

The Executive Commissioner of the Health and Human Services Commission (commission), on behalf of the Department of State Health Services (department), adopts amendments to §§1.132 - 1.137, concerning the definition, treatment, and disposition of special waste from health care-related facilities. Sections 1.132, 1.133, 1.134 and 1.136 are adopted with changes to the proposed text as published in the September 30, 2016 issue of the *Texas Register* (41 TexReg 7659). Sections 1.135 and 1.137 are adopted without changes to the proposed text and will not be published in the *Texas Register*.

BACKGROUND AND JUSTIFICATION

The rule amendments provide language and offer clarification to enhance the understanding of the rules, as well as to update outdated references, terminology, and disposition methods. Government Code, §2001.039 requires a review of rules, including an assessment of whether the reasons for initially adopting the rules continue to exist. Chapter 1, Subchapter K, Title 25 of the Texas Administrative Code (TAC) was originally adopted in 1989, and amendments were made in 1991 and 1994. The department also reviewed §§1.131 -1.137 and determined that the reasons for adopting the rules continue to exist because the rules on this subject are needed. The department not only addressed outdated terms and methods but its charge to ensure the health and safety of the public pursuant to Texas Health and Safety Code, Chapters 12 and 81 through, among many things, the proper disposition of tissue that results from spontaneous and induced abortions. In conjunction with its review, the department also considered and gave great weight to the Legislature's policy objective of ensuring dignity for the unborn, which is articulated in a number of Texas laws. In undertaking this review, the department took into consideration a variety of statutes that express the Legislature's will to afford the level of protection and dignity to unborn children as state law affords to adults and children. *See, e.g.,* Texas Penal Code, §1.07(26) (defining "individual" to include "an unborn child at every stage of gestation from fertilization until birth"); Texas Civil Practice and Remedies Code, §71.001(4) (defining "individual" in the wrongful death statute to include "an unborn child at every stage of gestation from fertilization until birth"); Texas Estates Code, §1002.002 (allowing for appointment of attorney ad litem for an unborn person in a guardianship proceeding); Texas Health and Safety Code, §241.010 (requiring hospitals to release to a parent remains of an unborn child who dies as a result of an unintended, intrauterine death). The rules carry out the department's duty to protect public health in a manner that is consonant with the State's respect for life and dignity of the unborn. The department accomplished this through amendments to the rules and inclusion of new provisions in the rules, including prohibiting the disposal of fetal tissue in a landfill and eliminating grinding as a method of fetal tissue disposition, that afford protection and dignity to the unborn consistent with the Legislature's expression of its intent. These rules provide a comparable level of protection to public health, while eliminating disposition options that are clearly incompatible with the Legislature's articulated objective of protecting the dignity of the unborn. The adopted rules meet the department's duties under law, while properly weighing considerations regarding public health, overall public benefit, and costs.

SECTION-BY-SECTION SUMMARY

Amendments to §1.132, Definitions, are modified at adoption in response to comments to achieve greater clarity while updating references to the department; define the terms cremation,

executive commissioner, and fetal tissue; remove the definition for the term cremated remains; amend the definition of interment; update references to the Texas Commission on Environmental Quality (TCEQ); correct a mathematical unit for "log₁₀;" and necessitate the renumbering of paragraphs. Paragraph (18) has been amended at adoption in response to comments received stating that the rule was not clear regarding the difference between incineration and cremation and that the rules appeared to emphasize cremation over incineration. The department has modified the definition to clarify that the term "cremation" in this subchapter includes the process of incineration. Paragraph (21) has been amended at adoption to update the term "Department" to read "Texas Department of State Health Services" instead of the outdated "Texas Department of Health" contained in the proposed rule. This update was inadvertently omitted while this reference was updated in all other parts of the proposed rules. Paragraph (33) has been amended at adoption in response to comments received stating that the rules did not provide direction on what to do with ashes after cremation. As a result, the definition of "interment" has been amended to include language regarding disposition of ashes after the process of cremation (and incineration) as authorized by law, unless prohibited by the adopted rules. The adopted rules prohibit the disposition of fetal tissue in a sanitary landfill, and the language added to paragraph (33) on adoption is subject to that limitation, prohibiting the scattering of ashes in a landfill. Paragraph (42) has been amended at adoption in response to comments received stating that the rules apply "at any gestational age" however, the rules contain exemptions that limit that application. As a result, paragraph (42)(B) under the definition of "pathological waste" in reference to "products of spontaneous or induced human abortion, regardless of period of gestation" contains a cross-reference to the exemptions in §1.133 that was added at adoption to assist the reader in applying the exemptions, which limit the applicability of the language in paragraph (42)(B).

Amendments to §1.133, Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of Health, are adopted to update references to the department and a legal reference. New subparagraph (G) has been added at adoption in response to comments received stating that the rule should be clarified to state that fetal tissue which results from a miscarriage or other abortion that occurs at home, whether induced or spontaneous, is not subject to the rules. An exemption was added at adoption under new subparagraph (G) that exempts from the rule's requirements human tissue, including fetal tissue, that is expelled or removed from the human body once the person is outside of a healthcare facility. New subparagraph (H) has been added at adoption in response to comments received stating that the rule did not comport with House Bill (HB) 635 (Acts 2015, 84th Legislature, Regular Session, Chapter 342), which requires a hospital to release the remains of an unintended, intrauterine fetal death on the request of a parent of the unborn child. An exemption was added at adoption under new subparagraph (H) that exempts from the rule's requirements fetal remains required to be released to the parent of an unborn child pursuant to Texas Health and Safety Code, §241.010. New subparagraph (I) has been added at adoption in response to comments received stating that the rule did not comport with HB 1670 (Acts 2015, 84th Legislature, Regular Session, Chapter 740), which added Chapter 172 to the Texas Health and Safety Code and requires a hospital or birthing center to allow a woman who gave birth in the facility to take the placenta from the facility in certain circumstances. Language was added under new subparagraph (I) at adoption which creates an exemption from the rules applicability

when a placenta is removed from a hospital or birthing center pursuant to Texas Health and Safety Code, Chapter 172.

Amendments to §1.134, Application, are adopted to update references to facilities providing mental health and intellectual disability services; and add freestanding emergency medical care facilities to the list of health care-related facilities to which this rule applies. New subsection (a) has been added at adoption in response to comments received stating that the rule would require that confidential and/or private information regarding an individual be part of public information and/or vital statistics data collected by the department and that a death certificate would be required to dispose of fetal tissue. To clarify the intended impact of the rules, language was added to this section at adoption to state that the rules are not to be used to require or authorize disclosure of confidential information, including personally identifiable or personally sensitive information, not permitted to be disclosed by state or federal privacy or confidentiality laws, and that the rules do not require the issuance of a birth or death certificate for the proper disposition of special waste from health care-related facilities, and that this subchapter does not extend or modify requirements of Texas Health and Safety Code, Chapters 711 and 716 or Texas Occupations Code, Chapter 651 to disposition of fetal tissue.

Amendments to §1.135, Performance Standards for Commercially-Available Alternate Treatment Technologies for Special Waste from Health Care-Related Facilities, are adopted to update references to the department and correct a mathematical unit to " \log_{10} ."

Amendments to §1.136, Approved Methods of Treatment and Disposition, are adopted to update references to the department; update terminology regarding the TAC; update references to TCEQ and its rules; clarify disposition methods for fetal tissue; clarify disposition methods for fetal tissue and other tissues that are products of spontaneous or induced human abortion; and clarify that disposition methods for anatomical remains are established in 25 TAC §479.4. Subsection (a)(4)(A)(v) and (B)(i) have been amended at adoption in response to comments received stating that the rules apply "at any gestational age" however, the rules contain exemptions that limit that application. As a result, subsection (a)(4)(A)(v) regarding "fetal tissue, regardless of period of gestation" and subsection (a)(4)(B)(i) regarding "fetal tissue, regardless of period of gestation" contain a cross-reference to the exemptions in §1.133 that was added at adoption to assist the reader in applying the exemptions, which limit the applicability of the language in paragraph (4)(A) and (B). Subsection (a)(4)(A)(v)(II) and (B)(i)(IV) have been amended at adoption in response to comments received stating that the rule was not clear regarding the difference between incineration and cremation and that the rules appeared to emphasize cremation over incineration. The stand-alone term "cremation" was deleted at adoption in both subsection (a)(4)(A)(v)(II) and (B)(i)(IV). This term already existed as a form of interment, and thus was included as method of disposition in the previous rules. It is retained in the adopted rules under the term "interment" along with the amendments made to §1.132(18) specified above.

Amendments to §1.137, Enforcement, are adopted to reflect the Executive Commissioner's role in rulemaking; remove home and community support services agencies from the list of the department's regulatory programs; and add end-stage renal disease facilities and freestanding emergency medical centers to the list of the department's regulatory programs.

COMMENTS

The department, on behalf of the commission, has reviewed and prepared responses to comments regarding the proposed rules that were submitted during two 30-day comment periods and at two public hearings, held on August 4, 2016 and November 9, 2016, which the commission has reviewed and considered. A total of 35,663 written and oral public comments were received.

The following interested groups and/or associations provided comments in favor of the rules: Texas House Republican Caucus, Texas Alliance for Life, Texas Right to Life, American Academy of Fertility Care Professionals, Houston Coalition for Life, Texans for Life Committee, Roman Catholic Diocese of Austin, Young Women for America and Concerned Women for America Legislative Action Committee, Choose Life Midland, Birth Choice Dallas, Woman to Woman Pregnancy Resource Center, Texas Catholic Conference, Life Choices Medical Clinic of San Antonio, Texas Values, St. Ignatius Martyr Catholic Parish, Southern Baptists of Texas Convention, Justice Foundation, Operation Outcry, Students for Life of America, Pro-Life Organization of Grimes and Waller Counties, Office of Life Charity and Justice of Roman Catholic Church, Our Lady of the Rosary Cemetery and Prayer Garden, Diocese of San Angelo, Trinity Legal Center, Cathedral of Our Lady of Walsingham Catholic Church and Shrine, Mercy Ministry of the Prince of Peace Catholic Community, Catholic Pro-Life Committee of North Texas, Catholic Healthcare Professionals of Houston, SA Pregnancy Care Center, 3d Houston, and St. Clair of Assisi Catholic Church.

The following interested groups and/or associations provided comments that were opposed to the rules: Texas House Women's Health Caucus, Texas Medical Association and Texas Hospital Association, American Civil Liberties Union, Center for Reproductive Rights, Funeral Consumers Alliance of Texas (FCAT), NARAL Pro-Choice Texas, Medical Students for Choice, Unite Women Texas, Planned Parenthood of Greater Texas, Inc., Planned Parenthood South Texas Surgical Center, Planned Parenthood Center for Choice, Inc., Planned Parenthood of Texas Votes, Lilith Fund, Austin National Organization for Women, Texas Equal Access Fund, Public Leadership Institute/Fund Texas Choice, National Abortion Federation, National Latina Institute for Reproductive Health, Physicians for Reproductive Health, Healthcare Waste Institute of the National Waste and Recycling Association, American Congress of Obstetricians and Gynecologists, League of Women Voters of Texas, Teaching Hospitals of Texas, and National Association of Social Workers.

The department, on behalf of the commission, acknowledges these comments and responds below, according to the various issues raised by these commenters.

Comment: The Center for Reproductive Rights stated that the department lacks statutory authority to promulgate the amendments; the amendments would unduly burden patients seeking abortion care while providing no health or safety benefit; are unconstitutionally vague and further shame and stigmatize women seeking reproductive health care. The commenter states that the rules do not confer any additional public health benefit to the patients or the general public and the fact that the new rules apply only to fetal tissue confirms as much. The commenter states that the U.S. Supreme Court held in *Whole Woman's Health v. Hellerstedt*, 136 S.Ct. 2292 (2016) (*Whole Woman's Health*), that a state's justification for an abortion restriction

must be supported by credible medical evidence which the state has not brought forth. Offers from religious entities to offset the cost of burial do not change the constitutional argument and fail to respect the diversity of faith and secular traditions and beliefs Texans hold. The commenter states that the rule is unconstitutionally vague in that it does not clarify whether the regulations apply to the transport and disposition of embryonic and fetal remains and do not adequately define interment or cremation. The commenter adds that the rules fail to provide legally sufficient clarity as to whether they are intended to apply to disposition of tissue across state lines. The commenter states that the amendments will burden abortion access and miscarriage management by mandating its own moral code upon Texas women.

Response: The commission respectfully disagrees. The rule does not restrict access to abortion. The department has the statutory authority to promulgate rules to protect the public from the spread of communicable disease pursuant to Texas Health and Safety Code, Chapters 12 and 81. In doing so, the department undertook the review of outdated rules in conjunction with this authority while trying to balance cost considerations, public benefit, legislative intent, and the state's history of protection of the unborn. These considerations resulted in the amended rules. The rules impose an obligation on facilities, not on individuals, and as a result do not shame or stigmatize women seeking abortions. The rules do not unduly burden individuals seeking abortions, as the department estimates that the costs for health care-related facilities to comply will be sufficiently low such that the costs can be absorbed by facilities as part of their operating costs while providing a public health benefit by ensuring the proper disposal of fetal tissue. The rules also do not require any facility to accept the offer of a religious entity to assist with the disposition of fetal tissue and, therefore, do not impose any particular faith or tradition on an individual. The rules are not unconstitutionally vague because they specify the procedures used and the facilities to which they apply. With regard to the issue of whether the rules are intended to apply to disposition across state lines, regardless of where the disposition of waste occurs, the health care-related facility remains responsible for ensuring that the fetal tissue disposition is in compliance with these rules. The department does not have jurisdiction over disposition methods in other states or across state lines. The health care-related facility will need to demonstrate to the department that it has provided for disposition in compliance with the rules.

Comment: The Healthcare Waste Institute of the National Waste and Recycling Association stated that the rules require the generator to separate out waste materials for proper handling. Most healthcare facilities use off-site waste management companies to dispose of regulated medical waste. These commercial facilities do not have the ability to segregate materials received. Even attempting to do so would place employees at great risk. The commenter states that compliance by the healthcare waste management industry is impractical, if not impossible and requests that the department remove "*incineration followed by interments {and} steam disinfection followed by interment*" from the proposed rules. The commenter also suggested that the department add the following language:

"Any transporter, treatment or final disposal facility who unknowingly fails to comply with subsections of this section because such waste has not been properly segregated or separated from other solid wastes by the generating facility is not guilty of a violation under this rule."

Response: The commission declines to add the suggested language because the department does not have the authority to regulate medical waste transporters, waste treatment facilities, or final disposal facilities. Instead, the TCEQ regulates medical waste transport, treatment, and disposition. The commission also declines to remove rules in §1.136(a)(4)(A)(v)(II) and (III), as these are practices and methods currently utilized by health care-related facilities for disposition of fetal tissue and do not adversely impact the balance of considerations the department was trying to achieve in the rules relating to the dignity of the unborn and public health protections and cost. The commission believes the methods allowed by the rules will protect the public by preventing the spread of disease while also preserving the dignity of the unborn in a manner consistent with Texas laws. The commission understands that many health care-related facilities already segregate fetal tissue from medical waste and, therefore, the rule would not impose additional requirements on those facilities.

Comment: FCAT submitted initial comments stating that the proposal for the rule changes appears to be incomplete in that it does not complete the small and micro-business impact analysis nor does it identify a fiscal impact to state or local governments. The commenter expressed their disappointment that a public hearing has not been called and that the exclusion of stakeholders, particularly women, is ethically negligent. The commenter states that proposed rules will forcibly increase the cost of abortion by requiring cremation or interment of all fetuses by state-licensed funeral establishments who charge a basic fee of \$2,000. The commenter calculated the annual cost for 48,000 – 54,000 total abortions, typically occurring at 13 weeks, to add up to \$96 million. The commenter assumes that the facilities will not bear this cost and will force the woman to pay, and if the woman cannot pay, the cost will be borne by county governments or that a woman would be put in jail for not paying. The commenter states that the proposed rules will force women into a narrower set of emotional and financial choices with no added benefit. This newly regulated life event will effect social, psychological, financial and pastoral services, with little to no experience on how to support the woman. The rule appears to force women to reveal to family, friends, and the community, her very personal choice as it requires the assistance of a funeral establishment or asking friends and family's support with fetal disposition. The commenter stated that women will be forced to "shop and trade in the dizzying emotional dither of the deathcare business," or dispose of the fetus themselves. FCAT submitted additional comments stating that cremation and burial are terms specified by the Texas Funeral Service Commission and only regulate the burial and cremation of "dead human bodies." Funeral directors are not regulated or ethically allowed to participate in the disposition of aborted fetuses. This apparent exclusion is positive to a woman's health as it protects her privacy and does not force her to assign disposition responsibility to a publicly accessible business and by eliminating actual or pass through costs from a funeral business. FCAT offered that under the legal definition of cremation, 89% of aborted fetuses can be cremated under current code by using a \$17 hand held propane torch from the hardware store. FCAT views cremation as being as insufferable to women as the grinding and discharging of a fetus in a commercial garbage disposer. The commenter recommends that earth burial be the only disposition method allowed. Simple earth burial requires no special skills or extra expense. A fetus or embryo burial place would not fit the definition of cemetery because a cemetery is defined as a place of interment with one "dead human body" or more, thus a fetus or embryo burial place provides a simple and less costly burial method and location than a designated and regulated cemetery. The proposed rule should state the process to follow, in detail, for burial of a human fetus or embryo; listing the

choices a woman must make and the expected results. To do otherwise would result in multiple interpretations. Practically speaking, an earth burial can be respectful, easy and an economical choice for women. Since the rules allow for group burial, the cubic volume of 89% of the aborted fetuses in Texas, in one year, would be 3x3x3 yards, the size of a very small bedroom. Spread out across 254 counties, the anticipated volume of fetal remains in a year for a large metropolitan area would be the size of a large household refrigerator. The commenter recommends that the woman bury the fetus on private property with the location recorded in the property deed, or, the woman choose for the county to bury in a designated location in the county with a simple durable marker. As each county already is required to have a policy for indigent burial, it is assumed that a county employee is budgeted and assigned this task as part of those duties.

Response: The commission respectfully disagrees. The department republished the rules with a more comprehensive small and micro-business impact analysis. The department received cost data from waste disposal companies, private and public landfills, FCAT (comments as noted above), the Funeral Services Commission, TCEQ, the University of Texas System, and others to determine the minimum cost in complying with the rules. Based upon the lowest stated costs of each entity able to provide cost estimates, the department has determined that the annual cost per facility would be approximately \$450. For those health care-related facilities not already disposing of fetal tissue through cremation and burial, the cost of any of the new available methods would be offset by the elimination of the cost of landfill disposition. The department believes this cost to be minimal and absorbable by health care-related facilities. The department also determined that there will be no fiscal implications for state or local governments during the first five years that the proposed rules will take effect. The department further notes that it has conducted a public hearing on the proposed rules that were withdrawn and another public hearing on the proposed rules at issue. The proposed rules will not narrow the choices of women, because the proposed rules apply to health care-related facilities and not to individuals. The proposed rules do not require a patient or a health care-related facility to obtain funeral services. The commission appreciates the suggestion but declines to eliminate cremation as a method of disposition of fetal tissue. The department agrees that Chapter 651 of the Texas Occupations Code does not apply to fetal tissue that does not meet the definition of a “dead human body.” Cremation was an option under the previous rules and continues to be an option in these rules. These are practices and methods currently utilized by health care-related facilities for disposition and do not adversely impact the balance of considerations the department was trying to achieve in the rules relating to the dignity of the unborn with the public health protections and cost. The proposed rules already specify which processes are authorized, and the department notes that it is the responsibility of facilities, not patients, to comply with the rules. The department has no authority to require an individual to bury a fetus in a certain location. The department believes the methods allowed by the rules will protect the public by preventing the spread of disease while preserving the dignity of the unborn in a manner consistent with Texas laws and the Legislature’s expressed intent.

