

July 2, 2018

Via electronic submission to:
hhsrulescoordinationoffice@hhsc.state.tx.us

PUBLIC COMMENT LETTER

Community Health Improvement Division
Texas Department of State Health Services
P.O. Box 149347
Mail Code 1920
Austin, TX
78714-9347

Re: Comments on Stem Cell Treatment Proposed Rules

On behalf of our more than 465 member hospitals and health systems, including rural, urban, children's, teaching and specialty hospitals, the Texas Hospital Association appreciates the opportunity to provide comments on the above-referenced proposed rules concerning investigational stem cell treatments. THA is pleased to offer the following comments:

THA is grateful to have participated in several stakeholder meetings at the Texas Medical Board and, on April 9th, at the Texas Department of State Health Services. Section 1003.052 of the Health & Safety Code requires the Executive Commissioner of the Texas Health and Human Services Commission to "adopt rules designating the medical conditions that constitute a severe chronic disease." At stakeholder meetings, THA has recommended that THHSC adopt a flexible definition of the medical conditions that qualify as severe chronic diseases, rather than an exhaustive list of such conditions, to afford physicians the opportunity to make informed medical decisions for their patients. THA is pleased that THHSC has proposed rules in 25 Tex. Admin. Code §§ 1.461(c)(1)-1.461(c)(2) that allow the patient's physician to determine whether a patient's condition meets the criteria of a severe chronic disease or terminal illness.

THA is also pleased that THHSC has proposed clear criteria for informed consent based on existing federal law set out in 45 C.F.R. 46.116. Using existing rules for informed consent will ensure that patients understand their rights and reduce the administrative burden placed on providers.

Thank you for your consideration of these comments. Should you have any questions, please do not hesitate to contact me at cduncan@tha.org or 512/465-1539.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "C. Duncan", with a long horizontal flourish extending to the right.

Cameron Duncan
Assistant General Counsel
Texas Hospital Association