

**Cecile Erwin Young** *Executive Commissioner* 

# **Health Facility Compliance Guidance Letter**

**Number:** GL 21-2006-A

**Title:** Abortion Complication Reporting and Regulation of Drug-Induced Abortion Procedures, Providers, and Facilities (SB 4-87-2) [Amended]

**Provider Types:** Abortion Facilities, Ambulatory Surgical Centers, Hospitals

Date Issued: November 30, 2022

### 1.0 Subject and Purpose

This amended guidance letter replaces the previous GL 21-2006, issued on November 12, 2021, to notify providers the Texas Health and Human Services Commission (HHSC) adopted rules in Texas Administrative Code Title 25 (25 TAC) Chapter 139 to implement Senate Bill (SB) 4, which are described in this guidance letter. These rules, which took effect November 24, 2022, were published in the November 18, 2022, issue of the *Texas Register* (47 TexReg 7696). Refer to new Section 2.4 below for more information about these rules.

HHSC provides guidance to licensed providers on legislation passed during the 87th Legislature, Second Called Session (2021). SB 4, relating to abortion complication reporting and the regulation of drug-induced abortion procedures, providers, and facilities; creating a criminal offense, takes effect December 2, 2021.

This letter provides instruction to abortion facilities, including ambulatory surgical centers and hospitals that perform abortions, on the passage of SB 4 and outlines provider responsibilities and expectations.

# 2.0 Legislative Details & Provider Responsibilities

SB 4 amended the abortion complication reporting requirements and the abortion-inducing drug provision requirements for medical abortions performed on or after December 2, 2021, under <u>Texas Health and Safety Code (HSC) Chapter 171</u>.

**Note:** All links to the online statutory text will reflect the changes made by SB 4 after the bill's effective date of December 2, 2021.

### 2.1 Updates to Abortion Complications Reporting Requirements

SB 4 amended HSC §171.006, as added by House Bill 13, 85th Legislature, 1st Called Session, 2017, to add the following additional abortion complications and adverse events<sup>1</sup> relating to an abortion that is performed or induced on a patient that a health care practitioner or a health care facility must report after diagnosing or treating a patient:

- Blood clots resulting in pulmonary embolism or deep vein thrombosis;<sup>2</sup>
- Failure to actually terminate the pregnancy;<sup>3</sup>
- Pelvic inflammatory disease;<sup>4</sup>
- Endometritis;<sup>5</sup>
- Missed ectopic pregnancy;<sup>6</sup>
- Cardiac arrest;<sup>7</sup>
- Respiratory arrest;<sup>8</sup>
- Renal failure:<sup>9</sup>
- Metabolic disorder;<sup>10</sup>
- Embolism;<sup>11</sup>
- Coma;<sup>12</sup>
- Placenta previa in subsequent pregnancies;<sup>13</sup>

¹ Defined at HSC §171.006(a).

<sup>&</sup>lt;sup>2</sup> HSC §171.006(a)(12).

<sup>&</sup>lt;sup>3</sup> HSC §171.006(a)(13).

<sup>&</sup>lt;sup>4</sup> HSC §171.006(a)(14).

<sup>&</sup>lt;sup>5</sup> HSC §171.006(a)(15).

<sup>&</sup>lt;sup>6</sup> HSC §171.006(a)(16).

<sup>&</sup>lt;sup>7</sup> HSC §171.006(a)(17).

<sup>&</sup>lt;sup>8</sup> HSC §171.006(a)(18).

<sup>&</sup>lt;sup>9</sup> HSC §171.006(a)(19).

<sup>&</sup>lt;sup>10</sup> HSC §171.006(a)(20).

<sup>&</sup>lt;sup>11</sup> HSC §171.006(a)(21).

<sup>&</sup>lt;sup>12</sup> HSC §171.006(a)(22).

<sup>&</sup>lt;sup>13</sup> HSC §171.006(a)(23).

- Preterm delivery in subsequent pregnancies; 14
- Fluid accumulation in the abdomen; 15
- Hemolytic reaction resulting from the administration of ABOincompatible blood or blood products; 16
- Adverse reactions to anesthesia or other drugs; or<sup>17</sup>
- Any other adverse event as defined by the United States Food and Drug Administration's criteria provided by the MedWatch Reporting System.<sup>18</sup>

### 2.2 Provision of Abortion-Inducing Drugs

SB 4 amended the requirements for the provision of an abortion-inducing drug<sup>19</sup> under HSC Chapter 171, Subchapter D.

