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HOUSE OF REPRESENTATIVES
AS REVISED BY THE COMMITTEE ON
BUSINESS DEVELOPMENT & INTERNATIONAL TRADE
ANALYSIS

BILL #: HB 951

RELATING TO: Sales Tax/Health Care Technology

SPONSOR(S): Representative Crist

COMPANION BILL(S): HB 431 (C) and SB 1396 (s)

ORIGINATING COMMITTEE(S)/COMMITTEE(S) OF REFERENCE:
(1) HEALTH CARE LICENSING & REGULATION YEAS 8 NAYS 3
(2) BUSINESS DEVELOPMENT & INTERNATIONAL TRADE
(3) FINANCE & TAXATION
(4) TRANSPORTATION & ECONOMIC DEVELOPMENT APPROPRIATIONS
(5)

I. SUMMARY:

This bill expands tax exemptions for computer-related industries to include technology industries. It exempts health technology from fees and registration requirements of the Florida Drug and Cosmetic Act.

The bill directs the State University System [SUS] and the University of Miami to perform certain evaluations relating to health technology business incubators and health technology companies. The bill also directs the State University System to submit a report of its findings to the Governor, the President of the Senate, and the Speaker of the House of Representatives. The bill encourages the State Board of Community Colleges to develop health technology curricula to support the industry's workforce needs. The bill directs the Division of Securities of the Office of the Comptroller to form a task force to review ch. 517, F.S., determine the impact on the ability of health technology firms to raise capital. The Division of Securities is required to submit a report of its findings to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

This bill reduces or eliminates state's duplicate review and fee on FDA approved regulated product manufacturing.

The Office of Tourism, Trade, and Economic Development is the final authority for tax exemption certification.

The Department of Health estimates that approximately 2,750 separate and distinct medical devices are registered with the department annually. Thus, on an annual basis, deposits to the Drug, Devices and Cosmetics Trust Fund will be reduced by an estimated $27,500. The Revenue Estimating Conference has not yet addressed this bill. The fiscal impact of the sales tax exemption has not yet been determined.

The bill would take effect July 1, 1999.

II. SUBSTANTIVE ANALYSIS:

A. PRESENT SITUATION:

Section 510 of the federal Food, Drug and Cosmetic Act requires United States device manufacturers and distributors to annually register their establishments and to file a list of their devices with the United States Food and Drug Administration. Section 201(h) of the federal Food, Drug and Cosmetic Act defines medical device to mean an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, which is: recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them; intended for use in the diagnosis of disease or other conditions, or cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action in or on the body of man or other animals and which does not metabolize for the achievement of any of its primary intended purposes.

Medical devices are subject to general controls and other controls of the federal Food, Drug and Cosmetic Act. General controls are baseline requirements that apply to all medical device manufacturers. Medical devices, unless otherwise exempt, must be properly labeled, and packaged, be approved for marketing by the FDA, meet their labeling claims, and be manufactured under good manufacturing practices, which is a mandated quality assurance system. The United States Food and Drug Administration has established classifications for approximately 1,700 different generic types of devices and has grouped them into 16 medical specialties referred to as panels. Each of these generic types of devices is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device. The three classes and the requirements which apply to them are: Class I (General Controls); Class II (General Controls and Special Controls); and Class III (General Controls and Pre-Market Approval). Most Class I devices are subject to general controls such as requirements for the manufacturer to annually register with and to file a list of their devices with the FDA, and design and manufacture devices under good manufacturing practices.

In addition to general controls, Class II and Class III devices are subject to further requirements including special controls and premarket approval by the FDA. Class II devices include any device for which reasonable assurance of safety and effectiveness can be obtained by the imposition of special labeling requirements, mandatory performance standards, patient registries and postmarket surveillance. Class III devices include devices that may support or sustain human life, are important in preventing impairment of human health, or present a potential, unreasonable risk of illness or injury. Class III devices require premarket approval by the FDA to be marketed (21 CFR Part 814). A premarket notification (510K) is a marketing application submitted to the FDA to demonstrate that the medical device to be marketed is as safe and as effective or substantially equivalent to a legally marketed device that was or is currently on the United States market and that does not require premarket approval (21 CFR Part 807, Subpart E). Class III devices must be submitted for premarket approval by the FDA to evaluate the safety and effectiveness of the devices.

