

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 497 Medical Negligence
SPONSOR(S): Cretul and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1944

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) <u>Judiciary Committee</u>	_____	<u>Hogge</u>	<u>Hogge</u>
2) <u>Health Care Regulation Committee</u>	_____	_____	_____
3) <u>Justice Council</u>	_____	_____	_____
4) _____	_____	_____	_____
5) _____	_____	_____	_____

SUMMARY ANALYSIS

The bill would treat the “collection, screening, testing, and processing of blood obtained (by blood banks) from donors for transfusion purposes” as a “professional medical service integral to the care and treatment of patients” and any negligence claim resulting from these activities would be handled as a medical negligence claim. As a result, under current law, presuit notice requirements would apply and damages would be subject to statutory caps.

Blood banks currently are regulated under both federal and, in Florida, state law. In 2003, the Legislature expressly included blood banks as a “health care provider” without qualification as to services performed under the medical negligence laws. However, for purposes of the presuit notice requirements, a “claim for medical malpractice” is defined as a claim “arising out of the rendering of, or the failure to render, medical care or services.” In the context of the statute of limitations, in 1992, the Florida Supreme Court refused to apply the medical malpractice statute of limitations to an action against a blood bank, finding it was not a “health care provider” within the statute of limitations because the allegations of negligence did not arise out of “any medical, dental, or surgical diagnosis, treatment, or care.” Concurring in part, dissenting in part, Justice Grimes wrote that “...it would be anomalous to conclude that when the Legislature passed the predecessor to (the medical negligence standard of care) in 1977 it intended blood banks to be a health care provider subject to the medical malpractice standard of care and yet at the same time be subject to a different nonmedical malpractice statute of limitations because it was not a health care provider.”

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

This bill does not directly implicate the House Principles.

B. EFFECT OF PROPOSED CHANGES:

PROPOSED CHANGES

The bill would treat the “collection, screening, testing, and processing of blood obtained (by blood banks) from donors for transfusion purposes” as a “professional medical service integral to the care and treatment of patients.” As a result, any claim of negligence related to these activities would be considered a medical negligence claim, rather than a general negligence claim.

PRESENT SITUATION

Regulation of blood banks

Federal

The United States government regulates human blood both as a drug and a biologic. The Division of Biologic Standards of the National Institute of Health issued the first blood bank license in 1946.

The primary regulator of blood banks at the federal level is the Department of Health and Human Services (HHS) through the Food and Drug Administration (FDA) and two centers within the FDA—the Center for Biologics Evaluation and Research (CBER) and the Center for Devices and Radiologic Health (CDRH).

The CBER handles the policy side of the regulatory equation. It sets donor interview and testing policy—for example, what types of tests must be conducted (as opposed to how they are to be conducted) and what questions donors should be asked. The CDRH handles the more technical aspect of blood bank operations; that is, it regulates their clinical laboratory operations. It does so through the application of the standards contained in the Clinical Laboratory Improvement Act (CLIA).

To be FDA-licensed or registered, blood banks must comply with regulations of both the CBER and the CDRH, both as a blood bank and as to their clinical laboratory operations. Any blood bank intending to ship blood or blood products in interstate commerce must be licensed; any that do not ship blood or blood products across state lines must only register with the FDA. In Florida, at a minimum, an estimated 80 percent of all blood collected is collected at FDA-licensed facilities.

The FDA inspects both licensed and registered facilities, although most inspections for compliance with CLIA standards are conducted by the American Association of Blood Banks (AABB), a nongovernmental accreditation organization. Furthermore, both must comply with “CGMPs,” or “current good manufacturing practices.” Inspections focus on such practices as donor screening, blood-borne infectious disease testing, the donor deferral registry, product quarantine and error reporting. Another regulatory agency with some involvement in blood bank regulation is the Occupational Safety and Health Administration.

In certain instances, states impose their own regulations in addition to the federal regulations.

State

At the state level, blood banks are a subset of clinical laboratories regulated by the Agency for Health Care Administration (AHCA) under Chapter 483, F.S. This chapter supplements federal CLIA standards with additional state standards. Since the state has supplemented the CLIA standards, Florida has its own licensing process and operates an inspection program. As a practical matter, however, the AHCA limits its inspections to those facilities that are not AABB-accredited.

