IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

WHOLE WOMAN'S HEALTH; ABORTION ADVANTAGE; AUSTIN WOMEN'S HEALTH CENTER; KILLEEN WOMEN'S HEALTH CENTER; NOVA HEALTH SYSTEMS d/b/a REPRODUCTIVE SERVICES; SHERWOOD C. LYNN, JR., M.D.; PAMELA J. RICHTER, D.O.; LENDOL L. DAVIS, M.D.; and LAMAR ROBINSON, M.D., on behalf of themselves and their patients, Plaintiffs, v. DAVID LAKEY, M.D., Commissioner of the Texas Department of State Health Services; MARI ROBINSON, Executive Director of the Texas Medical Board; DAVID ESCAMILLA, County Attorney for Travis County; JAIME ESPARZA, District Attorney for El Paso County; RENÉ GUERRA, Criminal District Attorney for Hidalgo County; JAMES E. NICHOLS, County Attorney for Bell County; SUSAN D. REED, Criminal District Attorney for Bexar County; JOE SHANNON, JR., Criminal District Attorney for Tarrant County; CRAIG WATKINS, Criminal District Attorney for Dallas County, in their official capacities, Defendants.	)	CIVIL ACTION CASE NO. _______________

COMPLAINT

Plaintiffs, by and through their undersigned attorneys, bring this complaint against the above-named Defendants, their employees, agents, and successors in office, and in support thereof allege the following:

I. PRELIMINARY STATEMENT

1. Pursuant to 42 U.S.C. § 1983, Plaintiffs, who are Texas health care providers, bring

this action on behalf of themselves and their patients. They seek declaratory and injunctive relief from certain unconstitutional requirements imposed by Texas House Bill No. 2 ("the Act"), Act of July 18, 2013, 83rd Leg., 2nd C.S., ch. 1, Tex. Gen. Laws, and its implementing regulations, *see* 38 Tex. Reg. 6536-46 (Sept. 27, 2013) (notice of proposed rules); 38 Tex. Reg. 9577-93 (adoption of proposed rules).[1]

2. The Act targets abortion providers for the imposition of unique regulatory burdens that are not imposed on any other health care providers in Texas, are inconsistent with accepted medical standards, impose costs that are far in excess of any potential benefits, and will dramatically reduce the number and geographic distribution of medical facilities in the State where women can access safe and legal abortion services.

3. These regulatory burdens include the "admitting privileges requirement," which provides, in relevant part, that "[a] physician performing or inducing an abortion must, on the date the abortion is performed or induced, have active admitting privileges at a hospital that is located not further than 30 miles from the location at which the abortion is performed or induced." Act, § 2 (codified at Tex. Health & Safety Code Ann. § 171.0031); 25 Tex. Admin Code §§139.53(c), 139.56(a).

4. They also include the "ASC requirement," which provides, in relevant part, that "the minimum standards for an abortion facility must be equivalent to the minimum standards adopted under [Texas Health & Safety Code] Section 243.010 for ambulatory surgical centers." Act, § 4 (codified at Tex. Health & Safety Code Ann. § 245.010(a)); 25 Tex. Admin. Code § 139.40.

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[1] A copy of the Act is attached hereto as Exhibit 1. The pages of the Texas Register providing notice of the proposed regulations and their adoption are attached hereto as Exhibit 2.

5. The Act was signed by Governor Rick Perry on July 18, 2013.

6. Initially scheduled to take effect on October 29, 2013, the admitting privileges requirement was the subject of a pre-enforcement, facial challenge by a coalition of abortion providers, including some of the Plaintiffs in this case. It was permanently enjoined by a judge of this Court on October 28, 2013, *Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott*, 951 F. Supp. 2d 891, 909 (W.D. Tex. 2013), but the U.S. Court of Appeals for the Fifth Circuit stayed that injunction on the evening of October 31, 2013, 734 F.3d 406, 419 (5th Cir. 2013), *motion to vacate denied*, 134 S. Ct. 506 (2013), and ultimately reversed the district court's judgment, ___ F.3d ___, 13-51008, 2014 WL 1257965 (5th Cir. Mar. 27, 2014). The Fifth Circuit expressly noted that "[l]ater as-applied challenges" could be brought to "deal with subsequent, concrete constitutional issues." *Id.* at * 2.

7. Here, Plaintiffs Whole Woman's Health and Dr. Lynn challenge the admitting privileges requirement as applied to the licensed abortion facility operated by Whole Woman's Health in McAllen (the "McAllen clinic"). The McAllen clinic is currently the only licensed abortion facility in the Rio Grande Valley. During the past ten years, over 14,000 abortions were performed at the McAllen clinic; only two of those patients needed to be transported from the clinic to a hospital. The McAllen clinic has not been able to provide abortion services since the admitting privileges requirement took effect.

8. Plaintiffs Nova Health Systems d/b/a Reproductive Services ("Reproductive Services") and Dr. Richter challenge the admitting privileges requirement as applied to the licensed abortion facility operated by Reproductive Services in El Paso (the "El Paso clinic"). The El Paso clinic is currently one of only two licensed abortion facilities located west of San Antonio. During the past ten years, over 17,000 abortions were performed at the El Paso clinic;

not one of those patients needed to be transported from the clinic to a hospital. Absent injunctive relief from the admitting privileges requirement, the El Paso clinic will be forced to cease providing abortion services after May 13, 2014, when Dr. Richter's temporary admitting privileges at an El Paso-area hospital are set to expire.

9. The ASC requirement is scheduled to take effect on September 1, 2014. *See* Act, § 4 (codified at Tex. Health & Safety Code Ann. § 245.010(a)).

10. All plaintiffs challenge the ASC requirement on its face.

11. In addition, Whole Woman's Health and Dr. Lynn challenge the ASC requirement as applied to the McAllen clinic, and Reproductive Services and Dr. Richter challenge the ASC requirement as applied to the El Paso clinic.

12. Prior to the passage of the Act, there were over three dozen licensed abortion clinics in Texas. Since the admitting privileges requirement has taken effect, that number has dropped significantly. If the ASC requirement is permitted to take effect, there will be fewer than ten abortion clinics in the State, all clustered in eastern metropolitan areas, with no clinics west or south of San Antonio.

II. JURISDICTION AND VENUE

13. Jurisdiction is conferred on this Court by 28 U.S.C. §§ 1331 and 1343(a)(3).

14. Plaintiffs' claims for declaratory and injunctive relief are authorized by 28 U.S.C. §§ 2201 and 2202, by Rules 57 and 65 of the Federal Rules of Civil Procedure, and by the general legal and equitable powers of this Court.

15. Venue is appropriate under 28 U.S.C. § 1391(b)(1) because some Defendants reside in this district.

III. PLAINTIFFS

16. Plaintiff Whole Woman's Health operates licensed abortion facilities in Austin, Fort

Worth, and San Antonio. In addition, it operates a licensed ASC in San Antonio. These medical facilities have provided high quality reproductive health care services, including abortion services, to Texas women for over a decade. Until the admitting privileges requirement took effect, Whole Woman's Health also operated licensed abortion facilities in Beaumont and McAllen. If the admitting privileges requirement were enjoined with respect to the McAllen clinic, Whole Woman's Health would immediately resume providing services at that location. Whole Woman's Health sues on behalf of itself and its patients.

17. Plaintiff Sherwood C. Lynn, Jr., M.D., is a board-certified obstetrician-gynecologist ("ob-gyn") licensed to practice medicine in the State of Texas. He has over 35 years of experience providing reproductive health care, including abortion care. He serves as the Medical Director of Whole Woman's Health's licensed abortion facility and ASC in San Antonio, and he seeks to provide abortion services at the McAllen clinic. Although he has admitting privileges at a hospital in San Antonio, no hospital within 30 miles of the McAllen clinic will grant him admitting privileges. Dr. Lynn sues on behalf of himself and his patients.

18. Plaintiff Abortion Advantage operates a licensed abortion facility in Dallas. It has provided high quality reproductive health care services, including abortion services, to Texas women for over 25 years. Abortion Advantage sues on behalf of itself and its patients.

19. Plaintiff Lamar Robinson, M.D., is an ob-gyn licensed to practice medicine in the State of Texas. He has over 28 years of experience providing reproductive health care, including abortion care. He currently serves as the Medical Director of Abortion Advantage. Dr. Robinson sues on behalf of himself and his patients.

20. Plaintiffs Austin Women's Health Center and Killeen Women's Health Center (collectively, the "Health Centers") operate licensed abortion facilities in Austin and Killeen,

respectively. These medical facilities have provided high quality reproductive health care services, including abortion services, to Texas women for over 35 years. The Health Centers sue on behalf of themselves and their patients.

21. Plaintiff Lendol L. "Tad" Davis, M.D., is a board-certified ob-gyn licensed to practice medicine in the State of Texas. He has over 35 years of experience providing reproductive health care, including abortion care. He serves as the Medical Director of Austin Women's Health Center and Killeen Women's Health Center. Dr. Davis sues on behalf of himself and his patients.

22. Plaintiff Nova Health Systems d/b/a Reproductive Services ("Reproductive Services") operates a licensed abortion facility in El Paso. The El Paso clinic has provided high-quality reproductive health care services, including abortion services, to Texas women for over 35 years. If the admitting privileges requirement is not enjoined prior to May 14, 2014, then the El Paso clinic will be forced to close on that date. Reproductive Services sues on behalf of itself and its patients.

23. Plaintiff Pamela J. Richter, D.O., is a board-eligible family medicine doctor licensed to practice medicine in the State of Texas. She has been providing reproductive health care, including abortion care, for over 20 years. She currently serves as Medical Director of the El Paso clinic. Dr. Richter has temporary admitting privileges at Foundation Surgical Hospital of El Paso, which will expire on May 13, 2014. No hospital within 30 miles of the El Paso clinic will grant Dr. Richter admitting privileges that are effective after May 13, 2014. She sues on behalf of herself and her patients.

IV. DEFENDANTS

24. Defendant David Lakey, M.D., is the Commissioner of the Texas Department of State Health Services ("the Department" or "DSHS"). The Department is generally charged with

enforcement of the provisions of the Act challenged here. Commissioner Lakey is sued in his official capacity and may be served with process at 1100 West 49th Street, Austin, Texas 78756-3199.

25. Defendant Mari Robinson is the Executive Director of the Texas Medical Board ("the Board"). The Board is empowered to undertake disciplinary proceedings against a physician who violates certain requirements of the Act. Ms. Robinson is sued in her official capacity and may be served with process at 333 Guadalupe, Tower 3, Suite 610, Austin, Texas 78701.

26. Defendant David Escamilla is the County Attorney for Travis County. He is responsible for prosecuting misdemeanors, including criminal violations of the Act, occurring in Travis County. He is sued in his official capacity and may be served with process at 314 West 11th Street, Room 300, Austin, Texas 78701.

27. Defendant Jaime Esparza is the District Attorney for El Paso County. He is responsible for prosecuting misdemeanors, including criminal violations of the Act, occurring in El Paso County. He is sued in his official capacity and may be served with process at El Paso County Courthouse, 500 East San Antonio Avenue, Room 201, El Paso, Texas 79901-2419.

28. Defendant René Guerra is the Criminal District Attorney for Hidalgo County. He is responsible for prosecuting misdemeanors, including criminal violations of the Act, occurring in Hidalgo County. He is sued in his official capacity and may be served with process at 100 North Closner Blvd., Room 303, Edinburg, Texas 78539-3563.

29. Defendant James E. Nichols is the County Attorney for Bell County. He is responsible for prosecuting misdemeanors, including criminal violations of the Act, occurring in

Bell County. He is sued in his official capacity and may be served with process at the Bell County Justice Center, 1201 Huey Road, Belton, Texas 76513.

30. Defendant Susan D. Reed is the Criminal District Attorney for Bexar County. She is responsible for prosecuting misdemeanors, including criminal violations of the Act, occurring in Bexar County. She is sued in her official capacity and may be served with process at 101 West Nueva Street, 4th Floor, San Antonio, Texas 78205-3406.

31. Defendant Joe Shannon, Jr. is the Criminal District Attorney for Tarrant County. He is responsible for prosecuting misdemeanors, including criminal violations of the Act, occurring in Tarrant County. He is sued in his official capacity and may be served with process at the Tim Curry Criminal Justice Center, 401 West Belknap Street, Fort Worth, Texas 76196-0201.

32. Defendant Craig Watkins is the Criminal District Attorney for Dallas County. He is responsible for prosecuting misdemeanors, including criminal violations of the Act, occurring in Dallas County. He is sued in his official capacity and may be served with process at 133 North Riverfront Boulevard, LB 19, Dallas, Texas 75207.

V. FACTUAL ALLEGATIONS

A. The Admitting Privileges Requirement

Overview

33. The admitting privileges requirement provides, *inter alia*, that "[a] physician performing or inducing an abortion must, on the date the abortion is performed or induced, have active admitting privileges at a hospital that is located not further than 30 miles from the location at which the abortion is performed or induced." Act, § 2 (codified at Tex. Health & Safety Code Ann. § 171.0031); 25 Tex. Admin. Code §§ 139.53(c), 139.56(a).

34. Any physician who violates this requirement commits a Class A misdemeanor offense. The physician is also subject to license revocation, and the abortion facility at which the

abortion is performed is subject to license revocation. *See* Tex. Health & Safety Code § 171.0031; Tex. Occ. Code § 164.055(a); 25 Tex. Admin. Code § 139.32.

35. Prior to the enactment of the admitting privileges requirement, Texas law required that: "A licensed abortion facility shall have a readily accessible written protocol for managing medical emergencies and the transfer of patients requiring further emergency care to a hospital. The facility shall ensure that the physicians who practice at the facility have admitting privileges or have a working arrangement with a physician(s) who has admitting privileges at a local hospital in order to ensure the necessary back up for medical complications." 25 Tex. Admin. Code § 139.56(a) (2012).

36. This regulation had been in effect since 2009 and had never been challenged in litigation.

37. Both the McAllen clinic and the El Paso clinic were in compliance with this regulation when the admitting privileges requirement was enacted.

38. Both the McAllen clinic and the El Paso clinic continue to have a readily accessible written protocol for managing medical emergencies and the transfer of patients requiring further emergency care to a hospital.

39. Both the McAllen clinic and the El Paso clinic continue to ensure that the physicians who practice at the respective facilities have a working arrangement with at least one physician who has admitting privileges at a local hospital.

40. The admitting privileges requirement effectively gives local hospitals veto power over the McAllen clinic's ability to provide abortion care to women in the Rio Grande Valley and the El Paso clinic's ability to provide abortion care to women in West Texas. Hospitals in Texas have broad discretion to set the criteria for granting admitting privileges and can thereby

grant or refuse privileges on the basis of idiosyncratic rules and regulations. *See* Tex. Health & Safety Code § 241.101.

41. Hospitals within Texas have varying requirements for admitting privileges. Some require a certain number of patient admissions each year; some require physicians to reside within a certain distance from the hospital; others limit admitting privileges to physicians who are directly employed by or under contract with the hospital; while others require a physician to designate an alternate physician with admitting privileges at the hospital who is willing to co-sign the application. These criteria, unrelated to a physician's ability to provide high-quality abortion care, may preclude physicians from obtaining admitting privileges at a local hospital.

The McAllen Clinic's Inability to Comply with the Admitting Privileges Requirement

42. After the admitting privileges requirement was enacted, four physicians affiliated with Whole Woman's Health, including Dr. Lynn, sought to obtain admitting privileges at a hospital within 30 miles of the McAllen clinic. Each physician is a board-certified ob-gyn and experienced abortion provider, and three of the four have admitting privileges at hospitals in other parts of the State.

43. None was able to obtain admitting privileges at a hospital within 30 miles of the McAllen clinic.

44. There are eight hospitals located within 30 miles of the McAllen clinic. Each of them requires, as a condition of granting admitting privileges, that an application be signed by a "designated alternate" physician willing to attend to the applicant's patients when the applicant is unavailable. The designated alternate physician must already have admitting privileges at the hospital. If an application is not signed by a designated alternate physician, it will not be considered, regardless of whether the applicant meets the hospital's other requirements.

45. Only one eligible physician was willing to serve as a designated alternate physician for the physicians affiliated with the McAllen clinic, and this physician only has privileges at one area hospital: Doctors Hospital at Renaissance. The other physicians approached by the clinic expressed concern about retaliation from the hospitals at which they had admitting privileges and the possibility that their privileges would be revoked or discontinued if they facilitated the application of a known abortion provider.

46. Thus, the physicians affiliated with the McAllen clinic were only able to satisfy the application criteria for Doctors Hospital at Renaissance. At this hospital, the first step in applying for admitting privileges is to submit a written request for an application.

47. In September 2013, all four physicians submitted such requests.

48. In November or December 2013, each of the physicians received a letter in response stating that, based on the recommendation of the hospital's Credentials Committee, the Medical Executive Committee was denying the physician's request for an application for privileges. Each letter further stated that the Board of Governors had considered the request and determined not to extend an application "as authorized under the Bylaws and Rules and Regulations of the Medical Staff for the Hospital" and that the "decision of the Governing Body was not based on clinical competence consideration." The letters provided no other explanation as to why each of the four physicians was denied the opportunity to apply for admitting privileges at the hospital.

49. Whole Woman's Health has been unable to recruit a physician with admitting privileges at a hospital within 30 miles of the McAllen clinic to provide abortion services at the clinic.

Challenges Facing Women in the Rio Grande Valley Who Seek Abortion Care

50. In 2010, the latest year for which DSHS data is available, 2,845 women from the Rio Grande Valley had abortions in Texas. *See* Texas Dep't of State Health Servs., Table 35: Induced Terminations of Pregnancy by County of Residence and Race/Ethnicity, http://www.dshs.state.tx.us/chs/vstat/vs10/t35.shtm (last accessed April 1, 2014).

51. The McAllen clinic is currently the only licensed abortion facility in the Rio Grande Valley.

52. Absent as-applied relief from the Court, the McAllen clinic will be unable to resume its provision of medical services, leaving women in the Rio Grande Valley without an abortion provider in their region. The closest abortion provider would be in Corpus Christi, which is over 150 miles from McAllen.

53. For many women in the Rio Grande Valley, a 150-mile distance is a substantial obstacle to accessing abortion care.

54. The Rio Grande Valley is comprised of four counties along the eastern border of Texas and Mexico: Starr County, Hidalgo County, Willacy County, and Cameron County. It has a population of approximately 1.3 million.[2]

55. There are some urban centers in the Rio Grande Valley—for example, in McAllen, Harlingen, and Brownsville—but much of the region is rural. The rural areas include unincorporated towns known as *colonias*, which are more prevalent in the Rio Grande Valley than anywhere else in the United States. *Colonias* can be hard to reach because they often do not

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[2] U.S. Census Bureau, Population Div., Annual Estimates of the Resident Population: Apr. 1, 2010 to July 1, 2012 (2010), http://factfinder2.census.gov/bkmk/table/1.0/en/PEP/2012/PEPANNRES/0500000US48061|0500000US48215|0500000US48427|0500000US48489 (last accessed April 1, 2014).

appear on maps. In many *colonias*, residents have a difficult time accessing basic public services, including water, electricity, sewage and drainage systems and paved roads. *See* Federal Reserve Bank of Dallas, *Texas Colonias: A Thumbnail Sketch of the Conditions, Issues, Challenges and Opportunities* (2007), http://www.dallasfed.org/assets/documents/cd/pubs/colonias.pdf.

56. The vast majority of people living in the Rio Grande Valley are Latino.[3] Latinos in Texas are three times as likely to live in poverty as white people.[4] Overall, approximately one-third of the population in the Rio Grande Valley lives in poverty.[5]

57. Nearly half of the population has less than a ninth-grade education,[6] and the region has a high proportion of farmworkers and seasonal migrant workers. Employment outside of the agricultural field, especially for uneducated and unskilled workers, is scarce. As a result, unemployment in the Rio Grande Valley is higher than in the rest of the State.[7]

58. Most of the Rio Grande Valley is designated as a medically underserved area by

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[3] U.S. Census Bureau, Population Div., ACS Demographic and Housing Estimates, 2009-2011 (2007-2011), http://factfinder2.census.gov/bkmk/table/1.0/en/ACS/11_5YR/DP05/0500000US48061|0500000US48215|0500000US48427|0500000US48489 (last accessed April 1, 2014).

[4] KFF, Poverty Rate by Race/Ethnicity (2010-2011), http://kff.org/other/state-indicator/poverty-rate-by-raceethnicity/ (last accessed April 1, 2014).

[5] U.S. Census Bureau, Poverty Status in the Past 12 Months (2009-2011), http://factfinder2.census.gov/bkmk/table/1.0/en/ACS/11_3YR/S1701/0500000US48061|0500000US48215|0500000US48427|0500000US48489 (last accessed April 1, 2014).

[6] U.S. Census Bureau, Educational Attainment –2009-2011 American Community Survey 3-year Estimates, 2009 – 2011 (2009-2011), http://factfinder2.census.gov/bkmk/table/1.0/en/ACS/11_3YR/S1501/0500000US48061|0500000US48215|0500000US48427|0500000US48489 (last accessed April 1, 2014).

[7] U.S. Census Bureau, Employment Status – 2009-2011 American Community Survey 3-Year Estimates, 2009–2011 (2009-2011), http://factfinder2.census.gov/bkmk/table/1.0/en/ACS/11_5YR/S2301/0400000US48|0500000US48061|0500000US48215|0500000US48427|0500000US48489 (last accessed April 1, 2014).

the federal government because the population has a shortage of health services and faces numerous socioeconomic barriers to health care access. *See* Texas Dep't of State Health Servs., *MUA and MUP Designations*, http://www.dshs.state.tx.us/CHS/hprc/MUAlist.shtm (last updated April 10, 2012).

59. Women living in the Rio Grande Valley face many challenges in accessing reproductive health care services generally and abortion care specifically. These challenges include poverty, lack of service providers, lack of access to transportation, need for childcare, and inability to take time off from work.

60. Many women in the Rio Grande Valley rely on State-subsidized health clinics for preventative reproductive health care, such as pap smears and contraceptives. In 2011, the number of these clinics was dramatically reduced as a result of changes in State law. Few of them remain in the Rio Grande Valley, and demand for their services now exceeds their capacity. As a result, women must endure long waits for appointments, and some simply live too far from the nearest clinic to access services. The reduction in State-subsidized clinics has had a devastating impact on women's ability to access preventative reproductive health care.

61. As a result, it is now much harder for women in the Rio Grande Valley to avoid unwanted pregnancies. Many women do not want to have additional children, but they no longer have access to affordable contraceptives and cannot afford the cost of a sterilization procedure. *See* Center for Reproductive Rights & National Latina Institute for Reproductive Health, *Nuestra Voz, Nuestra Salud, Nuestro Texas: The Fight for Women's Reproductive Health in the Rio Grande Valley* (2013), *available at* http://www.nuestrotexas.org/ pdf/NT-spread.pdf (last accessed April 1, 2014).

62. The obstacles preventing women in the Rio Grande Valley from accessing

preventative services at non-local clinics will likewise prevent women from accessing abortion services at non-local clinics.

63. As a result, women in the Rio Grande Valley are left with few options for controlling the number and spacing of their children.

The El Paso Clinic's Inability to Comply with the Admitting Privileges Requirement after May 13, 2014

64. After the admitting privileges requirement was enacted, Dr. Richter sought to obtain admitting privileges at a hospital within 30 miles of the El Paso Clinic. She is the Medical Director of the clinic and the only physician who provides abortion services there.

65. In addition to her work at the El Paso clinic, Dr. Richter also works for the State of Texas. She serves as a staff physician at the state supported living center ("State Center") in El Paso operated by the Texas Department of Aging and Disability Services ("DADS"). The State Center provides 24-hour residential services, comprehensive behavioral treatment services, vocational and rehabilitation services, and general health care services to people with intellectual and developmental disabilities.

66. Previously, from 1990 to 2001, Dr. Richter maintained a family medicine practice in El Paso.

67. From January 1990 to May 2003, Dr. Richter had admitting privileges at Del Sol Medical Center, which is located within 30 miles of the El Paso clinic. One of the criteria for maintaining admitting privileges at that hospital is admitting a minimum number of patients to the hospital each year. After Dr. Richter closed her private practice in 2001, she was no longer able to admit the requisite number of patients to the hospital. As a result, when her privileges came up for renewal in 2003, they were not renewed.

68. Subsequent to the enactment of the admitting privileges requirement, one hospital

within 30 miles of the El Paso clinic granted Dr. Richter temporary admitting privileges, effective through May 13, 2014. To date, no hospital within 30 miles of the El Paso clinic has been willing to grant Dr. Richter admitting privileges that are effective after May 13, 2014.

69. Reproductive Services has been unable to recruit a physician with admitting privileges at a hospital within 30 miles of the El Paso clinic to provide abortion services at the clinic.

Challenges Facing Women in West Texas Who Seek Abortion Care

70. Currently, the El Paso clinic is one of only two licensed abortion facilities west of San Antonio.

71. Absent as-applied relief from the Court, the El Paso clinic will be forced to stop providing abortion services after May 13, 2014, leaving a huge region of the State with only a single abortion provider. Women unable to get an appointment with that provider would have to travel to San Antonio to obtain abortion services. San Antonio is over 550 miles from El Paso.

