HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 673 Donated Organs

SPONSOR(S): Bogdanoff and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 2242

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Healthcare Council		Quinn-Gato/ Massengale	Gormley
2) Policy & Budget Council			
3)			
4)			
5)			

SUMMARY ANALYSIS

HB 673 creates section 765.5225, F.S., which requires that pharmacists to dispense original, specifically prescribed, immunosuppressive therapy drugs to individuals after they have received an organ transplant unless the pharmacist obtains written or oral consent from the prescribing practitioner to dispense a generic equivalent.

The bill has an $85,647 fiscal impact on the General Revenue Fund in Fiscal Year 2008-09 and $12,567 in Fiscal Year 2009-10.

The effective date of the bill is July 1, 2008.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Limited Government-This bill creates additional regulatory obligations for pharmacists to determine whether a generic or brand-name drug may be prescribed to a patient.

Empowering Families-Requiring patients to receive a brand-name drug will result in increased health costs and limits a patient's ability to make cost-based prescription choices other than choosing not to fill the prescription. Requiring patients to receive a brand-name drug may improve health outcomes.

Promote Personal Responsibility-The bill reduces the ability of a patient to make a prescription choice that may be harmful instead of relying on patient education and personal responsibility to reduce the incidence of harmful choices.

B. EFFECT OF PROPOSED CHANGES:

Present Situation

Organ Transplants

Before undergoing an organ transplant, transplant recipients are assigned a "transplant team," which is a multidisciplinary team of professionals comprised of transplant procurement coordinators, transplant clinical coordinators, transplant surgeons, transplant physicians, transplant unit staff nurses, financial coordinators, social workers, and transplant recipients' family doctors, specialists or primary care physicians.[1]

For example, at the Mayo Clinic, a multidisciplinary heart transplant team for adult heart transplant recipients is comprised of six cardiac surgeons and six cardiologists, with support from transplant specialists in Dermatology, Endocrinology, Infectious Disease, Nephrology, and Psychiatry.[2] In preparation for transplants, a transplant cardiologist and surgeon, who may consult with specialists in pulmonary medicine and nephrology, evaluate the eligibility of a transplant candidate.[3] A heart transplant candidate will also meet with endocrinologists, infectious disease doctors, and psychologists, while transplant coordinators and licensed social workers assist the candidate and his or her family throughout the process.[4] If a patient is approved for transplant, then the candidate will have regular check-ups from his or her primary care physician and members of the transplant team, with continued coordination between the transplant team and referring physician being essential while the candidate remains on the wait list for a new heart.[5]

After an organ transplant, a patient will generally remain hospitalized at Mayo and will be cared for by the transplant team for a couple of weeks.[6] Once released from the hospital, the patient is seen by the

---

[1] *See* U.S. Department of Health and Human Services (2004). *Partnering With Your Transplant Team: The Patient's Guide to Transplantation.* Rockville, MD: Health Resources and Services Administration, Special Programs Bureau, Division of Transplantation; located on March 3, 2008 at http://www.unos.org/SharedContentDocuments/Transplantation_Guide_Final-3-04-04.pdf.

[2] Mayo Clinic, Heart Transplant in Adults at Mayo Clinic, located on March 3, 2008 at http://www.mayoclinic.org/heart-transplant/adulttransplant.html.

[3] *Id.*

[4] *Id.*

[5] *Id.*

[6] *Id.*

transplant team several times a week for the first few weeks, with visits tapering off to one visit a month thereafter.[7] Recipients are generally asked to remain in the area for the first three months after transplantation for monitoring by the team.[8] Upon returning home, a transplant recipient is regularly seen by the primary care physician, and the transplant team remains available throughout the transplant recipient's course of treatment to provide primary or shared care and discuss modifications to the daily and lifelong immunosuppressive drug regimen that must be taken to prevent rejection of the organ.[9] Recipients must return to the Mayo Clinic annually for coronary angiography and general evaluation.[10]

Generic Drugs

In 1970, the United States Food and Drug Administration ("FDA"), which regulates the marketing of generic drugs, established a process for reviewing and approving abbreviated new drug applications ("ANDAs") that allowed generic versions of brand-name drugs approved between 1938 and 1962[11] to enter the market if the generic drugs had a comparable bioavailability to the brand-name drug.[12] For, brand-name drugs approved after 1962, however, there remained rigorous efficacy and safety requirements that had to be met before a generic equivalent could enter the market. This hindered the availability of generic drugs until Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Waxman-Hatch Act, which paved the way for allowing generic drug companies greater access to the market through the filing of ANDAs.[13] Today, a generic drug manufacturer may apply to enter the market once the patent or other period of exclusivity for its brand-name equivalent expires.

