

## Abortion restrictions in context

### SUMMARY OF SCIENTIFIC FINDINGS IN THIS LITERATURE REVIEW

- Abortion as it is currently performed and regulated is safe, with complication rates similar to outpatient oral surgery with intravenous sedation.
- Expanding the ASC requirement to include all abortions, rather than just those beyond 16 weeks, is not medically necessary, and it would decrease access without improving patient safety.
- Hospital admitting privileges for the providers of outpatient procedures like abortion do not increase patient safety, but requiring such privileges gives hospitals veto power over the existence of providers
- The 20-week ban is not substantiated by medical science and would disproportionately impact women with difficulty accessing reproductive healthcare, including poor women, women with low educational attainment, and victims of rape.
- The bill would restrict physicians to using specified protocols for medical abortion that are not commonly used or based on the most up-to-date evidence.

### Introduction

In the current special session of the Texas Legislature, HB2/SB1 includes several new restrictions on abortion care. These new restrictions included:

- A requirement that all abortion facilities meet the standards of ambulatory surgical centers (ASCs), including facilities that only provide medical (or nonsurgical) abortion
- A requirement that physicians have admitting privileges at a hospital within 30 miles of the facility
- A ban on abortions at 20 weeks of pregnancy or later, with an exception in the case of life endangerment to the pregnant woman or fetal anomaly (but not for rape)
- Additional restrictions on the use of medical abortion

In this brief we review the evidence related to these restrictions, both in terms of whether data support their utility, as well as how these restrictions might affect access.

### Safety of abortion

#### **Abortion as it is currently performed and regulated is safe, with complication rates similar to outpatient oral surgery with intravenous sedation.**

Abortion is a commonly performed medical procedure, with about one-third of women having at least one abortion in their lifetime.<sup>1</sup> At the same time, abortion as it is currently being performed is very safe. Over 90% of abortions in the US are performed in an outpatient clinic setting.<sup>2</sup> In a recent study of almost 6,000 first-trimester abortions performed in outpatient clinics by physicians, only 0.9% of patients had any complication with the procedure.<sup>3</sup> Most of these complications were minor and treated at the clinic; only 0.05% of patients had a complication that required treatment at a hospital. Another recent study found that the risk of an adverse event associated with outpatient abortions performed up to 18 weeks of pregnancy was 0.3%, and the risk of an adverse event requiring hospitalization was 0.07%.<sup>4</sup> Overall, this complication rate is similar to that of outpatient oral surgery with intravenous sedation, which has a complication rate of about 1% for patients aged 20-59.<sup>5</sup>

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### Ambulatory surgery center requirement

**Expanding the ASC requirement to include all abortions, rather than just those beyond 16 weeks, is not medically necessary, and it would decrease access without improving patient safety.**

The physical plant upgrades and staffing requirements for an ASC are not warranted for abortion performed up to 18 weeks. The evidence indicates that abortion performed in this gestational age window is currently being provided very safely with a very low rate of complications. The State has not provided evidence to the contrary, and DSHS testimony on July 2, 2013, in the House State Affairs Committee affirmed the safety of the current standards.

The requirement that clinics that only provide medical abortions also meet the requirements of an ASC makes even less sense. With medical abortion, the abortion does not take place at the facility; instead the woman takes medications that induce an abortion at home. Some providers of medical abortion have relationships with providers at other facilities who manage rare complications of the procedure, such as an ongoing pregnancy or heavy bleeding. This means that the only part of the procedure that takes place at the facility is ingesting the first tablet of mifepristone. The risks associated with taking this pill are similar to taking Tylenol.

The ASC requirement will reduce the number of abortion providers in the state to five. This will have a serious impact on abortion access, requiring women to travel farther, take more time off from work or school and spend more money to access abortion care.