72. For many women in West Texas, a 550-mile distance is a substantial obstacle to accessing abortion care.

73. West Texas is a vast region with numerous, largely rural, counties.

74. The "Trans-Pecos" region of West Texas is comprised of nine counties: Brewster, Culberson, El Paso, Hudspeth, Jeff Davis, Pecos, Presidio, Reeves, and Terrell. Approximately 877,000 people live in these counties, and over 80% of them are Latino. The region has high levels of poverty: 24% of the population as a whole, and 27% of the Latino population, live below the poverty line. Nearly one-third of the population has a household income less than $25,000 a year. *See* Institute for Demographic and Socioeconomic Research, TxDOT Data Analysis Tool, at http://idserportal.utsa.edu/txDoT/OneStop/Output.aspx?id=8137&tp

=single&l=11 (aggregate data for Brewster, Culberson, El Paso, Hudspeth, Jeff Davis, Pecos, Presidio, Reeves, and Terrell counties) (last accessed April 1, 2014).

75. Most of the Trans-Pecos region is designated as a medically underserved area by the federal government. *See* Texas Dep't of State Health Servs., *MUA and MUP Designations*, http://www.dshs.state.tx.us/CHS/hprc/MUAlist.shtm (last updated April 10, 2012).

76. In 2010, the latest year for which DSHS data is available, 2,278 women in the Trans-Pecos region had abortions in Texas; 2,216 of them were from El Paso County. *See* Texas Dep't of State Health Servs., Table 35: Induced Terminations of Pregnancy by County of Residence and Race/Ethnicity, http://www.dshs.state.tx.us/chs/vstat/vs10/t35.shtm (last accessed April 1, 2014).

77. If the El Paso clinic closes, the other licensed abortion facility in the region would not be able to meet patient demand for services. As a result, some women would have to endure long waits for an appointment, and other women would be turned away.

Safety of Abortion Care at the McAllen and El Paso Clinics

78. As applied to the McAllen and El Paso clinics, the admitting privileges requirement does not advance the State's interest in women's health.

79. There are generally two methods of performing abortions in the United States: surgical abortion, which involves the use of medical instruments to evacuate the contents of the uterus; and medical abortion, which involves the administration of medications that cause the termination of a pregnancy.

80. Both types of abortion are extremely safe. The mortality rate from use of penicillin is roughly three times higher than the mortality rate from abortion, and the mortality rate from childbirth is roughly 14 times higher. Serious complications from abortion are rare and hardly

ever require hospitalization.

81. The types of abortions performed at the McAllen and El Paso clinics are among the safest of all abortion procedures.

82. While abortion is extremely safe throughout pregnancy, a woman's risk of experiencing an abortion-related complication increases with the gestational age of her pregnancy. Therefore, earlier abortions have less risk of complications.

83. The McAllen clinic provided abortion services prior to 16 weeks of pregnancy. The highest level of sedation offered to patients at the McAllen clinic was moderate sedation/analgesia, also known as conscious sedation.

84. The El Paso clinic provides abortion services prior to 16 weeks of pregnancy. The highest level of sedation offered to patients at the El Paso clinic is minimal sedation/analgesia.

85. During the past ten years, the McAllen clinic only had to transfer two patients from the clinic to a hospital. Over 14,000 abortions were performed there during that period.

86. During the past ten years, the El Paso clinic has not had to transfer any patients from the clinic to the hospital. Over 17,000 abortions were performed there during that period.

Accepted Medical Standards for Outpatient Practice

87. The admitting privileges requirement is inconsistent with accepted medical standards.

88. In Texas, physicians and other licensed medical practitioners provide a variety of surgical and non-surgical procedures in outpatient settings, some of which are comparable in safety to abortion and some of which entail far greater risks than abortion. Yet only physicians providing abortion services are required to have admitting privileges at a local hospital.

89. Moreover, Texas law does not require any type of medical facility besides abortion

clinics to employ physicians with admitting privileges as a condition of licensure. The regulations governing freestanding emergency medical care facilities and end stage renal disease facilities require only that a facility have a transfer agreement with a hospital. *See* 25 Tex. Admin. Code §§ 131.52(s), 131.66, 131.67 (freestanding emergency medical care facilities); 25 Tex. Admin Code § 117.45(b)(4) (end stage renal disease facilities). The regulations governing ambulatory surgical centers ("ASCs") permit a facility to maintain a transfer agreement with a hospital as an alternative to employing physicians with admitting privileges. *See* 25 Tex. Admin. Code § 135.4(c)(11)(B). And, the regulations governing birthing centers and special care facilities for the treatment of terminally ill patients require only that a facility has a plan for managing patient emergencies. *See* 25 Tex. Admin. Code § 137.46 (birthing centers); 25 Tex. Admin. Code § 125.32(a)(3) (special care facilities).

90. Moreover, the nation's leading medical associations and accreditation bodies—including the American Medical Association ("AMA"), the American College of Obstetricians and Gynecologists ("ACOG"), the American College of Surgeons ("ACS"), the American Society of Anesthesiologists ("ASA"), the Accreditation Association for Ambulatory Health Care ("AAAHC"), the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF"), and the Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations or "JCAHO")—recognize that admitting privileges at a local hospital are not required for the safe performance of outpatient procedures.

91. In connection with the facial challenge to the admitting privileges requirement, the AMA and ACOG filed a brief in the Fifth Circuit explaining that admitting privileges at a local hospital are not required for the safe performance of abortion procedures in outpatient settings and are not part of the standard of care. *See* Br. of *Amicus Curiae* Am. Coll. of Obstetricians &

Gynecologists and Am. Med. Ass'n, *Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott*, ___ F.3d ___ (5th Cir. Mar. 27, 2014) (No. 13-51008), 2013 WL 6837500.

92. ACOG, ACS, and ASA have all issued guidelines concerning outpatient surgery. None requires that physicians performing outpatient surgery have admitting privileges at a local hospital.

93. The National Abortion Federation ("NAF") Clinical Policy Guidelines do not require physicians performing or supervising abortions to have admitting privileges at a local hospital.

94. Of the three major national organizations that accredit healthcare facilities—AAAHC, AAAASH, and the Joint Commission—none requires an outpatient facility to employ physicians with admitting privileges as a condition of accreditation.

95. In the rare event that a patient who has had an abortion requires hospitalization, the quality of care that she receives at the hospital will not be affected by whether her abortion provider has admitting privileges there. Upon the patient's arrival at the hospital via ambulance, an emergency room physician will evaluate the patient and consult with other specialists at the hospital as needed. The patient may require admission to the hospital, or she may simply be treated in the emergency room and then released. Either way, continuity of care can be maintained by direct telephone communication between the abortion provider and the emergency room physician, regardless of whether the abortion provider has admitting privileges at the hospital.

96. Physicians practicing in outpatient settings often refer patients for treatment at hospitals at which they do not have admitting privileges. This is standard medical practice.

97. In fact, the trend in medicine is toward bifurcation of outpatient practice and

hospital-based practice, such that physicians are increasingly specializing in one type of practice setting or the other. Coordination and continuity of care of a patient that is transferred from an outpatient setting to a hospital are achieved through communication between the physician referring the patient to the hospital and the physician treating the patient at the hospital.

Futility of the Admitting Privileges Requirement As Applied to the McAllen and El Paso Clinics

98. Many complications from abortion arise only after a patient has left the clinic and returned home. This is almost always true of complications arising from medical abortions because the medications used to induce those abortions take time to exert their effects.

99. If a patient experiences a serious complication after she has left the clinic and returned home, the appropriate course of action would be for her to go to the nearest emergency room.

100. By forcing the McAllen and El Paso clinics to close, the admitting privileges requirement would require all women in the Rio Grande Valley and many women in West Texas to travel hundreds of miles from their homes to access abortion services, guaranteeing that each of those women would be hundreds of miles from the facility at which her abortion was performed if she experienced a serious complication after she returned home. Thus, the admitting privileges requirement does not make it more likely that women from the Rio Grande Valley or West Texas who experience abortion-related complications would be treated at a hospital where their abortion-provider has admitting privileges.

101. As applied to the McAllen and El Paso clinics, the admitting privileges requirement is therefore futile.

Harms to Women in the Rio Grande Valley and West Texas Caused by the Admitting Privileges Requirement

102. By sharply restricting their access to safe and legal abortion services, the

admitting privileges requirement puts the health of women in the Rio Grande Valley and West Texas at risk.

103. As a result of the admitting privileges requirement, some women will be delayed in accessing abortion care, some will be forced to carry an unwanted pregnancy to term, and some will attempt to self-induce abortion. Each of these courses of action is riskier than having an abortion at the McAllen or El Paso clinic without delay.

104. Although abortion is very safe throughout pregnancy, the risks of experiencing an abortion-related complication increase with gestational age. As a result, women who are delayed in accessing abortion services are subject to greater health risks than women who are not delayed.

105. Women who are unable to obtain abortion services must instead carry their pregnancies to term and give birth. These women are also subject to increased health risks because the risk of death from childbirth is 14 times higher than the risk of death from abortion.

106. Additionally, some women who cannot access legal abortion services will instead attempt self-induction of abortion. Prior to the enactment of the admitting privileges requirement, self-abortion was already practiced by women in the Rio Grande Valley and West Texas who were desperate to end a pregnancy but did not have the means to obtain abortion services at a licensed clinic.

107. During the four-month period of time when the McAllen clinic was open but not providing abortion services, clinic staff members encountered a larger number of prospective patients who had attempted self-abortion. These women utilized a variety of methods, including herbal teas, douches, physical trauma to the abdomen, and medications purchased on the black market.

108. Many women are aware that misoprostol can be used to induce an abortion. This medication is available over-the-counter in Mexico and is widely trafficked in the Rio Grande Valley and West Texas, which both border Mexico. It is also sold on the internet.

109. Like any medication obtained on the black market, misoprostol obtained in this way can be counterfeit, inappropriate for a particular woman's medical needs, or used incorrectly because a woman does not have adequate information.

110. Self-induction of abortion is less safe than abortion performed by a trained medical practitioner.

111. In addition to abortion services, the McAllen clinic provided other gynecological and family planning services, such as diagnosis and treatment of sexually transmitted infections, contraceptive counseling and provision, pregnancy testing, and diagnosis and treatment of abnormal pap smears. The McAllen clinic also provided assistance, including counseling and referrals, to pregnant women interested in adoption.

112. Without the revenue generated from providing abortion services, the McAllen clinic was unable to sustain the remainder of its practice after the admitting privileges requirement took effect. As a result, it is no longer able to provide these other services to women in the Rio Grande Valley.

113. In addition to abortion services, the El Paso clinic provides other gynecological and family planning services, such as annual well-woman examinations, which include pelvic examinations, pap smears, and breast examinations; testing and treatment for STIs; provision of contraceptives; and pregnancy testing. The El Paso clinic also works with an affiliated adoption agency to help interested women place their children for adoption.

114. If the El Paso clinic is forced by the admitting privileges requirement to stop

providing abortion services, it would have to close, and would therefore be unable to provide these other services to women in West Texas.

B. The ASC Requirement

115. The ASC requirement provides that "[o]n or after September 1, 2014, the minimum standards for an abortion facility must be equivalent to the minimum standards . . . for ambulatory surgical centers." Act, § 4 (codified at Tex. Health & Safety Code Ann. § 245.010(a)); 25 Tex. Admin. Code § 139.40.

116. Failure to comply with those standards may give rise to criminal, civil, and administrative penalties. Tex. Health & Safety Code Ann. §§ 245.014 (criminal penalties), 245.015 (civil penalties), 245.017 (administrative penalties). It may also result in the denial, suspension, probation, or revocation of an abortion facility license. Tex. Health & Safety Code Ann. § 245.012.

117. Independently of the Act, Texas law requires that "[a]n abortion of a fetus age 16 weeks or more may be performed only at an ambulatory surgical center or hospital licensed to perform the abortion." Tex. Health & Safety Code Ann. §171.004. Plaintiffs do not challenge this requirement, which would remain in effect if the Act and its implementing regulations were enjoined.

118. The ASC requirement will force all licensed abortion facilities to meet detailed physical plant requirements, which specify, among other things, hallway widths; ceiling heights; area of various rooms; floor, wall, and ceiling finishes; HVAC system requirements; and number and configuration of bathrooms, janitorial closets, and parking spaces. *See* 25 Tex. Admin. Code § 139.40 (incorporating by reference, *inter alia*, 25 Tex. Admin. Code § 135.52).

119. An ASC is far more expensive to acquire and operate than a health care facility that meets existing abortion facility standards.

120. The licensed abortion facilities operated by Whole Woman's Health in Austin, Fort Worth, and San Antonio do not meet the minimum standards for ASCs. Likewise, the McAllen clinic does not meet the minimum standards for ASCs.

121. The licensed abortion facility operated by Abortion Advantage does not meet the minimum standards for ASCs.

122. The licensed abortion facilities operated by the Health Centers do not meet the minimum standards for ASCs.

123. The El Paso clinic does not meet the minimum standards for ASCs.

124. If the ASC requirement is permitted to take effect, there would be fewer than ten facilities in the State that are permitted to provide abortion services ("abortion-care ASCs"). Those facilities would be clustered in eastern metropolitan areas. There would be no abortion-care ASCs west or south of San Antonio.

125. The closest abortion-care ASC to McAllen would be in San Antonio, over 235 miles away. The closest abortion-care ASC to El Paso would also be in San Antonio, over 550 miles away.

126. Requiring licensed abortion facilities to meet the minimum standards for ASCs will not enhance the safety of abortion procedures. It will only reduce the availability of abortion services, and thereby threaten the health of women seeking abortion services.

127. Apart from abortion procedures, Texas law does not require any other outpatient surgical or medical procedures to be performed in an ASC.

128. Many procedures commonly performed in outpatient settings are comparable to surgical abortion in terms of risks, invasiveness, instrumentation, and duration. These include gynecological procedures such as dilation and curettage ("D&C") and non-gynecological

procedures such as colonoscopy. Texas law does not require the facilities in which these procedures are performed to meet the minimum standards for ASCs.

129. Procedures that are more complex than abortion and entail greater risks of morbidity and mortality are also commonly performed in outpatient settings, including gynecological procedures such as laparoscopy and vaginal hysterectomy and non-gynecological procedures such as plastic surgery and bariatric surgery. These procedures are usually performed while the patient is under general anesthesia, which by itself is much riskier than abortion. Texas law does not require the facilities in which these procedures are performed to meet the minimum standards for ASCs.

130. Moreover, Texas law does not require outpatient birthing centers to meet the minimum standards for ASCs. *See* Tex. Health & Safety Code Ann. § 244.010; 25 Tex. Admin Code §§ 137.1-137.55. But childbirth entails far more medical risks than abortion. As stated above, the risk of death from childbirth is approximately 14 times higher than the risk of death from abortion.

131. Certain characteristics of surgical abortion procedures render many of the minimum standards for ASCs inappropriate. For example, like other surgical procedures involving entry into the respiratory, alimentary, genital, or urinary tracts, surgical abortion procedures involve a clean-contaminated surgical site. Further, surgical abortion procedures do not entail an incision into the body; instead, they entail insertion of instruments into a body cavity through a natural orifice. In this respect, surgical abortion is analogous to insertion of a catheter.

132. Medical abortion does not involve surgery of any kind. As practiced in Texas, it entails the oral administration of medications—*i.e.*, the patient merely swallows a series of

tablets.

133. The ASC requirement will not advance the State's interest in women's health.

134. The ASC requirement will not increase the safety of surgical abortion.

135. The ASC requirement will not increase the safety of medical abortion.

136. By reducing the number and geographic distribution of abortion providers in Texas, the ASC requirement will place substantial obstacles in the path of Texas women seeking abortion services and will expose those women to increased health risks.

137. These obstacles and risks will be greatest for women living in the Rio Grande Valley and West Texas.

CLAIMS FOR RELIEF

COUNT I
(Undue Burden/Admitting Privileges Requirement)

138. The allegations of paragraphs 1 through 137 are incorporated as though fully set forth herein.

139. As applied to the McAllen clinic, the admitting privileges requirement—standing alone and in conjunction with burdens imposed by other provisions of Texas law—imposes an undue burden on the right of women in the Rio Grande Valley to terminate a pregnancy prior to viability in violation of the Due Process Clause of the Fourteenth Amendment.

140. As applied to the El Paso clinic, the admitting privileges requirement—standing alone and in conjunction with burdens imposed by other provisions of Texas law—imposes an undue burden on the right of women in West Texas to terminate a pregnancy prior to viability in violation of the Due Process Clause of the Fourteenth Amendment.

COUNT II
(Equal Protection/Admitting Privileges Requirement)

141. The allegations of paragraphs 1 through 140 are incorporated as though fully set

forth herein.

142. As applied to the McAllen clinic, the admitting privileges requirement denies equal protection of the laws to Whole Woman's Health, Dr. Lynn, and their patients in the Rio Grande Valley in violation of the Equal Protection Clause of the Fourteenth Amendment.

143. As applied to the El Paso clinic, the admitting privileges requirement denies equal protection of the laws to Reproductive Services, Dr. Richter and their patients in West Texas in violation of the Equal Protection Clause of the Fourteenth Amendment.

COUNT III
(Unlawful Delegation/Admitting Privileges Requirement)

144. The allegations of paragraphs 1 through 143 are incorporated as though fully set forth herein.

145. The admitting privileges requirement improperly delegates lawmaking authority to hospitals located within 30 miles of the McAllen clinic in violation of the Due Process Clause of the Fourteenth Amendment.

146. The admitting privileges requirement improperly delegates lawmaking authority to hospitals located within 30 miles of the El Paso clinic in violation of the Due Process Clause of the Fourteenth Amendment.

COUNT IV
(Arbitrary & Unreasonable State Action/Admitting Privileges Requirement)

147. The allegations of paragraphs 1 through 146 are incorporated as though fully set forth herein.

148. As applied to the McAllen clinic, the admitting privileges requirement constitutes arbitrary and unreasonable State action in violation of the Due Process Clause of the Fourteenth Amendment.

149. As applied to the provision of medical abortion at the McAllen clinic, the

admitting privileges requirement constitutes arbitrary and unreasonable State action in violation of the Due Process Clause of the Fourteenth Amendment.

150. As applied to the El Paso clinic, the admitting privileges requirement constitutes arbitrary and unreasonable State action in violation of the Due Process Clause of the Fourteenth Amendment.

151. As applied to the provision of medical abortion at the El Paso clinic, the admitting privileges requirement constitutes arbitrary and unreasonable State action in violation of the Due Process Clause of the Fourteenth Amendment.

COUNT V
(Undue Burden/ASC Requirement)

152. The allegations of paragraphs 1 through 151 are incorporated as though fully set forth herein.

153. The ASC requirement—standing alone and in conjunction with burdens imposed by other provisions of Texas law—imposes an undue burden on the right of women in Texas to terminate a pregnancy prior to viability in violation of the Due Process Clause of the Fourteenth Amendment.

154. As applied to the McAllen clinic, the ASC requirement—standing alone and in conjunction with burdens imposed by other provisions of Texas law—imposes an undue burden on the right of women in the Rio Grande Valley to terminate a pregnancy prior to viability in violation of the Due Process Clause of the Fourteenth Amendment.

155. As applied to the El Paso clinic, the ASC requirement—standing alone and in conjunction with burdens imposed by other provisions of Texas law—imposes an undue burden on the right of women in West Texas to terminate a pregnancy prior to viability in violation of the Due Process Clause of the Fourteenth Amendment.

COUNT VI
(Equal Protection/ASC Requirement)

156. The allegations of paragraphs 1 through 155 are incorporated as though fully set forth herein.

157. The ASC requirement denies equal protection of the laws to Plaintiffs and their patients in violation of the Equal Protection Clause of the Fourteenth Amendment.

COUNT IV
(Arbitrary & Unreasonable State Action/ASC Requirement)

158. The allegations of paragraphs 1 through 157 are incorporated as though fully set forth herein.

159. The ASC requirement constitutes arbitrary and unreasonable State action in violation of the Due Process Clause of the Fourteenth Amendment.

160. As applied to the provision of medical abortion, the ASC requirement constitutes arbitrary and unreasonable State action in violation of the Due Process Clause of the Fourteenth Amendment.

REQUEST FOR RELIEF

Plaintiffs respectfully request that this Court:

A. Issue a declaratory judgment that the admitting privileges requirement is unconstitutional and unenforceable:

a. as applied to the McAllen clinic; and/or

b. as applied to the provision of medical abortion at the McAllen clinic; and/or

c. as applied to the El Paso clinic; and/or

d. as applied to the provision of medical abortion at the El Paso clinic; and/or

B. Issue a declaratory judgment that the ASC requirement is unconstitutional and unenforceable:

a. on its face; and/or

b. as applied to the provision of medical abortion; and/or

c. as applied to the McAllen clinic; and/or

d. as applied to the El Paso clinic; and/or

C. Permanently enjoin Defendants and their employees, agents, and successors in office from enforcing the admitting privileges requirement:

a. as applied to the McAllen clinic; and/or

b. as applied to the provision of medical abortion at the McAllen clinic; and/or

c. as applied to the El Paso Clinic; and/or

d. as applied to the provision of medical abortion at the El Paso clinic; and/or

D. Permanently enjoin Defendants and their employees, agents, and successors in office from enforcing the ASC requirement:

a. on its face; and/or

b. as applied to the provision of medical abortion; and/or

c. as applied to the McAllen clinic; and/or

d. as applied to the El Paso clinic; and/or

E. Grant Plaintiffs attorney's fees and costs pursuant to 42 U.S.C. § 1988; and/or

F. Grant such other and further relief as the Court may deem just, proper, and equitable.

Dated: April 2, 2014

Respectfully submitted,

____

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Exhibit 1

1 AN ACT
2 relating to the regulation of abortion procedures, providers, and
3 facilities; providing penalties.
4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:
5 SECTION 1. (a) The findings indicate that:
6 (1) substantial medical evidence recognizes that an
7 unborn child is capable of experiencing pain by not later than 20
8 weeks after fertilization;
9 (2) the state has a compelling state interest in
10 protecting the lives of unborn children from the stage at which
11 substantial medical evidence indicates that these children are
12 capable of feeling pain;
13 (3) the compelling state interest in protecting the
14 lives of unborn children from the stage at which substantial
15 medical evidence indicates that an unborn child is capable of
16 feeling pain is intended to be separate from and independent of the
17 compelling state interest in protecting the lives of unborn
18 children from the stage of viability, and neither state interest is
19 intended to replace the other; and
20 (4) restricting elective abortions at or later than 20
21 weeks post-fertilization, as provided by this Act, does not impose
22 an undue burden or a substantial obstacle on a woman's ability to
23 have an abortion because:
24 (A) the woman has adequate time to decide whether

to have an abortion in the first 20 weeks after fertilization; and

(B) this Act does not apply to abortions that are necessary to avert the death or substantial and irreversible physical impairment of a major bodily function of the pregnant woman or abortions that are performed on unborn children with severe fetal abnormalities.

(b) The legislature intends that every application of this statute to every individual woman shall be severable from each other. In the unexpected event that the application of this statute is found to impose an impermissible undue burden on any pregnant woman or group of pregnant women, the application of the statute to those women shall be severed from the remaining applications of the statute that do not impose an undue burden, and those remaining applications shall remain in force and unaffected, consistent with Section 10 of this Act.