Comment: The Texas House Women’s Health Caucus submitted comments regarding the justifiable reasoning for the proposed changes; the lack of identified health benefit; the uncertainty around the full impact of the rules; the fiscal impact, and the potential violation of privacy of Texas women and their families. The department has not provided information on

why the current methods being removed from the rule do not provide a safe and effective manner to dispose of tissue. Nor has the department explained why the disposition of fetal tissue should be different from any other human tissue and how one endangers public health and safety more than another. The commenter states that the department is required to provide a reasoned justification and factual basis for the need to change the rule and it has not. Additionally, the department has not provided any research or evidence to explain how it developed the new rules and whether they meet medical standards. The emotional damage that may result from implementation of these new requirements cannot be known. The requirement that a grieving mother have to choose incineration or cremation after losing a pregnancy through miscarriage or due to an ectopic pregnancy where there is no hope of viability and the fetus is removed to save the mother's life, is cruel and intrusive. Many miscarriages occur outside of a clinical setting. Are these women required to carry the fetal tissue to a healthcare facility? If the rules apply at any gestational age, does this include a fertilized egg, and if so, will these rules apply to families undergoing in vitro fertilization? The commenter questions the fiscal impact of the rules and states that although the department indicated that there would be some absorbable costs associated with compliance, FCAT has stated that the average basic services fee for professional services starts at \$2,000. FCAT indicates that the rules will bring an additional \$96 million in revenue to the Texas funeral business. The commenter asks who will be responsible for the cost if the woman and her family are unable to pay. The commenter questions whether the department can ensure sufficient vendor availability to provide these additional services. The commenter asks for clarity on whether the rules will require a fetal death certificate and if so, privacy issues are a concern. The Texas Public Information Act protects death records from being publicly available until the 25th anniversary of the date of death, however, an unknown decedent's death record is public after only one year. The commenter further states that fetal death certificate data is used for a variety of health-related studies in the pursuit of improving patient health and advancing medical science. Requiring death certificates for fetal tissue will skew these numbers. The commenters go on to state that the rules would impose a heavy burden on women seeking abortion care in Texas and do not offer a proportional benefit, as required by the United States Constitution and further clarified in *Whole Woman's Health*. The commenter expresses concern that these rules will likely result in costly litigation in a budget cycle where agencies have been told to tighten their belts. These funds could be better spent on education or health care rather than wastefully litigating unconstitutional regulations.

Response: The commission respectfully disagrees with the commenter's assertions and responds accordingly. The department has the statutory authority to promulgate rules to protect the public from the spread of communicable disease pursuant to Texas Health and Safety Code, Chapters 12 and 81. In doing so, the department undertook the review of outdated rules in conjunction with this authority while trying to balance cost considerations, public benefit, and the Legislature's intent and history of the protection of the unborn. These considerations resulted in the amended rules. Inclusion of a reasoned justification is required on adoption pursuant to Texas Government Code, §2001.033, and is included in this adoption preamble under the section entitled "Background and Justification" above. The department stresses that the proposed amendments apply only to health care-related facilities and not to individuals, so the rules do not impose requirements on a individual who suffers a miscarriage or induced abortions; those requirements fall solely on the health care-related facility. The rules do not now, nor have they ever, imposed a requirement that a patient be informed of the method of disposition. The

department notes that the proposed rules do not prohibit mass cremation (including mass incineration) and interment, and believes such options are currently used. The department received cost data from waste disposal companies, private and public landfills, FCAT (comments as noted above), the Funeral Services Commission, TCEQ, the University of Texas System, and others to determine the minimum cost in complying with the rules. Based upon the lowest stated, the estimated cost of using such services would be no more than \$450 per year, per facility, a cost of business that facilities should be able to absorb. There should, therefore, be no undue burden placed on a woman seeking an abortion. A certificate of fetal death (fetal death certificate) is only required for a fetus weighing 350 grams or more, or if the weight is unknown, a fetus aged 20 weeks or more as calculated from the start date of the last normal menstrual period. *See* 25 TAC §181.7(a). Based on an exemption that was contained in the previous rules, fetal deaths subject to the fetal death certificate requirement are exempt from the adopted rules pursuant to §1.133(a)(2)(F). The department retained that exemption in these rules, and has not modified it in the proposed or adopted rules. As a result, vital statistics data collection and reporting results will not be affected. To further clarify the impact of the rules, the department added the following language to rule §1.134. Application: “(a) This subchapter may not be used to require or authorize disclosure of confidential information, including personally identifiable or personally sensitive information, not permitted to be disclosed by state or federal privacy or confidentiality laws. This subchapter does not require the issuance of a birth or death certificate for the proper disposition of special waste from health care-related facilities. This subchapter does not extend or modify requirements of Texas Health and Safety Code, Chapters 711 and 716 or Texas Occupations Code, Chapter 651 to disposition of fetal tissue.” Additionally, the rules do not unduly burden women seeking abortions, as the department estimates that the costs for health care-related facilities to comply will be sufficiently low such that the costs can be absorbed by facilities as part of their operating costs while providing a public health benefit by ensuring the proper disposal of fetal tissue. The amendments to the rules do not change the impact of the rules for in vitro fertilization. Pursuant to §1.132(28), the term “Fetal Tissue” is defined as “a fetus, body parts, organs or other tissue from a pregnancy” and does not include “the umbilical cord, placenta, gestational sac, blood or body fluids.” This term was added in the proposed rules and has not been amended at adoption. The rule amendments relating to fetal tissue do not apply prior to pregnancy. Once a pregnancy occurs, the rules application is the same to both the in vitro fertilized pregnancy and an unassisted natural pregnancy, if there is an induced or spontaneous abortion of the pregnancy.

Comment: The Texas Medical Association and Texas Hospital Association (TMA/THA) submitted joint comments and reiterated their comments from the earlier publishing of the rules. The commenters stated that the rules should not apply to miscarriages, ectopic or molar pregnancies regardless of the location of the woman at the end of her pregnancy. The commenters state that forcing a woman who miscarries at home to bring fetal tissue to her physician or whose ectopic or molar pregnancy was ended in a hospital setting, would make a difficult situation even more difficult. The commenters also inquire whether physicians and hospitals will be subject to penalties if their patients do not deliver fetal tissue to them after a pregnancy that ends outside of a health care setting. Should the department decide not to make the recommended exceptions stated above, TMA/THA suggested that the department should provide printed materials to Texas physicians and hospitals detailing the rule requirements and associated costs as well as who will be responsible for paying those costs. The commenters

inquire who will be responsible for the costs and note that one hospital estimates that an average of 140 fetal tissue specimens under 350 grams are disposed of each month from spontaneous miscarriages or ectopic pregnancies. The commenters inquire whether the rules apply to miscarriages that occur outside of a healthcare facility, and if so, in what time frame is the woman expected to carry the fetal tissue to the healthcare facility. The commenters ask who would be responsible for the \$1,500 to \$4,000 cremation cost and the \$7,000 to \$10,000 funeral service fees; and whether the department has done a cost estimate or established a governmental resource or exceptional item to cover the added process and procedure costs. The commenters state that 10% to 15% of women who know they are pregnant have a spontaneous miscarriage, usually during the first trimester, and question whether the department has conducted any research as to how the rules will affect health care-related facilities' and providers' processes relating to storage, cremation, interment and responsibility for cremated remains. The commenters ask whether a study has been conducted on the impact to rural health facilities where tissue disposal alternatives are limited or for high volume obstetric hospitals. TMA/THA state that funeral directors must have a fetal death certificate to accept fetal tissue and that the rules are in conflict with this requirement and inquire whether funeral directors' involvement is required. Additionally, burial transit permits are required and cemeteries are required to register plots so they know who is buried in each plot. The commenters state that the rules require fetal death certificates and that including miscarriages, ectopic and molar pregnancies in the recording of fetal death certificates and other required reporting will skew public health data. The commenters express concern about lack of awareness and the need to enter into new contractual arrangements and request a delayed implementation date to allow for such arrangements. The commenters also express concern over how these rules comport with HB 635 for the release of fetal remains to parents, if requested. The commenters inquire as to how third-party vendors will comply with the rules. The commenters inquire who will be responsible for the cremated remains.

Response: The commission appreciates the comments but respectfully disagrees with the commenters. Each health care-related facility is responsible for complying with the rules, regardless of whether it actually provides the disposition of fetal tissue or contracts with a third party vendor. The department has considered the impact of the proposed rules on costs and determined that they are absorbable by health care-related facilities required to comply with the rules. The department received cost data from waste disposal companies, private and public landfills, FCAT (comments as noted above), the Funeral Service Commission, TCEQ, the University of Texas System, and others to determine the minimum cost in complying with the rules. Based upon the lowest stated costs of each entity able to provide cost estimates, the department has determined that the annual cost per facility would be approximately \$450. This cost would be offset by the elimination of the current method of disposition. The department believes this cost to be minimal and absorbable by each health-care facility. Health care-related facilities will be responsible for ensuring that the cremated remains are handled in compliance with the rules. The commission emphasizes that the proposed rules do not require a individual who miscarries to deliver fetal tissue to a physician or a hospital and notes that the rules apply to health care-related facilities and not to individuals. The commission declines to change the proposed rules to exclude miscarriages, ectopic or molar pregnancies regardless of the location of the individual at the end of her pregnancy. The commission again notes that the rules apply to health care-related facilities and not to individual patients. The commission does not at this time

see a need for printed materials for Texas physicians and hospitals detailing the rule requirements. The rules were published in the *Texas Register* as required by the Administrative Procedure Act and also made available on the department's website. If it becomes necessary in implementation of the rules, the department will consider issuing guidance documents to all facilities required to comply. The department does not regulate costs of treatment and disposition of special waste, as these costs are the responsibility of each facility. The commission notes that Texas Occupations Code, Chapter 651 does not apply to fetal tissue weighing less than 350 grams or requires consent for comingling during cremation of fetal tissue, thus compliance with Chapter 651 or Funeral Service Commission's rules will not increase costs or limit currently available methods of disposition that are consistent with respect for life. A certificate of fetal death (fetal death certificate) is only required for a fetus weighing 350 grams or more, or if the weight is unknown, a fetus aged 20 weeks or more as calculated from the start date of the last normal menstrual period. See 25 TAC §181.7(a). Based on an exemption that was contained in the previous rules, fetal deaths subject to the fetal death certificate requirement are exempt from the adopted rules pursuant to §1.133(a)(2)(F). The department retained that exemption in these rules, and has not modified the language of the exemption in the proposed or adopted rules. Also, in response to public comments, to make the applicability of the exemption more evident to the reader, the department has added a cross reference to the exemption in three places in the rules: (1) §1.132(42)(B) regarding the definition of "pathological waste;" (2) §1.136(a)(4)(A)(v) regarding fetal tissue, "regardless of the period of gestation;" and (3) §1.136(a)(4)(B)(i) regarding "fetal tissue, "regardless of the period of gestation." Additionally, to further clarify the impact of the rules, the commission added the following language to rule §1.134. Application: "(a) This subchapter may not be used to require or authorize disclosure of confidential information, including personally identifiable or personally sensitive information, not permitted to be disclosed by state or federal privacy or confidentiality laws. This subchapter does not require the issuance of a birth or death certificate for the proper disposition of special waste from health-care related facilities. This subchapter does not extend or modify requirements of Texas Health and Safety Code, Chapters 711 and 716 or Texas Occupations Code, Chapter 651 to disposition of fetal tissue." Although the commenter expressed concern about lack of awareness of the proposed rules, there is evidence to the contrary that shows that the public is aware of and has commented on the rules. More than 35,000 comments were received by the department, including oral and written comments received at two public hearings conducted by the department and during two separate 30-day public comment periods on proposed rules that were substantially the same which followed a June 20, 2016 initial posting. Therefore, the commission declines to delay the implementation date.

The commission agrees that the commenters' concerns regarding whether the rules comport with HB 635 need to be addressed. House Bill 635 (Acts 2015, 84th Legislature, Regular Session, Chapter 342) added §241.010 to the Texas Health and Safety Code. This statute requires a hospital to release the remains of an unintended, intrauterine fetal death, including remains that weigh less than 350 grams, on the request of a parent, in a manner appropriate under law and the hospital's policy. In response to public comments and to conform with the impact of HB 635, the department has added subsection (a)(2)(H) to §1.133. Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of State Health Services, which states that the rules do not apply to "fetal remains required to be released to the parent of an unborn child pursuant to Texas Health and

Safety Code, §241.010{.}" Also in response to comments, the department has added a cross-reference to the exemption in §1.133 to §1.136(a)(4)(A)(v) and (B)(i) regarding "fetal tissue, regardless of the period of gestation."

Many health care-related facilities are already in compliance with the rules as adopted. Facilities will be responsible for disposition of cremated remains in a manner not otherwise prohibited by law. Regarding the comment pertaining to a burial transit permit, the rules do not invoke any new requirements that require a burial transit permit be issued. A fetal death certificate is only required for a fetus that weighs 350 grams or is 20 weeks or more. If fetal death meets this threshold age or weight requiring a death certificate, the fetal death is exempt from the rule pursuant to §1.133(a)(2)(F). If no fetal death certificate is required, due to age or weight, there is no requirement for a funeral director, who assumes custody of a fetus, to file a report; or to provide such documentation in order to cremate fetal tissue, as defined in this subchapter.

Comment: Three Planned Parenthood entities joined in submitting comments: Planned Parenthood of Greater Texas, Inc., Planned Parenthood South Texas Surgical Center, and Planned Parenthood Center for Choice, Inc. The commenters state that the rules go beyond the limits of statutory authority and do not further the aims of the department to protect and enhance public health and safety. The rules eliminate safe and effective disposal methods without any authority to adopt rules in order "to better preserve the dignity of these unborn lives." The commenters cite the statutory requirement that the department provide a summary of the factual basis for the rule as adopted which demonstrates a rational connection between the factual basis for the rule and the rule as adopted, and states that no such factual basis has been provided. The commenters ask for citations to studies or other documentary evidence that indicate that the methods of disposal that were removed from the rule endangered the safety of the public. The rules are another attempt to restrict access to abortion and shame, judge and stigmatize women in the process. The commenters state that the department has not provided any evidence that the proposed rules ensure current best practices or why this pathological waste should be treated different from other pathological waste. The commenters note that there is no practical difference between incineration and cremation beyond the administrative requirements. The commenters stated that the rules are silent as to where cremated tissue must be deposited. Incinerated material deposited in a landfill is subject to Texas statutes relating to solid waste management by controlling access and disease vectors and by preventing windblown waste. The commenters state that the department has not provided information as to how this is less safe than scattering cremated ash. Even assuming that scattering of cremated tissue might somehow be safer than depositing incinerated tissue in a sanitary landfill, the resulting ash – from either cremation or incineration – poses little or no risk to the public. Texas and federal law deem cremated or incinerated tissue no longer medical or infectious waste. The commenters state that the department has no statutory authority to base regulation amendments on a desire to preserve the dignity of "unborn lives" and to do so is likely unconstitutional. The commenter looks to the federal court's decision in *Planned Parenthood of Ind. & Ky, Inc. v. Comm'r, Ind. State Dep't of Health*, No. 1:16cv-00763-TWP-DML WL 3556914 at *11 (S.D. Ind. June 30, 2016) and *Margaret S. v. Edwards*, 488 F.Supp. 181, 222 (E.D. La. 1980) and *Margaret S. v. Treen*, 597 F.Supp. 636, 671 (E.D. La. 1984). The commenter states that courts have upheld the limits of state interest in the disposition of fetal tissue to those that ensure the sanitary disposal of fetal tissue. The commenter expresses concern over the apparent requirement that fetal death

certificates be issued for every miscarriage, abortion or ectopic pregnancy in the state, leading to private medical histories becoming part of Texas public record. The publication of the names and other identifying information of individual women is of grave concern. The commenter disagrees with the fiscal impact statement made by the department and states that the department did not provide details as to how it determined that the costs incurred will be offset and quotes the TMA/THA comment of a cost between \$1,500 and \$4,000 for cremation and from \$7,000 to \$10,000 for a traditional funeral. The commenter states that the department's statement that private parties offered to bury fetal remains without charge is wishful at best and specious at worst. The commenter expresses concern over being required to contract with such parties and that in doing so they would have to break patient privacy.

Response: The commission respectfully disagrees. The department has statutory authority to amend the rules to protect the public from the spread of communicable disease pursuant to numerous chapters of the Texas Health and Safety Code and other Texas laws, as cited in the Background and Justification Section above and the Statutory Authority Section below. These rules are necessary to maintain the protection of the health and safety of the public by ensuring that the disposition methods specified in the rules continue to be limited to methods that prevent the spread of disease. The department undertook the review of outdated rules in conjunction with this authority and with the goal of balancing cost considerations, public benefit and the Legislature's policy objective of ensuring the dignity for the unborn, which is articulated in a number of Texas laws. The proposed rules do not restrict access to abortion, but impose requirements on health care-related facilities regulated by the department. The department has reviewed the proposed rules with the above goals in mind. The rule does not require a funeral, it simply limits how fetal tissue may ultimately be disposed to exclude methods of disposition, such as grinding and placement in a landfill, that are contrary to demonstrating dignity for the unborn. Based on this and other comments regarding incineration versus cremation, the department has amended at adoption the proposed rules to clarify this matter and allow disposition in a manner that preserves the public health while affording dignity to the unborn. Cremation is a method of disposition under current rules and continues to be available under the adopted rules. The term was included under current rules as a form of interment under §1.132(31), which relates to the definition of "Interment" stated as "The disposition of pathological waste by *cremation*, entombment, burial or placement in a niche." (emphasis added). The department did not modify that definition in the proposed rules. The department did separate out the term "cremation" in the proposed rules under proposed changes to §1.136(a)(4)(A)(v) and (B)(i) but in response to public comments that read this to give "cremation" more emphasis than "incineration," which was not intended, the department determined a revision to the rules was warranted. As a result, the department has amended these provisions in the adopted rules and deleted the stand alone reference to "cremation.". Cremation will continue to exist as a form of interment, as it did in the previous rules. Additionally, in response to these public comments the department has added the term "incineration" to the forms of cremation that can occur for waste disposition by including it in the definition of "cremation" under adopted §1.132(18):

"(18) Cremation--The irreversible process of reducing tissue or remains to ashes or bone fragments through extreme heat and evaporation. Under this subchapter, this term includes the process of incineration."

The department disagrees that it does not have a statutory basis to propose rules based on preserving the dignity of the unborn. The Legislature has expressed its intent and policy to protect the unborn in several chapters of the Health and Safety Code, including Chapter 170 (regarding third-trimester abortions), Chapter 171 (requiring informed consent for abortions), Chapter 241, §241.010 (requiring hospitals to release to a parent remains of an unborn child who dies as a result of an unintended intrauterine death), and Chapter 245 (regulating abortion facilities). The rules are consistent with that expression of intent in the legislative history. The commenter cites the federal court injunction against Indiana's House Enrolled Act 1337 in *Planned Parenthood of Ind. & Ky, Inc. v. Comm'r, Ind. State Dep't of Health*. The State of Indiana passed House Enrolled Act 1337, which would require that a miscarried or aborted fetus be interred or cremated by a facility having possession of the remains and would exclude the final disposition of a miscarried or aborted fetus from the law governing the treatment of infectious or pathological waste. Although the Indiana law has been preliminarily enjoined by a federal court from taking effect, it is different from the department's adopted rules, which explicitly encompass treatment and disposition of material that includes fetal tissue. The federal court also determined that Indiana had no interest in treating the unborn with dignity. Here, however, the Texas Legislature has enacted numerous statutes demonstrating its interest in the dignity of the unborn. The rule provides many options for disposition, many of which are already in use, that do not increase the cost of disposition of fetal tissue but still protect the dignity of the unborn. The other cases the commenter cites, *Margaret S. v. Edwards* and *Margaret S. v. Treen*, overturned laws requiring a woman to decide on the disposal method for the fetal tissue. The proposed rules, on the other hand, leave that decision to the facility. The department stresses that the proposed rules will not require that fetal death certificates be issued for every miscarriage, abortion or ectopic pregnancy in the state and do not require or authorize an individual's private information to become part of the state's public record. A certificate of fetal death (fetal death certificate) is only required for a fetus weighing 350 grams or more, or if the weight is unknown, a fetus aged 20 weeks or more as calculated from the start date of the last normal menstrual period. See 25 TAC §181.7(a). Based on an exemption that was contained in the previous rules, fetal deaths subject to the fetal death certificate requirement are exempt from the adopted rules pursuant to §1.133(a)(2)(F). In response to public comments, to make the applicability of the exemption more evident to the reader, the department has added a cross reference to the exemption section of the rules in three places: (1) §1.132(42)(B) regarding the definition of "pathological waste;" (2) §1.136(a)(4)(A)(v) regarding "fetal tissue, regardless of the period of gestation;" and (3) §1.136(a)(4)(B)(i) regarding "fetal tissue, regardless of the period of gestation{.}" Regarding costs, the department received cost data from waste disposal companies, private and public landfills, FCAT (comments as noted above), the Funeral Service Commission, TCEQ and the University of Texas System and others to determine the minimum cost in complying with the rules. Based upon the lowest stated costs of each entity able to provide cost estimates, the department has determined that the annual cost per facility would be approximately \$450. For those health care-related facilities not already disposing of fetal tissue through cremation and burial, the cost of any of the new available methods would be offset by the elimination of the cost of landfill disposition. The department believes this cost to be minimal and absorbable by health care-related facilities. The department further notes that it would be facilities that would contract for disposition, not individuals, and patient privacy is not implicated by the proposed rules. To further safeguard patient privacy, the department added the

following language to rule §1.134. Application: “(a) This subchapter may not be used to require or authorize disclosure of confidential information, including personally identifiable or personally sensitive information, not permitted to be disclosed by state or federal privacy or confidentiality laws. This subchapter does not require the issuance of a birth or death certificate for the proper disposition of special waste from health care-related facilities. This subchapter does not extend or modify requirements of Texas Health and Safety Code, Chapters 711 and 716 or Texas Occupations Code, Chapter 651 to disposition of fetal tissue.” Additionally, in response to public comments which stated that the department had not specified what disposition follows cremation as it had for other methods of disposition, the department has clarified the definition of interment to include disposition of ashes resulting from cremation (and incineration) as authorized by current law, excluding placement of ashes in a landfill. The adopted language includes the process of scattering ashes as part of that particular method of disposition (which now includes incineration) as well as other disposition of ashes authorized by law. The scattering of ashes is permitted under certain circumstances, to be done at specified settings in other law (*see* Texas Health and Safety Code, Chapter 716). The adopted rules no longer allow disposition of fetal tissue in a sanitary landfill and thus would not allow scattering of ashes that result from cremation or incineration of fetal tissue on land, if that land was also a landfill, even if the scattering of ashes was otherwise permitted by law. As a result, the department has added the following amended definition of “interment” under §1.132(33) in the adopted rules:

"(33) Interment--The disposition of pathological waste using the process of cremation, entombment, burial, or placement in a niche or by using the process of cremation followed by placement of the ashes in a niche, grave, or scattering of ashes as authorized by law, unless prohibited by this subchapter."

