _____

V. CLIA Requirements

Does this facility hold a valid Clinical Laboratory Improvement Act (CLIA) certificate or waiver? Provide the CLIA number and a copy of certificate or waiver.

- ☐ CLIA certificate number: _____ ☐ Waiver

VI. Statutory Requirements

Statutory requirements include standards for physical environment areas or services. A check below for designated item affirms its presence at the facility.

- | | |
|--|--|
| <input type="checkbox"/> Adequate private space that is specifically designated space for patient interview counseling, and medical evaluation | <input type="checkbox"/> Dressing rooms for staff and patients |
| <input type="checkbox"/> Appropriate lavatory areas | <input type="checkbox"/> Areas for pre-procedure hand washing |
| <input type="checkbox"/> Private procedure rooms | <input type="checkbox"/> Adequate lighting and ventilation for abortion procedures |
| <input type="checkbox"/> Surgical or gynecologic examination tables and other fixed equipment | <input type="checkbox"/> Post-procedure recovery rooms that are supervised, staffed and equipped to meet the patient's needs |
| <input type="checkbox"/> Emergency exits to accommodate a stretcher or gurney | <input type="checkbox"/> Areas for cleaning and sterilizing instruments |
| | <input type="checkbox"/> Adequate areas for the secure storage of medical records and necessary equipment and supplies |

Include a check or money order in the amount of \$500.00, payable to: **Kansas Department of Health and Environment**, when submitting an initial or renewal application.

The undersigned is authorized to represent the Licensee of the above abortion facility and certifies that the above information is true and correct. Signature also affirms that the applicant possesses the ability to comply with the provisions of Section 9 of 2011 House Substitute for Senate Bill No. 36.

Signature

Printed/Typed Name

Title

Telephone Number

Date

Return to: Kansas Department of Health and Environment, Licensure Program
Bureau of Child Care & Health Facilities
1000 SW Jackson St. Suite 200, Topeka KS 66612-1365

Phone Number (785) 296-1240

Fax Number (785) 291-3419

K.A.R. 28-34-126. Definitions. (a) "Admitting privileges" means permission extended by a hospital to a physician to allow the physician to admit a patient to that hospital either as active or courtesy staff.

(b) "Applicant" means a person who has applied for a license but who has not yet been granted a license to operate a facility.

(c) "Clinical privileges" means permission extended by a hospital to a physician to allow the physician to provide treatment to a patient in that hospital.

(d) "Health professional" means an individual, other than a physician, who is one of the following:

(1) A nurse practitioner or a nurse licensed in the state of Kansas; or

(2) a physician assistant licensed in the state of Kansas.

(e) "Licensee" means a person who has been granted a license to operate a facility.

(f) "Person" means any individual, firm, partnership, corporation, company, association, or joint-stock association, and the legal successor thereof.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 1; effective, T-_____, _____.)

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

28-34-127. Application process. (a) Any person desiring to operate a facility shall apply for a license on forms provided by the department.

(b) Each applicant shall submit a fee of \$500 for a license. The applicable fee shall be submitted at the time of license application and shall not be refundable.

(c) Before initial licensing each applicant shall submit to the department the following information:

(1) Written verification from the applicable local authorities showing that the premises are in compliance with all local codes and ordinances, including all building, fire, and zoning requirements;

(2) written verification from the state fire marshal showing that the premises are in compliance with all applicable fire codes and regulations;

(3) documentation of the specific arrangements that have been made for the removal of biomedical waste and human tissue from the premises; and

(4) documentation that the facility is located within 30 miles of an accredited hospital.

(d) The granting of a license to any applicant may be refused by the secretary if the applicant is not in compliance with all statutes, rules, and regulations governing the provision of abortion services in the state of Kansas.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, secs. 2 and 3; effective, T-_____, _____.)

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-128. Construction standards. On and after the effective date of this regulation, each applicant and each licensee shall ensure that any abortion clinic construction, including new buildings and additions or alterations to existing buildings, is completed in accordance with the standards set forth in Part 3.7 of the facility guidelines institute publication no. ISBN 978-0-87258-859-2, entitled "guidelines for design and construction of health care facilities," 2010 edition, and hereby adopted by reference.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, secs. 2 and 9; effective,

T-_____, _____.)

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

28-34-129. Terms of a license. (a) Each license shall be effective for one year following the date of issuance.

(b) Each license shall be valid for the licensee and the address specified on the license.

When an initial, renewed, or amended license becomes effective, all licenses previously granted to the applicant or licensee at the same address shall become invalid.

(c) Only one physical location shall be described in each license.

(d) Any applicant may withdraw the application for a license. Any licensee may submit, at any time, a request to close the facility. If an application is withdrawn or a facility is closed, any license granted for that facility shall become void.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 2; effective, T-_____.

_____.)

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

28-34-130. Renewals; amendments. (a) No earlier than 90 calendar days before but no later than the renewal date, each licensee wishing to renew the license shall submit the following:

(1) The nonrefundable license fee of \$500; and

(2) an application to renew the license on the form provided by the department.

(b) Each licensee shall submit a request for an amended license to the department within 30 calendar days, pursuant to 2011 House substitute for SB 36, sec. 4.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 3; effective, T-_____, _____.)

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-131. Administration. (a) Each applicant and each licensee shall be responsible for the organization and management of the facility.

(b) Each applicant and each licensee shall:

(1) Ensure compliance with all applicable federal and state statutes, rules, and local ordinances;

(2) adopt policies and procedures for the administration and operation of the facility;

(3) serve as or designate a medical director who is a physician licensed by the Kansas board of healing arts, without restrictions that would prohibit the physician's ability to serve in the capacity as a medical director of a facility, pursuant to K.S.A. 65-2867, and amendments thereto;

(4) ensure that the secretary or the secretary's designee is allowed access to the facility for inspections authorized by and pursuant to 2011 House substitute for SB 36, Section 5; and

(5) ensure the following documents are conspicuously posted at the facility:

(A) The current facility license issued by the department;

(B) the current telephone number and address of the department; and

(C) the evacuation map.