SECTION 2. Subchapter A, Chapter 171, Health and Safety Code, is amended by adding Section 171.0031 to read as follows:

Sec. 171.0031. REQUIREMENTS OF PHYSICIAN; OFFENSE. (a) A physician performing or inducing an abortion:

(1) must, on the date the abortion is performed or induced, have active admitting privileges at a hospital that:

(A) is located not further than 30 miles from the location at which the abortion is performed or induced; and

(B) provides obstetrical or gynecological health care services; and

(2) shall provide the pregnant woman with:

(A) a telephone number by which the pregnant

1 woman may reach the physician, or other health care personnel
2 employed by the physician or by the facility at which the abortion
3 was performed or induced with access to the woman's relevant
4 medical records, 24 hours a day to request assistance for any
5 complications that arise from the performance or induction of the
6 abortion or ask health-related questions regarding the abortion;
7 and
8 (B) the name and telephone number of the nearest
9 hospital to the home of the pregnant woman at which an emergency
10 arising from the abortion would be treated.
11 (b) A physician who violates Subsection (a) commits an
12 offense. An offense under this section is a Class A misdemeanor
13 punishable by a fine only, not to exceed $4,000.
14 SECTION 3. Chapter 171, Health and Safety Code, is amended
15 by adding Subchapters C and D to read as follows:
16 SUBCHAPTER C. ABORTION PROHIBITED AT OR AFTER 20 WEEKS
17 POST-FERTILIZATION
18 Sec. 171.041. SHORT TITLE. This subchapter may be cited as
19 the Preborn Pain Act.
20 Sec. 171.042. DEFINITIONS. In this subchapter:
21 (1) "Post-fertilization age" means the age of the
22 unborn child as calculated from the fusion of a human spermatozoon
23 with a human ovum.
24 (2) "Severe fetal abnormality" has the meaning
25 assigned by Section 285.202.
26 Sec. 171.043. DETERMINATION OF POST-FERTILIZATION AGE
27 REQUIRED. Except as otherwise provided by Section 171.046, a

1 physician may not perform or induce or attempt to perform or induce
2 an abortion without, prior to the procedure:
3 (1) making a determination of the probable
4 post-fertilization age of the unborn child; or
5 (2) possessing and relying on a determination of the
6 probable post-fertilization age of the unborn child made by another
7 physician.
8 Sec. 171.044. ABORTION OF UNBORN CHILD OF 20 OR MORE WEEKS
9 POST-FERTILIZATION AGE PROHIBITED. Except as otherwise provided by
10 Section 171.046, a person may not perform or induce or attempt to
11 perform or induce an abortion on a woman if it has been determined,
12 by the physician performing, inducing, or attempting to perform or
13 induce the abortion or by another physician on whose determination
14 that physician relies, that the probable post-fertilization age of
15 the unborn child is 20 or more weeks.
16 Sec. 171.045. METHOD OF ABORTION. (a) This section
17 applies only to an abortion authorized under Section 171.046(a)(1)
18 or (2) in which:
19 (1) the probable post-fertilization age of the unborn
20 child is 20 or more weeks; or
21 (2) the probable post-fertilization age of the unborn
22 child has not been determined but could reasonably be 20 or more
23 weeks.
24 (b) Except as otherwise provided by Section 171.046(a)(3),
25 a physician performing an abortion under Subsection (a) shall
26 terminate the pregnancy in the manner that, in the physician's
27 reasonable medical judgment, provides the best opportunity for the

1 unborn child to survive.
2 Sec. 171.046. EXCEPTIONS. (a) The prohibitions and
3 requirements under Sections 171.043, 171.044, and 171.045(b) do not
4 apply to an abortion performed if there exists a condition that, in
5 the physician's reasonable medical judgment, so complicates the
6 medical condition of the woman that, to avert the woman's death or a
7 serious risk of substantial and irreversible physical impairment of
8 a major bodily function, other than a psychological condition, it
9 necessitates, as applicable:
10 (1) the immediate abortion of her pregnancy without
11 the delay necessary to determine the probable post-fertilization
12 age of the unborn child;
13 (2) the abortion of her pregnancy even though the
14 post-fertilization age of the unborn child is 20 or more weeks; or
15 (3) the use of a method of abortion other than a method
16 described by Section 171.045(b).
17 (b) A physician may not take an action authorized under
18 Subsection (a) if the risk of death or a substantial and
19 irreversible physical impairment of a major bodily function arises
20 from a claim or diagnosis that the woman will engage in conduct that
21 may result in her death or in substantial and irreversible physical
22 impairment of a major bodily function.
23 (c) The prohibitions and requirements under Sections
24 171.043, 171.044, and 171.045(b) do not apply to an abortion
25 performed on an unborn child who has a severe fetal abnormality.
26 Sec. 171.047. PROTECTION OF PRIVACY IN COURT PROCEEDINGS.
27 (a) Except as otherwise provided by this section, in a civil or

1 criminal proceeding or action involving an act prohibited under
2 this subchapter, the identity of the woman on whom an abortion has
3 been performed or induced or attempted to be performed or induced is
4 not subject to public disclosure if the woman does not give consent
5 to disclosure.
6 (b) Unless the court makes a ruling under Subsection (c) to
7 allow disclosure of the woman's identity, the court shall issue
8 orders to the parties, witnesses, and counsel and shall direct the
9 sealing of the record and exclusion of individuals from courtrooms
10 or hearing rooms to the extent necessary to protect the woman's
11 identity from public disclosure.
12 (c) A court may order the disclosure of information that is
13 confidential under this section if:
14 (1) a motion is filed with the court requesting
15 release of the information and a hearing on that request;
16 (2) notice of the hearing is served on each interested
17 party; and
18 (3) the court determines after the hearing and an in
19 camera review that disclosure is essential to the administration of
20 justice and there is no reasonable alternative to disclosure.
21 Sec. 171.048. CONSTRUCTION OF SUBCHAPTER. (a) This
22 subchapter shall be construed, as a matter of state law, to be
23 enforceable up to but no further than the maximum possible extent
24 consistent with federal constitutional requirements, even if that
25 construction is not readily apparent, as such constructions are
26 authorized only to the extent necessary to save the subchapter from
27 judicial invalidation. Judicial reformation of statutory language

1 is explicitly authorized only to the extent necessary to save the
2 statutory provision from invalidity.
3 (b) If any court determines that a provision of this
4 subchapter is unconstitutionally vague, the court shall interpret
5 the provision, as a matter of state law, to avoid the vagueness
6 problem and shall enforce the provision to the maximum possible
7 extent. If a federal court finds any provision of this subchapter
8 or its application to any person, group of persons, or
9 circumstances to be unconstitutionally vague and declines to impose
10 the saving construction described by this subsection, the Supreme
11 Court of Texas shall provide an authoritative construction of the
12 objectionable statutory provisions that avoids the constitutional
13 problems while enforcing the statute's restrictions to the maximum
14 possible extent, and shall agree to answer any question certified
15 from a federal appellate court regarding the statute.
16 (c) A state executive or administrative official may not
17 decline to enforce this subchapter, or adopt a construction of this
18 subchapter in a way that narrows its applicability, based on the
19 official's own beliefs about what the state or federal constitution
20 requires, unless the official is enjoined by a state or federal
21 court from enforcing this subchapter.
22 (d) This subchapter may not be construed to authorize the
23 prosecution of or a cause of action to be brought against a woman on
24 whom an abortion is performed or induced or attempted to be
25 performed or induced in violation of this subchapter.
26 SUBCHAPTER D. ABORTION-INDUCING DRUGS
27 Sec. 171.061. DEFINITIONS. In this subchapter:

1 (1) "Abortion" means the act of using, administering,
2 prescribing, or otherwise providing an instrument, a drug, a
3 medicine, or any other substance, device, or means with the intent
4 to terminate a clinically diagnosable pregnancy of a woman and with
5 knowledge that the termination by those means will, with reasonable
6 likelihood, cause the death of the woman's unborn child. An act is
7 not an abortion if the act is done with the intent to:
8 (A) save the life or preserve the health of an
9 unborn child;
10 (B) remove a dead, unborn child whose death was
11 caused by spontaneous abortion;
12 (C) remove an ectopic pregnancy; or
13 (D) treat a maternal disease or illness for which
14 a prescribed drug, medicine, or other substance is indicated.
15 (2) "Abortion-inducing drug" means a drug, a medicine,
16 or any other substance, including a regimen of two or more drugs,
17 medicines, or substances, prescribed, dispensed, or administered
18 with the intent of terminating a clinically diagnosable pregnancy
19 of a woman and with knowledge that the termination will, with
20 reasonable likelihood, cause the death of the woman's unborn child.
21 The term includes off-label use of drugs, medicines, or other
22 substances known to have abortion-inducing properties that are
23 prescribed, dispensed, or administered with the intent of causing
24 an abortion, including the Mifeprex regimen. The term does not
25 include a drug, medicine, or other substance that may be known to
26 cause an abortion but is prescribed, dispensed, or administered for
27 other medical reasons.

1 (3) "Final printed label" or "FPL" means the
2 informational document approved by the United States Food and Drug
3 Administration for an abortion-inducing drug that:
4 (A) outlines the protocol authorized by that
5 agency and agreed to by the drug company applying for authorization
6 of the drug by that agency; and
7 (B) delineates how a drug is to be used according
8 to approval by that agency.
9 (4) "Gestational age" means the amount of time that
10 has elapsed since the first day of a woman's last menstrual period.
11 (5) "Medical abortion" means the administration or use
12 of an abortion-inducing drug to induce an abortion.
13 (6) "Mifeprex regimen," "RU-486 regimen," or "RU-486"
14 means the abortion-inducing drug regimen approved by the United
15 States Food and Drug Administration that consists of administering
16 mifepristone and misoprostol.
17 (7) "Physician" means an individual who is licensed to
18 practice medicine in this state, including a medical doctor and a
19 doctor of osteopathic medicine.
20 (8) "Pregnant" means the female reproductive
21 condition of having an unborn child in a woman's uterus.
22 (9) "Unborn child" means an offspring of human beings
23 from conception until birth.
24 Sec. 171.062. ENFORCEMENT BY TEXAS MEDICAL BOARD.
25 Notwithstanding Section 171.005, the Texas Medical Board shall
26 enforce this subchapter.
27 Sec. 171.063. DISTRIBUTION OF ABORTION-INDUCING DRUG.

1 (a) A person may not knowingly give, sell, dispense, administer,
2 provide, or prescribe an abortion-inducing drug to a pregnant woman
3 for the purpose of inducing an abortion in the pregnant woman or
4 enabling another person to induce an abortion in the pregnant woman
5 unless:

6 (1) the person who gives, sells, dispenses,
7 administers, provides, or prescribes the abortion-inducing drug is
8 a physician; and

9 (2) except as otherwise provided by Subsection (b),
10 the provision, prescription, or administration of the
11 abortion-inducing drug satisfies the protocol tested and
12 authorized by the United States Food and Drug Administration as
13 outlined in the final printed label of the abortion-inducing drug.

14 (b) A person may provide, prescribe, or administer the
15 abortion-inducing drug in the dosage amount prescribed by the
16 clinical management guidelines defined by the American Congress of
17 Obstetricians and Gynecologists Practice Bulletin as those
18 guidelines existed on January 1, 2013.

19 (c) Before the physician gives, sells, dispenses,
20 administers, provides, or prescribes an abortion-inducing drug,
21 the physician must examine the pregnant woman and document, in the
22 woman's medical record, the gestational age and intrauterine
23 location of the pregnancy.

24 (d) The physician who gives, sells, dispenses, administers,
25 provides, or prescribes an abortion-inducing drug shall provide the
26 pregnant woman with:

27 (1) a copy of the final printed label of that

1 abortion-inducing drug; and
2 (2) a telephone number by which the pregnant woman may
3 reach the physician, or other health care personnel employed by the
4 physician or by the facility at which the abortion was performed
5 with access to the woman's relevant medical records, 24 hours a day
6 to request assistance for any complications that arise from the
7 administration or use of the drug or ask health-related questions
8 regarding the administration or use of the drug.
9 (e) The physician who gives, sells, dispenses, administers,
10 provides, or prescribes the abortion-inducing drug, or the
11 physician's agent, must schedule a follow-up visit for the woman to
12 occur not more than 14 days after the administration or use of the
13 drug. At the follow-up visit, the physician must:
14 (1) confirm that the pregnancy is completely
15 terminated; and
16 (2) assess the degree of bleeding.
17 (f) The physician who gives, sells, dispenses, administers,
18 provides, or prescribes the abortion-inducing drug, or the
19 physician's agent, shall make a reasonable effort to ensure that
20 the woman returns for the scheduled follow-up visit under
21 Subsection (e). The physician or the physician's agent shall
22 document a brief description of any effort made to comply with this
23 subsection, including the date, time, and name of the person making
24 the effort, in the woman's medical record.
25 (g) If a physician gives, sells, dispenses, administers,
26 provides, or prescribes an abortion-inducing drug to a pregnant
27 woman for the purpose of inducing an abortion as authorized by this

1 section and the physician knows that the woman experiences a
2 serious adverse event, as defined by the MedWatch Reporting System,
3 during or after the administration or use of the drug, the physician
4 shall report the event to the United States Food and Drug
5 Administration through the MedWatch Reporting System not later than
6 the third day after the date the physician learns that the event
7 occurred.
8 Sec. 171.064. ADMINISTRATIVE PENALTY. (a) The Texas
9 Medical Board may take disciplinary action under Chapter 164,
10 Occupations Code, or assess an administrative penalty under
11 Subchapter A, Chapter 165, Occupations Code, against a person who
12 violates Section 171.063.
13 (b) A penalty may not be assessed under this section against
14 a pregnant woman who receives a medical abortion.
15 SECTION 4. Section 245.010(a), Health and Safety Code, is
16 amended to read as follows:
17 (a) The rules must contain minimum standards to protect the
18 health and safety of a patient of an abortion facility and must
19 contain provisions requiring compliance with the requirements of
20 Subchapter B, Chapter 171. On and after September 1, 2014, the
21 minimum standards for an abortion facility must be equivalent to
22 the minimum standards adopted under Section 243.010 for ambulatory
23 surgical centers.
24 SECTION 5. Section 245.011(c), Health and Safety Code, is
25 amended to read as follows:
26 (c) The report must include:
27 (1) whether the abortion facility at which the

abortion is performed is licensed under this chapter;

(2) the patient's year of birth, race, marital status, and state and county of residence;

(3) the type of abortion procedure;

(4) the date the abortion was performed;

(5) whether the patient survived the abortion, and if the patient did not survive, the cause of death;

(6) the probable post-fertilization age of the unborn child [~~period of gestation~~] based on the best medical judgment of the attending physician at the time of the procedure;

(7) the date, if known, of the patient's last menstrual cycle;

(8) the number of previous live births of the patient; and

(9) the number of previous induced abortions of the patient.

SECTION 6. Section 164.052(a), Occupations Code, is amended to read as follows:

(a) A physician or an applicant for a license to practice medicine commits a prohibited practice if that person:

(1) submits to the board a false or misleading statement, document, or certificate in an application for a license;

(2) presents to the board a license, certificate, or diploma that was illegally or fraudulently obtained;

(3) commits fraud or deception in taking or passing an examination;

(4) uses alcohol or drugs in an intemperate manner that, in the board's opinion, could endanger a patient's life;

(5) commits unprofessional or dishonorable conduct that is likely to deceive or defraud the public, as provided by Section 164.053, or injure the public;

(6) uses an advertising statement that is false, misleading, or deceptive;

(7) advertises professional superiority or the performance of professional service in a superior manner if that advertising is not readily subject to verification;

(8) purchases, sells, barters, or uses, or offers to purchase, sell, barter, or use, a medical degree, license, certificate, or diploma, or a transcript of a license, certificate, or diploma in or incident to an application to the board for a license to practice medicine;

(9) alters, with fraudulent intent, a medical license, certificate, or diploma, or a transcript of a medical license, certificate, or diploma;

(10) uses a medical license, certificate, or diploma, or a transcript of a medical license, certificate, or diploma that has been:

(A) fraudulently purchased or issued;

(B) counterfeited; or

(C) materially altered;

(11) impersonates or acts as proxy for another person in an examination required by this subtitle for a medical license;

(12) engages in conduct that subverts or attempts to

1 subvert an examination process required by this subtitle for a
2 medical license;
3 (13) impersonates a physician or permits another to
4 use the person's license or certificate to practice medicine in
5 this state;
6 (14) directly or indirectly employs a person whose
7 license to practice medicine has been suspended, canceled, or
8 revoked;
9 (15) associates in the practice of medicine with a
10 person:
11 (A) whose license to practice medicine has been
12 suspended, canceled, or revoked; or
13 (B) who has been convicted of the unlawful
14 practice of medicine in this state or elsewhere;
15 (16) performs or procures a criminal abortion, aids or
16 abets in the procuring of a criminal abortion, attempts to perform
17 or procure a criminal abortion, or attempts to aid or abet the
18 performance or procurement of a criminal abortion;
19 (17) directly or indirectly aids or abets the practice
20 of medicine by a person, partnership, association, or corporation
21 that is not licensed to practice medicine by the board;
22 (18) performs an abortion on a woman who is pregnant
23 with a viable unborn child during the third trimester of the
24 pregnancy unless:
25 (A) the abortion is necessary to prevent the
26 death of the woman;
27 (B) the viable unborn child has a severe,

1 irreversible brain impairment; or
2 (C) the woman is diagnosed with a significant
3 likelihood of suffering imminent severe, irreversible brain damage
4 or imminent severe, irreversible paralysis; [~~or~~]
5 (19) performs an abortion on an unemancipated minor
6 without the written consent of the child's parent, managing
7 conservator, or legal guardian or without a court order, as
8 provided by Section 33.003 or 33.004, Family Code, authorizing the
9 minor to consent to the abortion, unless the physician concludes
10 that on the basis of the physician's good faith clinical judgment, a
11 condition exists that complicates the medical condition of the
12 pregnant minor and necessitates the immediate abortion of her
13 pregnancy to avert her death or to avoid a serious risk of
14 substantial impairment of a major bodily function and that there is
15 insufficient time to obtain the consent of the child's parent,
16 managing conservator, or legal guardian; or
17 (20) performs or induces or attempts to perform or
18 induce an abortion in violation of Subchapter C, Chapter 171,
19 Health and Safety Code.
20 SECTION 7. Section 164.055(b), Occupations Code, is amended
21 to read as follows:
22 (b) The sanctions provided by Subsection (a) are in addition
23 to any other grounds for refusal to admit persons to examination
24 under this subtitle or to issue a license or renew a license to
25 practice medicine under this subtitle. The criminal penalties
26 provided by Section 165.152 do not apply to a violation of Section
27 170.002 or Subchapter C, Chapter 171, Health and Safety Code.

1 SECTION 8. Effective September 1, 2014, Section 245.010(c),
2 Health and Safety Code, is repealed.
3 SECTION 9. This Act may not be construed to repeal, by
4 implication or otherwise, Section 164.052(a)(18), Occupations
5 Code, Section 170.002, Health and Safety Code, or any other
6 provision of Texas law regulating or restricting abortion not
7 specifically addressed by this Act. An abortion that complies with
8 this Act but violates any other law is unlawful. An abortion that
9 complies with another state law but violates this Act is unlawful as
10 provided in this Act.
11 SECTION 10. (a) If some or all of the provisions of this
12 Act are ever temporarily or permanently restrained or enjoined by
13 judicial order, all other provisions of Texas law regulating or
14 restricting abortion shall be enforced as though the restrained or
15 enjoined provisions had not been adopted; provided, however, that
16 whenever the temporary or permanent restraining order or injunction
17 is stayed or dissolved, or otherwise ceases to have effect, the
18 provisions shall have full force and effect.
19 (b) Mindful of Leavitt v. Jane L., 518 U.S. 137 (1996), in
20 which in the context of determining the severability of a state
21 statute regulating abortion the United States Supreme Court held
22 that an explicit statement of legislative intent is controlling, it
23 is the intent of the legislature that every provision, section,
24 subsection, sentence, clause, phrase, or word in this Act, and
25 every application of the provisions in this Act, are severable from
26 each other. If any application of any provision in this Act to any
27 person, group of persons, or circumstances is found by a court to be

1 invalid, the remaining applications of that provision to all other
2 persons and circumstances shall be severed and may not be affected.
3 All constitutionally valid applications of this Act shall be
4 severed from any applications that a court finds to be invalid,
5 leaving the valid applications in force, because it is the
6 legislature's intent and priority that the valid applications be
7 allowed to stand alone. Even if a reviewing court finds a provision
8 of this Act to impose an undue burden in a large or substantial
9 fraction of relevant cases, the applications that do not present an
10 undue burden shall be severed from the remaining provisions and
11 shall remain in force, and shall be treated as if the legislature
12 had enacted a statute limited to the persons, group of persons, or
13 circumstances for which the statute's application does not present
14 an undue burden. The legislature further declares that it would
15 have passed this Act, and each provision, section, subsection,
16 sentence, clause, phrase, or word, and all constitutional
17 applications of this Act, irrespective of the fact that any
18 provision, section, subsection, sentence, clause, phrase, or word,
19 or applications of this Act, were to be declared unconstitutional
20 or to represent an undue burden.

21 (c) If Subchapter C, Chapter 171, Health and Safety Code, as
22 added by this Act, prohibiting abortions performed on an unborn
23 child 20 or more weeks after fertilization is found by any court to
24 be invalid or to impose an undue burden as applied to any person,
25 group of persons, or circumstances, the prohibition shall apply to
26 that person or group of persons or circumstances on the earliest
27 date on which the subchapter can be constitutionally applied.

1 (d) If any provision of this Act is found by any court to be
2 unconstitutionally vague, then the applications of that provision
3 that do not present constitutional vagueness problems shall be
4 severed and remain in force.

5 SECTION 11. (a) The executive commissioner of the Health
6 and Human Services Commission shall adopt the standards required by
7 Section 245.010, Health and Safety Code, as amended by this Act, not
8 later than January 1, 2014.

9 (b) A facility licensed under Chapter 245, Health and Safety
10 Code, is not required to comply with the standards adopted under
11 Section 245.010, Health and Safety Code, as amended by this Act,
12 before September 1, 2014.

13 SECTION 12. This Act takes effect immediately if it
14 receives a vote of two-thirds of all the members elected to each
15 house, as provided by Section 39, Article III, Texas Constitution.
16 If this Act does not receive the vote necessary for immediate
17 effect, this Act takes effect on the 91st day after the last day of
18 the legislative session.

______________________________ ______________________________

President of the Senate Speaker of the House

I certify that H.B. No. 2 was passed by the House on July 10, 2013, by the following vote: Yeas 96, Nays 49, 1 present, not voting.

____

Chief Clerk of the House

I certify that H.B. No. 2 was passed by the Senate on July 12, 2013, by the following vote: Yeas 19, Nays 11.

____

Secretary of the Senate

APPROVED: _____________________

Date

____

Governor

Exhibit 2

TITLE 25. HEALTH SERVICES

PART 1. DEPARTMENT OF STATE HEALTH SERVICES

CHAPTER 139. ABORTION FACILITY REPORTING AND LICENSING

The Executive Commissioner of the Health and Human Services Commission on behalf of the Department of State Health Services (department) proposes amendments to §§139.1, 139.2, 139.4, 139.32, 139.53, 139.56, and 139.57 and new §139.9 and §139.40, concerning the regulation of abortion facilities.

BACKGROUND AND PURPOSE

Health and Safety Code, Chapter 245, Texas Abortion Facility Reporting and Licensing Act, requires certain abortion facilities to be licensed by the department. Health and Safety Code, Chapter 171, the Woman's Right to Know Act, details information to be given to a patient seeking an abortion. The Abortion Facility Reporting and Licensing rules in 25 Texas Administrative Code Chapter 139 implement Health and Safety Code, Chapters 171 and 245.

House Bill (HB) 2, 83rd Legislature, Second Called Session (2nd C.S.), 2013, amended Health and Safety Code, Chapter 171 by adding Health and Safety Code, §171.0031, which specifies requirements of admitting privileges of physicians who perform or induce abortions and requires specific information to be provided to the patient. Health and Safety Code, §245.011 mandates annual reporting to the department on each abortion that is performed in an abortion facility; HB 2 amended the data required to be reported. HB 2 also amended Health and Safety Code, §245.010(a), to require the minimum standards of abortion facilities to be equivalent to the minimum standards of ambulatory surgery centers in Chapter 135 of this title.

In developing these proposed rules, the department was guided by expressions of legislative intent that accompanied the enactment of HB 2, input of stakeholders, and public comments offered at the meetings of the State Health Services Advisory Council on August 28 and 29, 2013. In particular, the department was guided by the following legislative findings:

(1) substantial medical evidence recognizes that an unborn child is capable of experiencing pain by not later than 20 weeks after fertilization;

(2) the state has a compelling state interest in protecting the lives of unborn children from the stage at which substantial medical evidence indicates that these children are capable of feeling pain;

(3) the compelling state interest in protecting the lives of unborn children from the stage at which substantial medical evidence indicates that an unborn child is capable of feeling pain is intended to be separate from and independent of the compelling state interest in protecting the lives of unborn children from the stage of viability, and neither state interest is intended to replace the other. . . .

Act of July 15, 2013, 83rd Leg., 2nd C.S., ch. ___, §1(a)(1) - (3).

The department also was guided by its understanding that the statutory changes enacted in HB 2 were intended by the Legislature to improve the safety of women who seek services from a licensed abortion facility, but particularly women who receive surgical services at a licensed abortion facility. The department also understands that the Legislature determined that patient safety would be improved, in part, by ensuring that a patient of a licensed abortion facility is assured that (1) the physician who treats her or any patient at the facility is capable of attending to her care if she requires hospital care during or after receiving a service at the facility, and (2) the facility is prepared and qualified to meet potential complications resulting from a surgical procedure.

The department understands that the Legislature determined these objectives would principally be accomplished in three ways. First, the Legislature determined that each physician who provides care at a licensed abortion facility must maintain active admitting privileges at a hospital that is within 30 miles of the facility and provides obstetrical or gynecological services. Second, the Legislature concluded that a licensed abortion facility must be qualified to provide care that is "equivalent to" a licensed ambulatory surgical center. Third, the Legislature determined that these objectives would be better assured by submitting licensed abortion facilities to equivalent regulatory oversight.

The department relies on the Bill Analysis to HB 2 for these purposes:

--Women who choose to have an abortion should receive the same standard of care any other individual in Texas receives, regardless of the surgical procedure performed. HB 2 seeks to increase the health and safety of a woman who chooses to have an abortion by requiring a physician performing or inducing an abortion to have admitting privileges at a hospital and to provide certain information to the woman.

--In 1992, the Supreme Court ruled in *Casey v. Planned Parenthood* [sic] that states have the right to regulate abortion clinics. In 1997, Texas enforced increased regulations; however, today 38 licensed abortion facilities still operate at a second, lower standard for the most common surgical procedure in Texas performed solely on women. Six Texas abortion facilities meet the standard as ambulatory surgical facilities. In medical practice, Medicare is the national standard for insurance reimbursement. Abortion is an all cash (or limited credit card) business, so abortion facilities have not been subject to the same oversight as other surgical facilities.

HB 2 requires that the minimum standards for an abortion facility, on and after September 1, 2014, be equivalent to the minimum standards adopted under §243.010 (Minimum Standards) for ambulatory surgical centers.

Moving abortion clinics under the guidelines for ambulatory surgical centers will provide Texas women choosing abortion the highest standard of health care. Texas allows no other procedure to opt out of the accepted standard of care.

House Comm. on State Affairs, Bill Analysis, Tex. HB 2, 83rd Leg., 2nd C.S. (2013).

The department derives two principal understandings from these passages. First, the department understands that the Legislature was aware of the department's regulation of ambulatory surgical centers, including the operating standards adopted by the department in Chapter 135. Second, the department understands that the Legislature specifically determined that application of these standards would create the least burdensome set of minimum standards sufficient to improve the safety of patients at a licensed abortion facility.