Comment: The American Congress of Obstetricians and Gynecologists commented that there is no evidence that the current disposition methods are unsafe or disrespectful of fetal tissue and that limiting fetal tissue disposal to only interment by burial or cremation does nothing to improve the health and safety of Texans. The commenter stated that “the department has bypassed the normal rule-making process even though there was no existing emergency.” The commenter states that the current laws and professional standards already require safe and respectful disposition of medical waste. The commenter indicates that in some situations, fetal tissue is sent to a laboratory for pathological testing and that this material may not be returned and poses the question of how the rules would apply in this situation. The commenter states that the rules interfere with the patient/doctor relationship, especially in the case of miscarriage, ectopic or molar pregnancies when, frequently, there is little to no discernable tissue found. The commenter states that 15% to 20% of pregnancies result in miscarriage which may occur at home, at work or at a physician’s office and that mandating that fetal tissue be collected for cremation or interment could become a cruel mandate on a woman who lost a very wanted pregnancy. The commenter states that requiring a death certificate for every cremation or interment of fetal tissue could skew vital statistics data used to improve health and well-being of women and children in Texas. The commenter states that fetal deaths registered with the Vital Statistics Unit are public record and raises concerns over making public very private medical histories of women. The data collected in fetal death registrations provide valuable data when collected for the purpose of improving patient health and the advancement of medical and scientific progress. These rules do not further these goals. The commenter states that the rules

appear to be conflict with HB 635, which allows parents to request the remains of a miscarried fetus from hospitals or other health care-related facilities.

Response: The commission respectfully disagrees. The department complied with the requirements of the Administrative Procedure Act, Chapter 2001 of the Texas Government Code. The department gave at least 30 days' notice of its intent to adopt the proposed rules; it twice filed notice of the proposed rules with the Office of the Secretary of State for publication in the *Texas Register* as required by Chapter 2001 of the Texas Government Code, giving the public two 30-day periods for comment. The first set of proposed rules was filed on June 20, 2016 and the second on September 19, 2016. The same rules were proposed each time. Both notices for the proposed rules included the information required by Texas Government Code, §2001.024; and the department gave all interested persons an opportunity to submit oral and written comments as required by Texas Government Code, §2001.029. Two public hearings were held on August 4, 2016, and November 9, 2016, in compliance with Texas Government Code, §2001.029, in which the department received oral and written public comments. The department received more than 35,000 comments on the proposed rules. The department, on behalf of the commission, voluntarily considered and is responding in this Adoption Preamble to 20,000 comments from the first publication, public comment period and public hearing regarding the proposed rules. There is no legal requirement to consider and respond to the first set of comments, but the department felt it important to include the initial comments. The department has fully considered both the first and second set of public comments and includes its responses, and additional required elements set forth in Texas Government Code, §2001.033, in its adoption of the rules.

The department notes that the current rules already apply to clinical, diagnostic, and pathological laboratories, and these facilities would still be responsible for treatment and disposition of all materials under the proposed rules. The department stresses that the rules do not apply to a patient who miscarries outside a health care-related facility and notes that the facility, not the patient, is responsible for treatment and disposition of fetal tissue. The department is not expanding its authority to include any new topic or regulated entity or person. The proposed rules do not interfere with the doctor-patient relationship, and no changes have been made to the rules requiring notice or other changes to the physician's care of the patient. Additionally, the rules do not apply to individual patients, and the disposition of fetal tissue is the responsibility of the health care-related facility. Additionally, the rules have not included previously, and do not now impose, a requirement that a woman be informed of the method of disposition or choose that method of disposition. The proposed rules do not require that fetal death certificates be issued for every miscarriage, abortion or ectopic pregnancy in the state—meaning vital statistics reporting results will not be affected. The adopted rules do not require or authorize a patient's private information to become part of the state's public record. Under current law, a certificate of fetal death (fetal death certificate) is only required for a fetus weighing 350 grams or more, or if the weight is unknown, a fetus aged 20 weeks or more as calculated from the start date of the last normal menstrual period. *See* 25 TAC §181.7(a). Based on an exemption that was contained in the previous rules, fetal deaths subject to the fetal death certificate requirement are exempt from the adopted rules pursuant to §1.133(a)(2)(F). The department retained that exemption in these rules, and has not modified it in the proposed or adopted rules. As a result, vital statistics data collection and reporting results will not be affected. This rule does not create

a new requirement for a birth or death certificate and thus there is no additional privacy concerns created by the rule. Because hospitals are currently responsible for disposition of fetal tissue, it is very likely that many are already using methods authorized by this rule. To further safeguard patient privacy, and clarify the issues relating to death certificates, the department added the following language to rule §1.134. Application: “(a) This subchapter may not be used to require or authorize disclosure of confidential information, including personally identifiable or personally sensitive information, not permitted to be disclosed by state or federal privacy or confidentiality laws. This subchapter does not require the issuance of a birth or death certificate for the proper disposition of special waste from health-care related facilities. This subchapter does not extend or modify requirements of Texas Health and Safety Code, Chapters 711 and 716 or Texas Occupations Code, Chapter 651 to disposition of fetal tissue.”

The department agrees that the impact of HB 635, needs to be clarified. HB 635 added Texas Health and Safety Code, §241.010, requiring a hospital to release fetal remains to a parent upon request. In response to public comments and to conform with the impact of HB 635, the department has added subsection (a)(2)(H) to §1.133. Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of State Health Services, which states that the rules do not apply to “fetal remains required to be released to the parent of an unborn child pursuant to Texas Health and Safety Code, §241.010{.}” Also, in response to comments, the department has added a cross-reference to the exemption in §1.133 to §1.136(a)(4)(A)(v) and (B)(i) regarding “fetal tissue, regardless of the period of gestation.”

Comment: The National Abortion Federation submitted comments stating that the rules are not medically necessary and lack any health or safety benefit and do not adequately protect the privacy of patients, but rather create a significant burden on healthcare providers. Adding onerous disposal requirements while lacking a public health and safety benefit clearly show that these rules are a means for the State of Texas to continue its attack on access to abortion care. The requirement for facilities to obtain fetal death certificates raises serious concerns for patient privacy. The intrusive nature of the questions that must be answered to obtain a fetal death certificate are of concern as the rules provide no privacy protection to ensure this identifying information remains private, rather all of this information is presumably available as an open record under the Texas Public Information Act. Patients are targeted for harassment and there is a history of anti-abortion extremists seeking patient information in order to deter women from seeking abortion care and shame those that do. Likewise, abortion providers are often the targets of violence. If the rules do not require fetal death certificates, the commenter asks how the department will circumvent this requirement.

Response: The commission respectfully disagrees. The rule amendments, like the rules currently in effect for treatment and disposition, are targeted to prevent the spread of communicable disease. There are a variety of methods by which public health objectives can be furthered. The amendments to the rules eliminate unused or rarely used methods and also prohibit disposition of fetal tissue in a landfill, which is in line with the Legislature’s policy objective of ensuring the dignity for the unborn articulated in a number of Texas laws. To further clarify, the rules do not impinge on the privacy of patients because the rules apply to health care-related facilities and not to individuals. To further safeguard patient privacy, the

department added the following language to rule §1.134. Application: “(a) This subchapter may not be used to require or authorize disclosure of confidential information, including personally identifiable or personally sensitive information, not permitted to be disclosed by state or federal privacy or confidentiality laws. This subchapter does not require the issuance of a birth or death certificate for the proper disposition of special waste from health care-related facilities. This subchapter does not extend or modify requirements of Texas Health and Safety Code, Chapters 711 and 716 or Texas Occupations Code, Chapter 651 to disposition of fetal tissue.” The department also disputes that the proposed rules are onerous or create a significant burden on healthcare providers, which are already subject to regulation in this area. Many health care-related facilities are already in compliance with the rules as adopted. The proposed rules discontinue certain methods of treatment and disposition while allowing additional methods to remain part of the rules. The department received cost data from waste disposal companies, private and public landfills, FCAT (comments as noted above), the Funeral Services Commission, TCEQ, the University of Texas System, and others to determine the minimum cost in complying with the rules. Based upon the lowest stated costs of each entity able to provide cost estimates, the department has determined that the annual cost per facility would be approximately \$450. This cost would be offset by the elimination of some current methods of disposition. The department believes this cost to be minimal and absorbable by each health care-related facility. The current and proposed rules are not meant to, and do not, create a substantial obstacle to a woman seeking an abortion. Instead, the rules govern the treatment and disposition of special waste, including fetal tissue, from health care-related facilities.

Comment: The National Latina Institute for Reproductive Health submitted comments and states that rules create medically unnecessary burdens which can disproportionately impact the Texas “Latinx” community and perpetuate the stigma surrounding abortion care by regulating a private matter that should be left to patients. The commenter states that the rules institute unneeded procedures and complications for healthcare providers without contributing to the health and safety of Texans. The commenter states that the department does not provide information on who is to bear the additional cost burden or how women who miscarry at home are expected to properly dispose of fetal waste. The commenters asks the department to withdraw the rules and avoid the costs of unnecessary litigation.

Response: The commission respectfully disagrees and notes that the health care-related facilities are responsible for the costs of compliance. However, the department received cost data from waste disposal companies, private and public landfills, FCAT (comments as noted above), the Funeral Services Commission, TCEQ and the University of Texas System and others to determine the minimum cost in complying with the rules. Based upon the lowest stated costs of each entity able to provide cost estimates, the department has determined that the annual cost per facility would be approximately \$450. This cost would be offset by the elimination of some current methods of disposition. The department believes this cost to be minimal and absorbable by each healthcare facility. The proposed rules are necessary to protect the health and safety of the public in a manner that preserves the dignity of the unborn. As noted elsewhere, the proposed rules do not apply to women who miscarry outside of health care-related facilities, but to the facilities themselves. To further address this concern, the department has added subsection (a)(2)(G) to §1.133. Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of State Health Services,

which states that the rules do not apply to “human tissue, including fetal tissue, that is expelled or removed from the human body once the person is outside of a health care-related facility{.}” The commission declines to withdraw the proposed rules and believes they will withstand legal scrutiny.

Comment: Physicians for Reproductive Health submitted comments stating that current procedures are safe, sanitary and in line with standard medical practice and the proposed rules are medically unnecessary. The commenter states that, from a medical perspective, there is no basis to single out fetal tissue for special disposition. The commenter states that the rules take away the right of patients to determine the manner of disposition, and that in doing so the department is being intrusive and stigmatizing to patients. The commenter also stated that the state is interfering with patient care, engaging in shaming women and possibly breaching their privacy in order to complete forms necessary to cremate or inter fetal tissue. The commenter completes the comments with a concern that the rules substantially burden women and are similar in nature to the rules in *Whole Woman’s Health* which were invalidated by the U.S. Supreme Court.

Response: The commission respectfully disagrees and contends the rules balance protecting the public health with comporting with the state’s policy of recognizing the dignity of the unborn. The commission notes these rules have always required that the health care-related facility be responsible for the manner of disposition, not individual patients. However, there is no requirement contained in the rules that requires the disclosure or collection of private or sensitive personal information. To address that concern and to further protect patient privacy, the following provision has been added to the rules as adopted in §1.134. Application: “(a) This subchapter may not be used to require or authorize disclosure of confidential information, including personally identifiable or personally sensitive information, not permitted to be disclosed by state or federal privacy or confidentiality laws. This subchapter does not require the issuance of a birth or death certificate for the proper disposition of special waste from health care-related facilities. This subchapter does not extend or modify requirements of Texas Health and Safety Code, Chapters 711 and 716 or Texas Occupations Code, Chapter 651 to disposition of fetal tissue.” The rules do not contain a notice requirement for a patient to be notified of the disposition methods. The proposed rules do not create a substantial obstacle to an individual seeking an abortion because they place responsibility for compliance upon health care-related facilities. Furthermore, the proposed rules, regulating treatment and disposition of fetal tissue, are different from the rules regarding admitting privileges and ambulatory surgical center standards that the Supreme Court overturned in *Whole Woman’s Health*. The adopted rules relate to the disposition of fetal tissue from health care-related facilities that results from an induced or spontaneous abortion. It applies to multiple types of health care-related facilities, not just induced abortion facilities. The rules that were the subject of *Whole Woman’s Health* related to the care and treatment and the treatment environment of patients undergoing induced abortions in licensed abortion facilities and ambulatory surgical centers.

Comment: The Teaching Hospitals of Texas asked several questions about the proposed rules: (1) The commenter noted that for fetal remains massing less than 350 grams, separating fetal remains from other tissue may not be possible, and asked if all tissue may be treated consistently with the requirements or if fetal remains must be separated from other tissue; (2) The commenter

also asked if a family chose not to receive remains, would individual cremation or interment be required, and what interment would be required following cremation and whether it would be under the purview of funeral homes or determined by regulations; and (3) The commenter asked if, under the proposed rules, would all methods of disposal require hospitals to engage with a funeral home or similar service for cremation or interment. The commenter also stated that the economic impact analysis should account for the costs of individual cremation, interment, pathology time, storage, transportation to a funeral home, and disposition by the funeral home. The commenter requested a clearer definition of fetal tissue, interment, and the cremation process to aid health care-related providers in implementing the proposed rules. They also ask that the department allow providers up to November 1, 2016 to comply with the proposed rules.

Response: The commission appreciates the commenter's questions and responds as follows: (1) Fetal tissue need not be separated from other tissue as long as all the tissue is treated and disposed of in a manner consistent with the requirements for fetal tissue and other tissue. (2) If parents do not request the release of remains under Texas Health and Safety Code, §241.010, then the facility is responsible for treatment and disposition in compliance with the proposed rules. (3) The proposed rules do not require any health care-related facility subject to the rules to engage the services of a funeral director or crematory; instead, facilities will be responsible for disposition of fetal tissue by one of the methods specified by the rules. The commission also notes regarding economic impact that the department received cost data from waste disposal companies, private and public landfills, FCAT (comments as noted above), the Funeral Service Commission, TCEQ, the University of Texas System, and others to determine the minimum cost in complying with the rules. The department found that based upon the lowest stated costs of each entity able to provide cost estimates, the annual cost per facility would be approximately \$450. For those health care-related facilities not already disposing of fetal tissue through cremation and burial, the cost of any of the new available methods would be offset by the elimination of the cost of landfill disposition. The department believes this cost to be minimal and absorbable by health care-related facilities. In response to this and other comments, the department has clarified the definitions of cremation and interment in the proposed rules and declines to make any further changes to definitions. The commission does not see a need to delay implementation of the rules as they were initially published on July 1, 2016, and were unchanged in the subsequent publication on September 30, 2016. Once filed in the *Texas Register* as adopted, an additional 20 days will be given before the rules go into effect. As a result, there has been ample time to prepare to comply with the rules. The commission declines to delay the implementation date of the rules.

Comment: The American Civil Liberties Union submitted comments stating that the rules place unnecessary regulations upon abortion providers not imposed upon other health care-related facilities. The commenter states that the rules do not advance public health and create precisely the sort of impediments to accessing abortion care rejected by the Supreme Court in *Whole Woman's Health*. The commenter states that the proposed regulations eliminate current safe and sanitary disposal methods, imposing burial and cremation as the only permissible options for abortion providers. The commenter states that there is no evidence that the current disposition methods pose any risk to public health or that cremation would improve public health, nor is there a basis for treating fetal tissue different from other human tissue. The commenter states that while the department has authority to promulgate rules related to public health, it has no

legal authority to regulate in the interest of dignity. The commenter refers to the Indiana federal court that rejected similar regulations. The commenter identified the requirement to cremate and inter fetal tissue as making it more difficult for women to access abortion care by increasing the cost. The commenter states that nearly half of abortion patients in the United States are poor and another 26% are low-income, therefore even a modest increase in the cost can pose an insurmountable hurdle. Abortion providers unable to find a crematorium or cemetery willing to accept fetal tissue may have to close their doors. The closure of even one more clinic means access to abortion care would be substantially eroded.

Response: The commission respectfully disagrees. The proposed rules apply to twenty-four other types of health care-related facilities—including ambulatory surgical centers, hospitals, and clinical and research laboratories—in addition to abortion clinics. The proposed rules are intended to safeguard public health by providing for the safe treatment and disposition of fetal tissue in a manner that preserves the dignity of the unborn. They do not place a substantial obstacle to an individual seeking abortion because the proposed rules apply to health care-related facilities. These options provide for the safe disposal of fetal tissue while conforming with the state's policy of preserving the dignity of the unborn. The commission maintains that statutory authority to preserve the dignity of the unborn exists within the Texas Health and Safety Code, including §241.010 (requiring a hospital to release to a parent remains of an unborn child who died from an unintended, intrauterine death), §170.002 (prohibiting, with certain exceptions, third-trimester abortions), and §171.012 (requiring sonograms prior to abortion). The department notes that the Indiana statute enjoined by the federal court in *Planned Parenthood of Ind. & Ky, Inc. v. Comm'r, Ind. State Dep't of Health* is different from the proposed rules. The State of Indiana passed House Enrolled Act 1337, which would require that a miscarried or aborted fetus be interred or cremated by a facility having possession of the remains and would exclude the final disposition of a miscarried or aborted fetus from the law governing the treatment of infectious or pathological waste. Although the Indiana law has been preliminarily enjoined by a federal court from taking effect, it is different from the department's adopted rules, which explicitly encompass treatment and disposition of material that includes fetal tissue. The federal court also determined that Indiana had no interest in treating the unborn with dignity. Here, however, the Texas Legislature has enacted numerous statutes demonstrating its interest in the dignity of the unborn. The rule provides many options for disposition, many of which are already in use, that do not increase the cost of disposition of fetal tissue but still protect the dignity of the unborn. The department disagrees that the proposed rules will make it more difficult for a woman to access abortion services. The department has determined that the annual cost per facility would be approximately \$450, which would be offset by the elimination of a current disposition method. The department believes this cost to be minimal and absorbable by each health care-related facility.

Comment: Our Lady of the Rosary Cemetery and Prayer Gardens submitted a comment stating that it is in support of the rules which reflect the dignity of human life by requiring humane burial. The commenter stated its willingness to provide a reverent place of burial for fetal tissue and is open to all faiths. The commenter states that it has been providing quarterly services for babies who died before birth at St. David's Hospital in Round Rock and in Georgetown.

Response: The commission appreciates the comment, which illustrates the support for protecting the dignity of the unborn that exists among Texans and demonstrates that various options authorized by the rule are currently utilized.

Comment: Texas Right to Life submitted comments applauding the department for its work to improve the disposal procedures for fetal tissue. The proposed changes will improve upon existing disposition rules to ensure a more sanitary treatment but also afford dignity to deceased preborn children. The commenter asks for a change to existing language specifically clarifying that the rules do not apply to miscarriages that occur in homes, whether they be induced or spontaneous.