(c) Each medical director shall ensure the development of and shall approve written policies and procedures that shall be implemented for the operation of the facility. The medical director shall ensure the policies and procedures include the following requirements:

(1) An organized recordkeeping system to meet the requirements in K.A.R. 28-34-144;

(2) an adequate number of patient care staff and employees are present during the operating hours of the facility;

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-131, page 2

(3) documentation of personnel qualifications, duties, and responsibilities to meet the requirements in K.A.R. 28-34-132;

(4) that the facility is designed, constructed, equipped, and maintained to protect the health and safety of patients, staff, and visitors to meet the requirements in K.A.R. 28-34-128 and in K.A.R. 28-34-133 through 28-34-135;

(5) ensure proper and adequate medical screening and evaluation of each patient to meet the requirements in K.A.R. 28-34-137;

(6) informed consent is obtained from each patient, pursuant to K.S.A. 65-6709, and amendments thereto, including information required to be given to a patient, certification of receipt, offer to view the ultrasound image and hear the heartbeat of the unborn child, certification of the offers; and required signature;

(7) safe conduct of abortion procedures to meet the requirements in K.A.R. 28-34-138;

(8) the appropriate use of anesthesia, analgesia and sedation to meet the requirements in K.A.R. 28-34-138;

(9) ensure the use of appropriate precautions for any patient undergoing a second or third trimester abortion to meet the requirements in K.A.R. 28-34-138;

(10) post-procedure care of patients to meet the requirements in K.A.R. 28-34-139;

(11) identify and ensure a physician with admitting privileges at an accredited hospital located within 30 miles of the facility is available during facility hours of operations and the hospital has agreed to accept facility patients in transfer;

(12) if indicated, the transfer of any patient and newborn child to a hospital to meet

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-131, page 3

the requirements in K.A.R. 28-34-140;

(13) follow-up and aftercare for each patient receiving an abortion procedure in the facility to meet the requirements in K.A.R. 28-34-141;

(14) a written plan for risk management that meets the requirements of K.A.R. 28-52-1 to meet the requirements in K.A.R. 28-34-142, including policies and procedures for employee or volunteer reporting of any clinical care concerns to the risk manager, medical director, or the administrator;

(15) ensure incidents that require reporting to the department are completed on the forms provided by the department and are submitted within the timelines required in K.A.R. 28-34-143; and

(16) ensure that reporting of all statistical information to the department occurs as required in K.S.A. 65-445, and amendments thereto.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, secs. 2, 5, 9, and 10; effective,

T-_____, _____.)

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-132. Staff requirements. (a) Each physician performing surgery in a facility shall be approved by the medical director, licensed to practice medicine and surgery in the state of Kansas, and shall demonstrate competence in the procedure involved in the physician's duties at the facility. Competence shall be demonstrated through both of the following means and methods:

- (1) Documentation of education and experience; and
- (2) observation by or interaction with the medical director.

(b) Each applicant and each licensee shall ensure that any physician performing or inducing abortion procedures in the facility has clinical privileges at a hospital located within 30 miles of the facility.

(c) Each applicant and each licensee shall ensure that a physician with admitting privileges at an accredited hospital located within 30 miles of the facility is available.

(d) Each applicant and each licensee shall ensure that each individual who performs an ultrasound is one of the following:

(1) A physician licensed in the state of Kansas who has completed a course for the type of ultrasound examination the physician performs; or

(2) an individual who meets all of the following requirements:

(A) Has completed a hands-on course in performing ultrasounds under the supervision of a physician;

(B) has completed a course for the type of ultrasound examination the individual performs; and

(C) is not otherwise precluded by statute from performing ultrasound examinations.

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-132, page 2

(e) Each applicant and each licensee shall ensure that each physician assistant, each nursing, and each ancillary staff member employed by or contracted with the facility are licensed, if required by state statute, are qualified, and provide services to patients consistent with the scope of practice of the individual's training and experience.

(f) Each applicant and each licensee shall ensure that each surgical assistant employed by or contracted with the facility receives training in the specific responsibilities of the services the surgical assistant provides in the facility.

(g) Each applicant and each licensee shall ensure that each volunteer receives training as identified by the medical director in the specific responsibilities the volunteer provides at the facility, including counseling and patient advocacy.

(h) Each applicant and each licensee shall ensure that at least one physician or registered nurse is trained in advanced cardiac life support and is present at the facility during hours of operation.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-4-34-133. Facility environmental standards. (a) Each applicant and each licensee shall ensure that the facility is designed, constructed, equipped, and maintained to protect the health and safety of patients, staff members, volunteers, and visitors.

(b) Each facility shall include the following rooms and areas:

- (1) A private space designated for patient interviews, counseling, and medical examinations;
- (2) designated dressing rooms for patients;
- (3) designated dressing rooms for staff members;
- (4) separate toilet facilities designated for patients, staff members, and visitors;
- (5) separate facilities for pre-procedure handwashing by staff members;
- (6) private procedure rooms that are supervised, staffed, and equipped to meet the needs of the patients;
- (7) a recovery room;
- (8) a separate waiting area for patients and visitors;
- (9) business office facilities;
- (10) areas for cleaning and sterilizing instruments, equipment, and supplies;
- (11) a secure area for the storage of medications and controlled substances;
- (12) a storage area designated for janitorial supplies and equipment; and
- (13) a secure area for the storage of medical records.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-134. Health and safety requirements. (a) Each applicant and each licensee shall ensure that the facility meets the following health and safety requirements:

- (1) There shall be adequate lighting and ventilation to ensure the health and safety of each patient throughout the abortion procedure.
- (2) Each emergency exit shall accommodate a stretcher or a gurney.
- (3) The facility shall be maintained in a clean condition.
- (4) The facility shall be free from any condition or situation that may cause a patient to suffer physical injury.
- (5) The facility shall be free from insects and vermin infestation.
- (6) A warning notice shall be placed at the entrance to any room or area where oxygen is in use.
- (7) Soiled linen and clothing shall be kept in covered containers in a separate area from clean linen and clothing.