HB 2 also amended Health and Safety Code, §245.010(a), to require the minimum standards of licensed abortion facilities to be "equivalent to" the minimum standards of ambulatory surgery centers. The phrase "equivalent to" is not defined by HB 2. However, in its common and ordinary meaning, the word "equivalent" is defined to mean, among other things, "equal, as in value, force, or meaning . . . having similar or identical effects" or "[b]eing essentially equal, all things considered." *The American Heritage Dictionary of the English Language,* 4th ed., (2006) at 604. Accordingly, the department believes that the Legislature intended that the minimum standards for a licensed abortion facility be at least equal to the standards applicable to a licensed ambulatory surgical center, either in content or in effect, and that any exceptions would result in a lesser standard of care for a patient of a licensed abortion facility and thus should not be granted.

SCOPE OF THE PROPOSED RULES

As noted in the Bill Analysis, the department understands that the Legislature determined that the health and safety of patients of licensed abortion facilities will be improved by "moving abortion clinics under the guidelines for ambulatory surgical centers." But rather than require all licensed abortion facilities to be licensed as ambulatory surgical centers, the Legislature instead directed the department to determine and adopt rules that ensure the minimum standards for licensed abortion facilities are "equivalent to" the minimum standards for ambulatory surgical centers.

The current minimum standards for licensed abortion facilities are codified in the following provisions of Chapter 139:

§139.4. Annual Reporting Requirements for All Abortions Performed.

§139.5. Additional Reporting Requirements for Physicians.

§139.8. Quality Assurance.

§139.41. Policy Development and Review.

§139.42. Delegation of Authority and Organizational Structure.

§139.43. Personnel Policies.

§139.44. Orientation, Training, and Demonstrated Competency.

§139.45. Personnel Records.

§139.46. Licensed Abortion Facility Staffing Requirements and Qualifications.

§139.47. Licensed Abortion Facility Administration.

§139.48. Physical and Environmental Requirements.

§139.49. Infection Control Standards.

§139.50. Disclosure Requirements.

§139.51. Patient Rights at the Facility.

§139.52. Patient Education/Information Services.

§139.53. Medical and Clinical Services.

§139.54. Health Care Services.

§139.55. Clinical Records.

§139.56. Emergency Services.

§139.57. Discharge and Follow-up Referrals.

§139.58. Reporting Requirements.

§139.59. Anesthesia Services.

§139.60. Other State and Federal Compliance Requirements.

The minimum standards for licensed ambulatory surgical centers are codified throughout Chapter 135 and address all aspects of the operation of a licensed ambulatory surgical center, including the construction, safety, and physical maintenance of the facility. The department therefore believes that the minimum standards for a licensed abortion facility that are relevant to surgical services must be equal to the standards that the department adopts for an ambulatory surgical center except in instances where the standards for an ambulatory surgical center are redundant of current requirements under Chapter 139 or in instances where Chapter 139 prescribes more stringent qualifications or safety requirements.

The department accordingly has determined that it is appropriate and necessary to examine all of the provisions of Chapter 135 to determine whether a licensed abortion facility should be required to meet an equivalent standard of Chapter 135. Where a requirement of Chapter 135 is relevant to a surgical service, the department considered it for adoption by reference into Chapter 139. By the same measure, where a provision of Chapter 135 did not pertain to either an operating, safety or qualification requirement, the equivalent provision of Chapter 135 was not adopted by reference into Chapter 139. For example, the provisions of Chapter 135 relating to fees for ambulatory surgical centers are not adopted by reference.

Similarly, some definitions or parts of definitions of terms that are codified in Chapter 135 were excluded from the proposed rules because the excluded language would have resulted either in redundancy, confusion, or the extension of exceptions that were applicable to certain licensed ambulatory surgical centers. Because the Legislature did not require licensed abortion facilities to become licensed as ambulatory surgical centers, the department does not understand the Legislature to have intended to extend these exceptions to an abortion facility licensed pursuant to Health and Safety Code, Chapter 245 or Chapter 139 unless it was previously licensed as an ambulatory surgical center under Health and Safety Code, Chapter 243 or Chapter 135 and otherwise qualified for such exceptions.

SEVERABILITY

The department also understands that the Legislature intended that the separate requirements of HB 2 remain in effect, even if one or more of the provisions, or application of those provisions, is determined to be invalid or unenforceable:

- [I]t is the intent of the legislature that every provision, section, subsection, sentence, clause, phrase, or word in this Act, and every application of the provisions in this Act, are severable from each other. If any application of any provision in this Act to any person, group of persons, or circumstances is found by a court to be invalid, the remaining applications of that provision to all other persons and circumstances shall be severed and may not be affected. All constitutionally valid applications of this Act shall be severed from any applications that a court finds to be invalid, leaving the valid applications in force, because it is the legislature's intent and priority that the valid applications be allowed to stand alone.

. . . .

- If any provision of this Act is found by any court to be unconstitutionally vague, then the applications of that provision that do

not present constitutional vagueness problems shall be severed and remain in force.

Act of July 15, 2013, 83rd Leg., 2nd C.S., ch. ___, §10(b), (d).

Accordingly, the department proposes language to ensure the severability of the requirements of these proposed rules consistent with such intent.

SECTION-BY-SECTION SUMMARY

The proposed rule changes implement HB 2 or were required to be modified because of statutory changes in HB 2.

The department recognizes that minimum standards for licensed abortion facilities are required by HB 2 to be equivalent to the minimum standards for ambulatory surgical centers as stated by Health and Safety Code, §243.010(a) for the following aspects of their operation:

(1) the construction and design, including plumbing, heating, lighting, ventilation, and other design standards necessary to ensure the health and safety of patients;

(2) the qualifications of the professional staff and other personnel;

(3) the equipment essential to the health and welfare of the patients;

(4) the sanitary and hygienic conditions within the center and its surroundings; and

(5) a quality assurance program for patient care.

The proposed rule changes specifically address the following:

The amendment to §139.1 is proposed to clarify the purpose of the rules to include implementation of Woman's Right to Know Act, Health and Safety Code, Chapter 171.

The amendment to §139.2 omits the definition of "ambulatory surgical center" for clarification, and requires renumbering of the remaining definitions.

The amendment to §139.4 is proposed to reflect a change in data required by HB 2 to be reported annually to the department by abortion facilities.

New §139.9 is proposed to ensure the severability of the requirements of these proposed rules is consistent with the intent of the Legislature and language of HB 2.

Amendments to §139.32 are proposed to clarify the authority of the department to refuse, suspend or revoke a license for an abortion facility and adds the finding of noncompliance with Health and Safety Code, Chapter 171 as grounds for license probation, suspension or revocation.

New §139.40 is proposed to comply with HB 2, which establishes that the minimum standards for an abortion facility must be equivalent to the minimum standards of an ambulatory surgical center, by adopting by reference with certain changes for clarification the relevant rules for ambulatory surgical centers from Chapter 135. The department adopts by reference specific current ambulatory surgical center rules in order to ensure that the minimum standards governing licensed abortion facilities are equivalent to those of ambulatory surgical centers. The department finds that adopting the minimum standards for ambulatory surgical centers to licensed abortion facilities ensures compliance with HB 2 and provides the maximum guidance and consistency in the rules for regulated facilities.

25 TAC Chapter 135, Ambulatory Surgical Centers Rules.

Subchapter A. Operating Requirements for ASCs.

§135.1, Scope and Purpose, this rule was not adopted because a sufficient scope and purpose rule already exists in Chapter 139, and because HB 2 does not require the adoption of rules defining the scope and purpose of Chapter 139.

§135.2, Definitions, the following definitions were not adopted by reference.

(1) "Act," which referred to the Ambulatory Surgical Center Licensing Act, and not to the Texas Abortion Facility Licensing and Reporting Act.

(3) "administrator," is defined in more detail that requires higher qualification in §139.2(4) and §139.46(2). Furthermore, ambulatory surgical center rules that are adopted require a governing body (§135.4), and §135.6 describes in adequate detail the required administrative functions.

(4) "advance practice registered nurse," not adopted because Chapter 139 contains a definition of the same term which requires the nurse to have achieved approval by the Board of Nursing based on completion of an advanced higher education program, a standard not required in Chapter 135.

(5) "ASC," which is a term defined but not used in Chapter 139, and whose inclusion among adopted rules would have caused confusion. The definition also included portions limiting the length of patients stays within the facility that were felt to be inapplicable to licensed abortion facilities.

(8) "certified registered nurse anesthetist" is defined in exactly the same way in Chapter 139.

(9) "change of ownership" is defined the same in Chapter 139, with the exception that a requirement for the tax identification number to change in order to qualify as a change in ownership is not present in Chapter 139. This requirement does not fall within the minimum standards required by HB 2.

(11) "department" is defined in exactly the same way in Chapter 139.

(15) "licensed vocational nurse" is defined in exactly the same way in Chapter 139.

(17) "person" is defined in exactly the same way in Chapter 139.

(18) "physician" is defined in exactly the same way in Chapter 139.

(19) defines "premises" as a building where a patient receives outpatient surgical services. This was thought to be a source of potential confusion because medical abortions are not surgical procedures.

(20) "registered nurse" is defined in exactly the same way in Chapter 139.

The following definitions in §135.2 were adopted by reference because they are terms that were used or anticipated to be used in the ambulatory surgical center rules that were to be adopted, and are not terms whose meaning, without a definition, is clear to stakeholders. Thus, the following definitions are necessary for compliance with HB 2.

(2) Action plan--A written document that includes specific measures to correct identified problems or areas of concern; identifies strategies for implementing system improvements; and includes outcome measures to indicate the effectiveness of sys-

tem improvements in reducing, controlling or eliminating identified problem areas.

(6) Autologous blood units--Units of blood or blood products derived from the recipient.

(7) Available--Able to be physically present in the facility to assume responsibility for the delivery of patient care services within five minutes.

(10) Dentist--A person who is currently licensed under the laws of this state to practice dentistry.

(12) Disposal--The discharge, deposit, injection, dumping, spilling, leaking, or placing of any solid waste or hazardous waste (whether containerized or uncontainerized) into or on any land or water so that such solid waste or hazardous waste or any constituent thereof may enter the environment or be emitted into the air or discharge into any waters, including ground waters.

(13) Extended observation--The period of time that a patient remains in the facility following recovery from anesthesia and discharge from the postanesthesia care unit, during which additional comfort measures or observation may be provided.

(14) Health care practitioners (qualified medical personnel)--Individuals currently licensed under the laws of this state who are authorized to provide services in an ASC.

(16) Medicare-approved reference laboratory--A facility that has been certified and found eligible for Medicare reimbursement, and includes hospital laboratories which may be Joint Commission or American Osteopathic Association accredited or nonaccredited Medicare approved hospitals, and Medicare certified independent laboratories.

(21) Surgical technologist--A person who practices surgical technology as defined in Health and Safety Code, Chapter 259.

(22) Title XVIII--Title XVIII of the United States Social Security Act, 42 United States Code (USC), §§1395 et seq.

The following rules from Chapter 135, relating to ambulatory surgical centers, were adopted or not adopted for the reasons set out.

Section 135.3, Fees, was not adopted because HB 2 does not require the adoption of rules relating to licensure fees for licensed abortion facilities.

Section 135.4, Ambulatory Surgical Center (ASC) Operation, was adopted because it almost exclusively focuses on requiring a governing body for the facility and describing the functions of that body, which was thought to add more protection for the health and safety of women than the current rules for licensed abortion facilities, which require only a medical consultant and do not require a governing body.

Section 135.5, Patient Rights, was adopted because it directly affects patient care and contains rights that do not appear in a similarly titled licensed abortion facilities rule, §139.51.

Section 135.6, Administration, was adopted because it lays out the manner in which the governing body is to function by indicating some areas on which it is to focus. Chapter 139 contains no directly comparable rule.

Section 135.7, Quality of Care, was adopted as a supplement to §139.8 (Quality Assurance), the parallel rule in Chapter 139.

Section 135.8, Quality Assurance, was adopted as a supplement to §139.8 (Quality Assurance), the parallel rule in Chapter 139.

Section 135.9, Medical Records, was adopted as a supplement to §139.55 (Clinical Records), the parallel rule in Chapter 139. While §139.55 is more detailed, it does not contain, for instance, a requirement found in §135.9 that a "single person be designated to be in charge of medical records."

Section 135.10, Facilities and Environment, was adopted as a supplement to §139.48 (Physical and Environmental Requirements). For example, §135.10 contains more detailed provision concerning hazardous materials and emergency preparedness than §139.48.

Section 135.11, Anesthesia and Surgical Services, was adopted as a supplement to §139.54 and §139.59. For example, §135.11 addresses surgical services, which are not separately addressed in Chapter 139.

Section 135.11(b)(19) was not adopted because it conflicts with or at least confuses the provision of HB 2 Section 2 that requires a physician who performs an abortion to have admitting privileges at a hospital not further that 30 miles from the location where the abortion is performed or induced.

Section 135.12, Pharmaceuticals Services, was adopted because Chapter 139 has no similar provision concerning drugs except §139.60(a), which does not contain the same provisions as §135.12.

Section 135.13, Pathology and Medical Laboratory Services, was adopted because Chapter 139 has no similar provision, and pathology and medical laboratory services can improve patient health and safety. Therefore, HB 2 requires the adoption of §135.13 as a minimum standard to promote the health and safety of patients.

Section 135.14, Radiology Services, was adopted because Chapter 139 has no similar provision, and radiological services can improve patient health and safety. By adopting by reference the language of §135.14, it does not require a licensed abortion facility to provide such services except "when appropriate to meet the needs of the patients and adequately support" the facility's capabilities.

Section 135.15, Facility Staffing and Training, was adopted to supplement §139.46 (Licensed Abortion Facility Staffing Requirements and Qualifications) in order to make the rules for licensed abortion facilities "equivalent to" those of ASCs as required by HB 2.

Section 135.16, Teaching and Publication, was adopted because Chapter 139 contains no similar provision and in order to make the rules for licensed abortion facilities "equivalent to" those of ASCs as required by HB 2 in matters regarding minimum standards applicable to licensed abortion facility patients.

Section 135.17, Research Activities, was adopted because Chapter 139 contains no similar provision and in order to make the rules for licensed abortion facilities "equivalent to" those of ambulatory surgical centers as required by HB 2 in matters regarding minimum standards applicable to licensed abortion facility patients.

Section 135.18, Unlicensed Ambulatory Surgical Center, was not adopted because §139.3 has adequate provisions for dealing with unlicensed abortion facilities that are not exempted from licensure by Health and Safety Code, Chapter 245. HB 2 does not require the adoption of rules that provide standards and procedures for granting, denying, suspending, and revoking a license for licensed abortion facilities.

Section 135.19, Exemptions, was not adopted because the exemptions from licensure as an abortion facility are set forth in Health and Safety Code, §245.004. HB 2 does not require the adoption of rules for licensed abortion facilities that provide standards and procedures for granting and denying a license.

Section 135.20, Initial Application and Issuance of License, was not adopted because §§139.21 - 139.25 cover application and issuance of licenses for licensed abortion facilities. HB 2 does not require the adoption of rules for licensed abortion facilities that provide standards and procedures for granting or denying a license.

Section 135.21, Inspections, was not adopted because it only required inspections of licensed facilities every three years, whereas present §139.31 requires annual inspections of licensed abortion facilities. Thus, §135.21 is not directly related to minimum standards for the health and safety of patients of licensed abortion facilities, and, to the extent it may be considered to be related to those concerns, §139.31 provides greater protection by requiring more frequent (annual) inspections than the three-year minimum intervals prescribed by §135.21. Furthermore, HB 2 does not require the adoption of rules for licensed abortion facilities that provide standards and procedures for sanctioning a licensee.

Section 135.22, Renewal of License, was not adopted because §§139.21 - 139.25, especially §139.23, adequately address renewal of licenses for licensed abortion facilities. HB 2 does not require the adoption of rules for licensed abortion facilities that provide standards and procedures for granting or denying a license and licensure fees.

Section 135.23, Conditions of Licensure, was not adopted because §§139.21 - 139.25 adequately address conditions of licensure for licensed abortion facilities. HB 2 does not require the adoption of rules for licensed abortion facilities that provide standards and procedures for granting, denying, suspending, and revoking a license and licensure fees.

Section 135.24, Enforcement, was not adopted because §§139.31 - 139.33 adequately address enforcement issues. HB 2 does not require the adoption of rules for licensed abortion facilities that provide standards and procedures for enforcement.

Section 135.25, Complaints, was not adopted because §139.31(c) adequately addresses complaints. HB 2 does not require the adoption of rules for licensed abortion facilities that provide standards and procedures for handling complaints.

Section 135.26, Reporting Requirements, was adopted, because it adds additional requirements that protect the health and safety of patients, such as the obligation of the facility to report the transfer of a patient to a hospital and to report the development by a patient within 24 hours of discharge of a complication if they result in a patient's admission to a hospital. In contrast, §139.58 requires only the reporting of a woman's death from complications of an abortion.

Section 135.27, Patient Safety Program, was adopted because it requires the facilities to directly address patient safety, an issue to which no rule in Chapter 139 is entirely dedicated. For example, §135.27 requires facility management to coordinate all patient safety activities, while Chapter 139 does not.

Section 135.28, Confidentiality, was not adopted because more confidentiality is provided to abortion patients and licensed abortion facilities by existing rules in Chapter 139 than by this rule.

Section 135.29, Time Periods for Processing and Issuing a License, was not adopted because §§139.21 - 139.25 adequately address licensure of licensed abortion facilities. Both Chapters 135 and 139 provide a two-year interval for re-application and renewal of licenses. HB 2 does not require the adoption of rules for licensed abortion facilities that provide standards and procedures for granting, denying, suspending, and revoking a license and licensure fees.

Subchapter B. Fire Prevention and Safety Requirements.

Section 135.41, Fire Prevention and Safety Requirements, was adopted because, except for some brief and general references in §139.48, Chapter 139 does not address fire prevention, does not require the appointment of a safety officer who is familiar with safety practices in healthcare facilities, and does not forbid the use of extension cords for permanent wiring. Section 135.41 provides for all three and has other safety requirements not found in Chapter 139.

Section 135.42, General Safety, was adopted because it contains detailed requirements for facilities concerning patient safety that do not appear in the present Chapter 139, which contains no rule exclusively devoted to patient safety. In contrast, §135.42 requires the appointment of a safety officer; requires safety policies and procedures for each department or service and that those policies and procedures be implemented and enforced; and requires an emergency communication system that operates on power independent of the facility's power source.

Section 135.43, Handling and Storage of Gases, Anesthetics, and Flammable Liquids, was adopted because it contains detailed requirements for facilities concerning handling and storage of gases, anesthetics, and flammable liquids that do not appear in the present Chapter 139, which contains no rule exclusively devoted to these matters.

Section 135.43 requires that facility premises be kept free from accumulations of combustible materials not necessary for immediate operation of the facility, a requirement not in Chapter 139. Section 135.43 also details precautions to be taken concerning flammable gases, nonflammable gases, alcohol-based hand rubs, and gasoline-powered equipment that are not found in Chapter 139.

Subchapter C. Physical Plant and Construction Requirements.

Section 135.51, Construction Requirements for an Existing Ambulatory Surgical Center, was adopted because HB 2, by citing to Health and Safety Code, §243.010, requires the adoption of rules for licensed abortion facilities that "must contain minimum standards . . . for (1) the construction and design, including plumbing, heating, lighting, ventilation, and other design standards necessary to ensure the health and safety of patients." Chapter 139 does not contain similarly detailed construction requirements.

The text of §135.51(a)(1) and a reference in (2) was not adopted by reference in order to eliminate a grandfathering provision in §135.51(a)(1) and a reference in §135.51(a)(2). Adoption of that subsection would have precluded application of the requirements in Subchapter C of Chapter 135 to existing licensed abortion facilities, in contradiction of the stated intent of HB 2.

Chapter 139 presently contains only one section that addresses "Physical and Environmental Requirements," §139.48. That section has approximately one page of general requirements, such as "A facility shall have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the

health and safety of patients and staff at all times." Section 139.48 does not specify what constitutes proper construction for an existing licensed abortion facility, as does adopted §§135.51 - 135.56.

Section 135.52, Construction Requirements for a New Ambulatory Surgical Center, was adopted because HB 2 requires that the minimum standards for construction and design of licensed abortion facilities be "equivalent to" those for patients of ambulatory surgical centers.

Chapter 139 presently contains only one section that addresses "Physical and Environmental Requirements," §139.48. That section has approximately one page of general requirements, such as "A facility shall have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times." Section 139.48 does not specify what constitutes proper construction for a new licensed abortion facility, as does adopted §135.52.

Section 135.53, Elevators, Escalator, and Conveyors, was adopted because HB 2 requires that the minimum standards for construction and design of licensed abortion facilities be "equivalent to" those for patients of ambulatory surgical centers.

Chapter 139 presently contains only one section that addresses "Physical and Environmental Requirements," §139.48. That section does not contain requirements for elevators, escalators, or conveyors, as does adopted §135.53.

Section 135.54, Preparation, Submittal, Review and Approval of Plans, and Retention of Records, was adopted because HB 2 requires that the minimum standards for construction and design of licensed abortion facilities be "equivalent to" those for patients of ambulatory surgical centers. Chapter 139 does not contain requirements for preparation, submittal, review and approval of plans, and retention of records, as does adopted §135.54.

Section 135.55, Construction, Inspections, and Approval of Project, was adopted because HB 2 requires that the minimum standards for construction and design of licensed abortion facilities be "equivalent to" those for patients of ambulatory surgical centers.

Chapter 139 presently contains only one section that addresses "Physical and Environmental Requirements," §139.48. That section has approximately one page of general requirements, such as "A facility shall have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times." Chapter 139 contains no requirements for inspection and approval of construction projects, as does adopted §135.55.

Section 135.56, Construction Tables, was adopted because HB 2 requires that the minimum standards for construction and design of licensed abortion facilities be "equivalent to" those for ambulatory surgical centers. Chapter 139 does not contain tables or drawings of any kind that specify proper construction requirements, so it is not equivalent to rules for ambulatory surgical centers.

Amendments to §139.53 and §139.56 are proposed to specify the admitting privilege requirements of physicians who perform or induce abortions as required by HB 2.

Additional amendments to §139.56 and amendments to §139.57 are proposed to specify the information required by HB 2 to be given to the patient.

FISCAL NOTE

Renee Clack, Director, Health Care Quality Section, has determined that for each year of the first five years that the sections will be in effect, there will not be fiscal implications to state or local governments as a result of enforcing and administering the sections as proposed.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS AND ECONOMIC COSTS TO PERSONS

Ms. Clack has also determined that there may be an adverse economic impact on small businesses or micro-businesses and to persons who are required to comply with the sections as proposed. These costs may include, but are not limited to, architectural modifications such as new construction or renovation costs related to the requirement for an abortion facility to have a surgical suite, a pre-operative patient holding area, a post-operative recovery suite, and other physical plant and life safety code requirements. The cost to a licensed abortion facility or a person cannot be determined by the department due to the unique physical layouts and circumstances associated with each individual facility, and the significant number of variables that must be taken into consideration when comparing the new standards to existing abortion facilities.

It is estimated that approximately 25 currently licensed for-profit abortion facilities that are small or micro-businesses that may be affected by these requirements because they do not currently meet the standards required for ambulatory surgical centers. The cost to a small or micro-business licensed as an abortion facility or provider cannot accurately be projected by the department due to the unique physical layouts and circumstances associated with each small or micro-business licensed abortion facility, and the significant number of variables that must be taken into consideration when comparing the new standards to existing licensed abortion facilities.

Because HB 2 requires that all licensed abortion facilities meet standards equivalent to those set out in Health and Safety Code, §243.010 there are no legal alternatives to provide flexibility for small or micro-businesses for the department to consider. The express objective of the statute governing abortion facilities is to ensure that every licensed abortion facility in the state meet the same minimum health and safety standards for the protection of public health. Consequently, any variance from state law would not be consistent with the health, safety, and welfare of the state.

IMPACT ON LOCAL EMPLOYMENT

There is no anticipated impact on local employment.

PUBLIC BENEFIT

In addition, Ms. Clack has determined that for each year of the first five years the sections are in effect, the public benefit anticipated as a result of adopting and enforcing these rules will be implementation of HB 2 for the purpose of enhanced protection of the health and safety of patients of licensed abortion facilities, by requiring that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards adopted under Health and Safety Code, §243.010 for ambulatory surgical centers.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure

and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Allison Hughes, Health Facilities Rules Coordinator, Health Care Quality Section, Division of Regulatory Services, Department of State Health Services, P.O. Box 149347, Mail Code 2822, Austin, Texas 78714-9347, (512) 834-6775 or by email to allison.hughes@dshs.state.tx.us. Please specify "Comments on abortion facility licensing rules" in the subject line. The department intends by this section to invite public comment on each of the standards that is incorporated by reference, as well as the amended abortion facility rules. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register.*

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

SUBCHAPTER A. GENERAL PROVISIONS

25 TAC §§139.1, 139.2, 139.4, 139.9

STATUTORY AUTHORITY

The amendments and new rule are authorized by Health and Safety Code, Chapter 171, as amended by HB 2, concerning requirements for a physician who performs an abortion and the use of abortion-inducing drugs; by Health and Safety Code, §245.010, as amended by HB 2, concerning rules and minimum standards for the licensing and regulation of abortion facilities required to obtain a license under the chapter, clarification of the authority of the department to refuse, suspend or revoke a license for an abortion facility and add the finding of noncompliance with Health and Safety Code, Chapter 171, as grounds for license probation, suspension or revocation, and a change to the data required to be reported annually; and by Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The amendments and new rule affect Government Code, Chapter 531; and Health and Safety Code, Chapters 171, 245 and 1001.

§139.1. Purpose and Scope.

(a) Purpose. The purpose of this chapter is to implement the Texas Abortion Facility Reporting and Licensing Act, Health and Safety Code, Chapter 245, which provides the Department of State Health Services with the authority to establish rules governing the licensing and regulation of abortion facilities and to establish annual reporting requirements for each abortion performed. This chapter also implements the Woman's Right to Know Act, Health and Safety Code, Chapter 171.