Response: The commission appreciates the comment and agrees with the need for the suggested amendment. To address concerns raised by this and other comments, the department has added subsection (a)(2)(G) to §1.133. Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of State Health Services, which states that the rules do not apply to “human tissue, including fetal tissue, that is expelled or removed from the human body once the person is outside of a health care-related facility{.}”

Comment: The Texas House Republican Caucus submitted comments expressing its full support of the proposed rule change to allow for the humane disposal of aborted babies’ remains. The commenter states that the changes follow thousands of years of societal tradition in ensuring dignified treatment. The commenter specifically agrees with the elimination of grinding and discharging as a method of disposal. The commenter states that grinding is an abhorrent practice contrary to fundamental human dignity and how we value human life, regardless of its developmental stage. The commenter notes that opponents will claim a limitation on access but disputes this assertion and states that many abortion providers already use medical waste disposal companies and every hospital has a facility for cremation of human body parts with whom abortion facilities could enter into affordable agreements. The commenter also states that almost every state in the nation requires a more sensitive handling of these human remains and that Texas needs to update its standard of practice to rightfully ensure every sacred human life is treated with the utmost care and respect.

Response: The commission appreciates the comment and agrees that facilities that are not already in compliance with the rules will be able to absorb any additional costs of compliance with the proposed rules. The commission appreciates the support for the rules and information on the current practices relating to this issue, which are consistent with the information available to the department.

Comment: The Texas Catholic Conference stated the rule changes are long overdue and provide a more appropriate method for the disposal of human remains than current rules by affording the same dignity and respect as any other human body. The commenter notes that cadavers donated to science are afforded respect and honor including cremation ceremonies to memorialize their donation. The commenter states that the same respect should be shown for those lives that end before taking a breath. The proposed rules allow for disposition procedures that are practiced worldwide and are known as “sensitive disposal.” These rules honor a universal respect, beyond

religious, cultural or societal norms, for the sacred nature of the human person. The written testimony further provides that the bodies of unborn humans should be afforded the same dignity and respect as humans who have progressed in age. This respect conforms to the principles of Christians and people of good will across the world, who treat the dead with respect and charity.

Response: The commission appreciates the comment and remains committed to balancing the need to protect the public health with the state's policy of preserving the dignity of the unborn.

Comment: The Texans for Life Committee submitted comments applauding the department for righting an old wrong. The commenter states that it has worked hard to foster greater respect for human life at all stages and recognize fetal remains as human remains. The commenter notes that the Texas Legislature has passed legislation in recent years to increase respect and protection for the unborn. The commenter states that Planned Parenthood already contracts with companies that cremate the remains and it is only independent providers who object, based on cost; however, any additional cost, measured by weight, is negligible. As confirmed by the peer-reviewed Christchurch Health and Development Study, many women regret their abortion decisions and experience depression, anxiety, suicidal behaviors and substance use. The commenter states that trauma should not be increased by the haunting possibility that the remains of their babies were ground beyond recognition in a commercial garbage disposal. The commenter states that fetal remains deserve no less respect than bodies donated for medical research.

Response: The commission appreciates the comments and remains committed to balancing the need to protect the public health with the state's policy of preserving the dignity of the unborn.

Comment: The Texas Alliance for Life submitted a comment strongly supporting the proposed rules as a very good first step to require abortion facilities to treat the remains of the victims of abortion in a humane manner through cremation and burial and by banning the "grinding and discharging into a sanitary sewer system."

Response: The commission appreciates the comment and notes that the proposed rules will continue to protect the public health while providing for the disposition of fetal tissue in a dignified manner.

Comment: The Diocese of San Angelo submitted comments supporting the proposed rules to prevent facilities from using garbage disposals and flushing remains into municipal sewer systems. The commenter states that current law allows abortion providers to dispose of the bodies of the precious unborn in that very inhumane manner. The commenter states that each abortion is a tragedy and the state should not allow the victims to be treated like medicinal waste.

Response: The commission appreciates the comments and remains committed to balancing the need to protect the public health with the state's policy of preserving the dignity of the unborn.

Comment: NARAL Pro-Choice Texas submitted comments and stated that burial or cremation of fetal tissue is unnecessary and intended to restrict access to abortion care. The commenter states that healthcare facilities already follow standards for the sanitary disposal of medical

waste, including embryonic tissue. The commenter states that the politically motivated attacks on Texans' access to reproductive health care must stop and that the department should not interfere with the doctor-patient relationship.

Response: The commission respectfully disagrees. The proposed rules do not interfere with the doctor-patient relationship, because they do not apply to individuals. Instead, the proposed rules regulate the treatment and disposition of material, including fetal tissue, generated by health care-related facilities. The department is not expanding its authority to include any new topic or regulated entity or person. Additionally, the proposed rules do not interfere with the doctor-patient relationship, because they do not apply to individual patients and the disposition of fetal tissue the responsibility of the health-care-related facility. The rules have not included previously, and do not now impose a requirement that a patient be informed of the method of disposition or choose that method of disposition. The proposed rules are not intended to restrict access to abortion, but to protect the public health while affording dignity to the unborn. The proposed rules address the treatment and disposition of fetal tissue from health care-related facilities, which are already subject to rules regarding the disposition of fetal tissue. These rules eliminate methods not currently in use and retain some of the existing methods. Final disposition no longer includes depositing disinfected fetal tissue in landfills, but rather allows other methods. The department received cost data from waste disposal companies, private and public landfills, FCAT, the Funeral Services Commission, TCEQ, the University of Texas System, and others to determine the minimum cost in complying with the rules. Based upon the lowest stated costs of each entity able to provide cost estimates, the department has determined that the annual cost per facility would be approximately \$450. This cost would be offset by the elimination of the current method of disposition. The department believes this cost to be minimal and absorbable by each health-care facility. Because the department has determined that healthcare facilities can absorb any additional costs associated with these rules, it anticipates no change in access to abortion services.

Comment: The Justice Foundation submitted comments supporting the proposed regulations as in accordance with the treatment given to other human remains. The commenter states that they have collected statements from over 4,500 women hurt by abortion and that 600-700 of these women were Texas residents or had their abortions in Texas. The commenter states that many women have complaints of severe trauma after taking RU 486, the medical abortion pill, when they see the remains of the human fetus in their hands or in their toilets after the dead child is expelled from the womb. The commenter states that women have stated, "They lied to me, they said it wasn't a baby, but it is." The commenter states that women have asked if they can bury their baby in the back yard to give it more dignity than being flushed down a toilet.

Response: The commission appreciates the comment and notes that the proposed rules do not apply to fetal tissue that is expelled or removed from the human body once the person is outside of a health care-related facility. To address concerns raised by this and other comments, the department has added subsection (a)(2)(G) to §1.133. Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of State Health Services, which states that the rules do not apply to "human tissue, including fetal tissue, that is expelled or removed from the human body once the person is outside of a health care-related facility{.}"

Comment: The Lilith Fund submitted comments in opposition to the proposed rules. The commenter states that they provide financial assistance to primarily low-income women of color who already have children, working multiple jobs to make ends meet while caring for their families. The commenter states that abortion coverage is out of their reach due to lack of insurance, underinsurance, or due to the Medicaid ban under the Hyde Amendment. The commenter states that these barriers to coverage have pushed women who contact them into dire health care gaps that are both unacceptable and ethically unjust. The commenter states that the proposed rules requiring cremation or burial will further stigmatize women and increase costs, potentially by thousands of dollars, further burdening low-income Texans. The commenter states that this cost increase could effectively prevent them from accessing safe, legal abortion care altogether. The commenter states there is no discernible public health reason for these rules but rather the rules are an attempt to interfere with a patient's reproductive autonomy and further disenfranchise marginalized communities. The commenter states that if public health and "respect for life" are true motivators there should be more access to comprehensive reproductive health care for low-income communities. The commenter states that the department should focus on ensuring all people have the power, resources and community support to make their reproductive decision a reality and that individuals seeking abortion services should be treated with respect, dignity and compassion. The commenter states that these rules do nothing to improve reproductive healthcare and only serve to further burden, and possibly prevent, access to safe and legal abortion.

Response: The commission respectfully disagrees that the proposed rules will place a burden on women or reduce access to abortion. As noted elsewhere, the department received cost data from waste disposal companies, private and public landfills, FCAT, the Funeral Service Commission, TCEQ and the University of Texas System and others to determine the minimum cost in complying with the rules. Based upon the lowest stated costs of each entity able to provide cost estimates, the department has determined that the annual cost per facility would be less than \$450. The department also believes a number of regulated facilities are already in compliance with these rules, and thus would experience no additional cost. Any additional cost would be offset by the elimination of a current method of disposition. The department therefore believes this cost to be minimal and absorbable by health care-related facilities. The proposed rules do not interfere with a patient, as the rules apply to health care-related facilities and not to individuals.

Comment: Choose Life Midland submitted comments in support of the removal of grinding and discharge into a sanitary sewer system as a method of disposition. Birth Choice Dallas submitted a comment in support of removing grinding and discharge into a municipal sewer system as a method of disposition, and states that victims should not be treated like medical waste. Woman to Woman Pregnancy Resource Center submitted comments in support of the removal of grinding as a disposition method and urges the department to adopt the proposed rules.

Response: The commission appreciates the comments and notes that the proposed rules eliminate methods not currently in use and retain some of the existing methods in a manner consistent with the state's policy of preserving the dignity of the unborn.

Comment: St. Ignatius Martyr Catholic Parish submitted comments in support of the rule changes. The commenter states that the body of the deceased is in Christ a temple of the Holy Spirit. The commenter states that the Church's call is to respect and promote the dignity of the human person created in the image of God. The commenter supports the rules based upon their knowledge by the light of faith, the guidance of reason, and the tool of science, that at conception, a distinctly new member of the human family has been formed. This person has the dignity of being created in the image and likeness of God and the possibility for his or her life to be created new in Christ's life, death and resurrection. The commenter states that the life rightly deserves our utmost respect and reverence because it is destined for the future glory at the resurrection. The commenter supports the proposed changes to more properly give due reverence and respect to the bodies of our aborted brothers and sisters who are far more than mere medical waste to be ground up and discharged. The changes, while imperfect, are preferred over current procedure. A human corpse, though dead, is still a semblance of an image of the living God. The commenter continues by stating that the corpses of human embryos and fetuses, whether they have been deliberately aborted or not, must be respected just as the remains of other human beings. In particular, they cannot be subjected to mutilation. The commenter states that, at this moment, they cannot yet legally prevent the sanctity of our pre-born brothers and sisters' lives from being violated by abortion, we can do our utmost to ensure that their remains are at least treated with the common dignity and respect that is only deserving of human beings created in the image and likeness of God. The commenter, on behalf of the Parish and her 9,200 members, and in agreement with sacred scripture and the teaching of the Holy Catholic Church, they express their support for the proposed changes.

Response: The commission appreciates the comments and remains committed to balancing the need to protect the public health with the state's policy of preserving the dignity of the unborn.

Comment: Concerned Women for America of Texas submitted comments in support of the rule changes. The commenter states that human beings should not be treated like medical waste and that life is sacred. The commenter states that Texas needs to align our treatment of the remains of the born and unborn with the belief of the majority of Texans which is to treat remains with dignity and respect. The commenter says the practice of treating these remains equivalent to clinical waste products, rubbish or trash cannot continue.

Response: The commission appreciates the comments and remains committed to balancing the need to protect the public health with the state's policy of preserving the dignity of the unborn.

Comment: The American Academy of Fertility Care Professionals, Houston Coalition for Life submitted comments calling for humane disposition and dignity in death. The commenter relates an incident where in the case of a miscarriage, the parents couldn't obtain the body for burial. The hospital wouldn't return the babies remains. These rules would bring peace and closure for dead children. The commenter states that there is a gravesite in Houston where 500 babies have been named and buried and September 10th is the day of remembrance. The commenter states that these babies have been torn to pieces and targeted as undesirable. The commenter supports the rule amendments as it is humane and shows love and respect. The commenter states that in 2005, pieces of bodies clogged the sewer in Houston. These rules have nothing to do with women's health; there is nothing healthy about abortion. There is so little respect for human life.

Another commenter with the Houston Coalition for Life relayed her personal story and speaks for her unborn child ripped from her womb against her will; she is horrified that he was thrown away. Burial brings dignity and respect. The commenter states there is blood money from selling body parts. Victims of abortion are tiny and defenseless. They can't speak for themselves so we speak for them: they were denied the right. The commenter states that if there is an additional cost, abortion clinics should pay and that abortion harms women.

Response: The commission appreciates the comments and remains committed to balancing the need to protect the public health with the state's policy of preserving the dignity of the unborn.

Comment: The Roman Catholic Diocese of Austin submitted comments stating that medical students are lectured on treating cadavers with honor and respect. Their sacrifice is memorialized through cremation and a ceremony. The commenter stated that this method of disposal is practiced worldwide and honors and respects the sacred nature of human person.

Response: The commission appreciates the comments and remains committed to balancing the need to protect the public health with the state's policy of preserving the dignity of the unborn.

Comment: Young Women for America and Concerned Women for America Legislative Action Committee submitted comments stating that the disposition of unborn as trash in our cities where baby body parts are ground or deposited in a landfill is inhumane and absurd. The commenter supports higher ethical and health standards and common sense. The commenter states that there should be legislation in the future.

Response: The commission appreciates the comments and remains committed to balancing the need to protect the public health with the state's policy of preserving the dignity of the unborn. The members of the Texas Legislature will determine whether legislation regarding this matter will be considered in the future.

Comment: Life Choices Medical Clinic in San Antonio submitted comments and asked: How will we as a society be remembered – as respectful or with contempt? The commenter states that the proposed rules will eliminate health hazards of a contaminated water supply. The commenter stated that women in the clinic where she works became physically ill when they heard about a child being ground up.

Response: The commission appreciates the comments and remains committed to balancing the need to protect the public health with the state's policy of preserving the dignity of the unborn.

Comment: Texas Values submitted comments stating that the victims of abortion should be treated with respect. The human dignity should be afforded to children as image bearers of God. The commenter states that anti-life, pro-abortion commenters are fighting because of costs. Abortion profits are being put ahead of human life. The commenter states that victims of abortion should be treated with dignity and we should stop abortion facilities from selling baby body parts.

Response: The commission appreciates the comments and remains committed to balancing the need to protect the public health with the state's policy of preserving the dignity of the unborn.

Comment: Southern Baptist Convention of Texas, Concerned Women of Texas stated that these rules support God-given morality and validate sacred life. Aborted fetuses are not the equivalent of trash. The commenter stated that medical biology textbooks show the development of humans from conception and that tiny parts develop. The commenter states that the information provided in 1973 was a lie when it was stated that these were clumps of cells. The commenter states that God created the soul and that human beings should be provided dignity. The commenter stated that babies should be provided a proper burial and not abandoned in the garbage.

Response: The commission appreciates the comments and remains committed to balancing the need to protect the public health with the state's policy of preserving the dignity of the unborn.

Comment: Operation Outcry submitted comments through its representative regarding her personal experience when she hesitantly agreed to an abortion but didn't understand her options. The commenter states that she was convinced there was only one choice. The commenter stated that she heard the baby scream in pain. The commenter stated that the baby was torn to pieces while she couldn't move because of the drugs. She had no control over her body but she was aware of everything. The commenter states that the baby was thrown into a garbage can. The commenter stated that she hid and was in denial and that destructive grief comes out in unhealthy ways.

Response: The commission acknowledges the comments and remains committed to balancing the need to protect the public health with the state's policy of preserving the dignity of the unborn.

Comment: Students for Life submitted comments stating that tiny children should rest in peace and that their beautiful soul should be treated with humanity and not sold. The commenter stated that abortion is cruel and a waste that is unredeemable. Aborted babies should be laid to rest.

Response: The commission appreciates the comments and remains committed to balancing the need to protect the public health with the state's policy of preserving the dignity of the unborn.

Comment: Office of Life Charity and Justice of Roman Catholic Church submitted comments stating that women often ask about the remains of their lost child. Under the current rules, remains are not handled properly and with dignity. The commenter stated that people believe remains are treated with dignity and respect. The commenter related a time when a father asked for the remains of the miscarriage, and was told the facility wouldn't release the remains because it was medical waste.

Response: The commission appreciates the comments and remains committed to balancing the need to protect the public health with the state's policy of preserving the dignity of the unborn. The commission appreciates the comment and notes that it has further amended the proposed rules so they now conform with Texas Health and Safety Code, §241.010, which requires a hospital to release the remains of an unintended, intrauterine fetal death on the request of a parent.

Comment: Pro-Life Organization for Grimes and Waller Counties stated that depositing aborted fetuses like waste in a landfill or in our water system exposes the public to risk. The commenter stated that Houston babies were sold piece by piece and in Conroe, remains were dispersed into the air that we breathe and water we drink. The commenter supports burial and a funeral for miscarriage. The commenter stated that the enormous cost can be defrayed by Catholic charities who will help bury the baby. The cost of a funeral and burial for a baby is \$500.

Response: The commission appreciates the comments but notes that the proposed rules remove outdated methods of disposition while still ensuring dignified treatment of fetal tissue consistent with the state laws and the Legislature's intent to protect the dignity of the unborn.

Comment: Medical Students for Choice stated that the proposed rules make it harder for physicians to do their jobs and have a relationship with patients and the proposed rules increase the involvement of lawmakers in what should be a decision between a woman and her doctor. The commenter stated that the authors of the rules don't understand the issues. The commenter stated that lots of pregnancies end in miscarriage and the commenter is unclear how the rules apply to miscarriage.

Response: The commission respectfully disagrees. The proposed rules apply only to health care-related facilities; they do not govern individual patients. The department is not expanding its authority to include any new topic or regulated entity or person. The proposed rules do not interfere with the doctor-patient relationship, because they do not apply to individual patients and the disposition of fetal tissue is the responsibility of the health-care-related facility. Additionally, the rules have not included previously, and do not now impose, a requirement that a woman be informed of the method of disposition or choose that method of disposition. To further clarify that the rules do not apply to fetal tissue that is the result of a miscarriage at home, the department has added subsection (a)(2)(G) to §1.133 stating that the rules do not apply to "human tissue, including fetal tissue, that is expelled or removed from the human body once the person is outside of a health care-related facility{.}"

Comment: Unite Women Texas submitted comments through its representative relating to her experience of a fetal death occurring after a car wreck. The commenter stated that the fetus was removed and it would have been a burden to have had to make decisions about burial and cremation and would have been horrifying. The commenter stated that forcing women to make decisions about cremation and funerals would only add to the trauma of losing a pregnancy.

Response: The commission sympathizes with the commenter and notes that the proposed rules will not require patients to make decisions about burial, and cremation of fetal tissue. Instead, they require health care-related facilities to conduct the treatment and disposition of fetal tissue in a manner consistent with upholding the dignity of the unborn while protecting the public health.

Comment: Planned Parenthood of Texas Votes stated that the proposed rules were published with little or no public announcement, only four days after the Supreme Court struck down HB 2. The commenter states that abortion is a deeply personal decision made in consultation with health care providers. The commenter stated that the disposition of medical tissue is already safe

and respectful with no evidence of any health or safety risk. The commenter stated that the proposed rules are motivated by politics. The commenter stated that the requirement for a fetal death certificate will negatively affect the privacy of patients by making their personal medical histories available to the public. The only purpose for this is to shame women away from safe, legal abortion services. The commenter completed their comments by stating that the proposed rules exceed the statutory authority of the department.

Response: The commission respectfully disagrees and notes that the rules were filed with the *Texas Register* on June 20, 2016, prior to the Supreme Court ruling in *Whole Woman's Health*, which was issued on June 27, 2016. The filing and publication met the requirements of the Administrative Procedure Act, Texas Government Code, Chapter 2001, and the public has been given the opportunity to submit comments in writing during two 30-day periods and at two public hearings. The department has statutory authority under Texas Health and Safety Code, Chapters 12 and 81 to enact rules to protect the public from the spread of communicable disease and under Chapters 241, 243, 244, 245, 251, 254, and 773 to regulate health care-related facilities. The proposed rules regulate abortion providers only to the extent that they dispose of fetal tissue and other special waste. The proposed rules are intended to maintain the health and safety of the public while safeguarding the dignity of the unborn in accordance with the state's policies. The department also has added language to §1.134 clarifying that the proposed rules do not require the issuance of a death certificate for the disposition of fetal tissue from health care-related facilities. The commission further notes that the rules apply only to facilities, not to individuals, and are not intended to shame women or to restrict access to abortion.

Comment: Austin National Organization for Women stated that the decision to get an abortion is hard enough, especially after rape and having to pay for a burial would be rubbing the victim's face in the trauma of rape.

