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CLERK OF THE SHAWNEE COUNTY DISTRICT COURT
CASE NUMBER: 2011-CV-001298

IN THE DISTRICT COURT OF SHAWNEE COUNTY, KANSAS
DIVISION 7

HODES & NAUSER, MDs, P.A.; HERBERT C. HODES, M.D.; and TRACI LYNN NAUSER, M.D.,	)	
Plaintiffs,	)	
v.	)	**Case No. 2011-CV-1298**
SUSAN MOSIER, M.D., in her official capacity as Secretary of the Kansas Department of Health and Environment; STEPHEN HOWE, in his official capacity as District Attorney for Johnson County, Kansas; and DEREK SCHMIDT, in his official capacity as Attorney General for the State of Kansas,	)	
Defendants.	)	

Second Amended Verified Petition
(Pursuant to K.S.A. Chapter 60)

Plaintiffs, Hodes & Nauser, MDs, P.A.; Herbert Hodes, M.D.; Traci Nauser, M.D. (collectively "Plaintiffs"), by and through their undersigned attorneys, bring this petition 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 brought by a private obstetrics and gynecology ("ob-gyn") practice and the father-daughter team of physicians who own and operate that practice

(collectively "Drs. Hodes & Nauser"), seeking facial invalidation of an enabling statute and regulations promulgated thereunder, which govern the provision of abortions. Drs. Hodes and Nauser have provided safe, high-quality obstetrical and gynecological services, including pregnancy termination services, in their private medical office for decades.

2. This action facially challenges both the enabling Act, Kansas House Substitute for Senate Bill No. 36 (2011) (the "Act"), codified at K.S.A. §§ 65-4a01 - 4a12 (as amended by 2014 Kan. Sess. Laws Ch. 87 (S.B. 54) and 2015 Kan. Sess. Laws Ch. 84 (H.B. 2228)), and the Permanent Regulations promulgated thereunder by the Kansas Department of Health and Environment ("KDHE"), K.A.R. §§ 28-34-126 - 44 (2011) (the "Permanent Regulations").[1] The Act and Permanent Regulations are collectively referred to herein as the "Regulatory Scheme." Plaintiffs' claims against the Act are brought under the Kansas Constitution, and their claims against the Permanent Regulations are brought under the Kansas Judicial Review Act ("KJRA"), K.S.A. §§ 77-621(c)(1) and (c)(8). If the enabling Act is invalidated on its face, the Permanent Regulations will necessarily fall as well regardless of the merits of Plaintiffs' KJRA-based claims.

3. Plaintiffs' claims under the KJRA concern only one agency action: KDHE's promulgation of the Permanent Regulations. Plaintiffs seek a binding judicial ruling that the Permanent Regulations violate the KJRA and cannot be enforced because they are unreasonable, K.S.A. § 77-621(c)(8), and/or unconstitutional on their face, K.S.A. § 77-621(c)(1). Neither KDHE nor any other state agency has the authority to grant the relief sought; indeed, KDHE was mandated by the Act to promulgate the Permanent Regulations. Accordingly, no administrative

[1] A true and correct copy of the Act, which is codified at K.S.A. §§ 65-4a01 through 65-4a12 (as amended through the 2015 session), is attached hereto as Exhibit A. A true and correct copy of the Permanent Regulations is attached hereto as Exhibit B.

remedy is available, and Plaintiffs may proceed to seek judicial review at this time. K.S.A. § 77-612 (requiring exhaustion only of "administrative remedies available") (emphasis added). Moreover, if Plaintiffs were to pursue a license application under the challenged laws, that action would not only be futile in terms of the relief Plaintiffs seek, but it would also expose Plaintiffs to irreparable harm by precipitating a license denial that might harm their professional stature and credentials, even if the denial of licensure was later reversed. Such threat of irreparable harm provides an additional, independent ground for allowing Plaintiffs to obtain judicial review of the challenged regulations at this time. K.S.A. § 77-612 (d) (exhaustion not required where administrative remedies would result in irreparable harm).

4. Absent relief from this Court, the Regulatory Scheme will cause immediate, irreparable harms to Plaintiffs and their patients by: (a) singling out abortion providers for medically unnecessary and unduly burdensome regulation; (b) precluding a licensed and qualified health professional from administering an abortion-inducing drug at the direction of a physician, or without the physician in the same room while the medication is initially administered; (c) forcing Drs. Hodes and Nauser to cease providing abortion services in their practice because they cannot meet every requirement of the new regulations, despite the fact that their practice already meets the needs of their patients, the applicable standards of care, and the existing regulations governing medical facilities that perform office-based surgeries; (d) delaying or preventing Drs. Hodes' and Nauser's patients from obtaining abortions, even where the patient's medical circumstances make her ineligible to obtain an abortion from any other provider in the state or make Plaintiffs' specialized expertise particularly important to the performance of the procedure; and (e) unjustifiably giving state officials access to the complete

medical records of Plaintiffs' patients. Injunctive relief is necessary to prevent these harms and the violation of rights secured to Plaintiffs and their patients by the Kansas Constitution.

5. The Permanent Regulations supersede a set of temporary KDHE regulations that became effective on July 1, 2011 ("Temporary Regulations"). Plaintiffs in this case previously filed a federal action, in June 2011, to block enforcement of the Temporary Regulations and the two licensing provisions of the Act,[2] as they had been applied by KDHE to condition initial licensure upon virtually immediate compliance with the Temporary Regulations ("Licensing Process"), which included, *inter alia,* extensive structural requirements. On July 1, 2011, the United States District Court for the District of Kansas issued a preliminary injunction against the Temporary Regulations and the Licensing Process. *Hodes & Nauser, MDs, P.A. v. Moser*, No. 2:11-cv-02365-CM-KMH (D. Kan. July 1, 2011) (order granting preliminary injunction). While the Temporary Regulations were enjoined, KDHE moved forward with the notice and comment process for a set of proposed permanent regulations, which were identical to the Temporary Regulations. Plaintiffs submitted extensive written and oral comments on the proposed permanent regulations. On October 27, 2011, the Temporary Regulations expired, and KDHE published the final Permanent Regulations in the Kansas Register. The Permanent Regulations are similar in many respects to the Temporary Regulations; however, some of the temporary requirements have been omitted and some requirements have been changed. The Permanent Regulations are scheduled to take effect on November 14, 2011. *See* K.A.R. §§ 28-34-126 - 44. In this action, Plaintiffs state claims and seek relief against the Permanent Regulations and the Act on their face.

[2] K.S.A. §§ 65-4a02, 65-4a08.

6. Since the Licensing Process has been enjoined by the United States District Court, KDHE has had no ability to grant or deny a license to Plaintiffs (or any other abortion provider) on the basis of compliance with the Temporary Regulations.