Any person who only manufactures devices according to another person's specifications for commercial distribution by the person initiating specifications, is not required to list those devices with the FDA (21 CFR Part 807, Subpart B, s. 807.20). The FDA's current good manufacturing practice requirements do not apply to manufacturers of components or parts of finished devices (21 CFR Part 820, Subpart A, s. 820.1). "Component" is defined to mean any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device (21 CFR Part 820, Subpart A, s. 820.3).

Florida duplicates the federal requirements for the registration of medical devices. Chapter 499, Florida Statutes, provides for the regulation of drugs, cosmetics and household products by the Department of Health. Part I, ch. 499, F.S., (ss. 499.001-499.081, F.S.) sets forth the Florida Drug and Cosmetic Act. The purpose of this Act is to safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics. The part provides uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under, the federal Food, Drug, and Cosmetic Act and the applicable portions of the federal Trade Commission Act which prohibits the false advertising of drugs, devices, and cosmetics. The part specifies prohibited acts and

requirements for the distribution and manufacture of legend drugs and legend devices by pharmacies, manufacturers, and other entities.

Part I, ch. 499, F.S., defines manufacturer to mean any person who prepares, derives, manufactures, or produces a drug, device, or cosmetic. Section 499.015, F.S., requires any person who manufactures, packages, repackages, labels, or relabels a drug, device, or cosmetic in Florida to register the drug, device, or cosmetic every 2 years and pursuant to s. 499.041, F.S., to pay an annual product fee no less than $5 or greater than $15 for each separate and distinct product in package form. The Department of Health has adopted an administrative rule that provides for a two-year registration fee of $20 for each separate and distinct product (64F-12.018(4), Florida Administrative Code). Medical device manufacturers applying for an initial product registration must submit a product label or copy for every product registered, list each separate and distinct product, provide documentation that shows that the product is legal in interstate commerce (such as evidence of a premarket approval or pre-market notification letter (510K) from the FDA), and submit the appropriate fee (64F-12.016, Florida Administrative Code). The Department of Health may issue a certificate of Free Sale on any product that is required to be registered under ch. 499, F.S., to any applicant who requests the certificate and pays a fee of $25. A certificate of Free Sale, a document required by many foreign countries before a product may enter their country, attests to the marketable status of the product in Florida.

Section 499.013, F.S., requires any person who engages in the assembly or manufacture of medical devices for human use to obtain a permit, to annually pay a fee not less than $500 or greater than $600, and to comply with all appropriate state and federal manufacturing practices. Medical device manufacturers must pay a $150 initial application fee for each new permit which requires an onsite inspection.

As part of its review to improve access to investment capital, the Health Technology Industry Advisory Council to Enterprise Florida, Inc., recommended a reduction or elimination of Florida's medical device registration and fee for any device manufactured or assembled in Florida that has been approved by the FDA. The health technology industry in Florida receives no special tax or fee breaks. This bill includes health technology industries for tax exemptions. According to Florida Enterprise, Inc., the tax incentives would facilitate the growth of this industry and insure Florida as a location for the biotechnology and pharmaceutical/drug firms. This could result in the retention and creation of new medical manufacturing operations throughout the state.

B. EFFECT OF PROPOSED CHANGES:

The bill would provide an exemption from taxation under s. 212.08, F.S., for machinery and equipment used in the health technology industry similar to that provided for the silicon technology industry. The medical devices would have to be approved by and registered and listed with the United States Food and Drug Administration (USFDA). The manufacturer would have to submit evidence of such registration, listing, and approval at the time it submits its application for a permit to do business in the state. Evidence of USFDA approval and registration would include:

- A copy of the premarket notification letter (510K) for class II devices;
- A USFDA premarket approval number for class III devices;
- A USFDA registration number for subcontract medical device manufacturers who manufacture components of devices for manufacturer; or
- A USFDA registration number for medical device manufacturers whose devices are exempt from premarket approval.

The State University System and the University of Miami would evaluate the feasibility of establishing additional health technology business incubators.

The State Board of Community Colleges would be encouraged to continue its efforts to develop health technology curricula to support the industry's workforce needs. The Board would report its results to the Governor, the President of the Senate, and the Speaker of the House of Representatives by December 1, 1999.