Response: The commission notes that the proposed rules do not require an individual to pay for burial or other disposition of fetal tissue. Instead, the proposed rules require health care-related facilities to treat and dispose of fetal tissue in a manner that preserves the dignity of the unborn while also protecting the public health and preventing the spread of communicable disease.

Comment: Texas Equal Access Fund stated the impact of the proposed rules on low income and marginalized women amounts to an undue burden. The commenter stated that the rules will result in increased cost and reduced access. The commenter stated that abortion is healthcare, which is already regulated. The commenter stated that the new regulations are medically unnecessary and are intended to shame women and interfere with private healthcare decisions. The commenter stated that the rules would limit a woman's legal right to a vital and common procedure. The commenter calls on the State of Texas to increase other social benefits, wages, and access to healthcare.

Response: The commission respectfully disagrees that the proposed rules impose an undue burden on women seeking abortions. They are not intended to shame patients and do not limit a patient's right to any procedure. The proposed rules do not impinge on the doctor-patient relationship. Rather, the rules regulate the treatment and disposition of material, including fetal tissue, from health care-related facilities. The commission further disagrees that the proposed

rules will result in increased costs to patients. The department estimates that the costs for health care-related facilities to comply with the proposed rules will be sufficiently low such that the costs can be absorbed by facilities as part of their operating costs while still providing a public health benefit by ensuring the proper disposal of fetal tissue. The commission also disputes that the proposed rules are unnecessary and contends that they balance protecting the public health and comporting with the state's policy of protecting the dignity of the unborn.

Comment: Public Leadership Institute/ Fund Texas Choice stated that the proposed rules pose an undue burden intended to shame and stigmatize women. The commenter stated that taxpayers' money should be spent more efficiently and effectively and that the fiscal note is implausible. The commenter stated that the state has already spent \$1.6 million on two special sessions and additional money defending their anti-abortion agenda. The commenter stated that Texas should spend money on healthcare, child protective services and to fund foster care instead of this ruse to stigmatize abortion.

Response: The commission respectfully disagrees that the proposed rules create an undue burden on women seeking abortions because any additional costs associated with complying with these rules can be absorbed by the health care-related facility. The sources for the department's small and micro-business impact analysis include waste disposal companies, private and public landfills, FCAT, the Funeral Service Commission, TCEQ, the University of Texas System, and others. The department notes that the cost of compliance with the proposed rules would be offset by the elimination of current disposition methods. The department also notes that the proposed rules are not intended to shame or stigmatize women. They apply to health care-related facilities and not to individual patients.

Comment: Trinity Legal Center supports the proposed rules. The commenter stated that a human being is sacred and the unborn should be treated with dignity and respect and not like medical waste.

Response: The commission appreciates the comment. The proposed rules are intended to balance the desire to treat the unborn with dignity and the need to protect the public health.

Comment: Cathedral of Our Lady of Walsingham Catholic Church and Shrine stated that it is appalling that the bodies of children are disposed of like common waste, instead of buried with dignity. The commenter also stated that if we are legally murdering them, we can at least honor their passing with a caring burial.

Response: The commission appreciates the comment and agrees that the proposed rules should comport with the state's policy of ensuring the dignity of the unborn.

Comment: The Southern Baptists of Texas Convention strongly supports the proposed rules so that unborn human beings will not be treated like medical waste. The commenter stated that medical, biological, and scientific writings agree that the development of a human being begins with fertilization, marking the beginning of a unique individual. With the science and technology of today, we know that it is not "just a clump of cells." The commenter would be horrified to find the body of an abandoned baby in the garbage or elsewhere and would never

consider turning a blind eye, stating that we should not turn a blind eye to the unborn now or ever, but do the right thing by giving them a proper burial.

Response: The commission appreciates the comment and agrees that the proposed rules should comport with the state's policy of ensuring the dignity of the unborn.

Comment: The Mercy Ministry of the Prince of Peace Catholic Community stated that they are appalled and sickened that fetal tissue may be disposed of by grinding and discharging into a sanitary sewer system and deposition in a sanitary landfill and support ending these methods.

Response: The commission appreciates the comments. The proposed rules would eliminate these disposition methods and preserve the dignity of the unborn.

Comment: The Catholic Pro-Life Committee of North Texas supports the proposed rules. The commenter noted that women who have abortions face many consequences, and the knowledge that their child's body was not thrown away as trash but treated with respect and buried will only ease their suffering. There is a common-law right to a decent burial. The trauma of abortion affects the mother's ability to make a rational choice in relation to her aborted child, even though she has a vested interest in the remains. The general public also has a vested interest that the fetal remains be treated with respect. The aborted child is entitled to a burial.

Response: The commission appreciates the comment. The proposed rules address the concerns raised by this commenter.

Comment: Catholic Healthcare Professionals of Houston stated it supports the comments submitted by the Texas Catholic Conference.

Response: The commission appreciates this comment.

Comment: SA Pregnancy Care Center stated it supports the proposed rules. The commenter stated that Texas needs to align treatment of the remains of the born and unborn with the belief of the majority of Texans that they should be treated with dignity and respect. Our state cannot allow them to be equivalent to clinical waste or trash.

Response: The commission appreciates the comments and remains committed to balancing the need to protect the public health with the state's policy of preserving the dignity of the unborn.

Comment: 3d Houston stated that the rules should contain provisions for these deceased children to be claimed for burial. The commenter would like to see records of family lineage and date of death, and independent autopsy to verify they were not murdered, a chance to be named, a proper funeral service, and burial where their family can find them. The commenter noted that a gravesite provides healing for the living and dignity for the deceased. We do not treat executed criminals with the contempt and dishonor that the unborn receive. Let churches, funeral homes, and charitable organizations care for the dead, not abortion clinics.

Response: The commission notes that the proposed rules do not require or prohibit any funeral service and may not be used to require the disclosure of any personally identifiable or personally sensitive information. While the commission agrees that the dignity of the unborn should be protected, it declines to enact any of the additional requirements suggested by this commenter.

Comment: St. Clair of Assisi Catholic Church requested a decent burial for the unborn.

Response: The commission believes the proposed rules allow for the respectful disposition of fetal tissue in a manner that preserves privacy and protects public health.

Comment: The League of Women Voters of Texas submitted a comment in opposition of the fetal tissue rules.

Response: The commission respectfully disagrees but offers no further response as the basis for the commenter's opposition is not specified.

Comment: The National Association of Social Workers stated that it serves Texas residents across the state and reproductive health services, including abortion services, must be legally, economically and geographically accessible. The commenter states that denying people with low income access to contraception and abortion perpetuates poverty and dependence upon welfare programs, resulting in a status quo of class stratification. Fetal burial services can cost between \$250 and \$3,000; that equates to one week to two months of salary for a minimum-wage worker. The commenter states that the proposed policy change would create additional financial barriers, effectively making abortion inaccessible for some low-income Texans. The commenter goes on to state that healthcare providers follow medical standards for sanitary disposal of fetal tissue which is handled respectfully and safely. The commenter stated that they promote the right of clients to self-determination and non-medical ritual interferes with the doctor-patient relationship. The commenter closed by stating that we should value patients' dignity and worth by supporting and respecting their decision.

Response: The commission respectfully disagrees that the proposed rules would create any significant financial obstacles. The department received cost data from waste disposal companies, private and public landfills, FCAT, the Funeral Services Commission, TCEQ, the University of Texas System, and others to determine the minimum cost in complying with the rules. Based upon the lowest stated costs of each entity able to provide cost estimates, the department has determined that the annual cost per facility would be approximately \$450. For those health care-related facilities now already disposing of fetal tissue through cremation and burial, the cost of any of the new available methods would be offset by the elimination of the cost of landfill disposition. The commission believes any cost of compliance with the proposed rules to be minimal and absorbable by health care-related facilities. The commission disagrees that current rules are sufficiently respectful of the dignity of the unborn; which is why it has proposed these amended rules. The commission also disagrees that the rules interfere with the doctor-patient relationship. The proposed rules apply to health care-related facilities, not to individual patients.

Comments by Individuals.

Numerous comments were also received from interested individuals. The department received comments on topics concerning the substance of the rules, other comments relating to legal issues and issues concerning the preamble to the proposed rules. The responses to the comments appear by topic below.

Some comments received included matters that were outside the scope of the proposed rules. The department offers responses to clarify some of the most common misconceptions about the amended rules and their application, but otherwise offers no response regarding comments that are irrelevant to the rule amendments or outside of the scope of the proposed rules. For example, the department does clarify that the rule changes do not affect the use of tissue donated for medical research as this use is exempt from the application of the rules pursuant to §1.133(a)(2)(B) and that the rules do not create a requirement for ceremonial funeral services, but does not respond to comments relating to the patient booklet or laws relating to Woman's Right to Know, as the rules do not relate to these laws or booklet.

Other comments included vituperative language and political statements; for those comments the department offers no response.

The comments related to 24 general topics contained in the following categories: (1) Dignity in the treatment of the remains of the unborn; (2) Impact on miscarriages and other procedures, other tissue and body parts; (3) Concerns about criminal prosecution; (4) Woman's constitutional right to terminate a pregnancy; constitutionality of rules after the Supreme Court's ruling in *Whole Woman's Health*; potential lawsuits; (5) Access to abortion services; (6) Donation, research and testing; (7) Death certificates; (8) Funerals; (9) Burial sites at risk; (10) Religious considerations; separation of church and state; (11) Privacy concerns; (12) Removal of grinding and disposition in sewer system and landfill; (13) Water and air quality; (14) Costs; (15) Impact on low-income women and women who live in rural areas; (16) Rulemaking procedure; (17) Health and safety and public health impact; (18) Other legislation that impacts rules; (19) Existing laws sufficient for disposal of tissue; (20) Use of public funds; (21) Other states' laws; (22) Authority to adopt rules; (23) Expansion of government; (24) Enforcement of rules.

1. Dignity in the Treatment of the Remains of the Unborn.

Commenters generally approved of the new disposition requirements. They stated that fetuses are human beings and their remains should be treated with the same dignity as all other human remains. One commenter noted that even terrorists receive a proper burial. Others noted that the proposed rules may help women who have questions or regrets after an abortion or help them process grief.

Response: The commission appreciates the comments. The department has approached these rules such that its exercise of authority to protect public health be done in conformity with the view expressed in state law that similar dignity should be afforded unborn children. The adopted rules are the means by which the department is able to meet that objective, while balancing the need to address considerations regarding public health, public benefit and costs, through amendments to the rules, and inclusion of new provisions in the rules that afford the protection and dignity to unborn children consistent with the Legislature's expression of its intent.

2. Impact on Miscarriages and Other Procedures, Other Tissue and Body Parts.

Commenters generally did not want the rules to apply to miscarriages, especially those occurring outside a health care-related facility. Some stated the proposed rules infringe on patient autonomy or will have a chilling effect that might keep a woman who miscarried from attempting another pregnancy. Others noted that in an early-pregnancy miscarriage, fetal tissue may not be easily identifiable. Other commenters questioned the effect of the proposed rules on in vitro fertilization.

Response: The commission appreciates the comments. In response to these concerns, the department added subsection (a)(2)(G) to §1.133. Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of State Health Services, which states that the rules do not apply to “human tissue, including fetal tissue, that is expelled or removed from the human body once the person is outside of a health care-related facility{.}” A miscarriage that occurs outside of a health care-related facility is not subject to these rules and thus is not subject to the disposition requirements in the rules. Miscarriages, referenced as “spontaneous abortions” are included in the rules as these procedures result in fetal tissue. The inclusion of the procedure and methods do not adversely impact the balance of considerations the department was trying to achieve in the rules relating to the dignity of the unborn with the public health protections and cost. The department believes the methods allowed by the rules will protect the public by preventing the spread of disease while preserving the dignity of the unborn in a manner consistent with Texas laws.

The amendments to the rules do not change the impact of the rules for in vitro fertilization. Pursuant to §1.132(28), the term “Fetal Tissue” is defined as “a fetus, body parts, organs or other tissue from a pregnancy” and does not include “the umbilical cord, placenta, gestational sac, blood or body fluids.” This term was added in the proposed rules and has not been amended at adoption. The rule amendments relating to fetal tissue do not apply prior to pregnancy. Once a pregnancy occurs, the rules application is the same to both the in vitro fertilized pregnancy and an unassisted natural pregnancy, if there is an induced or spontaneous abortion of the pregnancy.

3. Concerns About Criminal Prosecution.

Commenters were concerned about women being prosecuted for inappropriately dealing with a miscarriage at home, and questioned why requirements for disposition of fetal tissue differ from requirements for disposition of other pathological waste.

Response: The commission respectfully disagrees with the comments and responds to the question posed as follows. The proposed rules are not criminal in nature but instead are administrative rules for the regulation of the treatment and disposition of material from certain health care-related facilities that may only be enforced by appropriate health care-related facility regulatory programs. The rules do not apply to individual patients and do not apply to miscarriages that occur outside of a healthcare facility, as stated in §1.133(a)(2)(G). The proposed rules are intended to ensure that fetal tissue that is the product of spontaneous or induced human abortion, and is subject to the rule, is disposed of in a proper manner by the facility. The disposition methods for fetal tissue differ from other pathological waste to ensure

the dignified treatment of fetuses consistent with other laws in Texas. The department's intent is to balance considerations of cost, public health and providing dignity to the unborn.

4. Woman's Constitutional Right to Terminate a Pregnancy; Constitutionality of Rules After the Supreme Court's Ruling in Whole Woman's Health; Potential Lawsuits.

Commenters felt that the proposed rules would violate a woman's constitutional right or would be an infringement upon that right, or would place an undue burden on an individual seeking an abortion. Commenters also stated that the proposed rules were in conflict with the court's decision or that the "state hadn't learned its lesson" and was promulgating more unnecessary regulations after losing at the Supreme Court. Commenters also voiced concerns that the rules would result in additional lawsuits as either being contrary to the ruling in *Whole Woman's Health* or as serving no public health purpose. Rather than unnecessarily plunge the department into yet another legal challenge, the department should immediately withdraw consideration of the new rules.

Response: The commission respectfully disagrees. The proposed rule amendments pertain to the disposition of fetal tissue from health care-related facilities and are intended to ensure fetal tissue is disposed of in a proper manner, without presenting a substantial obstacle to women seeking abortions. The rules do not apply to individuals, but only to health care-related facilities, which are already subject to specified methods of disinfection and disposition of fetal tissue. The department received cost data from waste disposal companies, private and public landfills, FCAT, the Funeral Services Commission, TCEQ, the University of Texas System, and others to determine the minimum cost in complying with the rules. Based upon the lowest stated costs of each entity able to provide cost estimates, the department has determined that the annual cost per facility would be approximately \$450. This cost would be offset by the elimination of the current method of disposition. The department believes this cost to be minimal and absorbable by each health-care facility.

Because the department has determined that any additional costs associated with complying with these rules can be absorbed by the health care-related facility, there should be no undue burden placed on women in terms of increased costs of abortion or lack of access to a facility. Absent an undue burden on the ability to obtain an abortion, the State may act to provide dignity to the unborn. The Supreme Court ruling in *Whole Woman's Health* is unrelated to whether the department has statutory authority to issue rules for the treatment and disposition of fetal tissue from health care-related facilities. Texas Health and Safety Code, §12.001 gives the Executive Commissioner of the commission, which oversees the department, general supervision and control over all matters relating to the health of the citizens of this state, including enforcement authority over health care-related facilities.

5. Access to Abortion Services.

Commenters expressed concern that these rules were politically motivated and proposed for no other reason than to limit, and eventually eliminate, access to abortion in Texas. Commenters also stated the proposed rules would impact the poor, minors, the disabled, and "genderqueer with uteruses." Other commenters remarked that the rules will increase emotional trauma and are intended to shame or punish women seeking abortions. A commenter noted restrictions under HB 2 already mean that women must travel out of state for abortions and have longer wait times,

and that there has been an increase in second trimester abortions. Another commenter noted the proposed rules bear a noticeable similarity to model legislation being pushed by Americans United for Life, a group which describes itself as the “legal architect of the pro-life movement.”

Response: The commission respectfully disagrees that the rules are intended to shame or punish women or limit access to abortion. The proposed rules address the treatment and disposition of fetal tissue from health care-related facilities, which are already subject to rules regarding the disposition of fetal tissue. These rules eliminate methods not currently in use and retain some of the existing methods. Final disposition no longer includes depositing disinfected fetal tissue in landfills, but rather allows other methods. The department received cost data from waste disposal companies, private and public landfills, FCAT, the Funeral Services Commission, TCEQ, the University of Texas System, and others to determine the minimum cost in complying with the rules. Based upon the lowest stated costs of each entity able to provide cost estimates, the department has determined that the annual cost per facility would be approximately \$450. This cost would be offset by the elimination of the current method of disposition. The department believes this cost to be minimal and absorbable by each health care-related facility. Because the department has determined that health care-related facilities can absorb any additional costs associated with these rules, it anticipates no change in access to abortion services.

6. Donation, Research and Testing.

Commenters were split between allowing donation for medical and scientific research as one positive outcome of a difficult choice, and others who felt that no human remains should be treated in any way other than funeral/burial. Other commenters were concerned about how the proposed rules would affect pathological or genetic testing of fetal tissue from miscarriages.

Response: The commission appreciates the comments. Neither the current nor the proposed rules prohibit donation for research. Human tissue, including fetal tissue, that is donated for research or teaching purposes is exempt from the treatment and disposition requirements under both the current and proposed versions of §1.133. There is no requirement, nor prohibition, in the rules for a funeral service. The proposed rules are not intended to prevent or otherwise have an adverse impact genetic or pathological testing. The previous rules have not adversely affected testing in the past, and no language was added in the proposed or adopted amendments that would change that impact or effect.

7. Death Certificates.

Commenters questioned whether a cremation or burial facility would accept fetal tissue without a death certificate and whether this requirement would require a coroner on duty to issue a death certificate. Commenters also expressed concern that this would increase expense to the woman or that the funeral services industry would need to alter their processes. One commenter noted the open nature of death records would make public a woman’s failure to carry a pregnancy to term. Another commenter stated that the collection of data from fetal death certificates issued for purposes of the rules would render the data useless, creating a barrier to the advancement of medical and scientific progress, and may very well impede our understanding of the state’s recent uptick in the rate of maternal mortality and morbidity and obstruct the ability to correct it.

Response: The commission appreciates the comments. Chapter 651 of the Texas Occupations Code applies to disposition of a human body for which a birth and death certificate is required. A certificate of fetal death (fetal death certificate) is only required for a fetus weighing 350 grams or more, or if the weight is unknown, a fetus aged 20 weeks or more as calculated from the start date of the last normal menstrual period. *See* 25 TAC §181.7(a). Based on an exemption that was contained in the previous rules, fetal deaths subject to the fetal death certificate requirement are exempt from the adopted rules pursuant to §1.133(a)(2)(F). Also in response to public comments, to make the applicability of the exemption more evident to the reader, the department has added a cross reference to the exemption in three places in the rules: (1) §1.132(42)(B) regarding the definition of “pathological waste;” (2) §1.136(a)(4)(A)(v) regarding “fetal tissue, regardless of the period of gestation;” and (3) §1.136(a)(4)(B)(i) regarding “fetal tissue, regardless of the period of gestation.” The department retained that exemption in these rules, and has not modified it in the proposed or adopted rules. As a result, vital statistics data collection and reporting results will not be affected nor does it impact maternal mortality and morbidity data. Furthermore, the adopted rules do not require or authorize a patient’s private information to become part of the state’s public record. This rule does not create a new requirement for a birth or death certificate, and thus there is no additional privacy concerns created by the rule nor is there a requirement for a ceremonial burial or application of the cremation requirements in Texas Occupations Code, Chapter 651 or rules that implement that chapter. A crematory requires a death certificate or other death record under 22 TAC, §205.11 in order to perform a cremation of “deceased human remains.” The rule retains many options currently used for disposition of fetal tissue. To help clarify these issues, the department has added language to §1.134 of the rules, which states: “(a) This subchapter may not be used to require or authorize disclosure of confidential information, including personally identifiable or personally sensitive information, not permitted to be disclosed by state or federal privacy or confidentiality laws. This subchapter does not require the issuance of a birth or death certificate for the proper disposition of special waste from health-care related facilities. This subchapter does not extend or modify requirements of Texas Health and Safety Code, Chapters 711 and 716 or Texas Occupations Code, Chapter 651 to disposition of fetal tissue.”

8. Funerals.

Some commenters stated that the proposed rule amendments would require funerals for the disposition of fetal tissue.

Response: The commission respectfully disagrees. Funeral services are not required under these rules or other laws in Texas, nor are they prohibited under these rules. None of the amendments adopted in the rules are intended to invoke a requirement for funeral services to be performed by health care-related facilities to be able to properly dispose of fetal tissue in compliance with the rules.

