



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

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INTERIM COMMISSIONER

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December 10, 2015

Dear Hospital Administrator:

RE: New Law Regarding the use of Adult Stem Cells

The purpose of this correspondence is to provide notification that a new law, House Bill 177, went into effect on September 1, 2015. The new law was passed during the 84th Regular Session of the Texas Legislature. Although the law is already in effect and you are expected to be in compliance, the department will not begin enforcing this new law until January 1, 2016. In addition, this law applies to the Texas Health and Safety Code Chapter 1003. A description of the requirements is listed below:

1003.002

The Governing Body of the Hospital shall adopt, implement and enforce a policy regarding the use of adult stem cells in the facility. The policy shall ensure that all physicians involved in the use of adult stem cells are approved for such use by the Hospital Medical Executive Committee. The staff engaged in the use of adult stem cells in the provision of health care shall comply with the following:

- (1) must use adult stem cells that are properly manufactured and stored and;
- (2) may only use adult stem cells in a clinical trial approved by the United States Food and Drug Administration

1003.003

The Governing Body of the Hospital shall adopt, implement and enforce a policy regarding the use of adult stem cells in the facility. The policy shall ensure that all physicians involved in the use of adult stem cells are approved for such use by the Hospital Medical Executive Committee. The staff engaged in the use of adult stem cells in the provision of health care shall comply with the following:

- (1) A physician providing services at the hospital determines that the use of adult stem cells in the procedure is appropriate;
- (2) The patient consents in writing to the use;
- (3) The requirements for stem cell use under Section 1003.002 are met;
- (4) The manufacturing processes for the adult stem cells satisfy current good manufacturing practices adopted by the United States Food and Drug Administration;
- (5) Appropriate state and federal guidelines on the use of adult stem cells are followed.

If you have further questions regarding this new law, please contact Patrick Waldron, Branch Manager, M.Ed., L.M.S.W., Patient Quality Care Unit at: (512) 834-6700, extension 2625.

Sincerely,

Renee Clack, L.N. F.A.
Director, Health Care Quality Section
Division for Regulatory Services