Medical negligence

“Medical negligence” is defined as medical malpractice whether grounded in tort or contract¹ and claims/actions for medical malpractice are variously defined in different contexts. For example:

- For purposes of the presuit notice requirements, a “claim for medical malpractice” is defined as a claim “arising out of the rendering of, or the failure to render, medical care or services.”²
- For purposes of the statute of limitations for medical malpractice actions, “an action for medical malpractice” is defined as a claim in tort or in contract for damages because of the death, injury, or monetary loss to any person arising out of “any medical, dental, or surgical diagnosis, treatment, or care by any provider of health care.”³

Medical negligence involves conduct by a health care provider that results in the injury or death of any person resulting from a breach of the prevailing professional standard of care of that health care provider.⁴ Under the medical negligence statute, the claimant must show that the health care provider breached the prevailing standard of care. Blood banks are expressly included within the definition of a “health care provider.”⁵

Medical malpractice actions are subject to a two year statute of limitations as opposed to a four year statute for negligence actions and other forms of professional negligence. However, in 1992, the Florida Supreme Court⁶ refused to apply the medical malpractice statute of limitations to an action against a blood bank, finding it was not a “health care provider” within the statute of limitations because the allegations of negligence did not arise out of “any medical, dental, or surgical diagnosis, treatment, or care,”⁷ the standard expressly adopted by the Legislature in the statute of limitations. Concurring in part, dissenting in part, Justice Grimes wrote that:

“...it would be anomalous to conclude that when the Legislature passed the predecessor to 766.102 in 1977 it intended blood banks to be a health care provider subject to the medical malpractice standard of care and yet at the same time be subject to a different *nonmedical malpractice* statute of limitations because it was not a health care provider.”⁸

¹Fla. Stat. 766.202(7) (2005).

²Fla. Stat. 766.106(1)(a) (2005).

³Fla. Stat. 95.11(4)(b) (2005).

⁴Fla. Stat. 766.102(1) (2005).

⁵Fla. Stat. 766.202(4) (2005). Blood banks have been included within the definition of “health care provider” for medical malpractice purposes since 1977. However, in 1986, the Legislature repealed the section [768.50(2)(b)] cross referenced as the source of the definition of the term “health care provider” for purposes of medical negligence. In 2003, the Legislature re-inserted a definition of “health care provider” in the medical negligence law. That definition included blood banks. See s. 68, Chapter 86-160, L.O.F.

⁶*Silva v. Southwest Florida Blood Bank, Inc.*, 601 So.2d 1184 (Fla. 1992). Concurring in part and dissenting in part, Justice Grimes separated the blood bank’s status as a “health care provider” from the issue of whether or not the medical malpractice statute of limitations applied to the action against the blood bank.

⁷The statute governing the limitation period for medical negligence defines these actions as tort or contract claim for damages because of death, injury, or financial loss to any person arising out of “any medical, dental, or surgical diagnosis, treatment, or care by any provider of health care.”

⁸See *supra* note 6, at 1190.

Damages⁹

Unlike in negligence actions generally, the amount of noneconomic damages¹⁰ in medical negligence actions are limited by law. Different caps apply in emergency care situations.¹¹

Presuit investigation and notice

The medical negligence law also requires the parties to conduct a presuit investigation¹² prior to filing notice of intent to initiate medical negligence litigation.¹³

Mediation and arbitration

The bill permits either or both parties to agree to submit the determination of damages to voluntary binding arbitration.¹⁴ Their decision to accept or reject voluntary binding arbitration has consequences for the amount of damages awardable. If the parties do not agree to voluntary binding arbitration, then they must attend mediation.¹⁵

C. SECTION DIRECTORY:

Section 1. Amends s. 766.102, F.S., to provide that claims against blood banks for performing certain activities constitutes a medical negligence action.

Section 2. Provides that this act shall take effect on July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

⁹Fla. Stat. 766.118 (2005). In limiting noneconomic damages, the medical negligence law distinguishes between two categories of defendants: "practitioners," such as physicians and "nonpractitioners" such as hospitals. In most medical negligence cases against practitioners, damages are capped at \$500,000 per practitioner per claimant and, against nonpractitioners, \$750,000 per claimant. If, in the case of death or entry into a permanent vegetative state (PVS), the trial court determines that these limits would present a "manifest injustice" and the patient suffered a catastrophic injury, then damages of up to twice these amounts may be awarded. In all instances, however, damages from all practitioner defendants in the aggregate may not exceed \$1 million and \$1.5 million from nonpractitioners. While the law defines the group of "practitioners," it does not define "nonpractitioners."

¹⁰For purposes of medical negligence actions, "noneconomic damages" are defined in s. 766.202(8), F.S., to mean "nonfinancial losses that would not have occurred but for the injury giving rise to the cause of action, including pain and suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of capacity for enjoyment of life, and other nonfinancial losses...." "Economic damages" are not similarly limited by law. As defined in s. 766.202(3), F.S., these are damages for "financial losses that would not have occurred but for the injury giving rise to the cause of action, including...past and future medical expenses and 80 percent of wage loss and loss of earning capacity"

¹¹There is a \$150,000 cap per claimant against practitioners providing emergency services with \$300,000 aggregate. There is a \$750,000 cap per claimant against non-practitioners providing emergency services with \$1,500,000 aggregate. There is no "piercing" of the emergency room cap.

¹²Fla. Stat. 766.203-766.206 (2005).

¹³Fla. Stat. 766.106 (2005).

¹⁴Fla. Stat. 766.207 (2005).

¹⁵Fla. Stat. 766.108 (2005).

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Indeterminate, but blood banks would presumably reduce their exposure to damage awards from negligence lawsuits.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

None.