7. KDHE had no ability to grant or deny a license to Plaintiffs (or any other abortion provider) based on compliance with the Permanent Regulations prior to the regulations' November 14, 2011, effective date, at which time Plaintiffs (and other abortion providers) were immediately required to possess a license in order to lawfully continue providing abortion services.

8. The Regulatory Scheme imposes medical practice requirements that are onerous, unrelated to the standard of care, and irrational, and that have no more relevance to abortion procedures than to other medical procedures performed in similar settings in this state. Moreover, the Regulatory Scheme singles out the few Kansas physicians who provide abortions from among all other physicians in the state for the imposition of these burdensome and unjustified requirements. This discriminatory treatment and the specific requirements imposed by the Regulatory Scheme are unjustified by any legitimate goal, and they will serve only to punish and irreparably harm the physicians who provide and women who seek legal and constitutionally-protected abortion services.

II. Jurisdiction and Venue

9. This Court has jurisdiction under K.S.A. § 20-301.

10. Plaintiffs' action for declaratory and injunctive relief is authorized by K.S.A. §§ 60-1701, 60-1703 (declaratory relief) and K.S.A. § 60-901-03 (injunction).

11. Venue in this Court is proper under K.S.A. §§ 60-602(2) and 77-609(B) because the promulgation of the Permanent Regulations occurred in this district and the enforcement authority of Defendants Mosier and Howe is exercised in this district.

III. Parties

A. Plaintiffs

12. 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 over 40 years.

13. 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, 16 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.

14. Plaintiff Hodes & Nauser, MDs, P.A. is the private medical practice owned and operated by Drs. Hodes and Nauser (the "practice"). The practice is located in Overland Park, Kansas, and advertises under the name "Center for Women's Health" ("CWH").

15. Plaintiffs Drs. Hodes and 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 office-based gynecological surgeries performed by Drs. Hodes and Nauser include endometrial ablation, tubal occlusion, diagnostic hysteroscopy and surgical completion of miscarriage.

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

17. 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. They also include occasional pregnancy terminations for patients who are suffering from serious medical complications that necessitate a hospital setting for their procedure.

18. Drs. Hodes and Nauser regularly provide pregnancy termination services in their private medical office. Their practice has offered such services in the same physical facility for over 30 years. That facility meets the applicable standards of care, the existing Kansas regulations governing providers of office-based surgery, K.A.R. § 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. Plaintiffs' practice is already subject to oversight and inspections by the Kansas Board of Healing Arts; KDHE, to the extent it administers the Clinic Laboratory Improvement Amendments ("CLIA") and the Occupational Safety and Health Act ("OSHA"); and the National Abortion Federation.

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

B. Defendants

20. Defendant Susan Mosier, M.D., is the Secretary of KDHE, the agency that promulgated the Permanent Regulations, and is responsible for enforcing the Permanent Regulations and licensing requirements of the Act, and for determining violations thereunder. K.S.A. §§ 65-4a02, 4a06, 4a09. Secretary Mosier is sued in her official capacity, as are her agents and successors.

21. Defendant Stephen Howe is the District Attorney for Johnson County, Kansas, in which Plaintiffs' practice is located, and in which the hospitals in which Plaintiffs provide hospital-based care are located. As District Attorney, Defendant Howe has the authority to prosecute violations of the Act occurring in Johnson County. *See* K.S.A. § 22a-104 (district attorney duties); K.S.A. § 22-2602 (place of trial). District Attorney Howe is sued in his official capacity, as are his agents and successors.

22. 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 ex rel. Miller v. Rohleder*, 208 Kan. 193, 194 (1971); *accord* K.S.A. § 22-2202(17) (2011). 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 ex rel. Stephan v. Reynolds*, 234 Kan. 574, 578-79 (1984). Defendant Schmidt is sued in his official capacity, as are his agents and successors.

V. Factual Allegations

A. Pregnancy Termination Services in Kansas

23. 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.

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

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

26. 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 minutes) and involves no incision into the woman's body.

27. Both surgical abortion and medication abortion are medically analogous to a number of other outpatient procedures in terms of duration, invasiveness, nature of potential complications, and the level of anesthesia/sedation used.

28. For example, first-trimester surgical abortion is essentially the same procedure as surgical completion of miscarriage (a procedure performed when a women has experienced a spontaneous miscarriage but has not completely expulsed the contents of the uterus), which is also commonly performed in medical offices and other outpatient settings. First-trimester surgical abortion is also analogous from a medical and surgical standpoint to a number of gynecological procedures performed in office settings. These include endometrial ablation, tubal occlusion, diagnostic and operative hysteroscopy, and loop electrosurgical excision procedure.

29. As a matter of medicine and public health, it is irrational to require that medical offices in which abortions are performed meet different and more stringent standards than those imposed on medical offices in which medically analogous procedures are performed.

30. 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/or mortality (death) for the patient. Imposing unnecessary requirements on abortion that will delay women's access to the procedure undermines both women's health and public health generally.

31. Upon information and belief, there are only three medical facilities in the State of Kansas that regularly provide abortions: CWH, Drs. Hodes' and Nauser's practice; South Wind Women's Center, a medical clinic in Wichita; and Comprehensive Health Center, a facility operated by Planned Parenthood of Kansas and Mid-Missouri ("PPKMM"), which was already licensed as an ambulatory surgery center and has been issued an abortion facility license by KDHE.[3] 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.

32. Plaintiffs perform approximately one-sixth of the total pregnancy terminations reported in the state annually. *See* Kansas Dep't of Health & Environment – Abortions in Kansas 2014 (Preliminary Report), http://www.kdheks.gov/hci/abortion_sum/2014_Preliminary_Abortion_Report.pdf (last visited Aug. 12, 2015) (providing total number of reported abortions

[3] When this action commenced in 2011, there were also only three medical facilities in the State of Kansas that regularly provided abortions: CWH, PPKMM, and, Aid for Women, a medical practice in Kansas City, to which KDHE sent an "intent to deny" letter when it applied for a license. Aid for Women has since closed. As a result, between the time that Aid for Women ceased operation and South Wind Women's Center opened, there were only two medical facilities in the State that regularly provided abortions.

performed in the state). The vast majority of the pregnancy terminations performed by Drs. Hodes & Nauser are performed in the first trimester of pregnancy.

33. Plaintiffs perform a significant number of pregnancy terminations in situations where the woman has been diagnosed with a medical complication. Perinatologists and other obstetrician-gynecologists (including other outpatient abortion providers) in the region regularly refer patients to Plaintiffs when the patient has a medical complication or condition (e.g. placenta previa, hypertension, preterm premature rupture of membranes) and seeks to terminate a pregnancy.