(b) A written emergency plan shall be developed and implemented, including procedures for protecting the health and safety of patients and other individuals in any of the following circumstances:

- (1) A fire;
 - (2) a natural disaster;
 - (3) loss of electrical power; or
 - (4) threat or incidence of violence.
- (c) An evacuation map shall be developed and posted.
- (d) An evacuation drill shall be conducted at least once every six months, including

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-134, page 2

participation by all staff members and volunteers in the facility on the day of the drill.

Documentation shall be maintained at the facility for one calendar year from the date of the drill and shall include the date and time and the names of all participating staff members.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-135. Equipment; supplies; drugs and medications. (a) Each applicant and each licensee shall ensure that supplies, equipment, drugs, and medications are immediately available for use or in an emergency.

(b) Equipment and supplies shall be maintained in the amount required to assure sufficient quantities of clean and sterilized durable equipment to meet the needs of each patient during any abortion procedure and for monitoring each patient throughout the procedure and recovery period.

(c) Each applicant and each licensee shall ensure that the following equipment and supplies are maintained in the facility for airway management:

- (1) An oxygen source with flowmeter;
- (2) simple face masks, in sizes for infants, children, and adults;
- (3) pediatric and adult masks for assisting ventilation;
- (4) self-inflating bag with reservoir, 500 cc and 1000 cc;
- (5) suction, either wall or machine;
- (6) suction catheters, Yankauer, 8, 10, and 14F;
- (7) oral airways, infant to adult sizes;
- (8) nasal cannulas in infant, child, and adult sizes 1-3;
- (9) options for intubation, if needed;
- (10) laryngoscope handle with batteries;
- (11) miller blades, 0, 1, 2, and 3;
- (12) endotracheal tubes, uncuffed, 3.0, 3.5, 4.0, 4.5, 5.0, 6.0, 7.0, and 8.0;
- (13) stylets, small and large; and

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-135, page 2

(14) adhesive tape to secure airway.

(d) Each applicant and each licensee shall ensure that the following supplies are maintained in the facility for fluid management:

- (1) Intraosseous needles, 15 or 18 gauge;
- (2) intravenous catheters, 18, 20, 22, and 24 gauge;
- (3) butterfly needles, 23 gauge;
- (4) intravenous boards, tape, alcohol swabs, and tourniquets;
- (5) pediatric drip chambers and tubing;
- (6) D5 ½ normal saline; and
- (7) isotonic fluids, either normal saline or lactated Ringer's solution.

(e) Each applicant and each licensee shall ensure that the following miscellaneous equipment and supplies are maintained in the facility:

-
- (1) Blood pressure cuffs, preemie, infant, child, and adult;
 - (2) nasogastric tubes, 8, 10, and 14F; and
 - (3) sphygmomanometer manual.

(f) Each applicant and each licensee may maintain the following optional equipment and supplies in the facility:

- (1) Portable monitor/defibrillator, with settings less than 10;
- (2) pediatric defibrillation paddles;
- (3) pediatric electrocardiogram (EKG) skin electrode contacts, peel and stick;

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-135, page 3

(4) pulse oximeter with reusable sensors for older children and non-reusable sensors for small children;

(5) device to check serum glucose;

(6) strips to check urine for glucose and blood; and

(7) central lines over guidewire catheters, 3, 4, and 5F.

(g) Each applicant and each licensee shall ensure that all equipment is safe for each patient and for the staff.

(h) Each applicant and each licensee shall ensure that each item of equipment meets federal standards applicable to that equipment and is installed and used according to the manufacturer's recommendations for use.

(i) Each applicant and each licensee shall ensure that each item of equipment is checked annually to ensure safety and appropriate calibration.

(j) Each applicant and each licensee shall ensure that equipment and supplies are clean and sterile, if applicable, before each use.

(k) Each applicant and each licensee shall ensure that the facility meets the following requirements for equipment:

(1) All equipment shall be clean, functional, and maintained in accordance with the manufacturer's instructions.

(2) The following equipment shall be available at all times for use by the medical staff:

(A) Ultrasound equipment;

(B) intravenous equipment;

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-135, page 4

- (C) laboratory equipment;
- (D) patient resuscitation and suction equipment;
- (E) equipment to monitor vital signs in each room in which an abortion is performed;
- (F) a surgical or gynecologic examination table;
- (G) equipment to measure blood pressure;
- (H) a stethoscope;
- (I) a scale for weighing a patient; and
- (J) additional equipment for any abortion procedure performed after the first trimester, including ultrasound equipment, drugs to support cardiopulmonary function, and equipment to monitor cardiopulmonary status.

(I) Each applicant and each licensee shall ensure that equipment and appropriate medications are located in the recovery room as needed for the provision of appropriate emergency resuscitative and life support procedures pending the transfer to a hospital of a patient or a newborn child.

(1) Each applicant and each licensee maintaining an emergency kit or stock supply of drugs and medications for the use of the physician in treating the emergency needs of patients, shall store this kit or medication in such a manner as to prohibit its access by unauthorized personnel. Contents of the kit or stock supplies of medications shall be regularly reviewed to ensure proper inventory control with removal or replacement of expired medications.

(2) Drugs and equipment shall be available within the facility to treat the following conditions consistent with standards of care:

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-135, page 5

- (A) Cardiac Arrest;
- (B) a seizure;
- (C) an asthma attack;
- (D) allergic reaction;
- (E) narcotic or sedative toxicity;
- (F) hypovolemic shock;
- (G) vasovagal shock; and
- (H) anesthetic reactions.

