

March 25, 2009

**H 801. TISSUE BANK ACCREDITATION.** Filed 3/25/09. *TO REQUIRE CERTAIN TISSUE BANKS OPERATING IN NORTH CAROLINA TO BE ACCREDITED BY THE AMERICAN ASSOCIATION OF TISSUE BANKS OR THE EYE BANK ASSOCIATION OF AMERICA.*

Adds new Article 8A to Chapter 131E of the General Statutes. Adds new GS 131E-171 to require registration with the Food and Drug Administration and accreditation by either the American Association of Tissue Banks (AATB) or the Eye Bank Association of America (EBAA) of any tissue bank that recovers human tissue at a location outside of a hospital, when such tissue is intended for human transplantation. Registration is not required if the establishment is an organ procurement organization that has been designated by the federal Secretary for Health and Human Services and is registered with the Food and Drug Administration as a tissue bank. Defines human tissue.

Adds new GS 131E-172 to authorize the Department of Health and Human Services to inspect the records of any tissue bank engaged in the recovery of human tissue for human transplantation to ensure compliance with the registration and accreditation requirements and to maintain an action in the name of the State for injunctive relief or other process against any tissue bank to restrain or prevent recovery of human tissue for human transplantation without the required registration or accreditation. Authorizes the Department to institute an action against any person who hinders the performance of its duties in the superior court of the county in which the hindrance occurs. Directs that any person who knowingly and willfully engages in the recovery of human tissue for human transplantation without registration with the Food and Drug Administration or accreditation by the AATB or EBAA as required by Article 8A is guilty of a Class 3 misdemeanor and, upon conviction, is liable only for a fine of not more than \$500.00 for the first offense and not more than \$500.00 for each subsequent offense. Effective October 1, 2009, and applies to tissue banks engaged in the recovery of human tissue or cells for human transplantation on or after that date.

**Intro. by Rep. Allen.**

GS 131E