34. These referrals are made based on the referring providers' confidence in Drs. Hodes' and Nauser's specialized expertise and ability to provide expert, high-quality care to patients in those circumstances.

35. Plaintiffs also perform a significant number of pregnancy terminations in situations where the fetus has been diagnosed with a serious fetal anomaly. Numerous perinatology and obstetrics-gynecology practices in the region regularly refer their patients to Plaintiffs when those patients seek terminations after receiving a diagnosis of fetal anomaly.

36. These referrals are made based on the referring providers' confidence in Drs. Hodes' and Nauser's specialized expertise and ability to provide expert, high-quality, and supportive care to patients in those circumstances.

37. Women seek abortion services from Drs. Hodes and Nauser, rather than another provider, for various reasons.

38. In some cases, the woman seeking an abortion is already a patient of Drs. Hodes and Nauser, and she prefers to obtain the service from her own physicians.

39. In some cases, the woman is ineligible, because of medical circumstances, to obtain an abortion procedure at any other facility in the state (e.g., where the patient has a complicating medical condition that puts her outside the eligibility criteria of other outpatient abortion providers in the region but does not fall within the limited permissible bases for hospital abortions in the state).

40. Some women seek abortion services from Drs. Hodes and Nauser because they have been referred to Drs. Hodes and Nauser by their own physicians, and the referral gives the patient confidence in the expertise and quality of care that Drs. Hodes and Nauser will provide.

41. Some patients feel comfortable in, and are familiar with, the ob-gyn office setting in which Drs. Hodes and Nauser practice, and they appreciate the level of privacy and individual care that can be provided in such a setting.

42. Finally, some patients fear that they will feel emotionally traumatized, in what is often already a difficult time, if they must walk past abortion protestors yelling hostile comments or waving graphic signs outside facilities that are known as abortion clinics and picketed by such protesters.

B. The Act

43. The Act, which took effect July 1, 2011, makes it unlawful to operate an abortion "facility" in the state without possessing a valid license issued by KDHE pursuant to the Act. K.S.A. § 65-4a08(a). There is no *mens rea* requirement for this crime. *Id.* Violation of this requirement is a Class A nonperson misdemeanor, K.S.A. § 65-4a08(c), punishable by up to one year of imprisonment and up to $2,500 in fines, K.S.A. §§ 21-6602(a)(1), 21-6611(b)(1) (2010). 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. K.S.A. § 65-2836(c). Violation of the

Act's licensing provision also constitutes unprofessional conduct under K.S.A. § 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. K.S.A. §§ 65-4a08(c), 65-2836(b).

44. Section 1(f) of the Act defines a "facility" that must obtain a license as one where "five or more" first-trimester abortions in a month, or any second- or third-trimester abortions are performed.[4] K.S.A. § 65-4a01(f). The licensing requirement does not apply to a qualified medical professional who performs fewer than five abortions in a month, and who does not perform any second- or third-trimester abortions.

45. The Act authorizes KDHE to license, inspect, and impose penalties on facilities subject to the Act. K.S.A. §§ 65-4a02-03, 4a05-06. The Act also requires KDHE to adopt rules and regulations for the licensure of facilities that perform abortions. K.S.A. § 65-4a09.

46. The Act includes two exceptions to the prohibition on performing an abortion in a facility not licensed under the Regulatory Scheme. The licensing requirement does not apply where a doctor in an unlicensed facility is performing an abortion for a patient who needs an abortion to "prevent [her] death." K.S.A. § 65-4a01(e),(f). Pursuant to an amendment to the Act which became effective on April 24, 2015, it also does not apply where the woman has:

> "[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 to avert her death, or for which a delay necessary comply with applicable statutory requirements will create serious risk of substantial and irreversible physical impairment of a major bodily function."

K.S.A. § 65-4a01(j) (as amended by 2014 Kan. Sess. Laws Ch. 87 (S.B. 54), § 1(j)) ("medical emergency exception"). A person permitted to provide abortions under Kansas

[4] The term "abortion" as used in the Regulatory Scheme applies to any attempt to remove a live embryo or fetus from the body of a pregnant woman unless the purpose of the act is to increase the likelihood of a live, healthy birth. K.S.A. § 65-4a01(a). This definition encompasses a range of procedures, including termination of an ectopic pregnancy or a pregnancy in which the woman's water breaks well before viability.

law will not be deemed in violation of the "applicable statutory requirements" referenced in K.S.A. 65-4a01(j) when he or she concludes, based on reasonable medical judgment, that one or more of the following conditions satisfies K.S.A. 65-4a01(j)'s definition of "medical emergency":

- preeclampsia with gestational age under 22 weeks;
- premature rupture of membranes with chorioamnionitis;
- ectopic pregnancy;
- placental abruption (Class 2 or 3); and,
- inevitable abortion.

This list is for purposes of clarification and is nonexclusive, and the physician remains allowed to exercise reasonable medical judgment in diagnosing conditions under K.S.A. 65-4a01(j).

47. Section 10 of the Act, which was also amended since its initial enactment and its amended version became effective on June 11, 2015, requires that "[e]xcept in the case of an abortion performed in a hospital through inducing labor: [] [w]hen RU-486 (mifepristone) is used for the purpose of inducing an abortion, the drug shall initially 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." K.S.A. § 65-4a10(b)(1) (as amended by 2015 Kan. Sess. Laws Ch. 84 (H.B. 2228), § 1(b)(1)) ("medication-in-person requirement").[5] There is no medical justification for requiring a physician to be in the room with a health professional qualified to administer mifepristone at the direction of a physician. Section 10 also provides that "when any

[5] Section 10 does not apply in the case of medical emergency. K.S.A. § 65-4a10(b)(2) (as amended by 2015 Kan. Sess. Laws Ch. 84 (H.B. 2228), § 2).

other drug is used for the purpose of inducing an abortion, the drug or the prescription for such drug shall be given to the patient by or in the room and in the physical presence of the physician who prescribed, dispensed or otherwise provided the prescription to the patient." *Id.* This provision is similarly medically unnecessary, and there is nothing distinctive about medications used in abortion procedures to demand this discriminatory treatment.

48. Section 2(g) of the Act allows ambulatory surgical centers and hospitals that provide abortions to apply to KDHE for waivers or exceptions from the requirements of the Regulatory Scheme. K.S.A. § 65-4a02(g). The Act contains no provision allowing medical offices that provide abortions to apply for such waivers. Plaintiffs have inquired with KDHE about the availability of waivers from the Permanent Regulations and have been told that no waiver requests from Plaintiffs would be entertained or granted.

C. The Permanent Regulations

49. Pursuant to the temporary injunctive relief entered by this Court, the Permanent Regulations did not take effect as scheduled on November 14, 2011. Order Granting Temporary Restraining Order Pending Hearing on Application for Temporary Injunction (Nov. 10, 2011); Agreed Order (Dec. 2, 2011) (agreeing and jointly stipulating that temporary restraining order shall remain in effect pending the Court's issuance of a final judgment in this matter).