(m) The following medications shall be maintained at the facility:

(1) Aqueous epinephrine – 1:1000 and 1:10,000 {1:1000 = 1 gram/1000 cc or 1 mg/cc and is available as both 1 cc glass vials which must be cracked and 30 cc multiple dose vials} {1:10,000 = 1 gram/10,000 cc or 0.1 mg/cc comes as a 10 cc bristojet};

-
- (2) atropine sulfate;
 - (3) dextrose in water – 50%;
 - (4) sodium bicarbonate – 1 meg/cc (approximately);
 - (5) lorazepam or diazepam;
 - (6) phenobarbital;
 - (7) antibiotics, parenteral, including ampicillin, gentamycin, and ceftriaxone;
 - (8) methylprednisolone or dexamethasone;
 - (9) naloxone (1 mg/cc);
 - (10) activated charcoal;

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-135, page 6

(11) albuterol concentrated for inhalation (5 mg/cc) {also supplied premixed with 2.5 mg/2.5 cc};

(12) lidocaine 2% (20 mg/cc); and

(13) Benadryl (50 mg/cc).

(n) Drugs and medications shall be administered to individual patients only by a facility physician or a facility health personnel duly licensed.

(o) If a stock of controlled drugs is to be maintained at the facility, the medical director shall ensure that the facility is registered by the Kansas board of pharmacy. The medical director shall be responsible for the proper safeguarding and handling of controlled substances within the facility, and shall ensure that all possible control measures are observed and that any suspected diversion or mishandling of controlled substances is reported immediately.

(p) Records shall be kept of all stock supplies of controlled substances giving an accounting of all items received or administered.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____,
_____.)

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-136. Ancillary services. (a) Each applicant and each licensee shall ensure that the facility maintains a clinical laboratory and current clinical laboratory improvement amendments of 1988 certification.

(b) Each applicant and each licensee shall ensure that the facility meets the requirements for radiology services specified in K.A.R. 28-34-59a (d) and (e).

(c) Each applicant and each licensee shall ensure that the facility meets the requirements for pharmaceutical services specified in K.A.R. 28-34-59a (g) and (i) through (l).

(d) Each applicant and each licensee shall ensure that there is a mechanism for the ongoing review and evaluation of the quality and scope of laboratory, radiology, and pharmaceutical services.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-137. Patient screening and evaluation. (a) Each medical director shall develop and implement policies and procedures for the medical screening and evaluation of patients. Each medical director shall ensure a medical screening and evaluation are completed on each patient before an abortion procedure is performed.

(b) The medical screening and evaluation shall consist of the following:

(1) A medical history shall be completed, including the following:

(A) Reported allergies to medications, antiseptic solution, or latex;

(B) obstetric and gynecologic history;

(C) past surgeries;

(D) medication currently being taken by the patient; and

(E) any other medical conditions.

(2) A physical examination shall be performed by a physician, including a bimanual examination to estimate uterine size and palpation of the adnexa.

(3) An ultrasound evaluation shall be completed for any patient who elects to have an abortion of an unborn child. The physician shall estimate the gestational age of the unborn child in keeping with established standards of care regarding the estimation of the age of the unborn child and shall verify the estimate in the patient's medical history. The physician shall keep the original prints of each ultrasound examination for each patient in the patient's medical history file.

(4) The appropriate laboratory tests shall be completed, including the following:

(A) For an abortion in which an ultrasound examination is not performed before the abortion procedure, urine or blood tests for pregnancy performed before the abortion procedure;

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-137, page 2

(B) a test for anemia as indicated;

(C) determination of Rh factor or Rh typing, unless the patient provides written documentation of blood type acceptable to the physician; and

(D) other tests recommended by the physician or the medical director on the basis of the physical examination, which may include tests for chlamydia and gonorrhea and other cultures, syphilis serology, and a papanicolaou procedure. Any positive finding of a reportable disease shall be reported pursuant to K.S.A. 65-118, et seq., and amendments thereto, K.S.A. 65-128, and amendments thereto, K.S.A. 65-6001 et seq., and amendments thereto, and K.A.R. 28-1-2, et seq.

(c) Each licensee shall ensure that another individual is present in the room during a pelvic examination or an abortion procedure. If the physician conducting the examination or the procedure is male, the other individual in the room shall be female.

(d) The physician or health care professional shall review, at the request of the patient, the ultrasound evaluation results with the patient before the abortion procedure is performed, including the probable gestational age of the unborn child.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-138. Abortion procedure. (a) Each licensee shall ensure that a physician and at least one health professional staff member are available to each patient throughout the abortion procedure.

(b) The medical director shall develop and implement policies and procedures for the safe conduct of abortion procedures that conform to obstetric standards in keeping with established standards of care regarding the estimation of the gestational age of the unborn child.

(c) The medical director shall ensure that the following procedures are followed for each patient before performance of an abortion:

(1) Information is provided to the patient on the abortion procedure, including alternatives, risks, and potential complications.

(2) Written informed consent is signed and dated by the patient or the patient's representative.

(d) The medical director shall ensure that all requirements for infection control in K.A.R. 28-34-58a are met.

(e) The medical director shall ensure that each abortion is performed according to the facility's policies and procedures and in compliance with the requirements of 2011 House substitute for SB 36, sec. 9.

(f) The medical director shall develop and implement policies and procedures for the appropriate use of local anesthesia, analgesia, and sedation if ordered by the physician. The policies and procedures shall meet the requirements in K.A.R. 28-34-56a (b) through (d).

(g) Staff members shall monitor each patient's vital signs throughout the abortion procedure to ensure the health and safety of the patient.

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-138, page 2

(h) The medical director shall develop and implement policies and procedures that ensure the use of appropriate precautions, including the establishment of intravenous access for any patient undergoing a second or third trimester abortion, unless the physician determines that establishing intravenous access is not appropriate for the patient and documents that fact in the medical record of the patient.

(i) The medical director shall ensure that the following steps are performed if a newborn child shows signs of life:

- (1) Resuscitative measures are used to support life;
- (2) the newborn child is transferred to a hospital;
- (3) resuscitative measures and the transfer to a hospital are documented; and
- (4) appropriate documentation is completed, including a birth certificate, pursuant to

K.S.A. 65-2409a, and amendments thereto.

(j) When RU-486 (mifepristone) or any other drug is used for the purpose of inducing an abortion, the medical director shall ensure that both of the following requirements are met:

(1) The drug shall be administered by or is administered in the same room and in the physical presence of the physician who prescribed, dispensed, or otherwise provided the drug to the patient.

