STORAGE NAME: h0849.hcl
DATE: February 17, 2000

HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH CARE LICENSING & REGULATION
ANALYSIS

BILL #: HB 849

RELATING TO: Reprocessed Medical Devices

SPONSOR(S): Representative Argenio and others

TIED BILL(S):

ORIGINATING COMMITTEE(S)/COMMITTEE(S) OF REFERENCE:

(1) HEALTH CARE LICENSING & REGULATION
(2) GOVERNMENTAL RULES & REGULATION
(3) HEALTH & HUMAN SERVICES APPROPRIATIONS
(4)
(5)

I. SUMMARY:

This bill allows certain medical devices to be reprocessed even if the manufacturer of the device has labeled the device for single-use only. Reprocessing includes cleaning, inspecting, and sterilizing medical devices that have already been used once. According to the industry, the purpose of reprocessing is decrease costs to health care facilities and patients by allowing medical devices to be used more than one time rather than purchased new for every use. Only certain types of medical devices can be reprocessed. The United States Food and Drug Administration has jurisdiction to regulate reprocessors of medical devices.

Reprocessing is not prohibited under current law. However, there is a nationwide movement to prohibit reprocessing and to require health care facilities and patients to pay the full cost of purchasing a new medical device for each use. This bill affirmatively states that reprocessing is permitted in Florida, provided the reprocessor is registered with the United States Food and Drug Administration and is reprocessing in compliance with the requirements enforced by the United States Food and Drug Administration.

Because this bill simply codifies existing practices, there is no fiscal impact on the state. However, there may be a fiscal impact on hospitals, ambulatory surgical centers, and other health care facilities required to register with the United States Food and Drug Administration if medical devices are reprocessed.

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

1.	Less Government	Yes [x]	No []	N/A []
2.	Lower Taxes	Yes []	No []	N/A [x]
3.	Individual Freedom	Yes [x]	No []	N/A []
4.	Personal Responsibility	Yes []	No []	N/A [x]
5.	Family Empowerment	Yes []	No []	N/A [x]

For any principle that received a "no" above, please explain:

B. PRESENT SITUATION:

According to the United States Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, the practice of reusing medical devices labeled, or otherwise intended, for only one use (referred to as “single-use devices”) began in hospitals in the late 1970s. Before that time, most medical devices were already considered to be reusable because they were made from glass, rubber, or metal.

When manufactures began making disposable equipment, many made out of plastic, the equipment was labeled “single-use only.” Even devices that were similar to devices that had been formerly marketed and distributed or continued to be marketed and distributed as reusable began to be labeled by manufacturers as “single-use only.” This was to the advantage of manufacturers who could sell more devices if hospitals and end users could only use them once and then throw them away.

When the amount of medical waste generated by disposable devices became noticeable and the costs to hospitals began to rise, the practice of reprocessing began to flourish. Hospitals needing to cut costs began researching and implementing advanced cleaning and sterilizing techniques for medical devices, including those that the manufacturer had label as “single-use only.” As the decontamination process became more complex and the demand by hospitals rose, an industry of third-party processors evolved.

As the reprocessing industry expanded, new concerns relating to patient safety, informed consent, and the ethics of reuse began to surface. Also, the manufacturers and reprocessors continued to disagree as to which process was better. In response, the United States Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (F.D.A.) began researching the issue and regulating establishments that engage in manufacturing activities and reprocessing of single-use devices. Under current federal law, such establishments are subject to all requirements of the Federal Food, Drug, and Cosmetic Act, including requirements for registration and listing, premarket notification and approval, submission of adverse event reports, manufacturing requirements under the Quality Systems regulation, labeling, medical device tracking, and medical device corrections and removals.

However, the F.D.A. has admittedly not regulated manufacturers, third-party reprocessors, and health care facilities in the same manner with respect to single-use devices. The

F.D.A. has held conferences regarding how to improve regulation of reprocessing single-use devices and has proposed a new strategy on the reuse of single-use devices. The F.D.A. is still considering comments and alternative approaches from stakeholders and interested parties.

Examples of medical devices that are currently being reprocessed despite being labeled as "single-use only" include:

- Blood pressure tourniquets
- Compression devices
- External fixation devices
- Surgical bits, burs, and blades
- Surgical electrodes and cautery devices
- Turn loops
- Laser probes
- Gastrointestinal and endoscopy instruments
- Laparoscopic instruments
- Pulse oximeter sensors
- Electrophysiology catheters
- Balloon inflation devices
- Femostops
- Phaco tips
- ERCP devices
- Open and unused items

However, not all items within each of the general categories listed above are reprocessed. Also, not all reprocessors reprocess all of the general categories of medical devices listed above.

There is currently one third-party reprocessor in Florida. The company is Vanguard Medical Concepts, Inc., located in Lakeland. It employs approximately 250 people. The majority of reprocessing in Florida is performed by hospitals within their facility.

C. EFFECT OF PROPOSED CHANGES:

This bill does not change existing practices in this state except that all reprocessors must register with the United States Food and Drug Administration. The purpose of this bill is to affirmatively support continued reprocessing of medical devices in compliance with reprocessing standards and requirements enforced by the F.D.A. It states that a significant body of peer-reviewed scientific research supports reprocessing with no added risk to patient safety, that unnecessary disposal of certain medical devices exacerbates Florida's growing environmental waste problem and leads to increased medical costs, and that proper reprocessing is safe and cost effective.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Provides that the use of reprocessed medical devices labeled as "single-use only" is permitted provided that the reprocessors register and comply with the reprocessor requirements enforced by the United States Food and Drug Administration.

Section 2. Provides an effective date of upon becoming law.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2, Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The cost to reprocessors to register with the United States Food and Drug Administration will be determined by the F.D.A.

D. FISCAL COMMENTS:

None.

IV. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

The bill does not require counties or municipalities to expend funds or to take any action requiring the expenditure of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

The bill does not reduce the authority that municipalities or counties have to raise revenues in the aggregate.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

This bill does not reduce the percentage of state tax shared with counties or municipalities.

IV. COMMENTS:

A. CONSTITUTIONAL ISSUES:

None.

B. RULE-MAKING AUTHORITY:

None.

C. OTHER COMMENTS:

The proponents of the bill have proposed an amendment to remove the requirement that all reprocessors must be registered with the F.D.A. Therefore, hospitals that do their own reprocessing instead of contracting with a third-party reprocessor will not have to register with the F.D.A. However, all reprocessors, including hospitals will still be required to comply with the applicable requirements enforced by the F.D.A.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

None.

VII. SIGNATURES:

COMMITTEE ON HEALTH CARE LICENSING & REGULATION:

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