50. The Permanent Regulations impose numerous irrational and burdensome requirements, including those described below.

51. The Regulatory Scheme imposes staffing requirements that are irrational and unjustified, and would force abortion providers to replace their medical assistants with physician assistants or nurses to perform tasks that are well within the training, competency, and typical

duties of medical assistants in Kansas office-based medical practices. These include the following five provisions.

52. K.A.R. § 28-34-135(m) precludes medical assistants from administering medication to patients, despite the fact that medical assistants are trained and qualified to perform this function and routinely do so in outpatient settings.

53. K.A.R. § 28-34-137(c)[6] requires that a female physician performing a pelvic exam have another staff person in the room regardless of whether the patient desires such a "chaperone," despite the fact that such a requirement is not part of the standard of care for abortion or other gynecological services, and that female physicians often perform such exams without the presence of a "chaperone."

54. K.A.R. § 28-34-138(f) requires that a nurse or physician assistant monitor a patient's vital signs throughout an abortion in which no sedation is used, despite the facts that a second licensed person is not called for during such a procedure, and vital signs are not monitored during such a procedure because the purpose of such monitoring would be to assess how the patient is responding to sedation.

55. K.A.R. § 28-34-138(c) requires that a licensed nurse be "available" to the patient throughout an abortion procedure, despite the fact that a second licensed person is not needed during an abortion in which no sedation is given.

56. K.A.R. § 28-34-139(a)(2) requires that a physician, nurse, or physician assistant monitor a patient's vital signs and bleeding during recovery, despite the fact that it is accepted and common practice for a trained medical assistant to check a patient's vital signs and bleeding after a procedure not involving sedation.

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[6] This requirement is also contained in the Act. K.S.A. § 65-4a09(d)(4).

57. The Permanent Regulations also contain patient recovery requirements that irrationally fail to distinguish between procedures based on the type and level of anesthesia used, and that impose requirements that are wholly unnecessary and outside the standard of care for procedures in which no sedation and only local anesthesia is given (such as the vast majority of abortions performed by Plaintiffs). These include the following two provisions.

58. K.A.R. § 28-34-139(a)(3)(A) requires that first-trimester abortion patients be kept in recovery a minimum of 30 minutes, despite the facts that Plaintiffs ordinarily perform such procedures using no sedation, and that the patient is typically fully recovered in well under 30 minutes, and that it is outside the standard of care, and likely upsetting for the patient, to require her to stay in recovery after she has met all discharge criteria and is ready to go home.

59. K.A.R. § 28-34-133(b)(7)(A) requires a recovery area that has a "nurse station with visual observation of each patient," despite the fact that no separate recovery room, nursing station or monitoring by a nurse is needed or part of the standard of care for the provision of a first-trimester abortion without sedation.

60. The Permanent Regulations also give KDHE broad access to patient medical records, including patient-identifying information, K.A.R. § 28-34-144(c), despite the facts that KDHE has no need for such identifying information in order to perform its oversight functions, and no other medical offices providing office-based procedures need give KDHE such access to their patients' medical records.

61. The Permanent Regulations require a facility seeking licensure to register with the Board of Pharmacy, K.A.R. § 28-34-135(n), despite the fact that no there is no mechanism by which the Board of Pharmacy registers physician's offices.[7]

62. K.A.R. § 28-34-141(b)(3) requires that any follow-up visit after a pregnancy termination include a urine pregnancy test. This requirement is irrational and outside the standard of care because it is common practice, and more accurate, to use an ultrasound or physical exam to confirm the termination of pregnancy in a follow-up visit soon after an abortion (a urine test is less accurate because the patient may still have pregnancy hormones in her system despite a successful termination procedure).

63. The Permanent Regulations fail to give notice of: what incidents must be reported under K.A.R. §§ 28-34-143(a) and 126(k); whether a separate recovery room is required by K.A.R. § 28-34-133(b)(7), what constitutes a nursing station in a procedure room under that provision, and whether recovery monitoring by a nurse is required by that provision; what it means for a nurse to be "available" under K.A.R. § 28-34-138(c); and what actions constitute "reasonable efforts" under K.A.R. § 28-34-141(c).

D. Harms Imposed by the Regulatory Scheme

64. For reasons more fully set forth in the affidavits filed herewith, if the Regulatory Scheme is not enjoined, it will cause the following immediate and irreparable harms.

65. Enforcement of the Regulatory Scheme will force Plaintiffs to cease providing pregnancy termination services in their practice because they cannot meet every requirement in

[7] Upon contacting KDHE about this requirement, Plaintiffs were told to identify their office-based medical practice as an ambulatory surgical facility on the Board of Pharmacy application form, which they declined to do out of concern for their ethical and legal responsibilities as physicians, since their facility is not in fact an ambulatory surgical center. In addition, the application form referenced by KDHE requires a facility to identify the pharmacist on staff who will be in charge at the registered facility; Plaintiffs do not employ a pharmacist, nor do they have need of one, since physicians are allowed to maintain and administer medications themselves under Kansas law. K.S.A. § 65-1635(a).

the Permanent Regulations (such as the need to hire many additional licensed nurses), despite the fact that their existing practice meets the needs of their patients, the applicable standards of care, and the existing state regulations governing medical facilities that perform office-based surgeries. As a result, many of Plaintiffs' patients will be unjustifiably delayed in obtaining abortion services. These delays will be particularly long—if not ultimately prohibitively so—for patients with medical conditions and/or a diagnosis of fetal anomaly. These delays will expose their patients to unnecessary, increased health risks.

66. Enforcement of the Regulatory Scheme will prevent or greatly hinder Kansas women from obtaining abortion services from physicians with substantial experience and expertise in treating women with medical complications or a diagnosis of fetal anomaly. Plaintiffs know of no other physician in the area who possesses such specialized expertise, and to whom they could refer their patients if the Court does not grant them injunctive relief.

67. Enforcement of the Regulatory Scheme will expose the private medical records of Plaintiffs' patients to unjustified intrusions by state officials.

68. Enforcement of the Regulatory Scheme will cause immediate and irreparable harms to Plaintiffs' medical practice, including loss of revenue, loss of future patients, and damage to their professional standing among their colleagues, current patients, and potential patients.

69. Enforcement of the Regulatory Scheme will deprive Plaintiffs and their patients seeking abortions of rights secured to them by the Kansas Constitution.

E. Lack of Harm, and Service of Public Interest, from Granting Injunctive Relief

70. Enjoining enforcement of the Regulatory Scheme will not create any risk of harm to women in Kansas because the Regulatory Scheme is 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 pregnancy termination services, the Regulatory Scheme will directly harm women's health.