(b) (No change.)

§139.2. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) - (7) (No change.)

[~~(8) Ambulatory surgical center--An ambulatory surgical center licensed under Health and Safety Code, Chapter 243.~~]

(8) [~~(9)~~] Applicant--The owner of an abortion facility which is applying for a license under the Act. For the purpose of this chapter, the word "owner" includes nonprofit organization.

(9) [~~(10)~~] Certified registered nurse anesthetist (CRNA)--A registered nurse who has current certification from the Council on Certification of Nurse Anesthetists and who is currently authorized to practice as an advanced practice registered nurse by the Texas Board of Nursing.

(10) [~~(11)~~] Change of ownership--A sole proprietor who transfers all or part of the facility's ownership to another person or persons; the removal, addition, or substitution of a person or persons as a partner in a facility owned by a partnership; or a corporate sale, transfer, reorganization, or merger of the corporation which owns the facility if sale, transfer, reorganization, or merger causes a change in the facility's ownership to another person or persons.

(11) [~~(12)~~] Condition on discharge--A statement on the condition of the patient at the time of discharge.

(12) [~~(13)~~] Critical item--All surgical instruments and objects that are introduced directly into the bloodstream or into other normally sterile areas of the body.

(13) [~~(14)~~] Decontamination--The physical and chemical process that renders an inanimate object safe for further handling.

(14) [~~(15)~~] Department--The Department of State Health Services.

(15) [~~(16)~~] Director--The director of the Patient Quality Care Unit of the department or his or her designee.

(16) [~~(17)~~] Disinfection--The destruction or removal of vegetative bacteria, fungi, and most viruses but not necessarily spores; the process does not remove all organisms but reduces them to a level that is not harmful to a person's health. There are three levels of disinfection:

(A) high-level disinfection--kills all organisms, except high levels of bacterial spores, and is effected with a chemical germicide cleared for marketing as a sterilant by the United States Food and Drug Administration;

(B) intermediate-level disinfection--kills mycobacteria, most viruses, and bacteria with a chemical germicide registered as a "tuberculocide" by the United States Environmental Protection Agency (EPA); and

(C) low-level disinfection--kills some viruses and bacteria with a chemical germicide registered as a hospital disinfectant by the EPA.

(17) [~~(18)~~] Education and information staff--A professional or nonprofessional person who is trained to provide information

on abortion procedures, alternatives, informed consent, and family planning services.

(18) [~~(19)~~] Facility--A licensed abortion facility as defined in this section.

(19) [~~(20)~~] Fetus--An individual human organism from fertilization until birth.

(20) [~~(21)~~] Health care facility--Any type of facility or home and community support services agency licensed to provide health care in any state or is certified for Medicare (Title XVIII) or Medicaid (Title XIX) participation in any state.

(21) [~~(22)~~] Health care worker--Any person who furnishes health care services in a direct patient care situation under a license, certificate, or registration issued by the State of Texas or a person providing direct patient care in the course of a training or educational program.

(22) [~~(23)~~] Hospital--A facility that is licensed under the Texas Hospital Licensing Law, Health and Safety Code, Chapter 241, or if exempt from licensure, certified by the United States Department of Health and Human Services as in compliance with the conditions of participation for hospitals in Title XVIII, Social Security Act (42 United States Code, §§1395 et. seq.).

(23) [~~(24)~~] Immediate jeopardy to health and safety--A situation in which there is a high probability that serious harm or injury to patients could occur at any time or already has occurred and may well occur again, if patients are not protected effectively from the harm or if the threat is not removed.

(24) [~~(25)~~] Inspection--An on-site inspection by the department in which a standard-by-standard evaluation is conducted.

(25) [~~(26)~~] Licensed abortion facility--A place licensed by the department under Health and Safety Code, Chapter 245, where abortions are performed.

(26) [~~(27)~~] Licensed mental health practitioner--A person licensed in the State of Texas to provide counseling or psychotherapeutic services.

(27) [~~(28)~~] Licensed vocational nurse (LVN)--A person who is currently licensed by the Texas Board of Nursing as a licensed vocational nurse.

(28) [~~(29)~~] Licensee--A person or entity who is currently licensed as an abortion facility.

(29) [~~(30)~~] Medical abortion--The use of a medication or combination of medications to induce an abortion, with the purpose of terminating the pregnancy of a woman known to be pregnant. Medical abortion does not include forms of birth control.

(30) [~~(31)~~] Medical consultant--A physician who is designated to supervise the medical services of the facility.

(31) [~~(32)~~] Nonprofessional personnel--Personnel of the facility who are not licensed or certified under the laws of this state to provide a service and shall function under the delegated authority of a physician, registered nurse, or other licensed health professional who assumes responsibility for their performance in the licensed abortion facility.

(32) [~~(33)~~] Noncritical items--Items that come in contact with intact skin.

(33) [~~(34)~~] Notarized copy--A copy attached to a notarized affidavit which states that the attached copy(ies) are true and correct copies of the original documents.

(34) [~~(35)~~] Patient--A pregnant female on whom an abortion is performed, but shall in no event be construed to include a fetus.

(35) [~~(36)~~] Person--Any individual, firm, partnership, corporation, or association.

(36) [~~(37)~~] Physician--An individual licensed by the Texas Medical Board and authorized to practice medicine in the State of Texas.

(37) [~~(38)~~] Physician assistant--A person licensed as a physician assistant by the Texas Physician Assistant Board.

(38) [~~(39)~~] Plan of correction--A written strategy for correcting a licensing violation. The plan of correction shall be developed by the facility, and shall address the system(s) operation(s) of the facility as the system(s) operation(s) apply to the deficiency.

(39) [~~(40)~~] Post-procedure infection--An infection acquired at or during an admission to a facility; there shall be no evidence that the infection was present or incubating at the time of admission to the facility. Post-procedure infections and their complications that may occur after an abortion include, but are not limited to, endometritis and other infections of the female reproductive tract, laboratory-confirmed or clinical sepsis, septic pelvic thrombophlebitis, and disseminated intravascular coagulopathy.

(40) [~~(41)~~] Pregnant unemancipated minor certification form--The document prepared by the Department of State Health Services and used by physicians to certify the medical indications supporting the judgment for the immediate abortion of a pregnant minor.

(41) [~~(42)~~] Pre-inspection conference--A conference held with department staff and the applicant or his or her representative to review licensure standards, inspection documents, and provide consultation prior to the on-site licensure inspection.

(42) [~~(43)~~] Professional personnel--Patient care personnel of the facility currently licensed or certified under the laws of this state to use a title and provide the type of service for which they are licensed or certified.

(43) [~~(44)~~] Quality assurance--An ongoing, objective, and systematic process of monitoring, evaluating, and improving the appropriateness, and effectiveness of care.

(44) [~~(45)~~] Quality improvement--An organized, structured process that selectively identifies improvement projects to achieve improvements in products or services.

(45) [~~(46)~~] Registered nurse (RN)--A person who is currently licensed by the Texas Board of Nursing as a registered nurse.

(46) [~~(47)~~] Semicritical items--Items that come in contact with nonintact skin or mucous membranes. Semicritical items may include respiratory therapy equipment, anesthesia equipment, bronchoscopes, and thermometers.

(47) [~~(48)~~] Standards--Minimum requirements under the Act and this chapter.

(48) [~~(49)~~] Sterile field--The operative area of the body and anything that directly contacts this area.

(49) [~~(50)~~] Sterilization--The use of a physical or chemical procedure to destroy all microbial life, including bacterial endospores.

(50) [~~(51)~~] Supervision--Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity that includes initial direction and periodic inspection of the actual act of accomplishing the function or activity.

(51) [(52)] Surgical abortion--The use of instruments, aspiration, and/or suction to induce an abortion, with the purpose of terminating the pregnancy of a woman known to be pregnant.

(52) [(53)] Third trimester certification form--The document prepared by the Department of State Health Services and used by physicians to certify the medical indications supporting the judgment for the abortion of a viable fetus during the third trimester of pregnancy.

(53) [(54)] Third trimester--A gestational period of not less than 26 weeks (following last-menstrual period (LMP)).

(54) [(55)] Unemancipated minor--A minor who is unmarried and has not had the disabilities of minority removed under the Family Code, Chapter 31.

§139.4. Annual Reporting Requirements for All Abortions Performed.

(a) - (b) (No change.)

(c) The report must include:

(1) - (5) (No change.)

(6) the probable post-fertilization age of the unborn child [period of gestation] based on the best medical judgment of the attending physician at the time of the procedure;

(7) - (16) (No change.)

(d) - (h) (No change.)

§139.9. Severability.

(a) The 83rd Legislature, in enacting House Bill 2 during its Second Session (2013), confirmed its intent that the provisions and the applications of the Health and Safety Code relating to the licensure and operation of abortion facilities were intended to be separately enforceable, if any of these separate provisions or the application of those provisions was determined unconstitutional, invalid, or unenforceable.

(b) Consistent with the intent of the Legislature, the department intends, that with respect to the application of this chapter to each woman who seeks or obtains services from a facility licensed under this chapter, every provision, section, subsection, sentence, clause, phrase, or word in this chapter and each application of the provisions of this chapter remain severable from every other provision, section, subsection, sentence, clause, phrase, word, or application of this chapter.

(c) The department further intends that if the application of any provision of this chapter is determined by a court of competent jurisdiction to impose an impermissible or undue burden on any pregnant woman or group of pregnant women, the application of the chapter to those women will be severed from the remaining applications of the chapter that do not impose an undue burden, and those remaining applications of this chapter will remain in force and unaffected, consistent with the intent of the Legislature.

(d) Accordingly, to the extent that any parts or applications of this chapter or this section are enjoined, the department may enforce the parts and applications of this chapter that do not violate the Constitution or impose an undue burden on women seeking abortions.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on September 16, 2013.

TRD-201304011

Lisa Hernandez
General Counsel
Department of State Health Services
Earliest possible date of adoption: October 27, 2013
For further information, please call: (512) 776-6972

SUBCHAPTER C. ENFORCEMENT

25 TAC §139.32

STATUTORY AUTHORITY

The amendment is authorized by Health and Safety Code, Chapter 171, as amended by HB 2, concerning requirements for a physician who performs an abortion and the use of abortion-inducing drugs; by Health and Safety Code, §245.010, as amended by HB 2, concerning rules and minimum standards for the licensing and regulation of abortion facilities required to obtain a license under the chapter, clarification of the authority of the department to refuse, suspend or revoke a license for an abortion facility and add the finding of noncompliance with Health and Safety Code, Chapter 171, as grounds for license probation, suspension or revocation, and a change to the data required to be reported annually; and by Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The amendment affects Government Code, Chapter 531; and Health and Safety Code, Chapters 171, 245 and 1001.

§139.32. License Denial, Suspension, Probation, or Revocation.

(a) - (b) (No change.)

(c) The department may deny a person a license or suspend or revoke an existing license on the grounds that the person has been convicted of a felony or misdemeanor that directly relates to the duties and responsibilities of the ownership or operation of a facility.

(1) - (2) (No change.)

(3) The following felonies and misdemeanors directly relate to the duties and responsibilities of the ownership or operation of a licensed abortion facility because these criminal offenses demonstrate impaired ability to own or operate a facility:

(A) a misdemeanor violation of Health and Safety Code, Chapter 171 or Chapter 245;

(B) - (G) (No change.)

(4) - (5) (No change.)

(d) - (j) (No change.)

(k) If the department finds that a licensed abortion facility is in repeated noncompliance with Health and Safety Code, Chapter 171 or Chapter 245, or rules adopted under this chapter, but the noncompliance does not in any way involve the health and safety of the public or an individual, the department may schedule the facility for probation rather than suspending or revoking the facility's license.

(l) The department may suspend or revoke the license of a licensed abortion facility that does not correct items that were in noncompliance or that does not comply with Health and Safety Code,

Chapter 171 or Chapter 245, or rules adopted under this chapter within the applicable probation period.

(m) - (r) (No change.)

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on September 16, 2013.

TRD-201304012
Lisa Hernandez
General Counsel
Department of State Health Services
Earliest possible date of adoption: October 27, 2013
For further information, please call: (512) 776-6972

SUBCHAPTER D. MINIMUM STANDARDS FOR LICENSED ABORTION FACILITIES

25 TAC §§139.40, 139.53, 139.56, 139.57

STATUTORY AUTHORITY

The new rule and amendments are authorized by Health and Safety, Code Chapter 171, as amended by HB 2, concerning requirements for a physician who performs an abortion and the use of abortion-inducing drugs; by Health and Safety Code, §245.010, as amended by HB 2, concerning rules and minimum standards for the licensing and regulation of abortion facilities required to obtain a license under the chapter, clarification of the authority of the department to refuse, suspend or revoke a license for an abortion facility and add the finding of noncompliance with Health and Safety Code, Chapter 171, as grounds for license probation, suspension or revocation, and a change to the data required to be reported annually; and by Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The new rule and amendments affect Government Code, Chapter 531; and Health and Safety Code, Chapters 171, 245 and 1001.

§139.40. Adoption by Reference of Ambulatory Surgical Centers Rules.

(a) Effective September 1, 2014, the department adopts by reference the following sections of Chapter 135 of this title (relating to Ambulatory Surgical Centers) that were in effect on January 1, 2014:

(1) Subchapter A (relating to Operating Requirements for Ambulatory Surgical Centers):

(A) The following definitions are incorporated by reference:

(i) §135.2(2) (defining "Action plan");

(ii) §135.2(6) (defining "Autologous blood units");

(iii) §135.2(7) (defining "Available");

(iv) §135.2(10) (defining "Dentist");

(v) §135.2(12) (defining "Disposal");

(vi) §135.2(13) (defining "Extended observation");

(vii) §135.2(14) (defining "Health care practitioners");

(viii) §135.2(16) (defining "Medicare");

(ix) §135.2(21) (defining "Surgical technologist");

(x) §135.2(22) (defining "Title XVIII");

(B) The following sections relating to ambulatory surgical centers operating requirements:

(i) §135.4 (relating to Ambulatory Surgical Center (ASC) Operation), except as specifically noted in subsection (d)(2) of this section;

(ii) §135.5 (relating to Patient Rights);

(iii) §135.6 (relating to Administration);

(iv) §135.7 (relating to Quality of Care);

(v) §135.8 (relating to Quality Assurance);

(vi) §135.9 (relating to Medical Records);

(vii) §135.10 (relating to Facilities and Environment);

(viii) §135.11(a) and (b)(1) - (18) (relating to Anesthesia and Surgical Services);

(ix) §135.12 (relating to Pharmaceutical Services);

(x) §135.13 (relating to Pathology and Medical Laboratory Services);

(xi) §135.14 (relating to Radiology Services);

(xii) §135.15 (relating to Facility Staffing and Training);

(xiii) §135.16 (relating to Teaching and Publication);

(xiv) §135.17 (relating to Research Activities);

(xv) §135.26 (relating to Reporting Requirements); and

(xvi) §135.27 (relating to a Patient Safety Program);

(2) Subchapter B (relating to Fire Prevention and Safety Requirements):

(A) §135.41 (relating to Fire Prevention and Protection);

(B) §135.42 (relating to General Safety); and

(C) §135.43 (relating to Handling and Storage of Gases, Anesthetics, and Flammable Liquids); and

(3) Subchapter C (relating to Physical Plant and Construction Requirements):

(A) §135.51 (relating to Construction Requirements for an Existing Ambulatory Surgical Center), except as specifically noted in subsection (d)(3) of this section;

(B) §135.52 (relating to Construction Requirements for a New Ambulatory Surgical Center);

(C) §135.53 (relating to Elevators, Escalators, and Conveyors);

(D) §135.54 (relating to Preparation, Submittal, Review and Approval of Plans, and Retention of Records);

(E) §135.55 (relating to Construction, Inspections, and Approval of Project); and

(F) §135.56 (relating to Construction Tables).

(b) As required by §4 of House Bill 2, passed in the Second Session, 83rd Legislature, 2013, the department intends by this adoption of rules to impose minimum standards for the health and safety of a patient of a licensed abortion facility, and that those minimum standards be equivalent to the minimum standards adopted under Health and Safety Code, §243.010, for ambulatory surgical centers.

(c) The minimum standards adopted by reference under this section are not applicable to a licensed abortion facility before September 1, 2014.

(d) Interpretive conventions. For purposes of this chapter:

(1) The words "ambulatory surgical center" and "ASC" and their plural forms in the rules that are adopted by reference in subsection (a) of this section are understood to mean "licensed abortion facility" or "licensed abortion facilities," as appropriate, for purposes of this chapter.

(2) The text of §135.4(c)(11)(B) that reads "or all physicians performing surgery at the ASC shall have admitting privileges at a local hospital" is not adopted by reference into this chapter.

(3) The text of §135.51(a)(1) and the portion of the text of §135.51(a)(2) that reads, "In lieu of meeting the requirements in paragraph (1) of this subsection," are not adopted by reference into this chapter.

(e) If the application of any particular rule that is incorporated by reference from Chapter 135 of this title is found by a state or federal court to violate the Constitution or impose an "undue burden" on women seeking abortions, the department shall continue to enforce the remaining incorporated rules that do not violate the Constitution or impose an "undue burden" on women seeking abortions, and shall continue to enforce all rules incorporated by reference from Chapter 135 of this title against abortion facilities for whom the application of such rules does not violate the Constitution or impose an "undue burden" on women seeking abortions.

§139.53. Medical and Clinical Services.

(a) - (b) (No change.)

(c) Requirements of a physician. A physician performing or inducing an abortion must, on the date the abortion is performed or induced, have active admitting privileges at a hospital that:

(1) is located not further than 30 miles from the location at which the abortion is performed or induced; and

(2) provides obstetrical or gynecological health care services.

§139.56. Emergency Services.

(a) A licensed abortion facility shall have a readily accessible written protocol for managing medical emergencies and the transfer of patients requiring further emergency care to a hospital. The facility shall ensure that the physicians who practice at the facility:

(1) have active admitting privileges at a hospital that provides obstetrical or gynecological health care services and is located not further than 30 miles from the abortion facility; [~~or have a working arrangement with a physician(s) who has admitting privileges at a local hospital in order to ensure the necessary back up for medical complications.~~]

(2) provide the pregnant woman with:

(A) a telephone number by which the pregnant woman may reach the physician, or other health care personnel employed by the physician or the facility at which the abortion was performed or induced with access to the woman's relevant medical records, 24 hours a day to request assistance for any complications that arise from the performance or induction of the abortion or ask health-related questions regarding the abortion; and

(B) the name and telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion would be treated.

(b) - (c) (No change.)

§139.57. Discharge and Follow-up Referrals.

(a) A licensed abortion facility shall develop and implement written discharge instructions which shall include:

(1) (No change.)

(2) a statement of the facility's plan to respond to the patient in the event the patient experiences any of the complications listed in the discharge instructions to include:

(A) a telephone number by which the patient may reach the physician, or other health care personnel employed by the physician or by the facility at which the abortion was performed or induced with access to the woman's relevant medical records, 24 hours a day to request assistance for any complications that arise from the performance or induction of the abortion or ask health-related questions regarding the abortion;

(B) the name and telephone number of the nearest hospital to the home of the patient at which an emergency arising from the abortion would be treated;

[~~(A) the mechanism by which the patient may contact the facility on a 24-hour basis by telephone answering machine or service, or by direct contact with an individual;~~]

[~~(B) the facility's requirement that every reasonable effort be made and documented to respond to the patient within 30 minutes of the patient's call;~~]

(C) - (D) (No change.)

(3) (No change.)

(b) - (c) (No change.)

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on September 16, 2013.

TRD-201304013
Lisa Hernandez
General Counsel
Department of State Health Services
Earliest possible date of adoption: October 27, 2013
For further information, please call: (512) 776-6972

CHAPTER 416. MENTAL HEALTH COMMUNITY-BASED SERVICES

Filed with the Office of the Secretary of State on December 10, 2013.

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Lisa Hernandez
General Counsel
Department of State Health Services
Effective date: December 31, 2013
Proposal publication date: July 5, 2013
For further information, please call: (512) 776-6972

CHAPTER 73. LABORATORIES

25 TAC §73.21

The Executive Commissioner of the Health and Human Services Commission (commission), on behalf of the Department of State Health Services (department), adopts the repeal of §73.21, concerning the Newborn Screening Program, without changes to the proposed text as published in the July 5, 2013, issue of the *Texas Register* (38 TexReg 4291), and the section will not be republished.

BACKGROUND AND PURPOSE

The department administers the Newborn Screening Program, which is designed to screen all newborns in the state for certain genetic or heritable disorders. If identified and treated early, serious problems such as developmental delays, intellectual disability, illness, or death can be prevented or ameliorated. The program is structured into two major components. The department's laboratory receives the blood specimens collected from newborns, performs the blood-based testing, and reports the results to submitters of the specimens. If the results for one of the laboratory tests are out of the expected range, the results are also sent to department clinical care coordination staff in the Newborn Screening Program for prompt follow up and intervention. Some testing for other conditions is done at the point-of-care (i.e., by health care professionals caring for the infant, as opposed to department staff). Limited benefits through the department are potentially available to eligible individuals. Benefits include confirmatory testing, medications, vitamins, and dietary supplements (metabolic foods, low-protein foods). The amendments to 25 TAC Chapter 37, which are adopted in this issue of the *Texas Register,* apply to the operations of both of these two main components of the Newborn Screening Program.

Government Code, §2001.039, requires that each state agency review and consider for re-adoption each rule adopted by that agency pursuant to Government Code, Chapter 2001 (Administrative Procedure Act). Section 73.21 has been reviewed and the department has determined that §73.21 should be repealed and moved into 25 TAC Chapter 37.

SECTION-BY-SECTION SUMMARY

Section 73.21, related to laboratory specimen submission for newborn screening, is repealed and the content placed in new 25 TAC §37.55 to accommodate the placement of information concerning newborn screening in one chapter of the rules. Certain summary information regarding specimen collection kits from §73.21 of this title has also been included in 25 TAC §37.51 and would specify that specimen collection kits are obtained from the department, and proposed new language would clarify that screening results are reported by the department as required by law.

COMMENTS

The department, on behalf of the commission, did not receive any comments regarding the proposed rule during the comment period.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the rule, as adopted, has been reviewed by legal counsel and found to be a valid exercise of the agencies' legal authority.

STATUTORY AUTHORITY

The repeal is authorized by Health and Safety Code, §33.002, which requires the department to adopt rules necessary to carry out the program, and by Chapter 33 in general; and Government Code, §531.0055(e), and the Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001. Review of the section implements Government Code, §2001.039.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on December 10, 2013.

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Lisa Hernandez
General Counsel
Department of State Health Services
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Proposal publication date: July 5, 2013
For further information, please call: (512) 776-6972

CHAPTER 139. ABORTION FACILITY REPORTING AND LICENSING

The Executive Commissioner of the Health and Human Services Commission on behalf of the Department of State Health Services (Department) adopts amendments to §§139.1, 139.2, 139.4, 139.32, 139.53, 139.56, and 139.57 and new §139.9 and §139.40, concerning the regulation of abortion facilities. The sections are adopted without changes to the proposed text as published in the September 27, 2013, issue of the *Texas Register* (38 TexReg 6536) and, therefore, the sections will not be republished.

BACKGROUND AND JUSTIFICATION

Health and Safety Code, Chapter 245, Texas Abortion Facility Reporting and Licensing Act, requires certain abortion facilities to be licensed by the Department. Health and Safety Code, Chapter 171, the Woman's Right to Know Act, details information to be given to a patient seeking an abortion. The Abortion Facility Reporting and Licensing Rules in 25 Texas Administrative Code (TAC) Chapter 139, implement Health and Safety Code, Chapters 171 and 245.

House Bill (HB) 2, 83rd Legislature, Second Called Session, 2013, effective October 29, 2013, amended Health and

Safety Code, Chapter 171 by adding Health and Safety Code, §171.0031, which specifies requirements of admitting privileges of physicians who perform or induce abortions and requires specific information to be provided to the patient. Health and Safety Code, §245.011 mandates annual reporting to the department on each abortion that is performed in an abortion facility; HB 2 amended the data required to be reported. HB 2 also amended Health and Safety Code, §245.010(a), to require the minimum standards of abortion facilities to be equivalent to the minimum standards of ambulatory surgery centers.

In developing these rules, the department was guided by expressions of legislative intent that accompanied the enactment of HB 2, input of stakeholders, and public comments offered at the meeting of the State Health Services Advisory Council on August 28 and 29, 2013. In particular, the department was guided by the following legislative findings:

(1) substantial medical evidence recognizes that an unborn child is capable of experiencing pain by not later than 20 weeks after fertilization;

(2) the state has a compelling state interest in protecting the lives of unborn children from the stage at which substantial medical evidence indicates that these children are capable of feeling pain;

(3) the compelling state interest in protecting the lives of unborn children from the stage at which substantial medical evidence indicates that an unborn child is capable of feeling pain is intended to be separate from and independent of the compelling state interest in protecting the lives of unborn children from the stage of viability, and neither state interest is intended to replace the other. . . .

Act of July 15, 2013, 83rd Leg., 2nd C. S., ch. ___, §1(a)(1)-(3).

The department also was guided by its understanding that the statutory changes enacted in HB 2 were intended by the Legislature to improve the safety of women who seek services from a licensed abortion facility, but particularly women who receive surgical services at a licensed abortion facility. The department also understands that the Legislature determined that patient safety would be improved, in part, by ensuring that a patient of a licensed abortion facility is assured that (1) the physician who treats her or any patient at the facility is capable of attending to her care if she requires hospital care during or after receiving a service at the facility, and (2) the facility is prepared and qualified to meet potential complications resulting from a surgical procedure.