9. Burial Sites at Risk.

Commenters are worried that the proposed rules will create new physical sites of social unrest as the burial places for these fetuses become grounds for protests and counter-protests. Others are worried that health care-related facilities would be unable to locate a crematory or cemetery willing to accept fetal tissue.

Response: The commission appreciates the comments. The rules do not designate any particular type or location for interment of fetal tissue or other applicable material.

10. Religious Considerations; Separation of Church and State.

Commenters stated that forcing women to take part in a religious ritual in the form of a funeral is a violation of their rights. Commenters voiced concerns at the attempt to legislate values and rituals regarding loss, in that there is a need for separation of church and state. Still others were in support of the proposed rules as consistent with their Christian beliefs in the dignity of life.

Response: The commission respectfully disagrees. The department notes that the proposed rules do not require regulated facilities or individuals to take part in a funeral or any other religious ritual for the health care-related facility to be able to properly dispose of fetal tissue in compliance with the rules. Additionally, the rules have not included previously, and do not now impose a requirement that a patient be informed of the method of disposition or choose that method of disposition. The health care-related facility that is subject to the rules must determine where and how it will arrange for disposition of the fetal tissue, including choosing an authorized method of interment. Facilities may already use a disposition method involving burial with a religious organization, but that is not now, nor will it be under the rules, either required or proscribed by the regulations. Nothing in the adopted rules dictate the nature or form of disposition that must be chosen (secular or non-secular) in relation to interment, including burial or cremation, in conjunction with a disposition method authorized by the rules.

11. Privacy Concerns.

Commenters were concerned that if women had to commission funeral services or obtain death certificates, their information would be required and therefore, their privacy would be compromised and that the rules are “a violation of HIPAA.”

Response: The commission respectfully disagrees. The rules do not require individuals to commission funeral services. Nothing in the rules requires the release of patient identifying information or other personally sensitive information. The current rules do not require the issuance of a death certificate for the disposition of medical waste. The adopted amendments did not add any language that was intended to invoke any requirement that would result in the need for a death certificate. To help clarify these issues, the department has added language to §1.134 of the rules, which states: “This subchapter may not be used to require or authorize disclosure of confidential information, including personally identifiable or personally sensitive information, not permitted to be disclosed by state or federal privacy or confidentiality laws. This subchapter does not require the issuance of a birth or death certificate for the proper disposition of special waste from health care-related facilities. This subchapter does not extend or modify requirements of Texas Health and Safety Code, Chapters 711 and 716 or Texas Occupations Code, Chapter 651 to disposition of fetal tissue.”

12. Removal of Grinding and Disposition in Sewer System and Landfill.

Some commenters approved of the removal of grinding as a disposition option. Commenters were split on the issue of landfill disposition. Many felt that it reduced the dignity of a human life as trash, others noted that this is the method commonly used for all other types of medical waste and this was no different. One commenter noted that rather than eliminating the use of the

grinding process entirely, the proposed rules subjectively delete it for one type of tissue while continuing to codify its use for other tissues.

Response: The commission appreciates the comments. The rule removes outdated methods, methods rarely used such as “grinding” and “chlorine disinfection/maceration” and ensures the proper and dignified treatment and disposition of fetal tissue, including prohibiting the disposal of fetal tissue in a landfill, which affords the protection and dignity to unborn children consistent with many state laws and the Legislature’s expression of its intent to respect life and protect the dignity of the unborn. The adopted rules are the means by which the department is able to conform its rules to that expression of intent, while accommodating the need to address considerations regarding public health, public benefit and costs.

13. Water and Air Quality.

Commenters were concerned about disposition via the sewer system and that it would negatively impact water quality and would possibly expose the public to HIV/AIDS and other infectious disease.

Response: The commission respectfully disagrees. The disposition of certain special waste into the sanitary sewer system has been in rule for decades. It is not possible to transmit HIV/AIDS through these means. These rules eliminate the option of disposition of fetal tissue via the sanitary sewer system.

14. Costs.

Commenters expressed concern that these rules would increase the cost of an abortion for women and/or that these rules would result in more litigation which would cost taxpayers money to defend. Another commenter stated that the small and micro-business impact analysis and economic costs to persons statement is wholly insufficient. Other commenters stated that abortion providers should absorb the costs and noted that low-cost burials and group burials are available and that home burial or burial through counties’ indigent burial programs are other available alternatives.

Response: The commission respectfully disagrees with the first set of comments and supports the assertions of the second set of comments. The department received cost data from waste disposal companies, private and public landfills, FCAT, the Funeral Service Commission, TCEQ, the University of Texas System, and others to determine the minimum cost in complying with the rules. Based upon the lowest stated costs of each entity able to provide cost estimates, the department has determined that the annual cost per facility would be approximately \$450. The department believes there are a number of regulated facilities that are already in compliance with these rules. For those health care-related facilities not already disposing of fetal tissue through cremation and burial, the cost of any of the new available methods would be offset by the elimination of the cost of landfill disposition. The department believes this cost to be minimal and absorbable by each health care-related facility.

15. Impact on Low-Income Women and Women Who Live in Rural Areas.

Commenters argued that the increased cost would disproportionately affect low-income women and women who lived in rural areas.

Response: The commission respectfully disagrees. The department's cost estimate indicates that the annual increased cost to health care-related facilities will be minimal and absorbable, thereby eliminating the need to pass on any additional cost to patients. The department received cost data from waste disposal companies, private and public landfills, FCAT, the Funeral Service Commission, TCEQ, and University of Texas System, and others to determine the minimum cost in complying with the rules. Based upon the lowest stated costs of each entity able to provide cost estimates, the department has determined that the annual cost per facility would be approximately \$450. For those health care-related facilities not already disposing of fetal tissue through cremation and burial, the cost of any of the new available methods would be off-set by the elimination of the cost of landfill disposition. The department believes this cost to be minimal and absorbable by each health care-related facility, whether in an urban or rural area.

16. Rulemaking Procedure.

Commenters stated that the department circumvented the standard rule-making process and tried to sneak this rule set by the public or ask if the rules are being shepherded through using an emergency or expedited process and felt that some remarks from the initial comment period were taken into account, while others were not. Other commenters questioned whether the department would take into account all comments received. At least one commenter stated that they submitted comments in response to the first proposed set of rules but the comments were disregarded, seemingly without consideration, along with a reported 12,000 other comments submitted.

Response: The commission respectfully disagrees. The department complied with the requirements of the Administrative Procedure Act, Chapter 2001 of the Texas Government Code. The department gave at least 30 days' notice of its intent to adopt the proposed rules: It twice filed notice of the proposed rules with the secretary of state for publication in the *Texas Register* as required by Chapter 2001, giving the public two 30-day periods for comment. The first set of proposed rules was filed on June 20, 2016 and the second on September 19, 2016. The same rules were proposed each time. Both notices for the proposed rules included the information required by Texas Government Code, §2001.024, and the department gave all interested persons an opportunity to submit oral and written comments as required by Texas Government Code, §2001.029. Two public hearings were held on August 4, 2016, and November 9, 2016, in compliance with Texas Government Code, §2001.029 in which the department received oral and written public comments. The department received more than 35,000 comments on the proposed rules. Therefore, the department, on behalf of the commission, voluntarily considered and is responding in this adoption preamble to 20,000 comments from the first publication, public comment period and public hearing regarding the proposed rules. There is no legal requirement to consider and respond to the first set of comments, but the department felt it important to include the initial comments. The department has fully considered both the first and second set of public comments and includes its responses, and additional required elements set forth in Texas Government Code, §2001.033, in its adoption of the rules.

17. Health and Safety and Public Health Impact.

Commenters were split. Some felt that the rules were necessary to protect the health and safety of women. Others commented that the rules were an ill-advised crusade that did nothing to

improve public health outcomes and actively worked against the public interest, served no public health purpose or had no medical benefit, or there is no indication that public health has been jeopardized by the rules as they exist today.

Response: The commission appreciates the comments. The proposed rules protect the health and safety of the public and serve a public health purpose by ensuring the proper treatment and disposition of fetal tissue from health care-related facilities. The rules carry out the department's duty to protect public health in a manner that is consonant with the state's respect for life and the dignity of the unborn. The adopted rules are the means by which the department is able to meet that objective, while balancing the need to address considerations regarding public health, public benefit, and costs through amendments to the rules and inclusion of new provisions in the rules that afford the protection and dignity to unborn children consistent with the Legislature's expression of its intent.

18. Other Legislation that Impacts Rules.

Commenters stated that the rules would impact other rules that touch on the issue including the placenta legislation from last session and that the quandary is made more apparent when recognizing the Legislature's recent passage of HB 635.

Response: The commission appreciates the comments. House Bill 1670 (Acts 2015, 84th Legislature, Regular Session, Chapter 740) added Chapter 172 to the Texas Health and Safety Code. This legislation requires a hospital or birthing center to allow a woman who gave birth in the facility to take the placenta from the facility in certain circumstances. Language was added under §1.133(a)(2)(I) at adoption which creates an exemption from the rules applicability when a placenta is removed from a hospital or birthing center pursuant to Texas Health and Safety Code, Chapter 172. Also in response to comments, the department has added a cross-reference to the exemption in §1.133(a)(2)(I) to §1.136(a)(4)(A)(v) and (B)(i) regarding "fetal tissue, regardless of the period of gestation."

House Bill 635 (Acts 2015, 84th Legislature, Regular Session, Chapter 342) added §241.010 to the Texas Health and Safety Code. This statute requires a hospital to release the remains of an unintended, intrauterine fetal death, including remains that weigh less than 350 grams, on the request of a parent, in a manner appropriate under law and the hospital's policy. In response to public comments and to conform with the impact of HB 635, the department has added subsection (a)(2)(H) to §1.133, which states that the rules do not apply to "fetal remains required to be released to the parent of an unborn child pursuant to Texas Health and Safety Code, §241.010{.}" Also in response to comments, the department has added a cross-reference to the exemption in §1.133 to §1.136(a)(4)(A)(v) and (B)(i) regarding "fetal tissue, regardless of the period of gestation."

19. Existing Laws Sufficient for Disposal of Tissue.

Commenters were against the proposed rules stating that current law is sufficient that there is no valid reason to amend the rules, that a patient already has the right to control the disposition of fetal tissue, or that facilities are already following sanitary methods of waste disposal. Some

commenters stated that it is hypocritical to have a separate set of rules just for the disposition of fetal tissue.

Response: The commission respectfully disagrees. Under Texas Government Code, §2001.039, each state agency must review and consider for readoption each of its rules. The department has done so in this case in accordance with Texas Government Code, §2001.039 and determined that amendment to the rules is necessary to remove outdated methods, methods rarely used such as “grinding” and “chlorine disinfection/maceration” and ensure the proper and dignified treatment and disposition of fetal tissue, including prohibiting the disposal of fetal remains in a landfill, which affords the protection and dignity to unborn children consistent with the Legislature’s expression of its intent. The adopted rules are the means by which the department is able to conform its rules to that expression of intent, while accommodating the need to address considerations regarding public health, public benefit and costs. The proposed rules are intended to ensure that fetal tissue that is the product of spontaneous or induced human abortion, and is subject to the rule, is disposed of in a proper manner. The disposition methods for fetal tissue differ from other pathological waste to ensure the dignified treatment of fetuses consistent with other laws in Texas. The department’s intent is to balance considerations of cost, public health and providing dignity to the unborn. The rules do not now, nor have they ever, imposed a requirement that a patient be informed of the method of disposition.

20. Use of Public Funds.

Commenters wanted the funds being expended to change the rules, enforce the new rules, and/or on anticipated litigation resulting from the new rules to be redirected to more direct public health impacts such as Zika prevention, education, caring for special needs children, protecting abused children, treating the uninsured, and public health and sanitation. Commenters stated that funds would be better utilized for birth control and sex education. At least one commenter complained of a waste of staff time regarding the new rules.

Response: The commission respectfully disagrees. The department has made fighting the spread of the Zika virus a priority. The department’s actions in relation to this rule set will not impact its focus or budgeting related to Zika control and elimination efforts or other public health, or women’s health services. These rules also have no relation to or impact on the state’s focus on children’s protective services. Any funding or resources needed for the enforcement or defense of these rules, if parties choose to challenge these rules, does not adversely impact the availability of funding for other public health and sanitation programs that the department oversees. Other areas, such as education, special needs services, care for the uninsured, and protection of abused children, fall outside of the department’s authority. The rules address the treatment and disposition of fetal tissue from health care-related facilities, which are already subject to rules regarding the disposition of fetal tissue. These rules eliminate methods not currently in use and retain some of the existing methods. Final disposition no longer includes depositing disinfected fetal tissue in landfills, but rather requires it to be interred. The department received cost data from waste disposal companies, private and public landfills, the Funeral Consumers Alliance, FCAT, TCEQ, the University of Texas System, and others to determine the minimum cost in complying with the rules. Based upon the lowest stated costs of each entity able to provide cost estimates, the department has determined that the annual cost per facility would be approximately \$450. This cost would be offset by the elimination of the

current method of disposition. The department believes this cost to be minimal and absorbable by each health-care facility. Because the department has determined that health care-related facilities can absorb any additional costs associated with these rules, there should be no change in access to abortion services.

21. Other States' Laws.

Commenters cited other states' laws similar to the proposed rules and how they have been struck down or enjoined, and asked why the decision was made to move ahead with these rules now, rather than waiting to see the outcome of the federal court case against an Indiana law with similar subject matter.

Response: The commission appreciates the comments. The department notes that measures in other states are distinguishable from the proposed rules.

The State of Indiana passed House Enrolled Act 1337, which would require that a miscarried or aborted fetus be interred or cremated by a facility having possession of the remains and would exclude the final disposition of a miscarried or aborted fetus from the law governing the treatment of infectious or pathological waste. Although the Indiana law has been preliminarily enjoined by a federal court from taking effect, it is different from the department's adopted rules, which explicitly encompass treatment and disposition of special waste, including pathological waste. The federal court also determined that Indiana had no interest in treating the unborn with dignity. Here, however, the Texas Legislature has enacted numerous statutes demonstrating its interest in the dignity of the unborn. The rule provides many options for disposition, many of which are already in use, that do not increase the cost of disposition of fetal remains, but still protect the dignity of the unborn.

The State of Louisiana passed HB 815, which would require burial or cremation of remains resulting from abortion. This provision is being challenged in federal court, where a request for preliminary injunction alleged that its requirements would constitute an effective ban on first trimester medication abortion. However, unlike the Louisiana statute, the department's rules do not apply to individuals; they apply only to health care-related facilities and are therefore the rules do not affect access, and there is no undue burden.

The State of Michigan enacted Public Health Code, §333.2836, which requires fetal remains from abortions to be disposed of by interment or cremation or by incineration by a person other than a cemetery. This provision has not been challenged in court. The department's rules are less restrictive than the Michigan law and as the rules allow for disposition by interment, incineration followed by interment, or steam disinfection followed by interment.

22. Authority to Adopt Rules.

Commenters questioned the department's authority to adopt rules beyond those necessary for public health and infectious disease control. Others noted that they are asking legislators to codify the proposed rules in statute. One commenter observed that the proposal takes a new policy direction, but does not result from a directive of the Texas Legislature as a whole.

Response: The commission appreciates the comments. The department has regulated special waste generated by health care-related facilities since 1989. These rules are necessary to ensure protection of the health and safety of the public by ensuring that the disposition methods specified in the rules continue to be limited to methods that prevent the spread of disease. The commission disagrees that the proposed rules do not result from a directive of the entire Legislature. Through these amendments to the rule, as set out in the reasoned justification and statutory authority sections, the department is exercising its policy discretion in a manner that more closely conforms to the many state laws that already protect the dignity of the unborn. The department has the statutory authority to promulgate rules to protect the public from the spread of communicable disease pursuant to Texas Health and Safety Code, Chapters 12 and 81. In doing so, the department undertook the review of outdated rules in conjunction with this authority while trying to balance cost considerations, public benefit and legislative intent and history of the protection of the unborn. These considerations resulted in the amended rules.

23. Expansion of Government.

Commenters were concerned about government expansion into areas they shouldn't be and stated that the government should leave women alone. Other commenters said the proposed rules would interfere with the doctor-patient relationship.

Response: The commission respectfully disagrees. The department notes that these rules apply to health care-related facilities already subject to these rules. The department is not expanding its authority to include any new topic or regulated entity or person. The proposed rules do not interfere with the doctor-patient relationship, because they do not apply to individual patients and the disposition of fetal tissue remains the responsibility of the health-care-related facility. Additionally, the rules have not included previously, and do not now impose a requirement that a patient be informed of the method of disposition or choose that method of disposition. Instead, the proposed rules regulate the treatment and disposition of special waste, including fetal tissue, generated by health care-related facilities. The proposed rules are not intended to restrict access to abortion, but to protect the public health while affording dignity to the unborn. While the rules eliminate certain outdated methods or methods of disposition that are clearly incompatible with demonstrating dignity for the unborn, the rules do not create a new type of regulation or regulate additional entities. Many health care-related facilities will be unaffected by these rules because those facilities' current disposition practices are already in compliance with the rules. These rules are necessary to ensure protection of the health and safety of the public by ensuring that the disposition methods specified in the rules continue to be limited to methods that prevent the spread of disease while providing dignity to the unborn. The department has the statutory authority to promulgate rules to protect the public from the spread of communicable disease pursuant to Texas Health and Safety Code, Chapters 12 and 81. In doing so, the department undertook the review of outdated rules in conjunction with this authority while trying to balance cost considerations, public benefit and legislative intent and history of the protection of the unborn. These considerations resulted in the amended rules.

24. Enforcement of Rules.

Comment: Some commenters asked how the department will enforce the new rules and asked whether there will be penalties for noncompliance.

Response: The department currently inspects health care-related facilities subject to the rules, which are within its jurisdiction, for compliance by reviewing documentation, practices, and procedures used by the facility for the disposition of medical waste. This may include the review of contracts with third-party waste companies to determine what methods of disposition are being utilized. The rules do not adopt additional enforcement actions, and the department intends to continue its current practice for the purposes of enforcing these rules. Any issues of noncompliance identified as part of this continuing practice of enforcement, and any proposed penalties or sanctions resulting from noncompliance, will be handled the same as any previous issues of noncompliance with these rules, or other applicable rules or statutes, including affording facilities due process in the assessment of penalties or other non-monetary sanctions.

PUBLIC BENEFIT

Ms. Sims 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 the continued protection of the health and safety of the public by ensuring that the disposition methods specified in the rules continue to be limited to methods that prevent the spread of disease. Additional public benefit will be realized in bringing up-to-date the department's rules to reflect the Legislature's articulated policy objectives of respect for life and protecting the dignity of the unborn. This will be accomplished by enforcing these rules in health care-related settings subject to the rules that handle special waste to ensure the rules are applied and followed consistently, which protects patients and staff of the facility, as well as the public.

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 a valid exercise of the agencies' legal authority.

STATUTORY AUTHORITY

The rule review and amendments are authorized by Texas Government Code, §2001.039, requiring that each agency periodically review its rules to determine that the reason for the rules continue to exist; Texas Health and Safety Code, §12.001; Texas Government Code, §531.0055 and Texas 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 Texas Health and Safety Code, Chapter 1001. The rule review and amendments are also authorized by Texas Health and Safety Code, §81.004, which authorizes the Executive Commissioner to adopt rules necessary for the effective administration of Texas Health and Safety Code, Chapter 81, concerning the control of communicable disease to ensure the health and safety of the public through, among many things, the proper disposition of tissue from health care-related facilities. The regulation of these health care-related facilities subject to the rules is governed by Texas Health and Safety Code, Chapter 241, concerning the licensing of hospitals; by Chapter 243, concerning the licensing of ambulatory surgical centers; by Chapter 244, concerning the licensing of birthing centers; by Chapter 245, concerning the licensing of abortion facilities; by Chapter 251, concerning the licensing of end stage renal disease facilities;

by Chapter 254, concerning the licensing of freestanding emergency medical care facilities; and by Chapter 773, concerning the licensing of emergency medical services.

The rule review and amendments implement Texas Government Code, Chapter 531 and §2001.039; and Texas Health and Safety Code, Chapters 12, 81, 241, 243, 244, 245, 251, 254 and 773.