71. To the extent that the Regulatory Scheme is enjoined, Plaintiffs' private medical practice—just like other medical offices that provide office-based procedures—will remain subject to inspections, regulation and oversight by the Kansas Board of Healing Arts, and Plaintiffs' provision of medical care—just like other physicians' provision of care in medically comparable circumstances—will remain subject to regulation and oversight by the Kansas Board of Healing Arts, the prevailing standards of care, and, to the extent the care is provided in a hospital setting, the oversight mechanisms of hospitals,.

FIRST CLAIM FOR RELIEF
(Equal Protection Rights of Plaintiffs and Their Patients – Differential Treatment of Medically Comparable Procedures)

72. Plaintiffs hereby re-allege and incorporate by reference paragraphs 1 through 74 above.

73. The Act, on its face and as implemented by KDHE through the promulgation of the Permanent Regulations, violates Section 1 of the Kansas Bill of Rights' guarantee of equal protection because it singles out providers and patients of pregnancy-termination services from providers and patients of all other medically comparable procedures for the imposition of significant burdens unrelated to any particulars of pregnancy termination.

SECOND CLAIM FOR RELIEF (Equal Protection Rights of Plaintiffs –Differential Treatment of Office-Based Practices)

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

75. The Act violates Section 1 of the Kansas Bill of Rights' guarantee of equal protection by authorizing KDHE to grant exceptions from the requirements of the Regulatory Scheme to ambulatory surgical centers and hospitals in which abortions are performed, K.S.A. § 65-4a02(g), but not to medical offices in which abortions are performed.

THIRD CLAIM FOR RELIEF (Plaintiffs' Constitutional Right to Be Free of Unreasonable and Oppressive Government Interference in Their Business)

76. Plaintiffs hereby re-allege and incorporate by reference paragraphs 1 through 78 above.

77. The Act, on its face and as implemented by KDHE through promulgation of the Permanent Regulations, violates Sections 1, 2 and 17 of the Kansas Bill of Rights because it subjects Plaintiffs to oppressive, unreasonable, and arbitrary government interference that would significantly impair, if not altogether eliminate, their ability to continue their existing medical practice.

FOURTH CLAIM FOR RELIEF (Patients' Privacy Rights – Medication-in-Person Requirement)

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

79. Section 10 of the Act violates Plaintiffs' patients' privacy rights under Section 1 of the Kansas Bill of Rights because it imposes significant and medically unjustified burdens on the provision of mifepristone and other medications used to induce an abortion. K.S.A. § 65-4a10(b)(1) (as amended by 2015 Kan. Sess. Laws Ch. 84 (H.B. 2228), § 1(b)(1)).

FIFTH CLAIM FOR RELIEF (Patients' Privacy Rights – Intrusion on Medical Records)

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

81. The Act, as implemented by KDHE through promulgation of the Permanent Regulations, violates Plaintiffs' patients' privacy rights under Section 1 of the Kansas Bill of Rights because it gives KDHE broad access to patients' complete medical records, including patient-identifying information in those records, without adequate justification for such an intrusion.

SIXTH CLAIM FOR RELIEF (Patients' Privacy Rights – Improper Purpose)

82. Plaintiffs hereby re-allege and incorporate by reference paragraphs 1 through 86 above.

83. The Act, on its face and as implemented by KDHE through promulgation of the Permanent Regulations, violates Plaintiffs' patients' rights to privacy under Section 1 of the Kansas Bill of Rights because it was enacted with the improper purpose of placing an undue burden on women's right to obtain pregnancy termination services.

SEVENTH CLAIM FOR RELIEF (Patients' Rights to Equal Protection - Sex Discrimination)

84. Plaintiffs hereby re-allege and incorporate by reference paragraphs 1 through 88 above.

85. The Act, on its face and as implemented by KDHE through promulgation of the Permanent Regulations, violates Plaintiffs' patients' right to equal protection under Section 1 of the Kansas Bill of Rights because it singles out a medical procedure sought only by women, and imposes on providers and patients of that procedure oppressive, burdensome, and unjustified regulations not imposed on medically comparable health care procedures sought by men; and because it perpetuates the patronizing and paternalistic stereotype that women are in need of special "protections" not needed by men.

EIGHTH CLAIM FOR RELIEF
(KJRA: Unreasonable, Arbitrary and Capricious Agency Action)

86. Plaintiffs hereby re-allege and incorporate by reference paragraphs 1 through 92 above.

87. The Permanent Regulations violate Plaintiffs' statutory rights under the KJRA, K.S.A. § 77-621(c)(8), because they impose unreasonable, arbitrary, and capricious requirements on Plaintiffs' medical practice and their patients' access to abortion services.

NINTH CLAIM FOR RELIEF (KJRA: Unconstitutional Agency Action)

88. Plaintiffs hereby re-allege and incorporate by reference paragraphs 1 through 94 above.

89. The Permanent Regulations violate the KJRA's prohibition on unconstitutional agency action, K.S.A. § 77-621(c)(1), by imposing requirements that violate: Plaintiffs' rights to equal protection under Kansas Bill of Rights § 1; Plaintiffs' rights to be free of oppressive, unreasonable, and arbitrary government interference under Kansas Bill of Rights §§ 1, 2, and 17; Plaintiffs' due process rights under Kansas Bill of Rights §§ 1, 2, and 18; Plaintiffs' patients' rights to equal protection under Kansas Bill of Rights § 1; and Plaintiffs' patients' rights to privacy under Kansas Bill of Rights § 1.

REQUEST FOR RELIEF

WHEREFORE Plaintiffs request that this Court:

1. Grant a Permanent Injunction restraining Defendants from enforcing the Permanent Regulations, K.A.R. § 28-34-126 - 44, and the Act, K.S.A. § 65-4a01 - 4a12, on their face.

2. Issue a Declaratory Judgment, K.S.A. §§ 60-1701, 1703, that the Permanent Regulations, K.A.R. § 28-34-126 - 44, and the Act, K.S.A. § 65-4a01 - 4a12, violate rights of Plaintiffs and their patients protected by the Kansas Bill of Rights.

3. Grant such other and further relief as this Court deems just and proper, including costs and attorneys' fees.

Respectfully submitted,

/s/ LJ Leatherman
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the above and foregoing was served on the following by email and U.S. mail, postage prepaid, on December 8th, 2015.

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/s/ LJ Leatherman
ATTORNEY FOR PLAINTIFFS

Exhibit A

West's Kansas Statutes Annotated
Chapter 65. Public Health
Article 4a. Abortion Facility Licensure

K.S.A. 65-4a01

65-4a01. Definitions

Currentness

As used in K.S.A. 65-4a01 through 65-4a12, 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) "Bodily function" means physical functions only. The term "bodily function" does not include mental or emotional functions.

