



Physicians Caring for Texans



TEXAS HOSPITAL ASSOCIATION

Aug. 1, 2016

Allison Hughes  
Health Facilities Rules Coordinator  
Health Care Quality Section  
Division of Regulatory Services  
Department of State Health Services  
Mail Code 2822  
PO Box 149347  
Austin, TX 78714-9347

[emailed to allison.hughes@dshs.state.tx.us](mailto:allison.hughes@dshs.state.tx.us)

RE: Proposed rules, 25 TAC §§ 1.132-1.137, regarding definition, treatment, and disposition of special waste from health care-related facilities, as published in the *Texas Register* on July 1, 2016 at 41 *TexReg* 4772-4778

Dear Ms. Hughes:

On behalf of the Texas Medical Association (TMA) Committee on Reproductive, Women's, and Perinatal Health (committee) and the Texas Hospital Association, we would like to share our comments regarding the Department of State Health Services' (DSHS') proposed changes to the rules concerning the definition, treatment, and disposition of special waste from health care-related facilities.

The TMA committee is comprised of a diverse membership serving patients with a variety of viewpoints relating to issues of life and death and supports the autonomy and dignity of the patient in the very personal decision-making processes related to these issues. The THA represents 450 hospitals and health systems across the state, each with policies and procedures in place to give parents and families compassionate choices to honor the loss of a pregnancy. Our analysis of the proposed special waste rules, and these comments, focus on questions surrounding the practical implications of the proposed rules for patients, hospitals and physicians. The following questions are based on the rules as proposed.

**1. Is "incineration followed by interment" a viable alternative for disposal of fetal tissue?**

The proposed rules allow for disposal of fetal tissue by incineration followed by interment. It is common practice for a health care facility to dispose of human tissue by incineration as a result of a contract with a third party vendor. Will a third party vendor incineration facility be able to comply with the requirement that the tissue be subsequently interred? Will the third party vendor incineration facility be able to functionally isolate incinerated fetal tissue for the purpose of interment? If possible, how will incinerated tissue be transported for burial?

**2. Will the disposition of fetal tissue require a death certificate and subsequent care by a funeral director in each case?**

The proposed rules allow for fetal tissue to be cremated or interred. "Interment" is defined in the current special waste rules as "[t]he disposition of pathological waste by cremation, entombment, burial, or placement in a niche." 25 TEX. ADMIN. CODE § 1.132(31). This language is retained in the proposed special

waste rules. Prop. 25 TEX. ADMIN. CODE § 1.132(33). Incineration followed by disposal in a sanitary landfill and other methods of disposition currently permitted for disposing of fetal tissue would no longer be options under the proposed special waste rules. DSHS' rules governing the custody of a dead body or fetus require "the funeral director, or person acting as such, who assumes custody of a dead body or fetus [to] obtain an electronically filed report of death ... before transporting the body." 25 TEX. ADMIN. CODE § 181.2(a). Does this mean that a death certificate will be required for every fetal tissue disposition? Would the involvement of a funeral director be required under the proposed rules in every fetal tissue case?

**3. If a death certificate is required to be issued, under what circumstances will the report be publicly available?**

The Texas Public Information Act protects death records from being publically available until "the 25th anniversary of the date of the death as shown on the record." TEX. GOVT. CODE §552.115. Would this protection also apply to fetal death records issued for fetal tissue? Further, the Public Information Act states that "if the decedent is unidentified," the death record is public information after only one year. Is there any chance that fetal tissue could be unidentified and thus lose the longer 25 year protection?

**4. How should the special waste rules address the disposition of fetal tissue resulting from spontaneous miscarriages, ectopic pregnancies, or molar pregnancies?**

The proposed rules define "fetal tissue" as "[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" (emphasis added). Prop. 25 TEX. ADMIN. CODE § 1.132(28). This proposed definition would trigger the special waste rules even in cases such as ectopic pregnancies, where there is no hope of fetal viability, and the fetal tissue is removed to save the mother's life. Requiring the physician to have a discussion with the woman undergoing such a procedure about whether to inter or cremate the fetal tissue would be difficult. 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. Should DSHS consider exceptions from the proposed rules' applicability for cases involving spontaneous miscarriages, ectopic pregnancies or molar pregnancies, or for a fetus under 350 grams?

**5. How would cases of spontaneous miscarriage be addressed when this occurs outside the physician's office or other health care setting?**

As the term implies, a spontaneous abortion (miscarriage) can occur in a nonclinical setting, away from a physician's office, hospital or other health care setting. Would the rules, if adopted as proposed, require a woman who experiences a spontaneous miscarriage to carry the fetal tissue to a physician's office or other health care setting for assessment? If so, is there a time period within which the woman is expected to carry the fetal tissue to that setting? What is that period?

**6. Who would be responsible for paying for the costs of cremation and/or interment of fetal tissue?**

The proposed rules will require that all fetal tissue be either cremated or interred, but the proposed rules are silent on the responsibility for the payment of these services. Average estimates range from \$1,500 to \$4,000 for cremation, and from \$7,000 to \$10,000 for a traditional funeral (including services, burial in a cemetery, and placement of a headstone). Would this responsibility rest with the parent or family, the physician, a health care facility, the funeral home or facility performing the cremation or burial, or a third-party payer? Has a cost estimate been performed? Does DSHS plan to establish special governmental resources or an exceptional item request to cover the added process and procedure costs?

**7. Has the department performed an analysis of the impact of this rule from a compliance and cost standpoint?**

The loss of a pregnancy is a traumatic event in the life of a parent. According to the March of Dimes, ten to fifteen percent of women who know they are pregnant have a resulting spontaneous miscarriage, with most occurring in the first trimester. Has the agency studied the impact of the proposed rules on the processes of

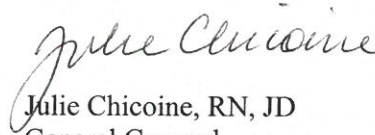
health care facilities and providers, including questions related to tissue storage requirements prior to cremation or interment, transportation costs and requirements, and who will be responsible for the remains after cremation? Has the agency examined the feasibility of compliance at rural health care facilities where there are limitations in the availability of the proposed tissue disposal alternatives? Has the agency examined the feasibility of compliance at health care facilities with a high percentage of obstetrical services?

We appreciate the opportunity to ask these questions and look forward to DSHS' response. If you have questions, or need clarification, please contact Margaret Mendez in TMA's Public Health Department at [margaret.mendez@texmed.org](mailto:margaret.mendez@texmed.org), or Matt Wall in TMA's Office of General Counsel at [matt.wall@texmed.org](mailto:matt.wall@texmed.org), or Jennifer Banda, [jbanda@tha.org](mailto:jbanda@tha.org) or Julie Chicoine [jchicoine@tha.org](mailto:jchicoine@tha.org) at the Texas Hospital Association.

Sincerely,



Shanna M. Combs, MD, FACOG  
Chair, Committee on Reproductive,  
Women's, and Perinatal Health  
Texas Medical Association



Julie Chicoine, RN, JD  
General Counsel  
Texas Hospital Association