The department understands that the Legislature determined these objectives would principally be accomplished in three ways. First, the Legislature determined that each physician who provides care at a licensed abortion facility must maintain active admitting privileges at a hospital that is within 30 miles of the facility and provides obstetrical or gynecological services. Second, the Legislature concluded that a licensed abortion facility must be qualified to provide care that is "equivalent to" a licensed ambulatory surgical center. Third, the Legislature determined that these objectives would be better assured by submitting licensed abortion facilities to equivalent regulatory oversight.

HB 2's legislative history reveals the Legislature's purposes. Among other things, the Legislature found that:

--Women who choose to have an abortion should receive the same standard of care, including adequate facilities in which their procedures are performed, any other individual in Texas receives, regardless of the procedure performed. HB 2 seeks to improve the health and safety of a woman who chooses to have an abortion by requiring a physician performing or inducing an abortion to have admitting privileges at a hospital and to provide certain information to the woman.

--In 1992, the Supreme Court ruled in *Casey v. Planned Parenthood* [sic] that states have the right to regulate abortion clinics. In 1997, Texas enforced increased regulations; however, today 30 licensed abortion facilities still operate at a second, lower standard for the most common surgical procedure in Texas performed solely on women. Six Texas abortion facilities meet the standard as ambulatory surgical facilities. In medical practice, Medicare is the national standard for insurance reimbursement. Abortion is an all cash (or limited credit card) business, so abortion facilities have not been subject to the same oversight as other surgical facilities.

--HB 2 requires that the minimum standards for an abortion facility, on and after September 1, 2014, be equivalent to the minimum standards adopted under §243.010 (Minimum Standards) for ambulatory surgical centers. Moving abortion clinics under the guidelines for ambulatory surgical centers will provide Texas women choosing abortion the higher accepted standard of health care. Texas allows no other kind of facilities or practitioners to opt out of the accepted standard of care.

The department derives two principal understandings from the legislative history. First, the department understands that the Legislature was aware of the department's regulation of ambulatory surgical centers, including the operating standards, fire protection and safety requirements, and construction and physical plant standards adopted by the department in Chapter 135. Second, the department understands that the Legislature specifically determined that application of these standards would create the least burdensome set of minimum standards sufficient to improve the safety of patients at a licensed abortion facility.

With these goals in mind, the Legislature passed HB 2 and thereby amended Health and Safety Code, §245,010(a), to require the minimum standards of licensed abortion facilities to be "equivalent to" the minimum standards of ambulatory surgical centers. The phrase "equivalent to" is not defined by HB 2. However, in its common and ordinary meaning, the word "equivalent" is defined to mean, among other things, "equal, as in value, force, or meaning . . . having similar or identical effects" or [b]eing essentially equal, all things considered." *The American Heritage Dictionary of the English Language,* 4th ed., (2006) at 604. Accordingly, the department concludes that the Legislature intended that the minimum standards for licensed abortion facilities be at least equal to the standards applicable to a licensed ambulatory surgical center, in content and effect, and that any exceptions would result in a lesser standard of care for a patient of a licensed abortion facility and thus should not be granted.

SEVERABILITY

The department also understands that the Legislature intended that the separate requirements of HB 2 remain in effect, even if one or more of the provisions, or application of those provisions, is determined to be invalid or unenforceable:

- [I]t is the intent of the legislature that every provision, section, subsection, sentence, clause, phrase, or word in this Act, and every application of the provisions in this Act, are severable from each other. If any application of any provision in this Act to any

person, group of persons, or circumstances is found by a court to be invalid, the remaining applications of that provision to all other persons and circumstances shall be severed and may not be affected. All constitutionally valid applications of this Act shall be severed from any applications that a court finds to be invalid, leaving the valid applications in force, because it is the legislature's intent and priority that the valid applications be allowed to stand alone.

. . . .

- If any provision of this Act is found by any court to be unconstitutionally vague, then the applications of that provision that do not present constitutional vagueness problems shall be severed and remain in force.

Act of July 15, 2013, 83rd Leg., 2nd C.S., ch. ___, §10(b), (d).

Accordingly, the department adopts the proposed language to ensure the severability of the requirements of these rules consistent with such intent.

SECTION BY SECTION SUMMARY

The amendment to §139.1 is adopted to clarify the purpose of the rules to include implementation of Woman's Right to Know Act, Health and Safety Code, Chapter 171.

The amendment to §139.2 omits the definition of "ambulatory surgical center" (§139.2(8)) to clarify that the rules adopted by reference in Chapter 139 apply to licensed abortion facilities, and requires renumbering of the remaining definitions.

The amendment to §139.4 is adopted to reflect a change in data required by HB 2 to be reported annually to the department by abortion facilities.

Section 139.9 is adopted to ensure that the severability of the requirements of these rules is consistent with the intent of the Legislature and language of HB 2.

Amendments to §139.32 are adopted to clarify the authority of the department to refuse, suspend or revoke a license for an abortion facility and adds the finding of noncompliance with Health and Safety Code, Chapter 171 as grounds for license probation, suspension or revocation.

New §139.40 is adopted to comply with HB 2, which establishes that the minimum standards for an abortion facility must be equivalent to the minimum standards of an ambulatory surgical center, by adopting by reference with certain changes for clarification the relevant rules for ambulatory surgical centers from Chapter 135. The department adopts by reference specific current ambulatory surgical center rules in order to ensure that the minimum standards governing licensed abortion facilities are equivalent to those of ambulatory surgical centers. The department finds that adopting the minimum standards for ambulatory surgical centers to licensed abortion facilities ensures compliance with HB 2 and provides the maximum guidance and consistency in the rules for licensed abortion facilities.

Chapter 135, relating to ambulatory surgical centers is set out below, along with a statement for each rule as to whether it was adopted or not, and the reasoning for its adoption or non-adoption.

25 TAC Chapter 135, Ambulatory Surgical Centers Rules.

Subchapter A. Operating Requirements for ASCs.

§135.1. Scope and Purpose. This rule was not adopted because a sufficient scope and purpose rule already exists in Chapter 139.

§135.2. Definitions. The following definitions were not adopted by reference for the reasons stated:

(1) "Act," which referred to the Ambulatory Surgical Center Licensing Act, and not to the Texas Abortion Facility Licensing and Reporting Act.

(3) "Administrator" is defined in more detail that requires higher qualifications in §139.2(4) and §139.46(2). Furthermore, ambulatory surgical center rules that are adopted require a governing body (§135.4), and §135.6 describes in adequate detail the required administrative functions.

(4) "Advanced practice registered nurse," because Chapter 139 contains a definition of the same term which is more consistent with the Board of Nursing's (which licenses APRNs) definition of the term "advanced practice nurse" which also requires the nurse to have achieved approval by the Board of Nursing based on completion of an advanced higher education program, a standard not yet incorporated in Chapter 135.

(5) "Ambulatory Surgical Center (ASC)," which is a term defined but not used in Chapter 139, and whose inclusion among adopted rules would have caused confusion. The definition also included portions limiting the length of patients stays within the facility that were felt to be inapplicable to licensed abortion facilities.

(8) "Certified registered nurse anesthetist" is defined in exactly the same way in Chapter 139.

(9) "Change of ownership" is defined the same in Chapter 139, with the exception that a requirement for the tax identification number to change in order to qualify as a change in ownership is not present in Chapter 139. This requirement does not create a minimum standard for the protection of the health and safety of patients.

(11) "Department" is defined in exactly the same way in Chapter 139.

(15) "Licensed vocational nurse" is defined in exactly the same way in Chapter 139.

(17) "Person" is defined in exactly the same way in Chapter 139.

(18) "Physician" is defined in exactly the same way in Chapter 139.

(19) "Premises" is defined as a building where a patient receives outpatient surgical services. This was thought to be a source of potential confusion because medical abortions are not surgical procedures.

(20) "Registered nurse" is defined in exactly the same way in Chapter 139.

The following definitions are adopted by reference because they are terms that are used or are anticipated to be used in connection with the ambulatory surgical center rules that are to be adopted, and are not terms whose meaning, without a definition, is clear to stakeholders. Thus, the following definitions are necessary for compliance with HB 2.

(2) "Action plan"--A written document that includes specific measures to correct identified problems or areas of concern; identifies strategies for implementing system improvements; and includes outcome measures to indicate the effectiveness of sys-

tem improvements in reducing, controlling or eliminating identified problem areas.

(6) "Autologous blood units"--Units of blood or blood products derived from the recipient.

(7) "Available"--Able to be physically present in the facility to assume responsibility for the delivery of patient care services within five minutes.

(10) "Dentist"--A person who is currently licensed under the laws of this state to practice dentistry.

(12) "Disposal"--The discharge, deposit, injection, dumping, spilling, leaking, or placing of any solid waste or hazardous waste (whether containerized or uncontainerized) into or on any land or water so that such solid waste or hazardous waste or any constituent thereof may enter the environment or be emitted into the air or discharge into any waters, including ground waters.

(13) "Extended observation"--The period of time that a patient remains in the facility following recovery from anesthesia and discharge from the postanesthesia care unit, during which additional comfort measures or observation may be provided.

(14) "Health care practitioners (qualified medical personnel)"--Individuals currently licensed under the laws of this state who are authorized to provide services in an ASC.

(16) "Medicare-approved reference laboratory"--A facility that has been certified and found eligible for Medicare reimbursement, and includes hospital laboratories which may be Joint Commission or American Osteopathic Association accredited or nonaccredited Medicare approved hospitals, and Medicare certified independent laboratories.

(21) "Surgical technologist"--A person who practices surgical technology as defined in Health and Safety Code, Chapter 259.

(22) "Title XVIII"--Title XVIII of the United States Social Security Act, 42 United States Code (USC), §§1395 et seq.

The requirements of the following rules from Chapter 135, relating to ambulatory surgical centers, were either adopted or not adopted for the reasons set out below.

Section 135.3, Fees. The requirements of this section were not adopted because HB 2 does not require the adoption of rules relating to licensure fees for licensed abortion facilities.

Section 135.4, Ambulatory Surgical Center (ASC) Operation. The requirements of this section were adopted because Chapter 139 has no identical provision and because the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. For purposes of this rule, the department concludes that the Legislature required each licensed abortion facility to be capable of providing a minimum standard of policies and a governing body to set and implement policies and to assume legal responsibility for operation of the facility.

Section 135.5, Patient Rights. The requirements of this section were adopted because Chapter 139 has no identical provision and because the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. For purposes of this rule, the department concludes that the Legislature required licensed abortion facilities to provide information, privacy, and the opportunity to participate in health care decisions.

Section 135.6, Administration. The requirements of this section were adopted because Chapter 139 has no similar provision and because the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. This section complements §135.4 by describing in greater detail the manner in which the governing body of a facility is to function and by indicating some areas on which it is to focus (patient satisfaction, for example).

Section 135.7, Quality of Care. Chapter 139 contains no directly comparable rule, and the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. For purposes of this rule, the department concludes that the Legislature required licensed abortion facilities to be capable of providing minimum standard quality of care to their patients.

The requirements of this section supplement the rules in Chapter 139 that address corresponding subject matter (§139.46 and §139.53). Section 135.7 provides additional protection for the patient that is not found in either §139.46 or §139.53, such as requirements that "[p]atient care responsibilities shall be delineated in accordance with recognized standards of practice" and that "[r]eferral to another health care practitioner shall be clearly outlined to the patient and arranged with the accepting health care practitioner prior to transfer."

Section 135.8, Quality Assurance. The requirements of this section were adopted because Chapter 139 has no similar provision and because the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. For purposes of this rule, the department concludes that the Legislature required licensed abortion facilities to be capable of providing a minimum level of quality assurance to provide for the health and safety of their patients.

The requirements of this section supplement and enhance §139.8 (Quality Assurance), the parallel rule in Chapter 139. Section 135.8 addresses quality assurance issues more extensively and in more detail than §139.8. For example, §135.8 specifically requires that "[a]ssessment techniques shall examine the structure, process, or outcome of care, and shall be assessed prospectively, concurrently, or retrospectively." The department believes that these requirements advance the legislative objective of improving the quality of care provided to patients and making the standards for licensed abortion facilities equivalent to the ASC minimum standards.

Section 135.9, Medical Records. The requirements of this section were adopted because Chapter 139 has no identical provision and because the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. For purposes of this rule, the department concludes that the Legislature required licensed abortion facilities to be capable of providing a minimum level of medical recordkeeping. This section supplements §139.55 (Clinical Records), the parallel rule in Chapter 139.

While §139.55 is more detailed, it does not contain, for instance, a requirement found in §135.9 that a "single person be designated to be in charge of medical records." The department believes that the requirements of §135.9 enhance the accountability of licensed abortion facilities and the accuracy and complete-

ness of patient records and therefore improve the health and safety of patients.

Section 135.10, Facilities and Environment. The requirements of this section were adopted because Chapter 139 has no identical provision and because the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. These requirements supplement §139.48 (Physical and Environmental Requirements) For example, §135.10 contains more detailed provisions concerning hazardous materials and emergency preparedness than §139.48. Section 135.10 primarily focuses on procedures and basic orderliness, such as eliminating hazards that might cause accidents, conducting fire drills, providing for safe evacuation of patients, and the like. Thus, adopting §135.10 makes the minimum standards for licensed abortion facilities equivalent to those for ASCs.

Section 135.11, Anesthesia and Surgical Services. The requirements of this section were adopted because Chapter 139 has no similar provision and because the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. For purposes of this rule, the department concludes that the Legislature intended to require licensed abortion facilities to be implement anesthesia and surgical services using standards equivalent to an ambulatory surgical center. One of the requirements of §135.11(b)(19)--i.e., that a licensed ASC either have a written transfer agreement with a hospital or have all physicians on staff at the ASC maintain admitting privileges at a local hospital--was not adopted because Health and Safety Code, §171.0031 (added by HB 2), provides a more specific standard concerning a physician's responsibility to maintain admitting privileges. The ASC rule, §135.11, offers an ASC the alternative of either requiring all physicians to maintain admitting privileges at a local hospital or maintaining a written transfer agreement. Section 171.0031 allows no such alternative. Instead, it requires a physician who performs an abortion to have admitting privileges at a hospital not further that 30 miles from the location where the abortion is performed or induced.

Section 135.12, Pharmaceuticals Services. The requirements of this section were adopted because Chapter 139 has no identical provision (§139.60(a) only requires a facility to comply with federal and state laws pertaining to the handling of drugs) and because the Legislature determined that provide pharmaceutical services using standards equivalent to an ambulatory surgical center's. These requirements add a significant resource for physician and patient alike and make the licensed abortion facility equivalent to an ASC.

Section 135.13, Pathology and Medical Laboratory Services. The requirements of this section were adopted because Chapter 139 has no similar provision and because the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. For purposes of this rule, the department concludes that the Legislature required licensed abortion facilities to be capable of providing minimum level of service adequate to meet the needs of the patients and to support an ambulatory surgical center's clinical capabilities.

Section 135.14, Radiology Services. The requirements of this section were adopted because Chapter 139 has no similar provision and because the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. For purposes of this rule, the department concludes that the Legislature required licensed abortion facilities to be capable of providing minimum level of service adequate to meet the needs of the patients and to support an ambulatory surgical center's clinical capabilities.

Section 135.15, Facility Staffing and Training. The requirements of this section were adopted because Chapter 139 has no identical provision and because the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. For purposes of this rule, the department concludes that the Legislature required licensed abortion facilities to be capable of providing a minimum level of qualified staff adequate to meet the needs of the patients and to support an ambulatory surgical center's clinical capabilities.

The requirements of this section supplement §139.46 (Licensed Abortion Facility Staffing Requirements and Qualifications), and make the rules for licensed abortion facilities "equivalent to" those of ASCs as required by HB 2.

Section 135.16, Teaching and Publication. The requirements of this section were adopted because Chapter 139 has no similar provision and because the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. For purposes of this rule, the department concludes that the Legislature required licensed abortion facilities to provide policies concerning teaching and publication services capable of providing a minimum level of service adequate to serve the needs of patients and the community.

Section 135.17, Research Activities. The requirements of this section were adopted because Chapter 139 has no similar provision and because the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. For purposes of this rule, the department concludes that the Legislature required licensed abortion facilities to be capable of providing minimum level of research activities.

Section 135.18, Unlicensed Ambulatory Surgical Center, was not adopted because §139.3 has adequate provisions for dealing with unlicensed abortion facilities that are not exempted from licensure by Health and Safety Code, Chapter 245.

Section 135.19, Exemptions, was not adopted because the exemptions from licensure as an abortion facility are set forth in Health and Safety Code, §245.004.

Section 135.20, Initial Application and Issuance of License, was not adopted because §§139.21 - 139.25 cover application and issuance of licenses for licensed abortion facilities.

Section 135.21, Inspections, was not adopted because it only required inspections of licensed facilities every three years, whereas present §139.31 requires annual inspections of licensed abortion facilities. Section 139.31 provides greater protection by requiring more frequent (annual) inspections than the three-year minimum intervals prescribed by §135.21, consistent with the department's understanding of HB 2, that its intent is to move licensed abortion facilities under ASC rules where they will provide equivalent standards to those of ASCs, but not to repeal enforcement provisions that apply to licensed abortion facilities.

Section 135.22, Renewal of License, was not adopted because §§139.21 - 139.25, especially §139.23, adequately address re-

newal of licenses for licensed abortion facilities, consistently with the department's understanding of HB 2, that its intent is to move licensed abortion facilities under ASC rules where they will provide equivalent standards to those of ASCs, but not to repeal enforcement provisions that apply to licensed abortion facilities.

Section 135.23, Conditions of Licensure, was not adopted because §§139.21 - 139.25 adequately address conditions of licensure for licensed abortion facilities, consistently with the department's understanding of HB 2, that its intent is to move licensed abortion facilities under ASC rules where they will provide equivalent standards to those of ASCs, but not to repeal enforcement provisions that apply to licensed abortion facilities.

Section 135.24, Enforcement, was not adopted because §§139.31 - 139.33 adequately address enforcement issues, consistently with the department's understanding of HB 2, that its intent is to move licensed abortion facilities under ASC rules where they will provide equivalent standards to those of ASCs, but not to repeal enforcement provisions that apply to licensed abortion facilities.

Section 135.25, Complaints, was not adopted because §139.31(c) adequately addresses complaints, consistently with the department's understanding of HB 2, that its intent is to move licensed abortion facilities under ASC rules so that patients of licensed abortion facilities will benefit from equivalent standards to those of ASCs, but not to repeal enforcement provisions that apply to licensed abortion facilities.

Section 135.26, Reporting Requirements. The requirements of this section were adopted because Chapter 139 has no identical provision and because the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. For purposes of this rule, the department concludes that the Legislature required licensed abortion facilities to be capable of providing a minimum level of incident reporting to enhance the safety of every facility's patients by allowing by providing accurate and timely input for statistical analysis of adverse incidents and monitoring the frequency of their occurrence.

Section 135.26 adds additional requirements that protect the health and safety of patients, such as the obligation of the facility to report the transfer of a patient to a hospital and to report the development by a patient within 24 hours of discharge of a complication if the complication results in a patient's admission to a hospital. In contrast, the only similar section that applies to licensed abortion facilities, §139.58, requires only the reporting of a woman's death from complications of an abortion.

Section 135.27, Patient Safety Program. The requirements of this section were adopted because Chapter 139 has no similar provision and because the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. For purposes of this rule, the department concludes that the Legislature required licensed abortion facilities to be capable of determining the root cause of adverse events that occur at the facility. Section 135.27 was adopted because it requires the facilities to directly address patient safety by developing and implementing a patient safety program, and by a root cause analysis of adverse events, issues to which no rule in Chapter 139 is entirely dedicated. For example, §135.27 requires facility management to coordinate all patient safety activities, while Chapter 139 does not.

Section 135.28, Confidentiality, was not adopted because more confidentiality is provided to abortion patients and licensed abortion facilities by existing rules in Chapter 139 than by this rule.

Section 135.29, Time Periods for Processing and Issuing a License, was not adopted because §§139.21 - 139.25 adequately address licensure of licensed abortion facilities. Both Chapters 135 and 139 provide a two-year interval for re-application and renewal of licenses.

Subchapter B. Fire Prevention and Safety Requirements.

Section 135.41, Fire Prevention and Safety Requirements. The requirements of this section were adopted because Chapter 139 has no similar provision and because the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. For purposes of this rule, the department concludes that the Legislature required licensed abortion facilities to be capable of providing a minimum level of fire prevention and safety measures.

Except for some brief and general references in §139.48, Chapter 139 does not address fire prevention, does not require the appointment of a safety officer who is familiar with safety practices in healthcare facilities, and does not forbid the use of extension cords for permanent wiring. Section 135.41 provides for all three and has other safety requirements not found in Chapter 139.

Section 135.42, General Safety. The requirements of this section were adopted because Chapter 139 has no similar provision and because the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. For purposes of this rule, the department concludes that the Legislature required licensed abortion facilities to be capable of providing minimum level of safety requirements adequate to protect the safety of patients.

Section 135.43, Handling and Storage of Gases, Anesthetics, and Flammable Liquids. The requirements of this section were adopted because Chapter 139 has no identical provision and because the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. For purposes of this rule, the department concludes that the Legislature required licensed abortion facilities to be capable of providing minimum level of safety regimen to ensure the health and safety of its patients.

Subchapter C. Physical Plant and Construction Requirements.

Section 135.51, Construction Requirements for an Existing Ambulatory Surgical Center. The requirements of this section were adopted because Chapter 139 has no similar provision and because the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. For purposes of this rule, the department concludes that the Legislature required licensed abortion facilities to be regulated by the construction standards that provide a minimum level of safety and utility equivalent to that of an ambulatory surgical center.

Chapter 139 presently contains only one section that addresses "Physical and Environmental Requirements," §139.48. That section has approximately one page of general requirements, such as "A facility shall have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the

health and safety of patients and staff at all times." Section 139.48 does not specify what constitutes proper construction for an existing licensed abortion facility, as does adopted §§135.51 - 135.56.

The adopted rules do not incorporate by reference the provisions of §135.51(a)(1) and (2) that exempt certain ambulatory surgical centers from compliance with the construction standards:

(1) A licensed ambulatory surgical center (ASC) which is licensed prior to the effective date of these rules is considered to be an existing licensed ASC and shall continue, at a minimum, to meet the licensing requirements under which it was originally licensed.

(2) In lieu of meeting the requirements in paragraph (1) of this subsection, an existing licensed ASC may, instead, comply with National Fire Protection Association (NFPA) 101, Life Safety Code 2003 Edition (NFPA 101), Chapter 21, Existing Ambulatory Health Care Occupancies. All documents published by NFPA as referenced in this section may be obtained by writing or calling the NFPA at the following address or telephone number: National Fire Protection Association, 1 Batterymarch Park, Quincy, Massachusetts 02269-9101 or (800) 344-3555.

The department declined to incorporate these provisions for three reasons. First, the plain language of the exemption applies only to an entity that was licensed as an ambulatory surgical center before June 18, 2009, the effective date of the §135.51. Unless a licensed abortion facility was also licensed as an ambulatory surgical center on that date, it would not be eligible for the exemption. Prior to the adoption of HB 2 a licensed abortion facility was permitted to become a licensed ambulatory surgical center, and was thus allowed to utilize any exemptions set out in §135.51. After the adoption of HB 2, all licensed abortion facilities are required to comply with the provisions of that law and Chapter 139. Therefore, the more specific provisions of HB 2, which provides no grandfathering provision, and applies to every licensed abortion facility is the more specific statute with which all licensed abortion facilities must now comply. (The specific statute is thus regarded as an exception to, or a qualification of, any previously enacted general statute on the same subject, which must yield in its scope and effect to the specific provisions of a later statute *Sam Bassett Lumber Co. v. City of Houston,* 145 Tex. 492 (Tex.1947)).

Second, the enactment of HB 2 evidenced the Legislature's intention to place licensed abortion facilities under minimum standards that are equivalent to licensed ambulatory surgical centers. To employ the limited exemption of §135.51 out of context to abortion facilities that were licensed on or before June 18, 2009, would be contrary to the Legislature's specific intent to improve the safety of licensed abortion facilities and contradict the Legislature's unequivocal decision to place licensed abortion facilities under enhanced regulation.

Third, it is well established that where the Legislature has unequivocally expressed its intent, a state agency is not at liberty to craft exceptions where the Legislature did not see fit to supply any. Accordingly, the department determined that it is not authorized to exempt currently licensed abortion facilities from the minimum standards applicable to licensed ambulatory surgical centers through the incorporation of the limited exceptions prescribed by §135.51(a)(1) and (2).

Section 135.52, Construction Requirements for a New Ambulatory Surgical Center. The requirements of this section were adopted because Chapter 139 has no similar provision and because the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. For purposes of this rule, the department concludes that the Legislature required licensed abortion facilities to be regulated by the construction standards that provide a minimum level of safety and utility equivalent to that of an ambulatory surgical center.

Section 135.53, Elevators, Escalator, and Conveyors. The requirements of this section were adopted because Chapter 139 has no similar provision and because the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. For purposes of this rule, the department concludes that the Legislature required licensed abortion facilities to be regulated by the construction standards that provide a minimum level of safety and utility equivalent to that of an ambulatory surgical center.

Chapter 139 presently contains only one section that addresses "Physical and Environmental Requirements," §139.48. That section does not contain requirements for elevators, escalators, or conveyors, as does adopted §135.53.