(d) "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.

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

(f) "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.

(g) "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.

(h) "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.

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

(j) "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 to avert her death, or for which a delay necessary to comply with the applicable statutory requirements 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.

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

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

Credits

Laws 2011, ch. 82, § 1, eff. July 1, 2011; Laws 2014, ch. 87, § 1, eff. April 24, 2014.

K. S. A. 65-4a01, KS ST 65-4a01
Statutes are current through laws enacted during the 2015 Regular Session of the Kansas Legislature.

End of Document

West's Kansas Statutes Annotated
Chapter 65. Public Health
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K.S.A. 65-4a02

65-4a02. Licensure, facilities performing abortions; posting; fee

Currentness

(a) A facility shall be licensed in accordance with K.S.A. 65-4a01 through 65-4a12, 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 K.S.A. 65-4a09, 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.

(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.

Credits

Laws 2011, ch. 82, § 2, eff. July 1, 2011.

K. S. A. 65-4a02, KS ST 65-4a02
Statutes are current through laws enacted during the 2015 Regular Session of the Kansas Legislature.

End of Document

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K.S.A. 65-4a03

65-4a03. License; annual renewal

Currentness

Applicants for an annual license renewal shall file an application with the department and pay the license fee in accordance with K.S.A. 65-4a02, and amendments thereto. Applicants for an annual license renewal shall also be subject to a licensing inspection in accordance with K.S.A. 65-4a05, and amendments thereto.

Credits

Laws 2011, ch. 82, § 3, eff. July 1, 2011.

K. S. A. 65-4a03, KS ST 65-4a03
Statutes are current through laws enacted during the 2015 Regular Session of the Kansas Legislature.

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K.S.A. 65-4a04

65-4a04. Facility name change; ownership change; notice

Currentness

(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 K.S.A. 65-4a01 through 65-4a12, 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.

Credits

Laws 2011, ch. 82, § 4, eff. July 1, 2011.

K. S. A. 65-4a04, KS ST 65-4a04
Statutes are current through laws enacted during the 2015 Regular Session of the Kansas Legislature.

End of Document

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K.S.A. 65-4a05

65-4a05. Inspections; frequency; confidentiality of certain records

Currentness

(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 K.S.A. 65-4a01 through 65-4a12, and amendments thereto, and rules and regulations adopted pursuant to K.S.A. 65-4a09, 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 K.S.A. 65-4a01 through 65-4a12, 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.

Credits

Laws 2011, ch. 82, § 5, eff. July 1, 2011.

K. S. A. 65-4a05, KS ST 65-4a05
Statutes are current through laws enacted during the 2015 Regular Session of the Kansas Legislature.

End of Document

West's Kansas Statutes Annotated
Chapter 65. Public Health
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K.S.A. 65-4a06

65-4a06. Licensure; denial, suspension or revocation; procedures license violation classes; penalties; fines

Currentness

(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 K.S.A. 65-4a01 through 65-4a12, 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 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.

Credits

Laws 2011, ch. 82, § 6, eff. July 1, 2011.

K. S. A. 65-4a06, KS ST 65-4a06
Statutes are current through laws enacted during the 2015 Regular Session of the Kansas Legislature.

End of Document

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K.S.A. 65-4a07

65-4a07. Late term abortions; performed in hospital or ambulatory surgical center only; exception

Currentness

Except in the case of a medical emergency, 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 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 and that is licensed pursuant to K.S.A. 65-425 et seq., and amendments thereto, may perform abortions.

Credits

Laws 2011, ch. 82, § 7, eff. July 1, 2011; Laws 2014, ch. 87, § 2, eff. April 24, 2014.

K. S. A. 65-4a07, KS ST 65-4a07
Statutes are current through laws enacted during the 2015 Regular Session of the Kansas Legislature.

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K.S.A. 65-4a08

65-4a08. Operating without a valid license; criminal penalties

Currentness

(a) It shall be unlawful to operate a facility within Kansas without possessing a valid license issued annually by the secretary pursuant to K.S.A. 65-4a02, 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.

Credits

Laws 2011, ch. 82, § 8, eff. July 1, 2011.

K. S. A. 65-4a08, KS ST 65-4a08
Statutes are current through laws enacted during the 2015 Regular Session of the Kansas Legislature.

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West's Kansas Statutes Annotated
Chapter 65. Public Health
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K.S.A. 65-4a09

65-4a09. Rules and regulations; secretary of health and environment

Currentness

(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 K.S.A. 65-4a01 through 65-4a12, 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 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 minimum 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 [these] 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 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 K.S.A. 65-4a01 through 65-4a12, 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 K.S.A. 65-4a01 through 65-4a12, and amendments thereto.

(l) The provisions of K.S.A. 65-4a01 through 65-4a12, 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 K.S.A. 65-4a01, 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.

Credits

Laws 2011, ch. 82, § 9, eff. July 1, 2011.

K. S. A. 65-4a09, KS ST 65-4a09
Statutes are current through laws enacted during the 2015 Regular Session of the Kansas Legislature.

End of Document

West's Kansas Statutes Annotated
Chapter 65. Public Health
Article 4a. Abortion Facility Licensure

K.S.A. 65-4a10

65-4a10. Performance of abortions; only physicians; RU-486 or any drug induced abortion requirements; violations

Currentness

(a) No abortion shall be performed or induced by any person other than a physician licensed to practice medicine in the state of Kansas.

(b)(1) Except in the case of an abortion performed in a hospital through inducing labor: (A) When RU-486 (mifepristone) is used for the purpose of inducing an abortion, the drug shall initially 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; and (B) when any other drug is used for the purpose of inducing an abortion, the drug or the prescription for such drug shall be given to the patient by or in the same room and in the physical presence of the physician who prescribed, dispensed or otherwise provided the drug or prescription to the patient.

(2) The provisions of this subsection shall not apply in the case of a medical emergency.

(c) 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.

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

Credits

Laws 2011, ch. 82, § 10, eff. July 1, 2011; Laws 2015, ch. 84, § 1, eff. June 11, 2015.

K. S. A. 65-4a10, KS ST 65-4a10
Statutes are current through laws enacted during the 2015 Regular Session of the Kansas Legislature.

End of Document

West's Kansas Statutes Annotated
Chapter 65. Public Health
Article 4a. Abortion Facility Licensure

K.S.A. 65-4a11

65-4a11. Act does not create right to abortion

Currentness

Nothing in K.S.A. 65-4a01 through 65-4a12, 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.

Credits

Laws 2011, ch. 82, § 11, eff. July 1, 2011.

K. S. A. 65-4a11, KS ST 65-4a11
Statutes are current through laws enacted during the 2015 Regular Session of the Kansas Legislature.