(2) The physician inducing the abortion, or a person acting on behalf of the physician inducing the abortion, shall make all reasonable efforts to ensure that the patient returns to the facility in 12 to 18 calendar days after the administration or use of the drug for a subsequent examination, so the physician can confirm that the pregnancy has been terminated and to assess

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-138, page 3

the patient's condition. Documentation of the efforts made to ensure the patient's return shall be included in the medical record of the patient, including the date, time, and name of the individual making the efforts.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, secs. 9 and 10; effective, T-_____,
_____.)

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-139. Recovery procedures; discharge. (a) Each medical director shall develop and implement policies and procedures for the post-procedure care of patients, which shall include the following:

(1) There shall be a specified minimum length of time a patient shall remain in the recovery room, based on the type of abortion procedure performed, the gestational age of the unborn child, and the post-procedure course and condition of the patient in accordance with the usual standards of patient care.

(2) A health professional who is trained in the management of the recovery area and is capable of providing basic cardiopulmonary resuscitation and related emergency procedures remains on the premises of the facility until all patients receiving abortion services are discharged.

(3) Immediate post-procedure care for each patient shall consist of observation in a supervised recovery room.

(4) The vital signs and bleeding of each patient shall be monitored by a physician or a health professional.

(5) A physician or a nurse who is certified in advanced cardiovascular life support shall remain on the premises of the facility until all patients receiving abortion services are discharged.

(b) A physician or an individual designated by a physician shall discuss Rho(d) immune globulin with each patient for whom it is indicated and assure that it is offered to the patient in the immediate post-procedure period or that it will be available to the patient within 72 hours after completion of the abortion procedure. If the patient refuses the Rho(d) immune globulin,

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-139, page 2

the refusal shall be documented on a form approved by the department, signed by the patient and a witness, and filed in the medical record of the patient.

(c) At the time of discharge from the facility, each patient shall receive the following written information:

- (1) Signs of possible complications;
 - (2) when to access medical care in response to complications;
 - (3) the telephone number to call in an emergency;
 - (4) instructions and precautions for resuming vaginal intercourse;
 - (5) any other instructions specific to a patient's abortion or condition.
- (d) A physician shall sign the discharge order for each patient.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, secs. 9 and 10; effective,

T-_____, _____.)

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-140. Transfers. Each medical director shall develop and implement policies and procedures for the transfer of patients and newborn children to a hospital, which shall include the following:

(a) A physician shall arrange the transfer of a patient to a hospital if any complications beyond the medical capability of the staff members occurs or is suspected.

(b) A physician shall arrange the transfer of a newborn child to a hospital if the child requires emergency care.

(c) A physician or a nurse who is certified in advanced cardiovascular life support shall remain on the premises of the facility to facilitate the transfer of an emergency case if hospitalization of a patient or a newborn child is required.

(d) Any transfer shall be documented in the patient's medical record.

(e) When a patient or a newborn child is transferred to a hospital, the following information shall accompany the patient or child:

- (1) Documentation of a medical evaluation;
- (2) all treatments given to the patient or child at the facility;
- (3) laboratory information; and
- (4) diagnostic information.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-141. Follow-up contact and care. Each medical director shall develop and implement policies and procedures for follow-up and aftercare for each patient receiving an abortion procedure in the facility, including the following:

(a) With the informed consent of the patient, a health professional from the facility shall contact the patient by telephone within 24 hours after the procedure to assess the patient's recovery.

(b) Each patient shall be offered a follow-up visit and, if requested by the patient, shall be scheduled no more than four calendar weeks after completion of the procedure. The follow-up visit shall include the following:

(1) A physical examination; and

(2) a review of all laboratory tests performed as required in K.A.R. 28-34-137.

(c) A urine pregnancy test shall be obtained. If a continuing pregnancy is suspected, a physician who performs abortion procedures shall be consulted.

(d) The physician who performs or induces the abortion, or an individual designated by the physician, shall make all reasonable efforts to ensure that the patient returns for a subsequent examination so the physician can assess the patient's medical condition. A description of the efforts made to comply with this regulation, including the date, time, and name of the individual making the efforts, shall be included in the patient's medical record.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-142. Risk management. (a) Each applicant and each licensee shall develop and implement a written plan for risk management that meets the requirements specified in K.A.R. 28-52-1.

(b) Each applicant and each licensee shall develop and implement policies and procedures for employee or volunteer reporting of any clinical care concerns to the risk manager, chief of staff, or administrator. The policies and procedures shall meet the requirements for incident reporting specified in K.A.R. 28-52-2.

(c) Each applicant and each licensee shall establish a risk management committee. The operations of the committee shall meet the requirements for a risk management committee specified in K.A.R. 28-52-3.

(d) Each applicant and each licensee shall develop policies and procedures for the analysis of patient care incidents, including the use of standard of care determinations for each incident. The policies and procedures shall meet the requirements for standard-of-care determinations specified in K.A.R. 28-52-4.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-143. Reporting requirements. In addition to the reporting requirements for risk management required in K.A.R. 28-34-141, each licensee or medical director shall ensure that the following incidents are reported to the department, on a form provided by the department, and to any other authorities in accordance with state statute:

(a) Each incident resulting in serious injury of a patient, a viable unborn child, or a newborn child shall be reported to the department within 10 calendar days after the incident. A serious injury is an injury that occurs at the facility and that creates a serious risk of substantial impairment of a major body organ.

(b) The death of a patient, other than the death of an unborn child, shall be reported to the department not later than the next department business day and to all other entities identified under Kansas statute for the reporting of the death of an individual.

(c) The death of a newborn child that occurs prior to transfer, or if no transfer to another facility occurs and the determination of time of death, place, and cause of death are certified by the physician in attendance under Kansas statute for the reporting of the death of an individual, shall be reported to the department no later than the next department business day and to all other entities identified under Kansas statute.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-144. Records. (a) Each applicant and each licensee shall develop and implement policies and procedures to ensure that there is an organized recordkeeping system that provides for identification, security, confidentiality, control, retrieval, and preservation of all employee and volunteer records, patient medical records, and facility information.