Under HSC §171.063, before a physician provides<sup>20</sup> an abortion-inducing drug to a patient, the physician must:

- Examine the patient in person;<sup>21</sup>
- Independently verify that a pregnancy exists;<sup>22</sup>
- Document, in the patient's medical record, the gestational age and intrauterine location of the pregnancy to determine whether an ectopic pregnancy exists;<sup>23</sup>
- Determine the patient's blood type, and for a patient who is Rh negative, offer to administer Rh immunoglobulin (RhoGAM) at the time the abortion-inducing drug is administered or used or the abortion is performed or induced to prevent Rh incompatibility, complications, or miscarriage in future pregnancies;<sup>24</sup>

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<sup>14</sup> HSC §171.006(a)(24).
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<sup>&</sup>lt;sup>15</sup> HSC §171.006(a)(25).

<sup>&</sup>lt;sup>16</sup> HSC §171.006(a)(26).

<sup>&</sup>lt;sup>17</sup> HSC §171.006(a)(27).

<sup>&</sup>lt;sup>18</sup> HSC §171.006(a)(28).

<sup>&</sup>lt;sup>19</sup> Defined at HSC §171.061(2).

<sup>&</sup>lt;sup>20</sup> Defined at HSC §171.061(8-a).

<sup>&</sup>lt;sup>21</sup> HSC §171.063(c)(1).

<sup>&</sup>lt;sup>22</sup> HSC §171.063(c)(2).

<sup>&</sup>lt;sup>23</sup> HSC §171.063(c)(3).

<sup>&</sup>lt;sup>24</sup> HSC §171.063(c)(4).

- Document whether the patient received treatment for Rh negativity, as diagnosed by the most accurate standard of medical care;<sup>25</sup> and
- Ensure the physician does not provide an abortion-inducing drug for a patient whose pregnancy is more than 49 days of gestational age.<sup>26</sup>

SB 4 also amended the patient's follow up visit timeframe requirements required under HSC §171.063(e). A physician who provides the abortion-inducing drug, or the physician's agent, must schedule a follow-up visit for the patient, which must occur within 14 days after the earliest date the physician administers or uses the abortion inducing drug or performs or induces the abortion.<sup>27</sup> At the follow-up visit, the physician must:

- Confirm that the patient's pregnancy is completely terminated; and<sup>28</sup>
- Assess any continued blood loss.<sup>29</sup>

SB 4 also amended <u>HSC §171.063</u> to prohibit a manufacturer, supplier, physician, or any other person from providing a patient any abortion-inducing drug by courier, delivery, or mail service.<sup>30</sup>

# 2.3 Voluntary and Informed Consent and Physician Reporting Requirements for Provision of Abortion Inducing Drugs

SB 4 added <u>HSC §171.0631</u>, which requires a person to satisfy the applicable informed consent requirements of <u>HSC Chapter 171 Subchapter B</u> before providing an abortion-inducing drug.

SB 4 also added <u>HSC §171.0632</u>, which requires a physician who provides an abortion-inducing drug to comply with the applicable abortion procedure reporting requirements under <u>HSC §245.011</u>.

# 2.4 HHSC Rules Implementing SB 4

To comply with SB 4's provisions, HHSC amended the following rules in <u>25</u> <u>TAC Chapter 139</u>, which took effect November 24, 2022:

25 TAC §139.2

<sup>&</sup>lt;sup>25</sup> HSC §171.063(c)(5).

<sup>&</sup>lt;sup>26</sup> HSC §171.063(c)(6).

<sup>&</sup>lt;sup>27</sup> HSC §171.063(e).

<sup>&</sup>lt;sup>28</sup> HSC §171.063(e)(1).

<sup>&</sup>lt;sup>29</sup> HSC §171.063(e)(2).

<sup>&</sup>lt;sup>30</sup> HSC §171.063(b-1).

- 25 TAC §139.4
- 25 TAC §139.5
- 25 TAC §139.50
- 25 TAC §139.52
- 25 TAC §139.53

### 3.0 Background/History

Abortion facilities, and hospitals and ambulatory surgical centers that perform abortions, are required to comply with HSC Chapter 171, including abortion complication reporting requirements under §171.006 and abortioninducing drug provision requirements under Subchapter D.

#### 4.0 Resources

View Senate Bill 4 (87th Legislature, Second Called Session, 2021) at: https://capitol.texas.gov/tlodocs/872/billtext/html/SB00004F.htm.

View Texas Health and Safety Code Chapter 171 at: https://statutes.capitol.texas.gov/Docs/HS/htm/HS.171.htm.

View Texas Administrative Code Title 25 Chapter 139 at: https://texreq.sos.state.tx.us/public/readtac\$ext.ViewTAC?tac\_view=4&ti=2 5&pt=1&ch=139.

To receive future updates, sign up for GovDelivery at: https://service.govdelivery.com/accounts/TXHHSC/subscriber/new.

### **5.0 Contact Information**

If you have any questions about this letter, please contact the Policies and Rules Unit by email at: HCR PRU@hhs.texas.gov.