The Division of Securities of the Office of the Comptroller, in collaboration with OTTED, EFI and its Health Technology Advisory Council, Bio+Florida, and The Florida Bar, would form a task force to

review and evaluate chapter 517, Florida Statutes, to determine its impact on the ability of Florida's health technology firms to raise capital. The Division of Securities would report to the Governor, the President of the Senate, and the Speaker of the House of Representatives by December 1, 1999, the task force's recommendations to modify and reform Chapter 517, F.S.

C. APPLICATION OF PRINCIPLES:

1. Less Government:

a. Does the bill create, increase or reduce, either directly or indirectly:

(1) any authority to make rules or adjudicate disputes?

No.

(2) any new responsibilities, obligations or work for other governmental or private organizations or individuals?

Yes. The bill requires Enterprise Florida Inc., to review each application and submit the application to OTTED with recommendations. It requires OTTED to certify or deny certification of the business before a business may receive the exemption. The SUS and the University of Miami are charged with studying and formulating strategies to facilitate the growth and expansion of the health technology industry in Florida in consultation with EFI. The State Board of Community Colleges is directed to develop curricula to support the workforce needs of the health technology industry.

(3) any entitlement to a government service or benefit?

The Comptroller, OTTED, EFI, Health Technology Advisory Council, Bio+Florida, and the Florida Bar required to review and evaluate Chapter 517, F.S. re securities transactions to determine its impact on the ability of the industry to raise capital.

b. If an agency or program is eliminated or reduced:

(1) what responsibilities, costs and powers are passed on to another program, agency, level of government, or private entity?

N/A

(2) what is the cost of such responsibility at the new level/agency?

N/A

(3) how is the new agency accountable to the people governed?

N/A

2. Lower Taxes:

a. Does the bill increase anyone's taxes?

No.

b. Does the bill require or authorize an increase in any fees?

No.

c. Does the bill reduce total taxes, both rates and revenues?

An exemption from sales tax is provided for machinery and equipment used to produce, research, and develop health technology products.

d. Does the bill reduce total fees, both rates and revenues?

Yes, certain medical device manufactures are exempt from payment of annual fees to the Drug, Devices and Cosmetics Trust Fund.

e. Does the bill authorize any fee or tax increase by any local government?

No.

3. Personal Responsibility:

a. Does the bill reduce or eliminate an entitlement to government services or subsidy?

No.

b. Do the beneficiaries of the legislation directly pay any portion of the cost of implementation and operation?

No.

4. Individual Freedom:

a. Does the bill increase the allowable options of individuals or private organizations/associations to conduct their own affairs?

No.

b. Does the bill prohibit, or create new government interference with, any presently lawful activity?

No.

5. Family Empowerment:

a. If the bill purports to provide services to families or children:

(1) Who evaluates the family's needs?

N/A

(2) Who makes the decisions?

N/A

(3) Are private alternatives permitted?

N/A

(4) Are families required to participate in a program?

N/A

(5) Are families penalized for not participating in a program?

N/A

b. Does the bill directly affect the legal rights and obligations between family members?

N/A

c. If the bill creates or changes a program providing services to families or children, in which of the following does the bill vest control of the program, either through direct participation or appointment authority:

(1) parents and guardians?

N/A

(2) service providers?

N/A

(3) government employees/agencies?

N/A

D. STATUTE(S) AFFECTED:

Section 212.08 and 499.015, F.S.

E. SECTION-BY-SECTION ANALYSIS:

Section 1. Provides legislative intent to encourage and facilitate the expansion of the state's health technology industry.

Section 2. Amends s. 212.08 F.S., to provide exemptions from state taxes for machinery and equipment used in research and development or manufacturing in a health technology facility. Defines "health technology products" to include: drugs; surgical, medical, and dental instruments and supplies; ophthalmic goods, laboratory apparatus, and laboratory analytical instruments; optical instruments and lenses and related health technology products as determined by the Office of Tourism, Trade, and Economic Development."

Section 3. Amends s. 499.015 F.S., to provide exemptions from fees and registration requirements for certain medical device manufacturers under the requirements of the Florida Drug and Cosmetic Act. Requires the manufacturers to submit evidence of registration, listing, and approval by the federal government of such devices.