(b) All records shall be available at the facility for review by the secretary.

(c) For employee and volunteer records, each applicant and each licensee shall ensure that an individual record is maintained at the facility for each staff member and volunteer that includes all of the following information:

- (1) The employee's or volunteer's name, position, title, and the first and last date of employment or volunteer service;
- (2) verification of qualifications, training, or licensure, if applicable;
- (3) documentation of cardiopulmonary resuscitation certification, if applicable;
- (4) if a physician, documentation of verification of competency, as required in K.A.R.

28-34-132, signed and dated by the medical director;

- (5) documentation of ultrasound training required in K.A.R. 28-34-132;
 - (6) if a surgical assistant, documentation of training required in K.A.R. 28-34-132; and
 - (7) if a volunteer, documentation of training required in K.A.R. 28-34-131.
- (d) For patient records, each licensee shall ensure that an individual record is maintained at the facility for each patient that includes all of the following information:

- (1) Patient identification, including the following:
 - (A) Name, address, and date of birth;

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-144, page 2

(B) name and contact information of the designated patient representative, if applicable;

and

(C) name and telephone number of an individual to contact in an emergency;

(2) medical history as required in K.A.R. 28-34-137;

(3) the physical examination required in K.A.R. 28-34-137;

(4) laboratory test results required in K.A.R. 28-34-137;

(5) ultrasound results required in K.A.R. 28-34-137;

(6) the physician's estimated gestational age of the unborn child as required in K.A.R. 28-34-137;

(7) Each informed consent form signed by the patient or the patient's representative;

(8) a record of all orders issued by a physician, physician assistant, or nurse practitioner;

(9) a record of all medical, nursing, and health-related services provided to the patient;

and

(10) documentation of the efforts to contact the patient within 24-hours of the procedure and offer and schedule a follow-up visit no more than four calendar weeks after the procedure, as required in K.A.R. 28-34-141.

(e) For facility records, each applicant and each licensee shall ensure that a record is maintained for the documentation of the following:

(1) Documentation of the reporting of all statistical information to the department as required in applicable state statute;

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

K.A.R. 28-34-144, page 3

- (2) compliance with construction standards required in K.A.R. 28-34-128;
- (3) all facility, equipment, and supply requirements specified in K.A.R. 28-34-133 through 28-34-135;
- (4) ancillary services documentation required in K.A.R. 28-34-136;
- (5) risk management activities required in K.A.R. 28-34-142; and
- (6) submission of all reports required in K.A.R. 28-34-143.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, secs. 2 and 9; effective,

T-_____, _____.)

DEPT. OF ADMINISTRATION

JUN 08 2011

APPROVED

Exhibit F

Division of Health
Curtis State Office Building
1000 SW Jackson St., Suite 300
Topeka, KS 66612-1368



Phone: 785-296-1086
Fax: 785-296-1562
www.kdheks.gov

Robert Moser, MD, Secretary

Department of Health & Environment

Sam Brownback, Governor

June 13, 2011

Aid for Women
ATTN: Mark
720 Central
Kansas City, KS 66101-3546

In a letter dated June 9, 2011 the Kansas Department of Health and Environment provided a copy of the draft regulations authorized by 2011 House Substitute for Senate Bill 36. These were provided to meet our commitment of providing draft regulations no later than June 13.

The draft provided had been reviewed by the Department of Administration. Since that date the draft regulations have been reviewed by the office of the Attorney General, who has requested edits and other amendments. We are in the process of making these changes.

Once the regulations are final as approved by the Department of Administration and Attorney General we will provide a copy to you.

As stated in our letter of May 26, 2011 we encourage you to review the enrolled legislation which sets forth many requirements and authorizes the content of regulation.

Sincerely,

Joseph F. Kroll, Director
Bureau of Child Care and Health Facilities
Topeka, Kansas 66612-1365
Phone: 785-296-1240
Fax: 785-296-3075
jkroll@kdheks.gov

cc: Greg Reser, Director of Health Facilities

Exhibit G

Division of Health
Curis State Office Building
1000 SW Jackson St., Suite 300
Topeka, KS 66612-1368



Phone: 785-296-1086
Fax: 785-296-1562
www.kdheks.gov

Robert Moser, MD, Secretary

Department of Health & Environment

Sam Brownback, Governor

June 17, 2011

Center for Women's Health
ATTN: Andrea
4840 College Blvd.
Overland Park, KS 66211-1601

Please find enclosed a copy of the proposed regulations implementing provisions of 2011 House Substitute for Senate Bill 36.

The proposed regulations enclosed have been approved by the Kansas Department of Administration and Office of the Attorney General. It is our intent to have the State Rules and Regulation Board consider these proposed regulations prior to July 1 with an effective date of July 1, 2011.

Sincerely,

Joseph F. Kroll, Director
Bureau of Child Care and Health Facilities
Topeka, Kansas 66612-1365
Phone: 785-296-1240
Fax: 785-296-3075
jkroll@kdheks.gov

cc: Greg Reser, Director of Health Facilities

Exhibit H

Date: June 20, 2011

Kansas Department of Health and Environment
Economic Impact Statement

Pursuant to the requirements of K.S.A. 2010 Supp. 77-416, Kansas Department of Health and Environment submits the following economic impact statement to implement the provisions of 2011 House substitute for SB 36. These regulations are being proposed as both temporary and permanent regulations.

1. Regulation(s):

New regulations to be implemented:

- K.A.R. 28-34-126. Definitions.
- K.A.R. 28-34-127. Application process.
- (K.A.R. 28-34-128. Reserved for future use.)
- K.A.R. 28-34-129. Terms of a license.
- K.A.R. 28-34-130. Renewals; amendments.
- K.A.R. 28-34-131. Operation of the facility.
- K.A.R. 28-34-132. Staff requirements.
- K.A.R. 28-34-133. Facility environmental standards.
- K.A.R. 28-34-134. Health and safety requirements.
- K.A.R. 28-34-135. Equipment; supplies; drugs and medications.
- K.A.R. 28-34-136. Ancillary services.
- K.A.R. 28-34-137. Patient screening and evaluation.
- K.A.R. 28-34-138. Abortion procedure.
- K.A.R. 28-34-139. Recovery procedures; discharge.
- K.A.R. 28-34-140. Transfers.
- K.A.R. 28-34-141. Follow-up contact and care.
- K.A.R. 28-34-142. Risk management.
- K.A.R. 28-34-143. Reporting requirements.
- K.A.R. 28-34-144. Records.

