

GENERAL ASSEMBLY OF NORTH CAROLINA



Session 2007

Legislative Fiscal Note

BILL NUMBER: House Bill 116 (First Edition)

SHORT TITLE: Tissue Bank Accreditation.

SPONSOR(S): Representatives Wright, England, and Allen

FISCAL IMPACT					
	Yes (X)	No ()	No Estimate Available ()		
	<u>FY 2007-08</u>	<u>FY 2008-09</u>	<u>FY 2009-10</u>	<u>FY 2010-11</u>	<u>FY 2011-12</u>
EXPENDITURES					
Judicial Dept.	No significant impact anticipated				
DHHS	\$ 57,264	\$ 72,320	\$ 76,587	\$ 81,106	\$ 85,729
POSITIONS (cumulative):	1	1	1	1	1
PRINCIPAL DEPARTMENT(S) & PROGRAM(S) AFFECTED: Department of Health and Human Services – Division of Facility Services and the Judicial Department					
EFFECTIVE DATE: October 1, 2007					

BILL SUMMARY:

The proposed legislation enacts a new Article 8 of GS Chapter 131E to require tissue banks, other than those that are federally designated organ procurement organizations, that recover tissue in locations other than a hospital to be registered with the Food and Drug Administration and accredited by the American Association of Tissue Banks, or accredited by the Eye Bank Association of America. The legislation also allows the Department of Health and Human Services to obtain an injunction against a tissue bank operating without the required registration or accreditation. The legislation makes recovering human tissue without registration or accreditation a Class 3 misdemeanor, with a fine of not more than \$500 for each offense. Effective October 1, 2007.

ASSUMPTIONS AND METHODOLOGY:

Department of Health and Human Services

In order to implement the proposed legislation, the Division of Facility Services would need staff to track and inspect tissue banks located in North Carolina. Preliminary research indicates that there are potentially twenty-nine tissue banks that would be affected by the proposed legislation.

1. This analysis assumes that one full-time equivalent registered nurse position (Facility Survey Consultant I - Pay Grade 73) would be required to track and inspect tissue banks on an annual basis. If the new position's initial total work capacity is not utilized by the tissue bank inspections, this analysis assumes that the position would also inspect and regulate other health care facilities.
2. The total annual salary and benefits for a Facility Survey Consultant I is \$68,485. The one-time cost to equip the position is \$5,900.
3. Since the effective date for the proposed legislation is October 1, 2007, this analysis assumes that the new position would be needed for nine months during FY 2007-08 and would be a twelve month position in FY 2008-09 through FY 2011-12.
4. This analysis assumes the following salary and wage inflationary increases in FY 2008-09 through FY 2011-12:

Fiscal Year	Inflationary Increase
2008-09	5.6%
2009-10	5.9%
2010-11	5.9%
2011-12	5.7%

Judicial Department

Proposed G.S. 131E-172 creates a new Class 3 misdemeanor offense, punishable by fine of not more than \$500, for a person to knowingly/willfully recover human tissue for transplantation without having first registered with the FDA or having been accredited by the AATB or EBAA. It also authorizes DHHS to petition for injunctive relief, or pursue any other remedy, to restrain/prevent the recovery of human tissue by a non-compliant tissue bank. DHHS may also petition for injunctive relief against any person who hinders the "proper performance" of its duties, as provided by the Article.

It is assumed that the 29 affected tissue banks would comply with the proposed registration and accreditation requirements. However, if charges for the new criminal offense or petitions for injunctive relief were to occur, the Courts could experience a slight increase in workload, court-time requirements, and associated costs. Because this offense is punishable only by fine, there is

no assumed impact for local jails. Any fines imposed would be remitted to the Civil Penalty and Forfeiture fund (G.S. 115C-457.1).

SOURCES OF DATA: Department of Health and Human Services and the Judicial Department

TECHNICAL CONSIDERATIONS: None

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DATE: April 27, 2007



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