Section 4. Charges the State University System [SUS] and the University of Miami with evaluating the feasibility of expanding health technology business incubators to other universities in the SUS. The State University System and the University of Miami shall consult with the Health Technology Advisory Council of Enterprise Florida, Inc., and Bio+Florida as part of these evaluations and recommendations. Results of the evaluation shall be reported to the Governor, the President of the Senate, and the Speaker of the House of Representatives by December 1, 1999.

Section 5. Encourages the State Board of Community Colleges to continue its efforts to develop health technology curricula to support the industry's workforce needs. Results of these efforts must be reported to the Governor, the President of the Senate, and the Speaker of the House of Representatives by December 1, 1999.

Section 6. Requires the Division of Securities of the Office for the Comptroller, in collaboration with the Office of Tourism, Trade, and Economic Development, Enterprise Florida, Inc., and its Health Technology Advisory Council, Bio+Florida, and The Florida Bar, to form a task force to review and

evaluate chapter 517, Florida Statutes, to determine its impact on the ability of Florida's health technology firms to raise capital. The findings must be reported to the Governor, the President of the Senate, and the Speaker of the House of Representatives, by December 1, 1999.

Section 7. Provides an effective date of July 1, 1999.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE AGENCIES/STATE FUNDS:

1. Non-recurring Effects:

The Revenue Estimating Conference has not yet addressed this bill.

2. Recurring Effects:

The Revenue Estimating Conference has not yet addressed this bill.

3. Long Run Effects Other Than Normal Growth:

None.

4. Total Revenues and Expenditures:

The Revenue Estimating Conference has not yet addressed this bill.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS AS A WHOLE:

1. Non-recurring Effects:

None.

2. Recurring Effects:

None.

3. Long Run Effects Other Than Normal Growth:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

1. Direct Private Sector Costs:

None.

2. Direct Private Sector Benefits:

Certain medical device manufacturers in Florida will no longer be required to pay annual fees to the state under the Florida Drug and Cosmetics Act.

3. Effects on Competition, Private Enterprise and Employment Markets:

There will be no effect on private enterprise and employment markets. However, exporters of Class II and Class III medical devices manufactured in Florida, will no longer be able to obtain a Certificate of Free Sale from the State of Florida. While they may obtain a certificate from the federal government, it involves a much longer processing period. This could impact their ability to compete internationally.

D. FISCAL COMMENTS:

The department estimates that approximately 2,750 separate and distinct medical devices currently registered with the department annually will no longer be required to be registered. The registration fee per device is $20 for two years, or $10 per year. Thus, on an annual basis, the Drug, Devices and Cosmetics Trust Fund will not collect annual fees of an estimated $27,500 (2,750 @ $10 each).

The Revenue Estimating Conference has not yet addressed this bill. The fiscal impact of the sales tax exemption has not yet been determined.

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

A. APPLICABILITY OF THE MANDATES PROVISION:

This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

This 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 a state tax shared with counties or municipalities.

V. COMMENTS:

This bill deletes the requirement for certain medical device manufactures to pay the product registration fee. As reported by the department, "other manufactures in Florida, ie., prescription drug, over-the-counter drug, compressed medical gas, and cosmetic manufacturers, are still required to register and pay the biennial registration fee for their products. They might decide that they shouldn't have to pay to register their products, if medical device manufacturers don't have to pay the registration fee." According to the department, the bill provides that a manufacturer submit evidence of registration, listing, and approval at the time the manufacturer submits an application to the department for a permit to do business in Florida as required by s. 499.013 (2)(d), F.S.

This bill is not clear as to whether the manufacturer is required to continue to submit to the department such evidence for new products or changes to previously reported products during the two year permit renewal period. According to the department, a manufacturer should report evidence for new products and any changes to previously reported products at the time they submit a renewal application for a permit. However, the language in the bill exempts the manufacturer from all of s. 499.015, F.S., except the requirement to obtain a permit to do business in Florida. This would appear to make it difficult for the department to enforce submission of evidence of new products or changes to previously reported products.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

None.

VII. SIGNATURES:

COMMITTEE ON HEALTH CARE LICENSING & REGULATION:

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