Section 135.54, Preparation, Submittal, Review and Approval of Plans, and Retention of Records. The requirements of this section were adopted because Chapter 139 has no similar provision and because the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. For purposes of this rule, the department concludes that the Legislature required licensed abortion facilities to be regulated by the construction standards that provide a minimum level of safety and utility equivalent to that of an ambulatory surgical center.

Section 135.55, Construction, Inspections, and Approval of Project. The requirements of this section were adopted because Chapter 139 has no similar provision and because the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. For purposes of this rule, the department concludes that the Legislature required licensed abortion facilities to be regulated by the construction standards that provide a minimum level of safety and utility equivalent to that of an ambulatory surgical center.

Chapter 139 presently contains only one section that addresses "Physical and Environmental Requirements," §139.48. That section has approximately one page of general requirements, such as "A facility shall have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times." Chapter 139 contains no requirements for inspection and approval of construction projects, as does adopted §135.55.

Section 135.56, Construction Tables. The requirements of this section were adopted because Chapter 139 has no similar provision and because the Legislature determined that the minimum standards for a licensed abortion facility must be equivalent to the minimum standards for a licensed ambulatory surgical center. For purposes of this rule, the department concludes that the Legislature required licensed abortion facilities to be regulated by the construction standards that provide a minimum level of safety and utility equivalent to that of an ambulatory surgical center.

Chapter 139 does not contain tables or drawings of any kind that specify proper construction requirements, so it is not equivalent to rules for ambulatory surgical centers.

Amendments to §139.53 and §139.56 are adopted to specify the admitting privilege requirements of physicians who perform or induce abortions as required by HB 2.

Additional amendments to §139.56 and amendments to §139.57 are adopted to specify the information required by HB 2 to be given to the patient and the requirement for the facility to make available the physician or a staff person with access to the patient's medical records to respond to patient phone calls 24 hours daily as required by Health and Safety Code, §171.0031(a)(2)(A) as amended by HB 2.

COMMENTS

The department has reviewed and prepared responses to comments regarding the proposed rules that were submitted during the comment period and at the State Health Services Council Meetings held on August 28 and 29, 2013.

The department received a total of 19,799 public comments. A total of 5,466 comments, representing approximately 27.6 percent of all comments, contained information that indicates the comments were filed by individuals who reside outside the State of Texas or the United States.

The Texas Alliance for Life, Texas Right to Life, and the Texas Medical Association filed comments in support of the rules. The first two organizations noted that the rules would promote the health and safety of women who seek an abortion in Texas by requiring licensed abortion facilities to comply with the construction and physical plant standards that are now required of ASCs, and by requiring physicians who perform abortions to have admitting privileges at a hospital within 30 miles of the place where the abortions are performed.

The Texas Alliance for Life proposed two changes: (1) that the department amend §139.53 to provide that a physician must be physically present at the abortion facility during the administration of an abortion-inducing drug, and (2) that the rules prohibit a physician from delegating this responsibility.

The Texas Medical Association endorsed the department's "measured approach" in drafting the rules and urged the continued use of "gestational age" as the criterion to estimate the length of a pregnancy. However, if using "gestational age" is not possible, the Texas Medical Association encouraged the department to adopt a rule that defines "probable post-fertilization age."

Response: The department appreciates the comments. The department is working to ensure that the rules will be adopted in time to go into effect January 1, 2014, although, in the case of the changes to make certain standards for ambulatory surgical centers equivalent to those for abortion facilities, abortion facilities are not required to comply with the adopted rules until September 1, 2014.

Regarding the proposed amendment to §139.53, the department notes that the proposed rule addresses matters that are within the practice of medicine and relate to the administration of drugs that are intended to terminate a pregnancy. Proposed §139.53 was intended to implement Section 2 of HB 2, which adds Subchapter D to Health and Safety Code, Chapter 171. This subchapter regulates the distribution, dispensing, and administration of abortion-inducing drugs.

The Texas Medical Board is delegated the authority to regulate the practice of medicine. Occupations Code, §151.003(2). Consistent with this regulatory scheme, Health and Safety Code, §171.062 expressly requires the Texas Medical Board to enforce Subchapter D. In light of this express delegation of authority, and because the Texas Medical Board is delegated principal authority to regulate the practice of medicine in Texas, the department believes that it is not within the department's authority to adopt rules on that subject. The department therefore declines to change the adopted rule to reflect the Texas Alliance for Life's recommendation.

Regarding the Texas Medical Association's recommendation that the department adopt a rule to define the statutory phrase "probable post-fertilization age," the department appreciates the comment but declines to adopt the recommendation for two reasons. First, the department observes that Health and Safety Code, §171.042 (as added by HB 2) employs a common scientific definition of "fertilization" to define the term "post-fertilization age." The department does not believe that the addition of the adjective "probable" creates an ambiguity that requires clarification in the rules.

Second, in the absence of a statutory definition, words and phrases in a statute must be read in context and construed according to the rules of grammar and common usage. Government Code, §311.011(a). In the context of Health and Safety Code, Chapter 171, and in the absence of a statutory definition of the word "probable," the department believes that the Legislature intended the public and the regulated community to resort to the common and ordinary meaning of the word in examining a physician's conduct or a patient's reasonable expectations. See, e.g., The American Heritage Dictionary of the English Language, 4th Ed. at 1397 (2006) ("probable" means, inter alia, "Likely to happen or to be true.... Likely but uncertain; plausible").

The department received comments from the American Civil Liberties Union, the American Congress of Obstetricians and Gynecologists, the Center for Reproductive Rights (Texas District), the League of Women Voters of Texas, the National Abortion Foundation, the National Organization for Women, Planned Parenthood of Greater Texas and other Planned Parenthood Entities commenting as one group, 34 Million Friends of the United Nations Population Fund, Rise Up Texas, and Texas Democratic Women. These commenters generally opposed the adoption of some or all of the adopted rules. The department acknowledges these comments and responds below, separately according to the various issues raised by the entire set of commenters.

Numerous comments also were received from interested individuals. The department received comments on topics concerning the substance of the rules, and other comments relating to legal issues and issues concerning the preamble to the proposed rules. The responses to the comments appear by topic. Some comments received included matters that were outside the scope of the proposed rules, including vituperative language and political statements. These comments do not affect the substance or scope of the rule.

The comments related to 14 general categories: (1) a woman's constitutional right to terminate a pregnancy; (2) access to abortion services; (3) the physician's admitting privileges requirement; (4) adoption of ASC construction and physical plant rules; (5) medical necessity for adoption of ASC and admitting privileges requirements; (6) grandfathering licensed abortion facilities regarding ASC rules; (7) exempting facilities where only

medical abortions are performed and waiving the statute for such facilities; (8) abortion facility rules assertedly not "equivalent to" those for ASCs; (9) challenges to statements in the preamble to the proposed rules; (10) retention of annual inspections for licensed abortion facilities; (11) Comments Relating to Disproportionate Impact on Low-Income Women and Women Who Live in Rural Areas; (12) Comments Relating to Assertions That the Department Is Singling Out Abortion Facilities For Punitive Regulation; (13) Comments Relating to Rules Requiring Facilities to Be Prepared to Respond Indefinitely to Abortion Patient Calls; and (14) Comments Relating to Request for Definition of "Admitting Privileges" in Connection with §139.53 and §139.56.

1. Comments Relating to the Right of Women to End a Pregnancy.

Comment: At least one commenter stated that the proposed rules do not show that the department considered women's constitutional right to end a pregnancy.

Response: The department respectfully disagrees. The preamble to the proposed rules quotes in detail the Bill Analysis for HB 2. (38 TexReg 6536) (September 27, 2013, issue); House Comm. on State Affairs, Bill Analysis, Tex. HB 2, 83rd Leg., 2nd C.S. (2013)). The bill analysis refers to the United States Supreme Court case, *Planned Parenthood of Southeastern Pennsylvania v. Casey,* 505 U.S. 833 (1992), which recognizes women's right to an abortion, but nevertheless holds that states may regulate abortion clinics.

Various commenters alleged, in very general terms, that the proposed rule would impose various burdens on unidentified clinics, and that the proposed rule could cause some unspecified number of abortion providers to stop providing abortion services in Texas. Some commenters claimed that those results would constitute an "undue burden" under *Planned Parenthood of Southeastern Pennsylvania v. Casey,* 505 U.S. 833 (1992). The department disagrees with these comments for three reasons.

First, the commenters misunderstand the rights at issue. In *Casey,* the Supreme Court recognized the State's profound and legitimate interest in unborn life and its right to reasonably regulate the operation of abortion facilities. The Court held that "[r]egulations designed to foster the health of a woman seeking an abortion are valid if they do not constitute an undue burden on a woman's right to terminate a pregnancy." *Id.* at 878. The Court instructed that "[a]n undue burden exists, and therefore a provision of law is invalid, if its purpose or effect is to place substantial obstacles in the path of a woman seeking an abortion before the fetus attains viability." *Id.* And in reaching those conclusions, the Court emphasized that "[w]hat is at stake is *the woman's right* to make the ultimate decision," *id.* at 877 (emphasis added); no commenter points to any decision that has interpreted the Constitution to afford *abortion providers' rights* to operate particular clinics, to operate those clinics in particular ways, or to maintain particular profit margins.

Second, the comments include only generalized claims that some unspecified number of unidentified clinics might struggle to comply with the rule or close for some undetermined time on account of it. While the department received more than 19,000 comments, the department is not aware of any comment that identified a particular clinic that will permanently shut down; nor is the department aware of any comment that identified a particular reason that a particular clinic would be unable to comply with the rule; and the department is not aware of any comment that identified a particular reason that new clinics will not open and comply with the rule. To the contrary, the department is aware of reports that at least three new ASCs that plan to open and comply with the rule in Dallas, Houston, and San Antonio by September of 2014. And in all events, the department is not aware of any comments that purport to show how any alleged effect on particular clinics will impact the only right recognized in Casey--namely, a woman's right to obtain an abortion. For example, the department is aware of no comments that explain how particular abortion-seeking patients will face unconstitutionally long travel distances, unconstitutionally long wait times, or unconstitutionally high costs for abortion services in any particular part of the State.

Third, even if commenters had provided specific allegations of future harms, the department reasonably could be skeptical of those predictions based on its experience with previous challenges to HB 2. In September 2013, various abortion providers sued to enjoin the department's commissioner from enforcing HB 2's admitting-privileges requirement. In that lawsuit, the abortion providers alleged that particular clinics would be forced to close if the admitting-privileges requirement went into effect. Those allegations proved to be overstated because multiple providers that allegedly would be forced to close nonetheless received admitting privileges and either stayed open or reopened. Not one of the comments received by the department provides any basis to believe that abortion providers would be unable to make similar adjustments and likewise comply with the rule.

The preamble to the proposed rules restated the Legislature's determination that application of certain ASC standards would "create the least burdensome set of minimum standards sufficient to improve the safety of patients of a licensed abortion facility." (38 TexReg 6536) (September 27, 2013 issue). However, as noted previously, the department has examined whether the requirements of the ASC standards in Chapter 135 that the department proposed to integrate into Chapter 139 establish substantial obstacles to a woman's right to elect to terminate a pregnancy. The department understands that the standards may negatively impact some current licensees that elect not to comply with the requirements of the adopted rules, but the department also believes that the Legislature carefully and thoroughly considered these issues in determining that ASC standards were appropriate and necessary to ensure the safety of patients who seek abortion services. In light of this unequivocal expression of legislative intent, the department is not, through the adoption of these rules, at liberty to craft exceptions where the Legislature did not see fit to supply any. See *Public Utilities Com'n v. Cofer,* 754 S.W.2d 121, 124 (Tex. 1988); *Spears v. City of San Antonio,* 223 S.W. 166,169 (Tex.1920); *Stubbs v. Lowrey's Heirs,* 253 S.W.2d 312, 313 (Tex.Civ.App.--Eastland 1952, writ ref'd n.r.e). The department also considered that the Legislature did not require licensed abortion facilities to become licensed as ambulatory surgical centers and established in HB 2 a grace period for compliance until September 1, 2014, more than a year after the bill's passage. From these events, the department inferred that the Legislature did not intend for the grandfathering provision of Chapter 135 to extend to abortion facilities licensed under Chapter 245 of the Health and Safety Code. (38 TexReg 6537) (September 27, 2013 issue)

In summary, the department believes that its preamble to the proposed rules and its selection of only a portion of the ASC rules for adoption demonstrate careful consideration of (1) the rights of women to end a pregnancy, and (2) legislative intent in the enactment of HB 2 to impose the least burdensome standards

sufficient to improve the safety of patients of a licensed abortion facility.

2. Comments Relating to Adequate Access to Abortion Services.

Comment: A number of commenters expressed concern that the adopted rules would limit access to abortion facilities. The commenters stated that many licensed abortion facilities will close if they are required to comply with the ASC rules for construction and physical plant standards and ensure that physicians who perform abortions at their facilities have admitting privileges at a hospital located within 30 mile of the facility. The commenters stated the impact would be particularly acute in rural areas of the state that are remote from large cities.

Response: As explained previously, generalized allegations of inadequate access are unhelpful and insufficient to show that old facilities actually will close, that new facilities will not open, or that any particular woman will be unable to access abortion services.

In 2011, all 72,000+ reported abortions in Texas were performed in only 18 counties. (Department of State Health Services, 2011 Vital Statistics Annual Report, Table 34: Induced Termination of Pregnancy by Age and County of Residence 2011); DSHS response to Public Information Act request Feb. 2, 2011 regarding addresses of all facilities where abortions are performed. March 1, 2011) Patients included women from all but six Texas counties, with more than 1,100 patients' county of residence not reported. *(Id.)*

The department can only infer from the existing geographic distribution of facilities and the number of abortions performed despite that distribution that even if a number of facilities were to close, the adverse impact on Texas women seeking an abortion, if any, would be relatively small.

Specific ASC construction and physical plant rules and physician admitting privilege requirements are addressed elsewhere Parts 4 and 3, respectively, of this Preamble. In general, the department believes that both requirements will significantly improve the quality of abortion care for women, in the first case by providing a safer and more comfortable working environment for staff and patients, thus enabling staff to perform its work better. Many of the ASC physical plant requirements are intended to provide space for health-related functions and goods that relate specifically to the health and safety of patients, such as ample room in the hallways for gurneys and staff, and storage for medical goods and clean linens. In the case of the admitting privileges requirement, the department anticipates that the requirement will enhance continuity of care as opposed to a women being left to find follow-up care in emergency rooms with a different physician, and will improve the quality of care by requiring physicians who perform abortions to have hospital credentials.

3. Comments Relating to Admitting Privileges Requirement.

Comment: Some commenters opposed §139.53(c)(1) - (2), which require a physician who performs abortions to have admitting privileges at a hospital which provides obstetrical and gynecological services and is located no farther than 30 miles from the place where the abortion is performed. These commenters stated that the requirement is unnecessary because often the hospital chosen by a patient for her follow-up treatment is one close to her home, not necessarily one close to where the abortion is performed. Commenters also assert that admitting privileges for a physician who performs abortions may be difficult to obtain, that obtaining such privileges often requires months, and that the result of this requirement will be the closure of some facilities and the resultant denial of abortion services to women in the affected areas. They urged that the department not adopt such rules.

Response: The department disagrees. The department is charged with enforcing Chapter 171 of the Health and Safety Code, including §171.0031 as amended by HB 2, the section that contains the provisions opposed by these commenters. The provisions of §171.0031 in question are expressed as conditions precedent to a physician's performing an abortion. ("[A] physician must. . . ."). Government Code, §311.016(3).

HB 2's plain language requires a physician who performs abortions to have active admitting privileges at a hospital which provides obstetrical or gynecological services and is located no farther than 30 miles from the place where the abortion is performed.

Section 139.53(c)(1) and (2) clarify that the department will, as the Legislature directed, enforce the statutory requirements by requiring the abortion facilities it licenses to require compliance by the physicians who perform abortions there.

The department understands that the principal objective of the admitting privileges requirement is not to restrict a woman's choice of provider of follow-up care, but to ensure safety and continuity of care by a treating physician in cases that require emergency hospital care. Furthermore, the proposed rules do not limit a woman's ability to seek follow-up care wherever she chooses.

While commenters stress the safety of abortion procedures, the department is aware that it is likely that complications from abortions are underreported. Furthermore, the department cannot overlook the fact that more than 70,000 such procedures are performed each year in Texas. Reported complications of medical abortions, which the commenters believe are the safest, are estimated in medical literature of which the department is aware, at 5-8% of medical abortions. (Re: Overall complication rates: U.S. Food and Drug Administration. Mifeprex Medication Guide. 2009).

Re: Heavy bleeding and failure to remove all products of conception: American Congress of Obstetricians and Gynecologists. Medical Management of Abortion. ACOG Practice Bulletin No. 67. Obstetrics and Gynecology. 2005;106:871-82. Texas Medical Disclosure Panel. List A, Procedures Requiring Full Disclosure of Specific Risks and Hazards; 2012. Royal College of Obstetricians and Gynaecologists (RCOG); The Care of Women Requesting Induced Abortion. London (England): Royal College of Obstetricians and Gynaecologists (RCOG); 2011 Nov. 130 p. (Evidence-based Clinical Guideline; no. 7). *Note: An evidence review of the guideline is available in the U.S. Health and Human Services, Agency for Healthcare Research and Quality National Guideline Clearinghouse.*

Therefore, applying a conservative estimate of 5%, more than 3,500 Texas patients of abortion facilities will experience complications.

4. Comments Relating to ASC Construction and Physical Plant Rules.

Comment: Some commenters addressed specifically the minimum space and plant arrangement requirements in §135.52(d)(1)(G)(i), requiring 30 square feet per operating room to be set aside for a general storage room; §135.52(d)(3)(A), a requirement for a minimum clear floor area of 80 square

feet in each examination room (but examination rooms are not required); §135.52(d)(9)(B)(i) - (ii), free space requirements for post-operative recovery suites and rooms, multi-bed and private; §135.52(d)(9)(E)(i), space requirements for extended observing room, which are not required; §135.52(d)(10)(B)(i) - (ii), requirement for a minimum of one patient station per operating room and spatial requirements; §135.52(d)(13)(A), a requirement for surgical staff dressing rooms; §135.52(d)(15)(A), clear space minimums for operating rooms (but no clear requirement for an operating room); §135.52(d)(15)(B)(iv) concerning scrub sinks and a viewing window; and the width requirement for doors and corridors, as well as that rule's requirement for swing type doors. Comment was made suggesting the elimination of §135.52(g)(5)(C)(iv) and Table 1 of §135.56(a) because there is no health or safety consideration for requiring a particular room temperature at a licensed abortion facility. Some commenters also objected to the application of off-street parking requirements contained in §135.52(b)(2). The commenters stated that these requirements would not improve patient care and hence are not medically necessary.

The commenters also expressed concern that a large number of licensed abortion facilities would close because they could not or would not meet the construction and physical plant rules, resulting in limited access to abortion for Texas women.

Response: The portions of these comments concerning facility closures are addressed separately under the headings "Adequate Access to Abortion Care" and "Comments Relating to Disproportionate Impact on Low-Income Women and Women Who Live in Rural Areas." Regarding the adopted ASC construction and physical plant rules generally, the department recognizes that some licensed abortion facilities may not be financially capable of complying with these requirements. However, because the physical and financial conditions of licensed abortion facilities will vary, the department cannot accurately estimate the impact of the adopted rules on licensees.

The department nevertheless believes that the Legislature recognized these potential consequences but also considered the state's vital interest in preserving potential life and improving patient safety, and concluded that the ASC standards would not unduly burden a woman's right to an abortion. In light of that legislative determination, the department believes that the adopted ASC construction and physical plant rules reasonably implement the Legislature's directive.

The department believes that higher construction and physical plant design standards for abortion facilities will improve the facilities' response to complications in those facilities by ensuring that the facility is prepared and qualified to address both routine procedures and adverse events when they inevitably do occur. As noted under Topic 3 above, the department is aware that some patients will suffer complications, and for many, if not most or all facilities, the number doing so annually is significant.

As noted in the responses below to comments concerning medical necessity, the true issue is not whether each adopted requirement is medically necessary; it is whether the adopted construction and physical plant requirements reasonably improve the health and safety of women who seek abortion services without creating a substantial obstacle for a woman seeking an abortion. The Legislature determined that the ASC standards would do so. The adoption of requirements from the ASC rules is intended to make licensed abortion facilities more safe, indirectly by providing minimal amenities for staff and patients, and directly by providing as clean and spacious working environment as was deemed reasonably feasible.

Each ASC construction requirement is a response to an issue, such as ample space in hallways for gurneys and attendants, that can reasonably be anticipated to preserve or improve patients' health and welfare, directly or indirectly. For instance, the off-street parking requirements provide safe access to the facility for patients, people who accompany them, visitors, and facility staff, and the HVAC (temperature and humidity) requirements of §135.52(g)(5)(C)(iv) and Table 1 of §135.56(a) help prevent accumulations of mold and pathogens in the facility as well as provide for comfort of patients and staff alike.

Therefore, the department believes that the requirements proposed for adoption not only fulfill HB 2's mandate to adopt standards for construction and physical plant design for licensed abortion facilities that are equivalent to those for ASCs, but also will improve the health and safety of patients at licensed abortion facilities without placing an undue burden on women seeking abortion services.

5. Comments Relating to Medical Necessity for Adoption of ASC and Admitting Privileges Requirements.

Comment: A number of commenters oppose the adoption of ambulatory surgical center standards (see §139.40) or the admitting privilege requirement (see §139.53 and §139.56). These commenters asserted that there is no medical necessity to apply ASC construction and plant standards to licensed abortion facilities, with several asserting that abortion is an extremely safe procedure, citing kinds of cases they assert are less safe than procedures that physicians are allowed to perform in their offices.

Some commenters wrote that the lack of medical necessity is especially true of facilities that provide only medical abortions, because no surgical and little infection risk exists in such procedures. Some commenters urged that abortion is no longer usually a surgical procedure and that requirements that are appropriate for ASCs are inappropriate for abortion facilities, especially those at which only medical abortions are performed.

Response: First, the department observes that the presence or absence of medical necessity does not govern the department's duty to adopt rules. These arguments are more appropriately directed to the Legislature, which is responsible in the first instance to establish state policy to govern elective abortions.

The Legislature determined that the operating standards for licensed abortion facilities were insufficient to protect the health and safety of patients and that the state's legitimate interest in protecting potential life outweighed a licensed abortion facility's desire to avoid improvements to assure patient health and safety. Moreover, the terms "medical necessity" and "medically necessary" do not appear in Health and Safety Code, Chapter 245, which authorizes regulation of abortion facilities, nor in Health and Safety Code, Chapter 171, which refers to informed consent and other issues related to abortion and abortion facilities.

Likewise, neither "medical necessity" nor "medically necessary" appear in the licensed abortion facility rules, 25 TAC Chapter 139. In the reporting rule section, there are two instances where a physician is instructed to certify that an abortion was necessary to save the mother's life. In Health and Safety Code, §245.016 there is one similar occurrence of the word "necessary." Accordingly, because the Legislature did not exercise its prerogative to incorporate a medical necessity requirement in either HB 2 or

prior legislation, the department believes that it would be inappropriate to impose one in the adopted rules.

Concerning comparisons with procedures performed by physicians in their offices, the department regulates only healthcare facilities, not physicians. Despite the commenters' belief in the relative safety of abortion, the department is aware of reports in medical literature that abortions are underreported. (Obstet Gynecol. 2005 Oct;106 (4):684-92. Abstract: Underreporting of pregnancy-related mortality in the United States and Europe. Deneux-Tharaux C, Berg C, Bouvier-Colle MH, Gissler M, Harper M, Nannini A, Alexander S, Wildman K, Breart G, Buekens P. Institut National de la Santé et de la Recherche Medicale U 149, Epidemiological Research Unit on Perinatal and Women's Health, Paris, France. Fam Plann. Perspect. 1998 May-Jun;30(3):128-33, 138; Alan Guttmacher Institute, New York, USA. Abstract: Measuring the extent of abortion underreporting in the 1995 National Survey of Family Growth. Fu H, Darroch JE, Henshaw SK, Kolb E.)

The department infers from those reports that complications and mortality whose initial cause is abortion may also be underreported. These reports cast doubt on the statistics relied on by opponents of the rules and the degree of safety of the abortion procedure.

In addition, the department is aware of medical literature that places the incidence of reported complications of medical abortions that occur in the first trimester and should be the safest at 5-8%. (U.S. Food and Drug Administration. Mifeprex Medication Guide. 2009. Re: Heavy bleeding and failure to remove all products of conception: American Congress of Obstetricians and Gynecologists. Medical management of abortion. ACOG Practice Bulletin No. 67. Obstetrics and Gynecology. 2005;106:871-82. Texas Medical Disclosure Panel. List A, Procedures Requiring Full Disclosure of Specific Risks and Hazards. 2012. Royal College of Obstetricians and Gynaecologists (RCOG). The care of women requesting induced abortion. London (England): Royal College of Obstetricians and Gynaecologists (RCOG); 2011 Nov. 130 p. (Evidence-based Clinical Guideline; no. 7). *Note: An evidence review of the guideline is available in the U.S. Health and Human Services, Agency for Healthcare Research and Quality National Guideline Clearinghouse.*

If a facility performed 3,000 abortions per year, it could expect 150 of its patients each year--approximately three per week--to suffer serious complications from an abortion, many of which ultimately require surgery. While it may be true, as some commenters suggest, that follow-up surgery for these complications often can and will be done at surgical facilities other than the abortion clinic, the department believes that the Legislature determined it is reasonable to anticipate that a significant number of patients with complications will want to have them treated at the same clinic where they arose. Presumably the patients originally chose that clinic at least in part for its relative convenience to them.