End of Document

West's Kansas Statutes Annotated
Chapter 65. Public Health
Article 4a. Abortion Facility Licensure

K.S.A. 65-4a12

65-4a12. Severability clause

Currentness

The provisions of K.S.A. 65-4a01 through 65-4a12, 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 K.S.A. 65-4a01 through 65-4a12, and amendments thereto.

Credits

Laws 2011, ch. 82, § 12, eff. July 1, 2011.

K. S. A. 65-4a12, KS ST 65-4a12
Statutes are current through laws enacted during the 2015 Regular Session of the Kansas Legislature.

End of Document

Exhibit B

(B) within 300 yards of any spillway, lock, dam, or the mouth of any tributary stream or ditch; and

(C) under or through ice or in overflow waters.

(7) Holding baskets and holding cages may be used.

(c) Each net or seine shall have an identification tag supplied by the department and attached as specified by the department during commercial fishing use. Identification tags supplied by the state of Missouri and approved by the department also shall be deemed to meet this requirement.

(d) The fee for identification tags shall be five dollars for each tag. The payment shall be submitted to the department with the initial or renewal application for a commercial fishing permit.

(e) The holding basket and holding cage used to hold fish shall not require an identification tag, but shall be identified by the permittee with the permittee's name and permit number attached. This regulation shall be effective on and after January 1, 2012. (Authorized by and implementing K.S.A. 32-807, K.S.A. 32-941, and K.S.A. 2010 Supp. 32-988; effective May 27, 1991; amended Sept. 27, 2002; amended Jan. 1, 2012.)

115-17-12. Commercial harvest of fish; legal species, seasons, size restrictions, daily limits, and possession limits. (a) The legal species of fish that may be taken under a commercial fishing permit shall be the following:

(1) Bowfin;

(2) suckers, including buffalo;

(3) common carp and exotic carp;

(4) freshwater drum;

(5) gar;

(6) shad;

(7) goldeye;

(8) goldfish; and

(9) skipjack herring.

(b) None of the following shall be possessed by a permittee while in possession of commercial fishing gear or while transporting fish taken using commercial fishing gear:

(1) All species of fish excluded from subsection (a); and

(2) any species of fish listed in K.A.R. 115-15-1 or K.A.R. 115-15-2.

The species of fish specified in this subsection shall be immediately returned unharmed to the water from which removed.

(c) There shall be no size restriction on fish taken by a permittee.

(d) There shall be no maximum daily or possession limit on the number of fish taken by a permittee.

(e) No live specimen of bighead carp, silver carp, or black carp may be transported after commercial harvest. This regulation shall be effective on and after January 1, 2012. (Authorized by and implementing K.S.A. 32-807 and K.S.A. 32-941; effective May 27, 1991; amended Sept. 27, 2002; amended Jan. 1, 2012.)

Robin Jennison
Secretary of Wildlife,
Parks, and Tourism

Doc. No. 039931

State of Kansas

Department of Health and Environment

Permanent Administrative Regulations

Article 34.—HOSPITALS

28-34-126. Definitions. For the purposes of K.A.R. 28-34-126, 28-34-127, and 28-34-129 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.

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

(k) "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.

(l) "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.

(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.

(continued)

(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. (Authorized by L. 2011, ch. 82, sec. 9; implementing L. 2011, ch. 82, sec. 1; effective, T-28-7-1-11, July 1, 2011; effective Nov. 14, 2011.)

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. (Authorized by L. 2011, ch. 82, sec. 9; implementing L. 2011, ch. 82, secs. 2 and 9; effective, T-28-7-1-11, July 1, 2011; effective Nov. 14, 2011.)

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. (Authorized by L. 2011, ch. 82, sec. 9; implementing L. 2011, ch. 82, sec. 2; effective, T-28-7-1-11, July 1, 2011; effective Nov. 14, 2011.)

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 after either of the following:

(1) A change of ownership by purchase or by lease; or

(2) a change in the facility's name or address. (Authorized by L. 2011, ch. 82, sec. 9; implementing L. 2011, ch. 82, secs. 2, 3, and 4; effective, T-28-7-1-11, July 1, 2011; effective Nov. 14, 2011.)

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;

(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. (Authorized by L. 2011, ch. 82, sec. 9; implementing L. 2011, ch. 82, secs. 2 and 9; effective, T-28-7-1-11, July 1, 2011; effective Nov. 14, 2011.)

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.

(d) Each applicant and each licensee shall ensure that each staff member employed by or contracted with the facility is licensed, if required by state law, is qualified, and provides 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 who is having an abortion procedure or recovering from an abortion procedure is present at the facility. (Authorized by and implementing L. 2011, ch. 82, sec. 9; effective, T-28-7-1-11, July 1, 2011; effective Nov. 14, 2011.)

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 designated for patient interviews, counseling, and medical evaluations, located and arranged to preserve patient privacy;

(2) at least one dressing room for patients only and arrangements for storage of patient clothing and valuables;

(3) at least one dressing room for staff members, including a toilet, hand washing station, and arrangements for storage for staff member clothing and valuables;

(4) a toilet room and hand washing station designated for patients;

(5) hand washing stations for pre-procedure hand washing by staff members;

(6) private procedure rooms and doorways of those rooms of sufficient size to accommodate the following:

(A) The equipment, supplies, and medical staff members required for performance of an abortion procedure; and

(B) emergency equipment and personnel in the event of a transfer, as described in K.A.R. 28-34-140;

(7) a recovery area that meets all of the following requirements:

(A) Has a nurse station with visual observation of each patient in the recovery area;

(B) provides privacy for each patient in the recovery area with at least cubicle curtains around each patient gurney or bed; and

(C) has sufficient space to accommodate emergency equipment and personnel in the event of a transfer, as described in K.A.R. 28-34-140;

(8) a waiting area for patients and visitors;

(9) an administrative area, including office space for the secure filing and storage of facility patient records;

(10) a workroom separate from the procedure rooms for cleaning, preparation, and sterilization of instruments, arranged to separate soiled or contaminated instruments from clean or sterilized instruments, including the following:

(A) A hand washing station;

(B) receptacles for waste and soiled items;

(C) designated counter space for soiled or contaminated instruments;

(D) a sink for cleaning soiled or contaminated instruments;

(E) designated counter space for clean instruments; and

(F) an area for sterilizing instruments, if sterilization is completed at the facility;

(11) storage space for clean and sterile instruments and supplies; and

(12) at least one room equipped with a service sink or a floor basin and space for storage of janitorial supplies and equipment. (Authorized by and implementing L.

(continued)

2011, ch. 82, sec. 9; effective, T-28-7-1-11, July 1, 2011; effective Nov. 14, 2011.)