2. Brief description of each regulation(s) and what is intended to be accomplished by adoption.

- K.A.R. 28-34-126. Definitions.
Provides specific definitions of terms used in these regulations.
- K.A.R. 28-34-127. Application process.
Requires any person desiring to operate a facility to apply for a license on forms provided by the department; \$500 license fee; documentation required prior to initial licensing; granting of license may be denied if applicant is not in compliance with all applicable laws, rules, and regulations.

(K.A.R. 28-34-128.) Reserved for future use.

K.A.R. 28-34-129. Terms of a license.
License effective one year; valid for licensee and address specified on the license; only one physical location to be described on each license; withdrawal of application; licensee's request to close; if closed, any license granted to that facility shall become void.

K.A.R. 28-34-130. Renewals; amendments.
Timeframe for submitting renewal application and fee; timeframe for submitting amendment request in any circumstance set forth in 2011 House Substitute for SB 36, sec. 4.

K.A.R. 28-34-131. Operation of the facility.
Applicant and licensee responsible for operation of facility; applicant and licensee ensure compliance with applicable laws, rules, ordinances, adopt policies and procedures for facility operation, serve as or designate a medical director, post the license and contact information for the department; requires policies and procedures for facility operation, including specific facility and services requirements.

K.A.R. 28-34-132. Staff requirements.
Physician requirements; ensure that a physician with admitting privileges at accredited hospital within 30 miles of facility is available and that physician performing abortion procedures has clinical privileges at hospital within 30 miles of facility; requirements for physician or other individual performing ultrasound; physician assistant, nursing, and ancillary staff members are licensed, if required, qualified, and provide services consistent with scope of practice; surgical assistant training; volunteer training; at least one physician or RN is trained in advanced cardiovascular life support and present at facility when any patient is present.

K.A.R. 28-34-133. Facility environmental standards.
Facility designed, constructed, equipped, maintained for health and safety of patients, staff, others; standard for rooms and areas required in facility.

K.A.R. 28-34-134. Health and safety requirements.
Ensure the facility meets specific health and safety requirements; written emergency plan required; evacuation drills.

- K.A.R. 28-34-135. Equipment; supplies; drugs and medications.
Equipment, supplies, drugs, medications are immediately available for use; equipment and supplies maintained in the amount required for needs of each patient; equipment and supplies for airway management; supplies for fluid management; miscellaneous equipment and supplies; optional equipment and supplies; equipment is safe for patient and staff; equipment installed and used per manufacturer's recommendations; each item of equipment checked annually; equipment and supplies are clean and sterile before each use; equipment requirements; equipment and medications in recovery area as needed for emergency resuscitative and life support procedures; medications to be maintained at facility; drugs and medications administered only by facility physician or licensed facility health professional; if stock of controlled drugs maintained at the facility, facility must be registered by Kansas board of pharmacy; records kept of all stock supplies of controlled substances.
- K.A.R. 28-34-136. Ancillary services.
Requires documentation that facility maintains certificate of compliance from centers for medicare and medicaid services for laboratory; requirements for radiology services; requires policies and procedures related to drugs; all drugs and medications to be ordered pursuant to written order from facility physician or facility health professional; reporting of adverse drug reaction; drugs and medications requiring refrigeration must be stored in refrigerator used only for drugs and medications; requires mechanism for ongoing review and evaluation of quality and scope of laboratory, radiology, and pharmaceutical services.
- K.A.R. 28-34-137. Patient screening and evaluation.
Requires policies and procedures for medical screening and evaluation to be completed before abortion procedure; components of medical screening and evaluation, including ultrasound; another individual in room during pelvic exam or abortion procedure, including female if physician is male; review of ultrasound results with patient.
- K.A.R. 28-34-138. Abortion procedure.
Requires policies and procedures for specific procedures; procedures for each patient before performance of an abortion; physician and at least one health professional available for each patient throughout procedure; requires an infection control program; each abortion performed according to facility policies and all applicable laws and rules and regulations; monitoring

patient's vital signs; steps to perform if abortion procedure results in delivery of newborn child.

- K.A.R. 28-34-139. Recovery procedures; discharge.
Requires policies and procedures, including minimum length of time in recovery area; discussion of Rho (d) immune globulin with each patient; written information to be provided patient at time of discharge; physician shall sign discharge order.
- K.A.R. 28-34-140. Transfers.
Requires policies and procedures for transfer of patients or newborn children to hospital; physician shall arrange transfer of patient if complications are beyond medical capability of health professionals; physician shall arrange transfer of newborn child if emergency care required; physician or nurse certified in advanced cardiovascular life support shall remain on premises to facilitate a transfer.
- K.A.R. 28-34-141. Follow-up contact and care.
Requires policies and procedures for follow-up and aftercare; contact with patient within 24 hours of discharge; offer of follow-up visit and examination no more than four weeks after completion of procedure; urine pregnancy test and consultation with a physician if continuing pregnancy is suspected; physician or designee efforts to ensure patient return to assess patient's medical condition.
- K.A.R. 28-34-142. Risk management.
Requires written risk management plan; plan shall be reviewed and approved annually; requires findings, conclusions, recommendations, actions taken, and results of actions taken to be documented and reported; patient services periodically reviewed and evaluated; components of risk management plan; components of standards-of-care determinations.
- K.A.R. 28-34-143. Reporting requirements.
In addition to requirements in K.A.R. 28-34-142, requires reporting to the department each incident resulting in serious injury of patient or viable unborn child or the death of a patient.
- K.A.R. 28-34-144. Records.
Organized recordkeeping system shall be maintained; only individuals authorized by applicant or licensee have access to patient medical records; all records shall be available to the secretary or the authorized agent of the secretary; requirements for

staff member and volunteer records, patient records, and facility records.