In conjunction with its review, the department also considered and gave great weight to the Legislature's policy objective of ensuring dignity for the unborn, which is articulated in a number of Texas laws. In undertaking this review, the department took into consideration a variety of statutes that express the Legislature's will to afford the level of protection and dignity to unborn children as state law affords to adults and children. Additional provisions considered in ensuring the department's exercise of its authority was consistent with other state laws, include: Texas Penal Code, §1.07(26) relating to criminal penalties for harm to unborn persons; Texas Civil Practice and Remedies Code, §71.001(4) relating to civil liability for killing unborn persons; Texas Estates Code, §1054.007 relating to guardianship representation for unborn persons in a guardianship proceeding; Texas Estates Code, §1002.002 regarding the definition of "attorney ad litem" which includes representation of an "unborn person;" Texas Property Code, §115.014 relating to authority of a court to appoint a guardian ad litem to represent the interest of an unborn person; Texas Health and Safety Code §241.010 relating to requirement that hospitals release to a parent remains of an unborn child who dies as a result of an unintended, intrauterine death; Preamble of HB 2, 83rd Legislature, Second Called Session, 2013, effective October 29, 2013, relating to 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; Texas Health and Safety Code, §170.002 relating to the prohibition against a person intentionally or knowingly performing an abortion on a woman who is pregnant with a viable unborn child during the third trimester of the pregnancy; and Texas Health and Safety Code, §171.012 relating to requirement for sonograms of pre-viable unborn children before abortion.

<rule>

§1.132. Definitions.

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

(1) Anatomical remains--The remains of a human body donated for the purposes of teaching or research to a medical school, a teaching hospital, or a medical research facility, after the completion of the activities for which the body was donated.

(2) Animal waste--Animal waste includes:

(A) carcasses of animals intentionally exposed to pathogens;

(B) body parts of animals intentionally exposed to pathogens;

(C) whole bulk blood and blood products, serum, plasma, and other blood components from animals intentionally exposed to pathogens; and

(D) bedding of animals intentionally exposed to pathogens.

(3) Approved alternate treatment process--A process for waste treatment which has been approved by the department in accordance with §1.135 of this title (relating to Performance Standards for Commercially-Available Alternate Treatment Technologies for Special Waste from Health Care-Related Facilities).

(4) Biological indicators--Commercially-available microorganisms (e.g., United States Food and Drug Administration-approved strips or vials of *Bacillus* species endospores) which can be used to verify the performance of waste treatment equipment and/or processes.

(5) Blood and blood products--All waste bulk human blood, serum, plasma, and other blood components.

(6) Body fluids--Those free-flowing body substances other than blood, plasma, or serum identified under universal precautions as recommended by the United States Centers for Disease Control and Prevention, and includes, but are not limited to:

(A) semen;

(B) vaginal secretions;

(C) any body fluid containing visible blood;

(D) saliva in dental settings;

(E) amniotic fluid;

(F) cerebrospinal fluid;

(G) peritoneal fluid;

(H) pleural fluid;

(I) pericardial fluid; and

(J) synovial fluid.

(7) Bulk--A containerized, aggregate volume of 100 milliliters (mL) or more.

(8) Bulk human blood, bulk human blood products, and bulk human body fluids--All free-flowing waste: human blood; serum; plasma; other blood components; and body fluids; including disposable items saturated with blood or body fluids.

(9) Burial--The act of depositing a pathological waste in a grave, a crypt, vault, or tomb, or at sea.

(10) Burial park--A tract of land that is used or intended to be used for the interment of pathological waste in graves.

(11) Cemetery--A tract of land that is used or intended to be used for the permanent interment of pathological waste, and includes:

- (A) a burial park for earth interments;
- (B) a mausoleum for crypt or vault interments;
- (C) a columbarium for cinerary interments; or
- (D) a combination of one or more thereof.

(12) Challenge waste load--A surrogate waste load assembled for use during waste treatment protocols to evaluate the efficacy of microbial inactivation processes. The composition of the challenge waste load will vary depending on the technology being evaluated.

(13) Chemical disinfection--The use of a chemical agent to reduce significantly the numbers of active microorganisms, but not necessarily their endospores, from the surfaces of inanimate objects.

(14) Chlorine disinfection/maceration--The process of shredding waste in the presence of a chlorine solution under negative pressure.

(15) Columbarium--A structure or room or other space in a building or structure of most durable and lasting fireproof construction; or a plot of earth, containing niches, used, or intended to be used, to contain cremated pathological waste.

(16) Contagious--Capable of transmission from human or animal to human.

(17) Contaminated--The presence or the reasonably anticipated presence of blood or those body fluids as defined elsewhere in this section.

(18) Cremation--The irreversible process of reducing tissue or remains to ashes or bone fragments through extreme heat and evaporation. Under this subchapter, this term includes the process of incineration.

(19) Crematory--A building or structure containing one or more furnaces used, or intended to be used, for the reduction (by burning) of pathological waste to cremated remains.

(20) Crypt or vault--The chamber in a mausoleum of sufficient size to inter the uncremated pathological waste.

(21) Department--The Texas Department of State Health Services.

(22) Deposition in a sanitary landfill--Deposition in a sanitary landfill in accordance with 30 TAC Chapter 330.

(23) Discharge to sanitary sewer system--A discharge or flushing of waste into a sanitary sewer system which is done in accordance with provisions of local sewage discharge ordinances.

(24) Disinfection--A somewhat less lethal process compared to sterilization which destroys or inactivates viruses, fungi, and bacteria (but not necessarily their endospores) on inanimate surfaces.

(25) Encapsulation--The treatment of waste using materials which, when fully reacted, will encase such waste in a solid protective matrix.

(26) Entombment--The permanent interment of pathological waste in a crypt or vault.

(27) Executive Commissioner--In this title, Executive Commissioner means the Executive Commissioner of the Health and Human Services Commission.

(28) Fetal Tissue--A fetus, body parts, organs or other tissue from a pregnancy. This term does not include the umbilical cord, placenta, gestational sac, blood or body fluids.

(29) Grave--A space of ground in a burial park that is used, or intended to be used for the permanent interment in the ground of pathological waste.

(30) Grinding--That physical process which pulverizes materials, thereby rendering them as unrecognizable, and for sharps, reduces the potential for the material to cause injuries such as puncture wounds.

(31) Immersed--A process in which waste is submerged fully into a liquid chemical agent in a container, or that a sufficient volume of liquid chemical agent is poured over a containerized waste, such that the liquid completely surrounds and covers the waste item(s) in the container.

(32) Incineration--That process of burning SWFHCRF in an incinerator as defined in 30 TAC Chapter 101 under conditions in conformance with standards prescribed in 30 TAC Chapter 111 by the Texas Commission on Environmental Quality.

(33) Interment--The disposition of pathological waste using the process of cremation, entombment, burial, or placement in a niche or by using the process of cremation followed by

placement of the ashes in a niche, grave, or scattering of ashes as authorized by law, unless prohibited by this subchapter.

(34) Log₁₀--Logarithm to the base ten.

(35) Log₁₀ reduction--A mathematically defined unit used in reference to level or degree of microbial inactivation. A 4 log₁₀ reduction represents a 99.99% reduction in the numbers of active microorganisms, while a 6 log₁₀ reduction represents a 99.9999% reduction in the numbers of active microorganisms.

(36) Mausoleum--A structure or building of most durable and lasting fireproof construction used, or intended to be used, for the entombment pathological waste.

(37) Microbial inactivation--Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a 6 log₁₀ reduction or greater; and inactivation of *Bacillus subtilis* endospores or *Bacillus stearothermophilus* endospores at a 4 log₁₀ reduction or greater.

(38) Microbiological waste--Microbiological waste includes:

(A) discarded cultures and stocks of infectious agents and associated biologicals;

(B) discarded cultures of specimens from medical, pathological, pharmaceutical, research, clinical, commercial, and industrial laboratories;

(C) discarded live and attenuated vaccines, but excluding the empty containers thereof;

(D) discarded, used disposable culture dishes; and

(E) discarded, used disposable devices used to transfer, inoculate or mix cultures.

(39) Moist heat disinfection--The subjection of:

(A) internally shredded waste to moist heat, assisted by microwave radiation under those conditions which effect disinfection; or

(B) unshredded waste in sealed containers to moist heat, assisted by low-frequency radiowaves under those conditions which effect disinfection, followed by shredding of the waste to the extent that the identity of the waste is unrecognizable.

(40) Niche--A recess or space in a columbarium used, or intended to be used, for the permanent interment of the cremated remains of pathological waste.

(41) Parametric controls--Measurable standards of equipment operation appropriate to the treatment equipment including, but not limited to pressure, cycle time, temperature, irradiation dosage, pH, chemical concentrations, or feed rates.

(42) Pathological waste--Pathological waste includes but is not limited to:

(A) human materials removed during surgery, labor and delivery, autopsy, embalming, or biopsy, including:

- (i) body parts;
- (ii) tissues or fetuses;
- (iii) organs; and
- (iv) bulk blood and body fluids;

(B) products of spontaneous or induced human abortions, regardless of the period of gestation except as provided by §1.133 of this title (relating to Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of State Health Services) including:

- (i) body parts;
- (ii) tissues or fetuses;
- (iii) organs; and
- (iv) bulk blood and body fluids;

(C) laboratory specimens of blood and tissue after completion of laboratory examination; and

(D) anatomical remains.

(43) Saturated--Thoroughly wet such that liquid or fluid flows freely from an item or surface without compression.

(44) Sharps--Sharps include, but are not limited to the following materials:

(A) when contaminated:

- (i) hypodermic needles;
- (ii) hypodermic syringes with attached needles;
- (iii) scalpel blades;
- (iv) razor blades, disposable razors, and disposable scissors used in surgery, labor and delivery, or other medical procedures;

(v) intravenous stylets and rigid introducers (e.g., J wires);

(vi) glass pasteur pipettes, glass pipettes, specimen tubes, blood culture bottles, and microscope slides;

(vii) broken glass from laboratories; and

(viii) tattoo needles, acupuncture needles, and electrolysis needles;

(B) regardless of contamination:

(i) hypodermic needles; and

(ii) hypodermic syringes with attached needles.

(45) Shredding--That physical process which cuts, slices, or tears materials into small pieces.

(46) Special waste from health care-related facilities--A solid waste which if improperly treated or handled may serve to transmit an infectious disease(s) and which is comprised of the following:

(A) animal waste;

(B) bulk blood, bulk human blood products, and bulk human body fluids;

(C) microbiological waste;

(D) pathological waste; and

(E) sharps.

(47) Steam disinfection--The act of subjecting waste to steam under pressure under those conditions which effect disinfection. This was previously called steam sterilization.

(48) Thermal inactivation--The act of subjecting waste to dry heat under those conditions which effect disinfection.

(49) Unrecognizable--The original appearance of the waste item has been altered such that neither the waste nor its source can be identified.

§1.133. Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of State Health Services.

(a) Exemptions.

(1) Unless an item is specifically exempted, all special waste from health care-related facilities must be treated as provided in these sections.

(2) These sections do not apply to:

(A) teeth;

(B) human tissue, including fetal tissue, donated for research or teaching purposes, with the consent of the person authorized to consent as otherwise provided by law, to an institution of higher learning, medical school, a teaching hospital affiliated with a medical school, or to a research institution or individual investigator subject to the jurisdiction of an institutional review board required by 42 United States Code 289;

(C) placentas designated for sale and obtained from a licensed hospital or a licensed birthing center;

(D) in vitro tissue cultures that have not been intentionally exposed to pathogens;

(E) any material included in the definition of special waste from health care-related facilities which has been sold, donated, or in any way transferred from one health care-related facility to a subsequent facility(s) and other entities specified in subparagraph (B) of this paragraph for research or teaching purposes until it is discarded;

(F) disposition of fetal remains of a single pregnancy, body parts, or tissue (including bulk blood), transferred for disposition to a licensed funeral director in accordance with the Health and Safety Code, Chapter 711, and Chapter 181 of this title (relating to Vital Statistics) with the consent of the person or persons authorized to consent to the disposition of the fetal remains, body parts, or tissue (including bulk blood). All subcategories of pathological waste, unless otherwise exempted, must be treated and disposed of in accordance with §1.136 of this title (relating to Approved Methods of Treatment and Disposition);

(G) human tissue, including fetal tissue, that is expelled or removed from the human body once the person is outside of a healthcare facility;

(H) fetal remains required to be released to the parent of an unborn child pursuant to Texas Health and Safety Code, §241.010; and

(I) a placenta removed from a hospital or birthing center pursuant to Texas Health and Safety Code, Chapter 172.

(b) Minimum parametric standards for waste treatment technologies previously approved by the department.

(1) Chemical disinfection.

(A) Waste treatment via direct contact with chemical agents only shall utilize a registered chemical agent or an approved unregistered chemical agent as follows.

(i) Registered chemical agents.

(I) The chemical agent used shall be registered with the United States Environmental Protection Agency and the Texas Department of Agriculture.

(II) The chemical agent shall be used according to the manufacturer's instructions.

(ii) Unregistered chemical agents.

(I) Those unregistered chemical agents previously approved are:

(-a-) a freshly prepared solution of household chlorine bleach diluted 1:10 (volume/volume) with water; or

(-b-) a solution of 70% by volume 2-propanol (isopropyl alcohol).

(II) The containerized waste items shall be totally immersed in either solution for a period of time not less than three minutes.

(B) If a chemical agent has been included by a manufacturer of a commercially-available waste treatment technology as the principle step in the treatment process, then:

(i) the chemical agent (or its precursor(s)) or the microbial inactivating process must be registered with the United States Environmental Protection Agency for the purpose of waste treatment; or

(ii) the manufacturer must provide evidence that the technology utilizing said chemical agent (or its precursor(s)) or the microbial inactivating process has been approved for use in another state; or

(iii) the manufacturer must obtain approval for the process in accordance with §1.135 of this title (relating to Performance Standards for Commercially-Available Alternate Treatment Technologies for Special Waste from Health Care-Related Facilities).

(C) Waste immersed in a liquid chemical agent must be thoroughly drained before disposal.

(2) Chlorine disinfection/maceration.

(A) The waste must be shredded prior to or during treatment and made unrecognizable as to source.

(B) The chlorine solution must have a free available chlorine concentration of at least 1,100 parts per million (ppm) when applied to the waste.

(C) The chlorine solution must be drained from the waste prior to disposal.

(3) Moist heat disinfection. Moist heat disinfection shall utilize either of the following processes.

(A) When subjecting internally shredded waste to moist heat assisted by microwave radiation, the temperature of the waste must reach at least 95 degrees Celsius under atmospheric pressure for at least 30 minutes.

(B) When subjecting unshredded waste in sealed containers to moist heat assisted by low-frequency radiowaves, the temperature of the waste must reach at least 90 degrees Celsius under atmospheric pressure for at least two hours, followed by shredding of the waste to the extent that the identity of the waste is unrecognizable.

(4) Steam disinfection. Steam disinfection shall meet all of the following requirements.

(A) To allow for sufficient steam access to or penetration of the waste, the waste shall be:

(i) packaged according to the recommendations provided by the manufacturer; and

(ii) loaded into the chamber so as to not exceed the capacity limits as set by the manufacturer.

(B) When subjecting waste to steam under pressure, the temperature in the chamber of the autoclave must reach at least 121 degrees Celsius and there must be at least 15 pounds per square inch gauge pressure for at least 30 minutes.

(C) The autoclave must be operated according to the manufacturer's instructions.

(5) Thermal inactivation. Thermal inactivation shall meet all of the following requirements.

(A) To allow for sufficient dry heat access to or penetration of the waste, the waste shall be:

(i) packaged according to the recommendations provided by the manufacturer; and

(ii) loaded into the chamber so as to not exceed the capacity limits as set by the manufacturer.

(B) Waste shall be subjected to dry heat of at least 160 degrees Celsius under atmospheric pressure for at least two hours.

(C) Waste shall be subjected to dry heat according to the manufacturer's instructions.

§1.134. Application.

(a) This subchapter may not be used to require or authorize disclosure of confidential information, including personally identifiable or personally sensitive information, not permitted

to be disclosed by state or federal privacy or confidentiality laws. This subchapter does not require the issuance of a birth or death certificate for the proper disposition of special waste from health care-related facilities. This subchapter does not extend or modify requirements of Texas Health and Safety Code, Chapters 711 and 716 or Texas Occupations Code, Chapter 651 to disposition of fetal tissue.

(b) These sections apply to special waste from health care-related facilities generated by the operation of the following publicly or privately owned or operated health care-related facilities, including but not limited to:

- (1) ambulatory surgical centers;
- (2) abortion clinics;
- (3) birthing centers;
- (4) blood banks and blood drawing centers;
- (5) clinics, including but not limited to medical, dental, veterinary;
- (6) clinical, diagnostic, pathological or biomedical research laboratories;
- (7) educational institution health centers;
- (8) educational institution research laboratories;
- (9) electrolysis facilities;
- (10) emergency medical services;
- (11) end stage renal dialysis facilities;
- (12) freestanding emergency medical care facilities;
- (13) funeral establishments;
- (14) home and community support services agencies;
- (15) hospitals;
- (16) long term care facilities;
- (17) facilities providing mental health and intellectual disability services, including but not limited to hospitals, schools, and community centers;
- (18) minor emergency centers;

- (19) occupational health clinics and clinical laboratories;
- (20) pharmacies;
- (21) pharmaceutical manufacturing plants and research laboratories;
- (22) professional offices, including but not limited to the offices of physicians, dentists, and acupuncturists;
- (23) special residential care facilities;
- (24) tattoo studios; and
- (25) veterinary clinical and research laboratories.

§1.135. Performance Standards for Commercially-Available Alternate Treatment Technologies for Special Waste from Health Care-Related Facilities.

All manufacturers of commercially-available alternate technologies, equipment, or processes designed or intended for the treatment of special waste from health care-related facilities, except those meeting the standards of §1.133(b) of this title (relating to Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of State Health Services), shall apply to the department on forms prescribed by the department for approval of said technologies, equipment, or processes to ensure that established performance standards are met.

(1) Levels of microbial inactivation.

(A) All laboratory evidence submitted to the department for review shall be provided by a laboratory that meets the standards of either the NSF International, the American Association for Laboratory Accreditation, or other accrediting agencies or organizations as approved by the department.

(B) All manufacturers of commercially-available alternate technologies, equipment, or processes designed and intended for the treatment of special waste from health care-related facilities shall provide specific laboratory evidence that demonstrates:

(i) inactivation of representative samples of vegetative bacteria, mycobacteria, lipophilic/hydrophilic viruses, fungi, and parasites at a level of 6 log₁₀ reduction or greater, as determined by the department; and

(ii) inactivation of *Bacillus stearothermophilus* endospores or *Bacillus subtilis* endospores at a level of 4 log₁₀ reduction or greater, as determined by the department.

(C) One or more representative surrogate microorganisms from each microbial group shall be used in treatment efficacy evaluation. The department shall determine the appropriate microorganisms to serve as representative surrogate microorganisms.

(D) The department shall prescribe those categories (types) and percent composition of special waste from health care-related facilities that present the most challenge to said treatment effectiveness under normal operating conditions of the equipment or process.

(E) Protocols developed for efficacy testing shall incorporate, as applicable, recognized, standard procedures. The protocols shall be congruent with the treatment method under review. The department shall determine the specific pieces of information to be provided by the manufacturer to assure a thorough evaluation of the alternate treatment technology.

(2) Documentation requirements.

(A) The manufacturer of the alternate treatment technology, equipment, or process shall provide to the department the following information:

(i) a detailed description of the treatment equipment, equipment specifications, operating instructions, and parameters of normal operation, and information detailing the intended use and typical site for which the equipment is designed;

(ii) complete documentation that the alternate treatment technology, equipment, or process meets microbial inactivation criteria for all required representative microorganisms for all department-specified challenge waste load compositions, including a description of the test methods used, and, upon request, the original data from test procedures conducted by the manufacturer;

(iii) documentation on available parametric controls, and, where technically feasible, evidence that demonstrates the efficacy relationship between biological indicator data and data derived from real-time parametric monitoring equipment;

(iv) details relating to waste residues including their potential hazards/toxicities and their specific mode of disposal or recycling;

(v) documentation providing occupational health assurance, and the means of providing required training in equipment operations;

(vi) evidence of United States Environmental Protection Agency registration and Texas Department of Agriculture registration for those treatment processes that employ a chemical agent to inactivate microorganisms, or evidence of approval of the treatment process by a state other than Texas;

(vii) documentation that user verification testing protocols are workable and valid; and

(viii) documentation of approval of the alternate treatment process or technology in other state(s) utilizing performance standard review, if applicable.

(B) Documentation must be submitted to the department on forms provided by the department.

(3) Alternate treatment technology approval conditions.