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 temperature in each procedure room and in each recovery area shall be between 65 and 75 degrees Fahrenheit unless otherwise ordered by a physician in order to meet the comfort or medical needs of the patient.

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

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

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

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

(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 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. (Authorized by and implementing L. 2011, ch. 82, sec. 9; effective, T-28-7-1-11, July 1, 2011; effective Nov. 14, 2011.)

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) face masks, in child and adult sizes for assisting ventilation;

(3) a non self-inflating bag with face mask;

(4) suction, either wall or machine;

(5) suction catheters, in sizes 8, 10, 14F, and Yankauer;

(6) oral airways, in child and adult sizes;

(7) nasal cannulas, in child and adult sizes; and

(8) the following additional equipment and supplies for airway management for any abortion procedure performed when the gestational age of the unborn child is 22 weeks or more:

(A) A self-inflating bag with reservoir, 500 cc and 1000 cc;

(B) oral airways, in infant sizes;

(C) a laryngoscope handle with batteries;

(D) straight blades or curved blades, in sizes 0, 1, 2, and 3;

(E) endotracheal tubes, uncuffed, in sizes 3.0, 3.5, 4.0, 4.5, 5.0, 6.0, 7.0, and 8.0;

(F) stylets, small and large; and

(G) 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) tourniquets, alcohol swabs, and tape;

(5) isotonic fluids, either normal saline or lactated Ringer's solution; and

(6) for any abortion procedure performed when the gestational age of the unborn child is 22 weeks or more, pediatric drip chambers and tubing.

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

(1) Blood pressure cuffs, in small, medium and large adult sizes;

(2) adult nasogastric tubes;

(3) manual sphygmomanometer; and

(4) for any abortion procedure performed when the gestational age of the unborn child is 22 weeks or more, blood pressure cuffs in preemie and infant sizes.

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

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

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

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

(j) 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;

(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; and

(I) a scale for weighing a patient.

(k) Each applicant and each licensee shall ensure that, for any abortion procedure performed when the gestational age of the unborn child is 22 weeks or more, the following equipment and supplies are maintained in the facility:

(1) Equipment to monitor cardiopulmonary status; and

(2) drugs to support cardiopulmonary function.

(l) 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 a stock supply of drugs and medications for the use of the physician in treating the emergency needs of patients.

(2) The medications shall be stored in such a manner as to prohibit access by unauthorized personnel.

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

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

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

(n) 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.

(o) Records shall be kept of all stock supplies of controlled substances giving an accounting of all items received or administered. (Authorized by and implementing L. 2011, ch. 82, sec. 9; effective, T-28-7-1-11, July 1, 2011; effective Nov. 14, 2011.)

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.

(d) Each applicant and each licensee shall ensure that all drugs and medications shall be administered 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. (Authorized by and implementing L. 2011, ch. 82, sec. 9; effective, T-28-7-1-11, July 1, 2011; effective Nov. 14, 2011.)

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 stan-

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dards 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. The original prints may consist of a digitized record or an electronic record.

(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, 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. (Authorized by and implementing L. 2011, ch. 82, sec. 9; effective, T-28-7-1-11, July 1, 2011; effective Nov. 14, 2011.)

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 estimated 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 after completion of all requirements for patient screening and evaluation required in K.A.R. 28-34-137 and 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 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. (Authorized by and implementing L. 2011, ch. 82, sec. 9; effective, T-28-7-1-11, July 1, 2011; effective Nov. 14, 2011.)

28-34-139. Recovery procedures; discharge. (a) Each applicant and each licensee shall ensure that written policies and procedures are developed and implemented for the post-procedure care of patients who are administered local anesthesia, analgesia, or sedation, including the following:

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

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

(3) Each patient shall remain in the recovery area following the abortion procedure for the following time periods, based on the gestational age of the unborn child:

(A) For a gestational age of 12 weeks or less, a minimum of 30 minutes;

(B) for a gestational age of 13 to 15 weeks, a minimum of 45 minutes; and

(C) for a gestational age of 16 weeks or more, a minimum of 60 minutes. The patient shall remain in the recovery area for a longer period of time when necessary based on the physician's evaluation of the patient's medical condition.

(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

(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. (Authorized by and implementing L. 2011, ch. 82, sec. 9; effective, T-28-7-1-11, July 1, 2011; effective Nov. 14, 2011.)

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 of the facility 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. (Authorized by and implementing L. 2011, ch. 82, sec. 9; effective, T-28-7-1-11, July 1, 2011; effective Nov. 14, 2011.)

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 make a good faith effort to 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;

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

(3) a urine pregnancy test.

If a continuing pregnancy is suspected, a physician who performs abortion procedures shall be consulted.

(c) 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. (Authorized by and implementing L. 2011, ch. 82, sec. 9; effective, T-28-7-1-11, July 1, 2011; effective Nov. 14, 2011.)

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

(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. (Authorized by and implementing L. 2011, ch. 82, sec. 9; effective, T-28-7-1-11, July 1, 2011; effective Nov. 14, 2011.)

28-34-143. Reporting requirements. In addition to the reporting requirements for risk management required

(continued)

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. (Authorized by and implementing L. 2011, ch. 82, sec. 9; effective, T-28-7-1-11, July 1, 2011; effective Nov. 14, 2011.)

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 staff member'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) if an individual who performs ultrasounds, 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:

(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.

(f) 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;

(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. (Authorized by L. 2011, ch. 82, sec. 9; implementing L. 2011, ch. 82, secs. 5 and 9; effective, T-28-7-11, July 1, 2011; effective Nov. 14, 2011.)

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Secretary of Health
and Environment

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State of Kansas

State Corporation Commission

Permanent Administrative Regulations

Article 4.—MOTOR CARRIERS OF PERSONS AND PROPERTY

82-4-1. Definitions. The following terms used in connection with the regulations of the state corporation commission governing motor carriers shall be defined as follows:

(a) "Affiliate" means a person or company controlling, controlled by, or under common control or ownership with, another person or company.

(b) "Authorized agent" and "authorized representative" mean any authorized special agent or employee of the commission, any member of the Kansas highway patrol, or any law enforcement officer in the state certified in the inspection of motor carriers and authorized in accordance with the requirements of the Kansas motor carrier safety program.

(c) "Certificate" means a document evidencing a certificate of convenience and necessity or a certificate of public service issued to an intrastate common carrier to operate motor vehicles as a common carrier.

(d) "Commercial motor vehicle" means any of the following, except when used in 49 C.F.R. Part 382 as adopted by K.A.R. 82-4-3c:

(1) A vehicle that has a gross vehicle weight rating or gross combination weight rating, or a gross vehicle weight or gross combination weight, of 4,536 kg (10,001 pounds) or more, whichever is greater;