For more information, see this recent article in the Guttmacher Policy Review:

<http://www.guttmacher.org/pubs/gpr/16/2/gpr160207.html>

For more information on the projected impact on the ASC requirement on five Texas communities, see our other brief: [http://www.utexas.edu/cola/orgs/txpep\\_files/pdf/ImpactBrief-ProposedHB2-SB1AbortionBill.pdf](http://www.utexas.edu/cola/orgs/txpep_files/pdf/ImpactBrief-ProposedHB2-SB1AbortionBill.pdf)

### Hospital admitting privileges

**Hospital admitting privileges for the providers of outpatient procedures like abortion do not increase patient safety, but requiring such privileges gives hospitals veto power over the existence of providers.**

As noted above, the risk of transferring a patient from an outpatient abortion clinic to a hospital is less than 1 out of 1,000. When such a transfer occurs, it is important that the physician most qualified to care for that patient treat her; in many cases, that may not be the abortion provider. In addition, hospitals are obligated to provide emergency care to any patient experiencing a medical emergency under the federal Emergency Medical Treatment and Labor Act of 1986 (EMTALA). It is standard practice for the abortion provider as the referring physician to contact the emergency room physician in order to inform the medical staff about the patient, regardless of whether the referring physician has admitting and staff privileges there. A recent analysis of complications of office-based surgery in Florida and Alabama concluded that “requiring physician board certification and physician hospital privileges does not seem to increase safety of patients undergoing surgical procedures in the office setting.”<sup>6</sup>

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The American College of Obstetricians and Gynecologists (ACOG) recently released a statement opposing “legislation or other requirements that single out abortion services from other outpatient procedures” such as “laws or other regulations that require abortion providers to have hospital admitting privileges.”<sup>7</sup>

### 20-week ban

**The 20-week ban is not substantiated by medical science and would disproportionately impact women with difficulty accessing reproductive healthcare, including poor women, women with low educational attainment, and victims of rape.**

The proposed legislation states that “substantial medical evidence recognizes that an unborn child is capable of experiencing pain by not later than 20 weeks after fertilization;” however, no medical evidence is cited in the bill. In contrast, reviews on this topic conclude that fetal perception of pain may not occur until the third trimester of pregnancy (or 28 weeks gestation).<sup>8</sup> A recent ACOG Practice Bulletin states that “second-trimester abortion is an important component of comprehensive women’s health care.”<sup>9</sup>

In 2011, only 706 abortions at 20 weeks or later were registered with the state. While this represents only about 0.8% of all abortions, this is a particularly vulnerable population of women who would be affected by this ban. Research indicates that a variety of circumstances can lead to second-trimester abortion, including delays in suspecting and testing for pregnancy, delay in obtaining insurance or other funding, and delay in obtaining referrals from other physicians, as well as difficulties in locating and traveling to a provider.<sup>10</sup> Poverty, lower education level, and having multiple disruptive life events have been associated with higher rates of seeking second-trimester abortion.<sup>11</sup>

It is particularly concerning that HB2/SB1 does not have an exception for victims of sexual assault. Women who experience rape may be more likely to hide the pregnancy or be in denial about the pregnancy due to the traumatic circumstances, and only a minority of women seek medical care after a rape.<sup>12</sup> This may lead to late recognition of the pregnancy and need for abortion after 20 weeks of pregnancy.

### Restrictions on medical abortion

**The bill would restrict physicians to using specified protocols for medical abortion that are not commonly used or based on the most up-to-date evidence.**

The proposed legislation would restrict the protocol that physicians may use to prescribe medical abortion drugs to protocols described in the drug label approved by the Food and Drug Administration (FDA) or the protocol described in the ACOG Practice Bulletin that existed on January 1, 2013 (and was written in 2005). Since mifepristone (also known as Mifeprex or RU-486) was approved in 2000, medical practice has evolved, and more effective protocols that allow medical abortion later in pregnancy have been developed. The most commonly used protocol for medical abortion involves the use of mifepristone 200 mg taken orally, followed 24-48 hours later by misoprostol 800 mcg taken buccally (between the cheek and gums) up to 63 days of pregnancy. This protocol has been shown in multiple large studies to be very safe and effective.<sup>13,14</sup>

Legislating the way a particular drug is used in practice makes no sense. Use of medications in ways other than the way they are described in the FDA-approved label is very common. This is called “off-

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label use.” Off-label use is particularly common in obstetrics because many drug regimens have not been specifically approved for use in pregnant women.<sup>15</sup> But if there is sufficient medical evidence supporting a particular off-label use, such use is considered acceptable medical practice. It is also highly unusual that the legislation would enforce the use of an ACOG document created in 2005; when this document is updated in the near future, the law would not allow practicing gynecologists in Texas to follow ACOG’s recommendations.