Therefore, the department believes that it is wise to adopt a proactive approach that requires enhanced precautions to enhance patient safety without placing an undue burden on women who seek services at the regulated facilities.

6. Comments Relating to Grandfathering Licensed Abortion Facilities.

Comment: A number of commenters suggested that the rules should extend a provision from Chapter 135 (§135.21(a)(1) and (2)) to grandfather existing licensed abortion facilities so that they would not be required to comply with construction and design standards imposed on ASCs. They urge that, by failing to adopt this grandfathering provision, the department has imposed stricter standards on abortion facilities than on ASCs rather than making the standards "equivalent to" those for ASCs.

Response: The department disagrees. As noted in the Section-by-Section Summary of the provisions of Chapter 135, Subsection C in this Preamble, HB 2 gives the department no authority to exempt any licensed abortion facility from its provisions, nor to waive the application of its provisions or the rules adopted pursuant to HB 2 to particular facilities. Nor does any other provision of Health and Safety Code, Chapter 245 grant the department such authority. Therefore, the department has no authority to exempt by rule or grant waivers for "medical-only" providers from the provisions of HB 2 or the rules adopted pursuant to HB 2.

7. Comments Relating to Exempting Facilities Where Only Medical Abortions Are Performed and Waiving the Statute for Such Facilities.

Comment: Regarding the adoption of ASC construction and plant rules for licensed abortion facilities, some commenters suggested that facilities that perform only medical abortions be exempted by rule from these requirements. The commenters reasoned that if a facility performs only medical procedures, it should not be required to comply with the ASC rules, which, according to the commenters, were designed only for clinics where surgery is performed.

Similarly, some commenters urged that facilities that provide only medical abortions be granted waivers from the application of the requirements regarding the adoption of ASC construction and plant rules for licensed abortion facilities. These commenters believe that if a facility performs only medical procedures, it should not be required to comply with the ASC rules. Some commenters state that waivers can be issued on a case-by-case basis that would be better tailored to the needs of the community in which the facility is located than a statute that is the same for all licensed facilities in Texas.

Response: HB 2 gives the department no authority to exempt any licensed abortion facility from its provisions or to waive the application of its provisions or the rules adopted pursuant to HB 2, to particular facilities. No other provision of Health and Safety Code, Chapter 245 or any other statute that grants the department rulemaking authority also grants the department the power to waive statutory provisions or exempt licensed abortion facilities from complying with statutes by rule, with the sole exception of Health and Safety Code, §241.06(c), which applies only to licensed hospitals. The department infers that the legislature would have, if that was its intent, written into HB 2 a waiver provision. It did not do so; therefore, the department has no authority to exempt by rule or grant waivers for "medical-only" providers from the provisions of HB 2 or the rules adopted pursuant to HB 2.

8. Comments Relating to Abortion Facility Rules Assertedly Not "Equivalent to" Those for ASCs.

Comment: Some commenters asserted that the adopted rules are not "equivalent to" those of ASCs, and question the department's proposal to adopt the rules as being outside the department's authority granted by HB 2.

Others stated that by adopting many ASC requirements from 25 TAC Chapter 135 and retaining most abortion facility rules that

existed before HB 2 was passed, the department is exceeding its authority and is adopting a set of rules that are, as a whole, more strict that those for ASCs, and not "equivalent to" ASC rules. These commenters note that each other type of health facility has only one set of rules that regulate the licensed facilities, and assert that the department has singled out licensed abortion facilities for excessive and burdensome regulation.

Response: The department disagrees. Adopting rules by reference is a common procedure, with the result being one set of rules containing provisions that it lacked before the adoption by reference. 1 TAC §91.40. In this case, HB 2 required the addition of a number of rules that are "equivalent to" rules identified by the five topic areas listed in Health and Safety Code, §243.010. The department determined that the most appropriate method to achieve the intent that the rules for licensed abortion facilities in 25 TAC Chapter 139 be "equivalent to" those in Chapter 135 for ASCs listed by topic in Health and Safety Code, §243.010 is to select the appropriate rules from Chapter 135 and adopt them by reference.

Regarding the department's authority to adopt ASC rules and retain abortion facility rules, the department's rulemaking authority is not limited to that provided by HB 2. The department also has rulemaking authority under Health and Safety Code, Chapter 171, as amended by HB 2, concerning requirements for a physician who performs an abortion; under Health and Safety Code, §245.010 as amended by HB 2, concerning rules and minimum standards for the licensing and regulation of abortion facilities; and under Government Code, §531.0055 and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The department observes that HB 2 did not direct the department to replace all its pre-existing rules with those for ASCs. Nor did HB 2 repeal any part of Health and Safety Code, Chapter 245, the pre-existing statutes governing abortion facilities. Thus, the department also has rulemaking authority under other statutes that allows it discretion to adopt rules necessary to implement the intent of HB 2 as the department understands it. That many rules in Chapter 139 were retained or that some few of the adopted rules may be more stringent for ASCs than similar rules for other facilities does not mean that the department has exceeded its authority by adopting them.

Finally, the department understands HB 2 to intend to enhance the existing abortion facilities regulations in part by extending the regulatory scheme for licensed abortion facilities to include construction and physical plant design, in order to enhance the health and safety of patients of those facilities without unduly burdening a woman seeking to obtain an abortion in Texas. The department is required to carry out that intent.

9. Comments Relating to Challenged Statements in the Preamble to the Proposed Rules.

Comment: A few commenters stated that the preamble to the proposed rules contained factual errors. Firstly, there was objection to the statement in the proposal preamble that "Texas allows no other procedure to opt out of the accepted standard of care." Commenters asserted that licensed abortion facilities are, in fact, well-regulated under existing state law and departmental practice, and do not operate at a lower standard than other facilities or at a standard of care lower than that applied to other medical procedures.

Secondly, one commenter asserted that the preamble statement "[T]oday 38 licensed abortion facilities still operate at a second, lower standard for the most common surgical procedure in Texas performed solely on women[.]" is false because licensed abortion facilities have a safety record that demonstrates a high standard of care and Texas licensed abortion facilities are already extensively regulated under existing state statutes and rules.

Thirdly, at least one commenter stated that the proposal preamble's statement that "[W]omen who choose to have an abortion should receive the same standard of care any other individual in Texas receives, regardless of the surgical procedure performed[.]" is false for the same reasons recited concerning the previous two comments.

One of the commenters supported this objection by writing that "abortion providers in Texas absolutely follow the standard of care" because they conform to unidentified regulatory standards and, according to the commenter, have an exemplary safety record. These comments referred to procedures that physicians are allowed to perform in their offices or outpatient facilities without state regulation and without a requirement that these procedures be done under the rules for ASCs. The commenter asserted that many of these unregulated procedures are more dangerous than abortions.

Response: The department notes that all three of the statements objected to are taken verbatim from Bill Analysis. Tex. HB 2, 83rd Leg., 2nd C.S. (2013); (38 TexReg 6537) (September 27, 2013 issue). These comments are more appropriately addressed in the first instance to the Legislature. However, the department will respond to the comments as they relate to the adopted rules.

The department disagrees that any of the statements quoted by the commenters are false. When read in context, it becomes clear that the phrase "standard of care" in the bill analysis was not referring to the standard of care applicable to a licensed physician, but generally to the quality of care that all consumers of healthcare should reasonably expect to receive in a licensed healthcare facility.

The portion of the preamble to the rules proposed for licensed abortion facilities dedicated to the "standard of care" contains four paragraphs. The sentence to which objection is made is the final sentence of the portion. The reference to "standard of care" first occurs in the first sentence of that portion. That first sentence is quoted from the Bill Analysis for HB 2, and reads: "Women who choose to have an abortion should receive the same standard of care any other individual in Texas receives, regardless of the surgical procedure performed."

The third paragraph recites the requirement of HB 2 that the minimum standards for abortion facilities, on and after September 1, 2014, be equivalent to the minimum standards for ambulatory surgical centers.

The fourth and last paragraph quoted from the Bill Analysis reads as follows:

Moving abortion clinics under the guidelines for ambulatory surgical centers will provide Texas women choosing abortion the highest standard of health care. Texas allows no other procedure to opt out of the accepted standard of care.

Thus, the "standard of care" that the Legislature referred to is one that generally is applicable to healthcare facilities, which the department regulates, not to individual physicians, whom the department has no authority to regulate. That standard is derived from the Medicare standard, which applies to facilities but is also recognized by physicians and other healthcare professionals. Compliance with it is a necessary condition for reimbursement for services that are paid for by Medicare and by Medicaid. The preamble to the proposed rules correctly states that licensed abortion facilities "opt[ed] out" of the higher standard enforced by Medicare in the sense that licensed abortion facilities chose not to pursue licensure as ASCs, and that licensed abortion facilities, as noted above, are paid by cash or credit card and are thus not subject to the Medicare (and Medicaid) standard.

10. Comments Relating to Retention of Annual Inspections for Licensed Abortion Facilities.

Comment: Some commenters opposed retaining the requirement in Chapter 139 for annual inspections (§139.31(b)(1)) instead of adopting the 3-year inspection standard for ASCs (§135.21).

Response: The department disagrees. This section of the ASC rules relating to inspection was not adopted because it only requires inspections of licensed facilities every three years, whereas present §139.31 requires annual inspections of licensed abortion facilities. Section 139.31 provides greater protection by requiring more frequent (annual) inspections than the three-year minimum intervals prescribed by §135.21.

Further, as noted previously, the department believes that abortion facilities operate primarily on a self-pay basis and therefore are not subject to oversight by the Centers for Medicare and Medicaid Services, so that they should be inspected more frequently than facilities which are subject to such oversight, to ensure that minimum standards are being met and to better protect the health and safety of patients as required by HB 2.

As previously noted, medical literature suggests that abortions are underreported, raising a concern that morbidity and mortality resulting from abortions is also underreported. The department believes that applying a significantly less frequent ASC survey rate to licensed abortion facilities would jeopardize the health and safety of patients at those facilities.

Furthermore, annual inspections are reasonable given (1) the high priority that the Legislature has placed on improving the health and safety of women who receive abortion services, and (2) the department's understanding that the Legislature intended licensed abortion facilities to comply with minimum standards that at least equal to those applicable to a licensed ambulatory surgical center.

Given these factors, the department believes that in some areas such as frequency of inspections, more stringent standards for licensed abortion facilities are useful means of protecting the health and safety of patients by better implementing HB 2 and enforcing the rules for licensed abortion facilities. The department believes also that, while more frequent inspections may create a small additional burden on facilities, they create no burden at all on women who seek an abortion.

11. Comments Relating to Disproportionate Impact on Low-Income Women and Women Who Live in Rural Areas.

Comment: Commenters expressed concern that facility closures resulting from the rules would have a more severe adverse impact on low-income women and those living in rural areas of the state than others. A premise of the commenters' position is that abortion and preventive care services are available for smaller fees than a hospital or ASC must charge. Primarily, two provisions of the proposed rules may cause extensive facility closures, according to the commenters: they are the ASC construction and physical plant rules (adopted by reference in §139.40) and the admitting privileges requirement (§139.53 and §139.56).

The commenters anticipate that all or most of the facility closures would occur in Lubbock, the Rio Grande Valley, El Paso, Beaumont and Fort Worth, leaving facilities operating only in Dallas, Houston, Austin, and San Antonio, where the large local populations can support licensed facilities even if those facilities charge more than licensed abortion facilities.

Commenters state that if licensed abortion facilities operated in only the largest cities, all located along I-35 from Dallas to San Antonio plus Houston on I-10, then women who live south of I-10 or west of I 35 would be required to travel relatively long distances to a licensed abortion facility. Nor are ASCs where abortions are performed located outside the I-35 and I-10 corridors, and none are south of Austin. For this reason, the commenters assert that the financial and logistical difficulties of traveling 500 miles or more (e.g., from El Paso to San Antonio).

Commenters also point out that many women who lack the means or ability to be away from their jobs or families will choose to have possibly illicit abortions in Mexico, where they assert abortions are performed unsafely.

Response: The department disagrees. As noted previously (in Comments Relating to the Adoption of ASC Construction and Physical Plant Rules), the department believes the proposed construction and physical plant requirements will improve the outcomes for women seeking abortion. The same is true for the rules requiring admitting privileges. (See response under Comments Relating to Admitting Privileges Requirement.) The department believes that neither rule creates an obstacle that prevents any Texas woman from obtaining an abortion for several reasons: (1) it is unlikely that all licensed abortion facilities will close; (2) abortions by licensed physicians can still be obtained at ASCs and some hospitals, so the lack of a nearby licensed abortion facility, though challenging, is not an absolute bar to even a low-income or rural-based woman; and (3) any facility's decision to close is purely an economic one, not a direct result of the rules, because the rules do not require any facility to close rather than comply.

Finally, if the demand for abortions in low-income areas of the state and areas remote from Texas's large cities is as great as commenters urge, one or more providers would find it profitable (or a non-profit would be able to operate within its means) by locating an ASC designed, built, and operated mainly to provide abortions and reproductive care at low prices at a place chosen to minimize the travel distance for a disadvantaged patient population.

12. Comments Relating to Assertions That the Department Is Singling Out Abortion Facilities For Punitive Regulation.

Comment: Several commenters wrote that the proposed rules evidence the department's intent to punitively adopt excessively burdensome rules that only apply to licensed abortion facilities. Among the rule changes they suggest exhibit punitive regulation are:

(1) selectively leaving in place abortion facility rules that are more stringent than the comparable ASC rules, such as the annual mandatory inspection requirement (§139.31(b)(1));

(2) declining to adopt §135.2(19), a definition of "premises" that included a reference to surgery, allegedly so that it could apply the ASC rules to medical-only facilities;

(3) applying two sets of rules, Chapters 135 and 139, to licensed abortion facilities; and

(4) exceeding the "equivalent to" requirement of HB 2 in favor of more stringent rules for licensed abortion facilities.

Response: The department acknowledges the comments, but disagrees, and declines to alter the proposed rules to remedy any alleged punitive intent.

As noted in the Section-By-Section Summary, the department agrees that on several occasions it chose not to adopt an ASC rule where there was already an abortion facility rule that implemented a more stringent requirement, such as the annual inspections versus three years (and not mandatory) for ASC inspections. Doing otherwise would not have given effect to the intent of HB 2, which was to enhance the level of regulation of licensed abortion facilities so that the effect of the new rule set would be equivalent to that of ASC rules on ASCs, a higher standard and more safety for patients of licensed abortion facilities. HB 2 required the adoption of some ASC rules, or rules equivalent to them in their effect on licensed abortion facilities, but did not require or authorize the repeal of Chapter 139 rules.

Licensed abortion facilities are unique in that they are not subject to Medicare inspection because, unlike almost all other licensed facilities, they operate on a cash and credit card basis. Abortion facilities are also unique among Texas medical facilities in that they are places where death is intentionally caused. In such facilities, it is reasonable to anticipate higher staff burnout and turnover rates, with the resultant lack of experienced caregivers as compared to other kinds of facilities. Thus, differing requirements for the different facilities are required in order to achieve rules that have an effect on licensed abortion facilities that is "equivalent to" the effect of the ASC rules on ASCs. If the Legislature had intended for the two rule sets to be identical, it could easily have required the department to do so.

The department notes that it did not always choose against abortion facilities and in favor of more stringent regulation of them. As examples, it proposes to keep in effect:

(1) $5,000 license fee (§139.22(a)(1) - (3)) versus the $5,200 ASC license fee (§135.3(a));

(2) §139.31(c)(2), which requires that complaints be in writing and signed by the complainant versus §135.25(b), which allows anonymous complaints by telephone.

Regarding §135.2(19), its definition of "premises" was not adopted, but not in order to evade any prohibition against the department's applying ASC rules to medical-only facilities as some commenters suggest. The application of ASC rules was required by HB 2, which did not create an exception for medical-only facilities in Health and Safety Code, §245.010(a) as amended by HB 2. Instead, the department did not adopt §135.2(19) because its reference to "premises" as places "where surgery is performed" was an inappropriate and confusing description of abortion facilities, in which the procedure may be either medical or surgical.

The department believes its selection of rules for adoption under HB 2 is even-handed, appropriate to the intent of HB 2, is not based on any intent to punish or single out licensed abortion facilities for excessive regulation, and does not pose a substantial obstacle to a woman who seeks an abortion in Texas.

13. Comment Relating to Rules Requiring Facilities to Be Prepared to Respond Indefinitely to Abortion Patient Calls.

Comment: At least one commenter stated that §§139.56(a)(2)(A) and 139.57(a)(2)(A) are unduly burdensome, unnecessarily extensive, and often impractical and unworkable. The comment specifies as excessive regulation the requirement that the patient's medical record must, by implication, be available to the physician or qualified staff person 24 hours a day, as well as the absence of a termination date for the responsibility to respond to patient calls with her medical records accessible.

Response: The department disagrees. The rule simply restates Health and Safety Code, §171.0031(a)(2)(A), as amended by HB 2.

The rules allow a staff person as well as a physician to respond to calls. Therefore, the duties may be rotated among facility staff. With the advent of electronic medical records, access to patient records should not cause a problem other than protecting patient confidentiality. The rules specify that the responding staff member have access to only the patient's "relevant medical records," not her entire medical history. Presumably, these records would not be voluminous, so that paper copies may be compiled and given to the responder, so long as patient confidentiality is protected. Nor do the rules require an instant answer to the patient's questions, so a reasonable time to search on a computer or through paper files is implied.

No time is specified after which a duty person is not required for 24-hour coverage of follow-up calls because complications, for instance scarred or weakened tissue that tears, can first present symptoms many months after an abortion.

14. Comments Relating to Request for Definition of "Admitting Privileges" in Connection with §139.53 and §139.56.

Comment: At least one commenter requested that the department define what "admitting privileges" mean. The commenter stated that the term is vague because different hospitals define it differently and it has no single, clearly articulated meaning that is commonly accepted in the medical community.

Response: The department acknowledges the comment. It has considered the issue, and believes that defining what admitting privileges are is not practical for the reason the commenter offers: there is no single, accepted definition in common use. If the department were to adopt a definition, it would incidentally affect many facilities and physicians whose admitting privileges might be acceptable in substance, but did not fit the department's definition. The department anticipates enforcing this rule by inspecting each facility's copies of the admitting privileges of each physician who performs abortions there, to determine whether each physician has such privileges at a qualifying hospital. Thus, the exact wording of the privileges will not be an issue, as it would be if there were a single definition for all admitting privileges issued across Texas.

FISCAL NOTE

Renee Clack, Director, Health Care Quality Section, has determined that for each year of the first five years that the sections

will be in effect, there will not be fiscal implications to state or local governments as a result of enforcing and administering the sections as adopted. For purposes of this fiscal note, the department assumes that some of the 30 currently licensed abortion clinics will attempt to comply with the newly adopted standards. Assuming all 30 licensees were to attempt to comply, the department has reviewed its capacity to inspect licensed facilities and to enforce these new provisions and has determined that the additional inspection and enforcement can be absorbed within existing resources.

PUBLIC BENEFIT

In addition, Ms. Clack has determined that for each year of the first five years the sections are in effect, the public benefit that is anticipated as a result of adopting and enforcing these rules will be to enhance the protection of the health and safety of patients that receive services in licensed abortion facilities. This will be accomplished because as a result of these rules, a licensed abortion facility must be equivalent to the minimum standards adopted under Health and Safety Code, §243.010, for ambulatory surgical centers.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the rules, as adopted, have been reviewed by legal counsel and found to be a valid exercise of the agencies' legal authority.

SUBCHAPTER A. GENERAL PROVISIONS

25 TAC §§139.1, 139.2, 139.4, 139.9

STATUTORY AUTHORITY

The amendments and new rule are authorized by Health and Safety Code, Chapter 171, as amended by HB 2, concerning requirements for a physician who performs an abortion and the use of abortion-inducing drugs; by Health and Safety Code, §245.010, as amended by HB 2, concerning rules and minimum standards for the licensing and regulation of abortion facilities required to obtain a license under the chapter, clarification of the authority of the department to refuse, suspend or revoke a license for an abortion facility and add the finding of noncompliance with Health and Safety Code, Chapter 171, as grounds for license probation, suspension or revocation, and a change to the data required to be reported annually; and by Government Code, §531.0055 and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on December 12, 2013.

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Lisa Hernandez
General Counsel
Department of State Health Services
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Proposal publication date: September 27, 2013
For further information, please call: (512) 776-6972

SUBCHAPTER C. ENFORCEMENT

25 TAC §139.32

STATUTORY AUTHORITY

The amendment is authorized by Health and Safety Code, Chapter 171, as amended by HB 2, concerning requirements for a physician who performs an abortion and the use of abortion-inducing drugs; by Health and Safety Code, §245.010, as amended by HB 2, concerning rules and minimum standards for the licensing and regulation of abortion facilities required to obtain a license under the chapter, clarification of the authority of the department to refuse, suspend or revoke a license for an abortion facility and add the finding of noncompliance with Health and Safety Code, Chapter 171, as grounds for license probation, suspension or revocation, and a change to the data required to be reported annually; and by Government Code, §531.0055 and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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SUBCHAPTER D. MINIMUM STANDARDS FOR LICENSED ABORTION FACILITIES

25 TAC §§139.40, 139.53, 139.56, 139.57

STATUTORY AUTHORITY

The new rule and amendments are authorized by Health and Safety Code, Chapter 171, as amended by HB 2, concerning requirements for a physician who performs an abortion and the use of abortion-inducing drugs; by Health and Safety Code, §245.010, as amended by HB 2, concerning rules and minimum standards for the licensing and regulation of abortion facilities required to obtain a license under the chapter, clarification of the authority of the department to refuse, suspend or revoke a license for an abortion facility and add the finding of noncompli-

ance with Health and Safety Code, Chapter 171, as grounds for license probation, suspension or revocation, and a change to the data required to be reported annually; and by Government Code, §531.0055 and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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TITLE 28. INSURANCE

PART 2. TEXAS DEPARTMENT OF INSURANCE, DIVISION OF WORKERS' COMPENSATION

CHAPTER 41. PRACTICE AND PROCEDURE

The Texas Department of Insurance, Division of Workers' Compensation (Division) adopts the repeal of §41.50, concerning Carrier's Address; §41.101, concerning Purpose; §41.105, concerning Definitions; §41.110, concerning Availability; §41.115, concerning Inspection; §41.120, concerning Duplication and Related Services; §41.125, concerning Duplicating Charges; §41.130, concerning Certified Copies; §41.135, concerning Subpoenas for Confidential Records; §41.140, concerning Record Checks; §41.150, concerning Publications; and §41.160, concerning Annual Review of Charges.

The repeal of §41.50 and Chapter 41, Subchapter B, §§41.101, 41.105, 41.110, 41.115, 41.120, 41.125, 41.130, 41.135, 41.140, 41.150, and 41.160 is adopted without changes to the proposed repeal as published in the July 5, 2013, issue of the *Texas Register* (38 TexReg 4292) and the text of the repealed sections will not be published. No comments were received and there was not a request for a public hearing submitted to the Division.

In accordance with Government Code §2001.033, this preamble contains a summary of the factual basis for the repeal.

The repeal of §41.50 is necessary because it is redundant. Section 41.50, concerning Carrier's Address, was adopted effective November 20, 1977 (2 TexReg 4315). It provides that unless otherwise approved by the board, all notices and communications to insurance carriers will be addressed to the carrier at an address designated by the carrier as its Texas mailing address. Section 41.60, concerning Communication to Insurance Carriers, was adopted November 11, 1983 (8 TexReg 4491). Section 41.60 supersedes §41.50 because it was adopted almost six years after §41.50 and is more specific. Section 41.60 provides that unless otherwise required by statute or a board rule all notices and other communications to insurance carriers will be sent either to an address designated by the insurance carrier as its principal Texas mailing address or to its designated Austin representative.

The repeal of Subchapter B is necessary because its sections are outdated and have been replaced by other statutory and regulatory provisions. The statutes and rules cited in this adoption order are not an exhaustive list of all the statutes and rules that apply and that have superseded these repealed rules. The issues addressed by Subchapter B pertain to confidentiality provisions and open records which are currently addressed by other statutes and rules including, Government Code Chapter 552, known as the Texas Public Information Act; Labor Code §§402.081, 402.083 - 402.088, 402.090, 402.091, 402.092, 413.0513, and 413.0514; 1 TAC Chapter 63, concerning Public Information; 1 TAC Chapter 70, concerning Cost of Copies of Public Information; and 28 TAC §108.1, concerning Charges for Copies of Public Information.

Because §§41.50, 41.101, 41.105, 41.110, 41.115, 41.120, 41.125, 41.130, 41.135, 41.140, 41.150, and 41.160 are unnecessary they are repealed.

The adoption of the repeal of §41.50 and Chapter 41, Subchapter B, will eliminate unnecessary sections.

The Division did not receive any comments on the proposed repeal.

SUBCHAPTER A. COMMUNICATIONS

28 TAC §41.50

The repeal is adopted pursuant to Labor Code §§402.0111, 402.00116, and 402.061. Section 402.00111 provides that the Commissioner of Workers' Compensation shall exercise all executive authority, including rulemaking authority, under the Labor Code. Section 402.00116 grants the powers and duties of chief executive and administrative officer to the Commissioner and the authority to enforce Labor Code Title 5, and other laws applicable to the Division or Commissioner. Section 402.061 provides that the Commissioner of Workers' Compensation shall adopt rules as necessary for the implementation and enforcement of Title 5, Labor Code.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on December 16, 2013.

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Dirk Johnson
General Counsel
Texas Department of Insurance, Division of Workers' Compensation
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For further information, please call: (512) 804-4703

SUBCHAPTER B. ACCESS TO BOARD RECORDS