3. **Is this regulation mandated by federal law as a requirement for participating in or implementing a federally subsidized or assisted program?**

Yes _____

No X

If yes, please explain.

4. **Do the proposed regulations exceed the requirements of applicable federal law?**

Yes _____

No X

5. **Description of Costs:**

(a) Cost to the agency:

Development of these proposed regulations was accomplished with existing staff, by reassignment of staff from other duties. Licensing, inspection and enforcement of the requirements in these regulations will be accomplished by existing staff in the health facilities program and legal office.

(b) Cost to persons who will bear the costs and those who will be affected (i.e., private citizens and consumers of the products or services) and are subject to the proposed rules and regulations or the enforcement:

These proposed regulations are consistent with recognized standards of care for outpatient surgical procedures for environmental and operating requirements, and should not impose any unusual cost on regulated providers or consumers of provider services.

(c) Costs to other governmental agencies or units:

None identified.

6. **Description of any less costly or less intrusive methods that were considered by the agency for the purpose of the rules and regulations and why such methods were rejected in favor of the proposed rules and regulations.**

No less costly or less intrusive methods were identified. Section 9 of 2011 House substitute for SB 36 requires KDHE to adopt rules and regulations for licensing abortion facilities and the performance of abortions.

7. Verification of economic impact statement with League of Kansas Municipalities, Kansas Association of Counties and the Kansas Association of School Boards.

The above mentioned regulation was determined as appropriate for consultation as to the economic impact with the League of Kansas Municipalities, Kansas Association of Counties and the Kansas Association of School Boards, pursuant to K.S.A. 77-416.

Yes _____

No X

If yes:

Date Contacted and by what means (i.e., letter, FAX, etc.):

Response and comments received by:

League of Kansas Municipalities:

Kansas Association of Counties:

Kansas Association of School Boards:

Exhibit I

From: Joseph F. Kroll [mailto:jkroll@kdheks.gov]
Sent: Tuesday, June 21, 2011 10:47 AM
To: Dr Hodes
Cc: nausers@kc.rr.com; merry.mullins@hमेkc.com
Subject: RE:

Dr. Hodes, we can commence your initial inspection on Monday June 27. If that date is not agreeable we will need at least 30 days notice to commence an inspection on another date. Please respond and advise of your intentions. Thank you.

Joseph F. Kroll
Director, Bureau of Child Care and Health Facilities

Exhibit J

From: Dr Hodes [mailto:hhodes@hodesnauser.com]
Sent: Tuesday, June 21, 2011 2:13 PM
To: Joseph F. Kroll
Subject: Waiver

Dear Mr. Kroll,

Having reviewed the newly-revised regulations, it appears that there are a number of new requirements that we cannot meet in our existing practice. We are writing to ask whether KDHE is willing to entertain requests from us for waivers of particular provisions of the regulations and, if so, whether KDHE will provide our practice with a provisional license to allow us to continue providing abortions while the department considers our waiver requests.

Given the date you have proposed for our inspection and the looming compliance deadline, we would appreciate a response to this inquiry by the end of the business day tomorrow. Thank you for your prompt attention to this matter,

Herbert C. Hodes, M.D.
Traci L. Nauser, MD

Herbert C Hodes, MD, FACOG
Center for Women's Health
4840 College Blvd
Overland Park, Kansas 66211
Phone: 913-491-6878
Fax: 913-491-6808

CONFIDENTIALITY NOTICE: This e-mail message and any attachments are for the sole use of the intended recipient(s) and may contain proprietary, confidential, trade secret or privileged information. Any unauthorized review, use, disclosure or distribution is prohibited and may be a violation of law. If you are not the intended recipient or a person responsible for delivering this message to an intended recipient, please contact the sender by reply e-mail and destroy all copies of the original message.

Exhibit K

From: Joseph F. Kroll [mailto:jkroll@kdheks.gov]
Sent: Tuesday, June 21, 2011 2:25 PM
To: Dr Hodes
Subject: RE: Waiver

Dr. Hodes, the legislation establishing the licensing of abortion facilities does not provide for waiver of any requirement , nor does it provide for a provisional license.

Joseph F. Kroll
Director, Bureau of Child Care and Health Facilities

Exhibit L

From: Dr Hodes [mailto:hhodes@hodesnauser.com]
Sent: Tuesday, June 21, 2011 4:36 PM
To: Joseph F. Kroll
Cc: nausers@kc.rr.com
Subject: Inspection

Mr. Kroll,

In light of the new requirements imposed by the recently-amended regulations, we cannot be ready for an inspection on June 27.

We therefore request that KDHE postpone our inspection date to June 29.

Would you please let me know if that can be arranged?

Thank you in advance for consideration of this request.

Herbert Hodes, MD
Traci Nauser, MD

Herbert C Hodes, MD, FACOG
Center for Women's Health
4840 College Blvd
Overland Park, Kansas 66211
Phone: 913-491-6878
Fax: 913-491-6808

CONFIDENTIALITY NOTICE: This e-mail message and any attachments are for the sole use of the intended recipient(s) and may contain proprietary, confidential, trade secret or privileged information. Any unauthorized review, use, disclosure or distribution is prohibited and may be a violation of law. If you are not the intended recipient or a person responsible for delivering this message to an intended recipient, please contact the sender by reply e-mail and destroy all copies of the original message.

Exhibit M

From: Joseph F. Kroll [mailto:jkroll@kdheks.gov]
Sent: Wednesday, June 22, 2011 8:49 AM
To: Dr Hodes
Cc: nausers@kc.rr.com
Subject: RE: Inspection

Dr. Hodes, we have arranged for your initial inspection to commence June 29. By accommodating your request, however, we cannot assure completion of the inspection or a licensing decision prior to July 1.

Our State Survey Manager will contact your facility on June 28 to confirm.

Joseph F. Kroll
Director, Bureau of Child Care and Health Facilities