(A) The alternate treatment technology approval is contingent upon the following conditions:

(i) Alternate treatment technology approval is granted only for the conditions specified in the manufacturer's instructions, equipment specifications, and operating procedures and conditions, including but not limited to:

(I) treatment time(s);

(II) temperature(s);

(III) pressures;

(IV) chemical concentration(s);

(V) irradiation dose(s);

(VI) feed rate(s); and

(VII) waste load composition(s).

(ii) Any significant revision on the part of the manufacturer to either the operating conditions of the equipment's existing process or technology, or the fundamental principles of the process itself, i.e., the equipment now utilizes a different technology in part or altogether, will require re-application for approval to the department.

(B) Prior approval granted by a state other than Texas that utilizes a performance standards approach to review alternate treatment technologies shall be considered as a basis for approval by the department if the department is provided with a valid and current approval, license, or permit issued by such state and substantial evidence to indicate that the performance standards upon which the approval, license, or permit was issued are equal to or more stringent than the performance standards included in this section.

(C) Facilities are not obligated to petition the department for approval for previously approved waste treatment technology they have currently on site, but the following items will apply should current equipment be replaced, regardless of reason:

(i) if the new equipment reflects a previously approved technology and is operated in accordance with §1.133(b) of this title, then purchase and installation can proceed without further action on the part of the department or the purchaser; or

(ii) if the new equipment represents an alternate treatment technology subject to prior approval by the department, based on performance standards as outlined in this section, then it is the purchaser's responsibility to ensure that the manufacturer has obtained such approval prior to purchase.

(4) Fees and annual listing.

(A) Initial application fee.

(i) The department shall charge an initial application fee for the evaluation of an alternate treatment technology pursuant to this section in the amount of \$4,000.

(ii) The initial application fee must be paid in full before the department undertakes its evaluation of the manufacturer's alternate treatment technology.

(B) Annual listing.

(i) Alternate treatment technologies must be listed at the time of the manufacturer's first sale of the product in Texas and prior to the product's purchase by a health care-related facility or any other person.

(ii) Failure by the manufacturer to maintain the listing after purchase does not preclude use of the alternate treatment technology, its transfer or re-sale, so long as compliance with §1.136(c) of this title (relating to Approved Methods of Treatment and Disposition) is achieved.

(iii) The department shall maintain a list of those approved alternate treatment technologies, including manufacturer, product name, model number, or other appropriate identifying information. The list shall be made available and distributed upon request by contacting the department.

§1.136. Approved Methods of Treatment and Disposition.

(a) Introduction. The following treatment and disposition methods for special waste from health care-related facilities are approved by the department for the waste specified. Where a special waste from a health care-related facility is also subject to the sections in Chapter 289 of this title (relating to Radiation Control), the sections in Chapter 289 shall prevail over the sections in this subchapter. Disposal of special waste from health care-related facilities in sanitary landfills or otherwise is under the jurisdiction of the Texas Commission on Environmental Quality and is governed by its rules found in 30 TAC Chapter 326 (relating to Medical Waste Management) and Chapter 330 (relating to Municipal Solid Waste).

(1) Animal waste. Animal waste shall be subjected to one of the following methods of treatment and disposal.

(A) Carcasses of animals intentionally exposed to pathogens shall be subjected to one of the following methods of treatment and disposal:

(i) steam disinfection followed by deposition in a sanitary landfill;

(ii) incineration followed by deposition of the residue in a sanitary landfill;

(iii) carcasses of animals intentionally exposed to pathogens which are not contagious may be buried on site under the supervision of a veterinarian licensed to practice veterinary medicine in the State of Texas;

(iv) carcasses of animals intentionally exposed to pathogens which are not contagious may be sent to a rendering plant;

(v) moist heat disinfection followed by deposition in a sanitary landfill;

(vi) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(vii) an approved alternate treatment process followed by deposition in a sanitary landfill.

(B) Body parts of animals intentionally exposed to pathogens shall be subjected to one of the following methods of treatment and disposal:

(i) steam disinfection followed by deposition in a sanitary landfill;

(ii) steam disinfection followed by grinding and discharging into a sanitary sewer system;

(iii) incineration followed by deposition of the residue in a sanitary landfill;

(iv) body parts of animals intentionally exposed to pathogens which are not contagious may be buried on site under the supervision of a veterinarian licensed to practice veterinary medicine in the State of Texas;

(v) moist heat disinfection followed by deposition in a sanitary landfill;

(vi) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(vii) an approved alternate treatment process followed by deposition in a sanitary landfill.

(C) Bulk whole blood, serum, plasma, and/or other blood components from animals intentionally exposed to pathogens shall be subjected to one of the following methods of treatment and disposal:

- (i) steam disinfection followed by deposition in a sanitary landfill;
- (ii) steam disinfection followed by grinding and discharging into a sanitary sewer system;
- (iii) incineration followed by deposition of the residue in a sanitary landfill;
- (iv) thermal inactivation followed by deposition in a sanitary landfill;
- (v) thermal inactivation followed by grinding and discharging into a sanitary sewer system;
- (vi) chemical disinfection followed by deposition in a sanitary landfill;
- (vii) chemical disinfection followed by grinding and discharging into a sanitary sewer system;

(viii) bulk blood, serum, plasma, and/or other blood components of animals intentionally exposed to pathogens which are not contagious may be buried on site under the supervision of a veterinarian licensed to practice veterinary medicine in the State of Texas;

- (ix) moist heat disinfection followed by deposition in a sanitary landfill;
- (x) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or
- (xi) an approved alternate treatment process followed by deposition in a sanitary landfill.

(D) Bedding of animals intentionally exposed to pathogens shall be subjected to one of the following methods of treatment and disposal:

- (i) steam disinfection followed by deposition in a sanitary landfill;
- (ii) incineration followed by deposition of the residue in a sanitary landfill;
- (iii) bedding of animals intentionally exposed to pathogens which are not contagious may be buried on site under the supervision of a veterinarian licensed to practice veterinary medicine in the State of Texas;

- (iv) moist heat disinfection followed by deposition in a sanitary landfill;
- (v) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or
- (vi) an approved alternate treatment process followed by deposition in a sanitary landfill.

(2) Bulk human blood, bulk human blood products, and bulk human body fluids. Bulk human blood, blood products, and body fluids shall be subjected to one of the following methods of treatment and disposal:

- (A) discharging into a sanitary sewer system;
- (B) steam disinfection followed by deposition in a sanitary landfill;
- (C) incineration followed by deposition of the residue in a sanitary landfill;
- (D) chemical disinfection followed by deposition in a sanitary landfill;
- (E) chemical disinfection followed by grinding and flushing into a sanitary sewer system;
- (F) thermal inactivation, followed by deposition in a sanitary landfill;
- (G) thermal inactivation, followed by grinding and discharging into a sanitary sewer system;
- (H) moist heat disinfection followed by deposition in a sanitary landfill;
- (I) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or
- (J) an approved alternate treatment process followed by deposition in a sanitary landfill.

(3) Microbiological waste. Microbiological waste shall be subjected to one of the following methods of treatment and disposal.

(A) Discarded cultures and stocks of infectious agents and associated biologicals shall be subjected to one of the following methods of treatment and disposal:

- (i) steam disinfection followed by deposition in a sanitary landfill;
- (ii) incineration followed by deposition of the residue in a sanitary landfill;
- (iii) thermal inactivation followed by deposition in a sanitary landfill;
- (iv) chemical disinfection followed by deposition in a sanitary landfill;
- (v) moist heat disinfection followed by deposition in a sanitary landfill;
- (vi) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or
- (vii) an approved alternate treatment process followed by deposition in a sanitary landfill.

(B) Discarded cultures of specimens from medical, pathological, pharmaceutical, research, clinical, commercial, industrial and veterinary laboratories shall be subjected to one of the following methods of treatment and disposal:

- (i) steam disinfection followed by deposition in a sanitary landfill;

- (ii) incineration followed by deposition of the residue in a sanitary landfill;
- (iii) thermal inactivation followed by deposition in a sanitary landfill;
- (iv) chemical disinfection followed by deposition in a sanitary landfill;
- (v) moist heat disinfection followed by deposition in a sanitary landfill;
- (vi) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or
- (vii) an approved alternate treatment process followed by deposition in a sanitary landfill.

(C) Discarded live and attenuated vaccines, but excluding the empty containers thereof, shall be subjected to one of the following methods of treatment and disposal:

- (i) steam disinfection followed by deposition in a sanitary landfill;
- (ii) incineration followed by deposition of the residue in a sanitary landfill;
- (iii) thermal inactivation followed by deposition in a sanitary landfill;
- (iv) chemical disinfection followed by deposition in a sanitary landfill;
- (v) moist heat disinfection followed by deposition in a sanitary landfill;
- (vi) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or
- (vii) an approved alternate treatment process followed by deposition in a sanitary landfill.

(D) Discarded disposable culture dishes shall be subjected to one of the following methods of treatment and disposal.

(i) All discarded, unused disposable culture dishes shall be disposed of in accordance with 30 TAC Chapters 326 and 330.

(ii) Discarded, used disposable culture dishes shall be subjected to the following methods of treatment and disposal:

- (I) steam disinfection followed by deposition in a sanitary landfill;
- (II) incineration followed by deposition of the residue in a sanitary landfill;
- (III) thermal inactivation followed by deposition in a sanitary landfill;
- (IV) chemical disinfection followed by deposition in a sanitary landfill;

- (V) moist heat disinfection followed by deposition in a sanitary landfill;
- (VI) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or
- (VII) an approved alternate treatment process followed by deposition in a sanitary landfill.

(E) Discarded disposable devices used to transfer, inoculate or mix cultures shall be subjected to one of the following methods of treatment and disposal:

- (i) steam disinfection followed by deposition in a sanitary landfill;
- (ii) incineration followed by deposition of the residue in a sanitary landfill;
- (iii) thermal inactivation followed by deposition in a sanitary landfill;
- (iv) chemical disinfection followed by deposition in a sanitary landfill;
- (v) moist heat disinfection followed by deposition in a sanitary landfill;
- (vi) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or
- (vii) an approved alternate treatment process followed by deposition in a sanitary landfill.

(4) Pathological waste. Pathological waste shall be subjected to one of the following methods of treatment and disposal.

(A) Human materials removed during surgery, labor and delivery, autopsy, embalming, or biopsy shall be subjected to one of the following methods of treatment and disposal:

- (i) body parts, other than fetal tissue:
 - (I) interment;
 - (II) incineration followed by deposition of the residue in a sanitary landfill;
 - (III) steam disinfection followed by interment;
 - (IV) moist heat disinfection, provided that the grinding/shredding renders the item as unrecognizable, followed by deposition in a sanitary landfill;
 - (V) chlorine disinfection/maceration, provided that the grinding/shredding renders the item as unrecognizable, followed by deposition in a sanitary landfill; or
 - (VI) an approved alternate treatment process, provided that the process renders the item as unrecognizable, followed by deposition in a sanitary landfill;

(ii) tissues, other than fetal tissue:

(I) incineration followed by deposition of the residue in a sanitary landfill;

(II) grinding and discharging to a sanitary sewer system;

(III) interment;

(IV) steam disinfection followed by interment;

(V) moist heat disinfection followed by deposition in a sanitary landfill;

(VI) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(VII) an approved alternate treatment process, provided that the process renders the item as unrecognizable, followed by deposition in a sanitary landfill;

(iii) organs, other than fetal tissue:

(I) incineration followed by deposition of the residue in a sanitary landfill;

(II) grinding and discharging to a sanitary sewer system;

(III) interment;

(IV) steam disinfection followed by interment;

(V) moist heat disinfection followed by deposition in a sanitary landfill;

(VI) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(VII) an approved alternate treatment process, provided that the process renders the item as unrecognizable, followed by deposition in a sanitary landfill;

(iv) bulk human blood and bulk human body fluids removed during surgery, labor and delivery, autopsy, embalming, or biopsy:

(I) discharging into a sanitary sewer system;

(II) steam disinfection followed by deposition in a sanitary landfill;

(III) incineration followed by deposition of the residue in a sanitary landfill;

(IV) thermal inactivation followed by deposition in a sanitary landfill;

(V) thermal inactivation followed by grinding and discharging into a sanitary sewer system;

(VI) chemical disinfection followed by deposition in a sanitary landfill;

(VII) chemical disinfection followed by grinding and discharging into a sanitary sewer system;

(VIII) moist heat disinfection followed by deposition in a sanitary landfill;

(IX) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(X) an approved alternate treatment process, provided that the process renders the item as unrecognizable, followed by deposition in a sanitary landfill;

(v) fetal tissue, regardless of the period of gestation, except as provided by §1.133 of this title (relating to Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of State Health Services):

(I) interment;

(II) incineration followed by interment; or

(III) steam disinfection followed by interment.

(B) The products of spontaneous or induced human abortion shall be subjected to one of the following methods of treatment and disposal:

(i) fetal tissue, regardless of the period of gestation, except as provided by §1.133 of this title (relating to Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of State Health Services):

(I) incineration followed by interment;

(II) steam disinfection followed by interment; or

(III) interment;

(ii) blood and body fluids:

(I) discharging into a sanitary sewer system;

(II) steam disinfection followed by deposition in a sanitary landfill;

(III) incineration followed by deposition of the residue in a sanitary landfill;

- (IV) thermal inactivation followed by deposition in a sanitary landfill;
 - (V) thermal inactivation followed by grinding and discharging into a sanitary sewer system;
 - (VI) chemical disinfection followed by deposition in a sanitary landfill;
 - (VII) chemical disinfection followed by grinding and discharging into a sanitary sewer system;
 - (VIII) moist heat disinfection followed by deposition in a sanitary landfill;
 - (IX) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or
 - (X) an approved alternate treatment process, provided that the process renders the item as unrecognizable, followed by deposition in a sanitary landfill;
- (iii) any other tissues, including placenta, umbilical cord and gestational sac:
- (I) grinding and discharging to a sanitary sewer system;
 - (II) incineration followed by deposition of the residue in a sanitary landfill;
 - (III) steam disinfection followed by interment;
 - (IV) interment;
 - (V) moist heat disinfection followed by deposition in a sanitary landfill;
 - (VI) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or
 - (VII) an approved alternate treatment process, provided that the process renders the item as unrecognizable, followed by deposition in a sanitary landfill.

(C) Discarded laboratory specimens of blood and/or tissues shall be subjected to one of the following methods of treatment and disposal:

- (i) grinding and discharging into a sanitary sewer system;
- (ii) steam disinfection followed by deposition in a sanitary landfill;
- (iii) steam disinfection followed by grinding and discharging into a sanitary sewer system;
- (iv) incineration followed by deposition of the residue in a sanitary landfill;
- (v) moist heat disinfection followed by deposition in a sanitary landfill;

(vi) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(vii) an approved alternate treatment process, provided that the process renders the item as unrecognizable, followed by deposition in a sanitary landfill.

(D) Anatomical remains shall be disposed of in a manner specified by §479.4 of this title (relating to Final Disposition of the Body and Disposition of Remains).

(5) Sharps.

(A) All discarded unused sharps shall be disposed of in accordance with 30 TAC Chapters 326 and 330.

(B) Contaminated sharps shall be subjected to one of the following methods of treatment and disposal.

(i) Hypodermic needles, and hypodermic syringes with attached needles, shall be subjected to one of the following methods of treatment and disposal:

(I) chemical disinfection, and if the item can cause puncture wounds, placement in a puncture-resistant, leak-proof container followed by deposition in a sanitary landfill;

(II) steam disinfection, and if the item can cause puncture wounds, placement in a puncture-resistant container followed by deposition in a sanitary landfill;

(III) incineration, and if the item can cause puncture wounds, placement in a puncture-resistant container followed by deposition in a sanitary landfill;

(IV) encapsulation in a matrix which will solidify and significantly reduce the possibility of puncture wounds followed by deposition in a sanitary landfill;

(V) moist heat disinfection followed by deposition in a sanitary landfill;

(VI) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(VII) an approved alternate treatment process, provided that the process renders the item as unrecognizable and can no longer cause puncture wounds, followed by deposition in a sanitary landfill.

(ii) Razor blades, disposable razors, and disposable scissors used in surgery, labor and delivery, or other medical procedures; and scalpel blades shall be subjected to one of the following methods of treatment and disposal:

(I) chemical disinfection, and if the item can cause puncture wounds, placement in a puncture-resistant, leak-proof container followed by deposition in a sanitary landfill;

(II) steam disinfection, and if the item can cause puncture wounds, placement in a puncture-resistant container followed by deposition in a sanitary landfill;

(III) incineration, and if item can cause puncture wounds, placement in a puncture-resistant container followed by deposition in a sanitary landfill;

(IV) encapsulation in a matrix which will solidify and significantly reduce the possibility of puncture wounds followed by deposition in a sanitary landfill;

(V) moist heat disinfection followed by deposition in a sanitary landfill;

(VI) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(VII) an approved alternate treatment process, provided that the process renders the item as unrecognizable and can no longer cause puncture wounds, followed by deposition in a sanitary landfill.

(iii) Intravenous stylets and rigid introducers (e.g., J wires) shall be subjected to one of the following methods of treatment and disposal:

(I) chemical disinfection, and if the item can cause puncture wounds, placement in a puncture-resistant, leak-proof container followed by deposition in a sanitary landfill;

(II) steam disinfection, and if the item can cause puncture wounds, placement in a puncture-resistant, leak-proof container followed by deposition in a sanitary landfill;

(III) incineration, and if the item can cause puncture wounds, placement in a puncture-resistant, leak-proof container followed by deposition in a sanitary landfill;

(IV) encapsulation in a matrix which will solidify and significantly reduce the possibility of puncture wounds, followed by deposition in a sanitary landfill;

(V) moist heat disinfection followed by deposition in a sanitary landfill;

(VI) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(VII) an approved alternate treatment process, provided that the process renders the item as unrecognizable and can no longer cause puncture wounds, followed by deposition in a sanitary landfill.

(iv) Glass pasteur pipettes, glass pipettes, specimen tubes, blood culture bottles, and microscope slides, and broken glass from laboratories shall be subjected to one of the following methods of treatment and disposal:

(I) chemical disinfection, and if the item can cause puncture wounds, placement in a puncture-resistant, leak-proof container followed by deposition in a sanitary landfill;

(II) steam disinfection, and if the item can cause puncture wounds, placement in a puncture-resistant container followed by deposition in a sanitary landfill;

(III) incineration, and if the item can cause puncture wounds, placement in a puncture-resistant container followed by deposition in a sanitary landfill;

(IV) encapsulation in a matrix which will solidify and significantly reduce the possibility of puncture wounds followed by deposition in a sanitary landfill;

(V) moist heat disinfection followed by deposition in a sanitary landfill;

(VI) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(VII) an approved alternate treatment process, provided that the process renders the item as unrecognizable and can no longer cause puncture wounds, followed by deposition in a sanitary landfill.

(v) Tattoo needles, acupuncture needles, and electrolysis needles shall be subjected to one of the following methods of treatment and disposal:

(I) chemical disinfection, and if the item can cause puncture wounds, placement in a puncture-resistant, leak-proof container followed by deposition in a sanitary landfill;

(II) steam disinfection, and if the item can cause puncture wounds, placement in a puncture-resistant, leak-proof container followed by deposition in a sanitary landfill;

(III) incineration, and if the item can cause puncture wounds, placement in a puncture-resistant, leak-proof container followed by deposition in a sanitary landfill;

(IV) encapsulation in a matrix which will solidify and significantly reduce the possibility of puncture wounds, followed by deposition in a sanitary landfill;

(V) moist heat disinfection followed by deposition in a sanitary landfill;

(VI) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(VII) an approved alternate treatment process, provided that the process renders the item as unrecognizable and can no longer cause puncture wounds, followed by deposition in a sanitary landfill.

(b) Records. The facility treating the wastes shall maintain records to document the treatment of the special waste from health care-related facilities processed at the facility as to method and conditions of treatment in accordance with 30 TAC Chapter 326.

(c) Facility responsibility. The facility treating the wastes shall be responsible for establishing the conditions necessary for operation of each method used at the facility to insure the reduction of microbial activity of any waste treated according to the manufacturer's specifications and according to any approval granted by the department.

§1.137. Enforcement.

The appropriate regulatory programs of the department shall incorporate the definition and methodology contained in these provisions into their respective general program rules and shall formulate and present for the Executive Commissioner's consideration such additional rules as are necessary for the internal collection, storage, handling, movement, and treatment of special waste from health care-related facilities generated within or by the following facilities or activities:

- (1) abortion clinics;
- (2) ambulatory surgical centers;
- (3) birthing centers;
- (4) emergency medical service providers;
- (5) end stage renal disease facilities;
- (6) freestanding emergency medical care facilities;
- (7) hospitals;
- (8) special residential care facilities; and
- (9) tattoo studios.

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