The proposed restrictions on medical abortion would limit access to this abortion method by forcing providers to use protocols that are inferior to the current, evidence-based protocol. In 2011, 23,263 medical abortions took place in Texas or to Texas residents (about 26% of all abortions).

*A team of researchers at the Population Research Center, the University of Texas at Austin, in collaboration with researchers at the University of Alabama at Birmingham and Ibis Reproductive Health, is studying the impact of Texas state’s legislation on women’s reproductive health services, enacted during the 2011 legislative session.*

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<sup>1</sup> Jones RK, Kavanaugh ML. Changes in abortion rates between 2000 and 2008 and lifetime incidence of abortion. *Obstet Gynecol.* 2011 Jun;117(6):1358-66.

<sup>2</sup> Jones RK, Kooistra K. Abortion incidence and access to services in the United States, 2008. *Perspect Sex Reprod Health.* 2011 Mar;43(1):41-50.

<sup>3</sup> Weitz TA, Taylor D, Desai S, Upadhyay UD, Waldman J, Battistelli MF, Drey EA. Safety of aspiration abortion performed by nurse practitioners, certified nurse midwives, and physician assistants under a California legal waiver. *Am J Public Health.* 2013 Mar;103(3):454-61.

<sup>4</sup> Wilson LC, Chen BA, Creinin MD. Low-dose fentanyl and midazolam in outpatient surgical abortion up to 18 weeks of gestation. *Contraception.* 2009 Feb;79(2):122-8.

<sup>5</sup> Rodgers SF, Rodgers MS. Safety of intravenous sedation administered by the operating oral surgeon: the second 7 years of office practice. *J Oral Maxillofac Surg.* 2011 Oct;69(10):2525-9.

<sup>6</sup> Starling J 3rd, Thosani MK, Coldiron BM. Determining the safety of office-based surgery: what 10 years of Florida data and 6 years of Alabama data reveal. *Dermatol Surg.* 2012 Feb;38(2):171-7.

<sup>7</sup> Press Release, The American Congress of Obstetricians and Gynecologists, Statement on State Legislation Requiring Hospital Admitting Privileges for Physicians Providing Abortion Services (April 25, 2013).

<sup>8</sup> Lee SJ, Ralston HJ, Drey EA, Partridge JC, Rosen MA. Fetal pain: a systematic multidisciplinary review of the evidence. *JAMA.* 2005 Aug 24;294(8):947-54.

<sup>9</sup> Committee on Practice Bulletins-Gynecology, American College of Obstetricians and Gynecologists, with Steinauer J, Jackson A, Grossman D. Practice Bulletin No 135: Second-trimester abortion. *Obstet Gynecol* 2013;121(6):1394-1405.

<sup>10</sup> Drey EA, Foster DG, Jackson RA, Lee SJ, Cardenas LH, Darney PD. Risk factors associated with presenting for abortion in the second trimester. *Obstet Gynecol.* 2006 Jan;107(1):128-35.

<sup>11</sup> Jones RK, Finer LB. Who has second-trimester abortions in the United States? *Contraception.* 2012 Jun;85(6):544-51.

<sup>12</sup> Zinzow HM, Resnick HS, Barr SC, Danielson CK, Kilpatrick DG. Receipt of post-rape medical care in a national sample of female victims. *Am J Prev Med.* 2012 Aug;43(2):183-7.

<sup>13</sup> Cleland K, Creinin MD, Nucatola D, Nshom M, Trussell J. Significant adverse events and outcomes after medical abortion. *Obstet Gynecol.* 2013 Jan;121(1):166-71.

<sup>14</sup> Raymond EG, Shannon C, Weaver MA, Winikoff B. First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review. *Contraception.* 2013 Jan;87(1):26-37.

<sup>15</sup> Rayburn WF, Farmer KC. Off-label prescribing during pregnancy. *Obstet Gynecol Clin North Am.* 1997 Sep;24(3):471-8.