In order to be approved for distribution and use by the FDA, a generic equivalent drug must:

- Be bioequivalent[14] to a brand name drug
- Contain the same active ingredients as the brand name drug
- Be identical in dosage form, strength, and route of administration
- Meet the same batch requirements for identity, strength, quality, and purity
- Have the same intended use as its brand-name counterpart
- Meet the FDA's same strict standards for good manufacturing practices that the brand-name drug was required to meet before entering the market[15]

Although generic drugs must meet the same rigid standards as their brand-name counterparts, one of the reasons generic drugs are less expensive is because the generic manufacturer is not required to conduct animal or clinical research on the ingredients or dosage forms, as those processes have been completed by the brand-name manufacturer and the drug has already been approved for safety and effectiveness by the FDA.[16] However, the reduction in drug cost takes time to realize. The FDA has recognized that the first generic competitor that enters the drug market usually results in product prices only slightly lower than its brand-name equivalent; however, once the second generic manufacturer

---

[7] *Id.*
[8] *Id.*
[9] *Id.*
[10] *Id.*
[11] For drugs initially marketed before 1938, no FDA approval is necessary for the marketing of a generic equivalent drug.
[12] Bioavailability means that a drug has the same availability of the active ingredient when used in the body. *See* June 12, 2003 FDA White Paper, "New FDA Initiative on 'Improving Access to Generic Drugs;'" located on February 27, 2008 at http://www.fda.gov/oc/initiatives/generics/whitepaper.html.
[13] Florida Senate Interim Project Report 2000-55 (September 1999).
[14] "Bioequivalent Drug Products" are defined as pharmaceutical equivalent or alternative products that display Comparable bioavailability when studied under similar experimental conditions. *Id.*
[15] *See* United States Food and Drug Administration, Office of Generic Drugs; located on February 28, 2008 at http://www.fda.gov/cder/ogd/#Introduction.
[16] *Id.*

enters the market, the average generic price is reduced to approximately half of the brand-name price.[17] The Congressional Budget Office has estimated that generic drugs save consumers $8 to $10 billion a year, with that number increasing when hospitals use generic drugs.[18]

The competitive market for generic drugs in the United States has also made prices more affordable than the cost of generic or brand-name drugs in other countries. For example, a 2003 FDA white paper determined that generic equivalent drugs in the United States cost less than both brand name and generic drugs in Canada.[19] In fact, the white paper revealed that of the seven largest selling chronic-use generic drugs (alprazolam, clonazepam, enalapril, fluoxetine, lisinopril, metformin, and metoprolol) from 1993-2003, six were priced less than the Canadian brand-name versions, and five were priced less than the Canadian generic versions.[20] Only one of the seven drugs, metformin, was higher than the Canadian price.[21]

Generic Drug Substitution

Section 465.025, F.S., requires a less expensive generically equivalent drug to be substituted for a brand name drug unless the patient objects or the prescribing practitioner affirmatively prohibits the substitution by writing on the prescription that the brand name drug is medically necessary. A "generically equivalent drug product" is defined to mean a drug product with the same active ingredient, finished dosage form, and strength.[22] The generic substitution law only applies to drugs that are prescribed by brand name.[23] If the prescription is written for a drug identified by its generic name, the pharmacist may use his or her professional judgment to select any drug product with the same active ingredients, including a brand-name drug product.[24] The pharmacist must maintain a record of any drug substitution.[25]

With regard to the Medicaid Program, section 409.908(14), F.S., requires that Medicaid providers dispense generic drugs if available at a lower cost and the Agency for Health Care Administration has not determined that the branded product is more cost effective, unless the prescriber has requested and received approval to require the branded product.

Generic Immunosuppressive Therapy Drugs for Organ Transplant Patients

On May 18, 2003, the American Society of Transplantation publicized its report from its Conference on Immunosuppressive Drugs and the Use of Generic Immunosuppressants. The report recognized that "medication side effects and the cost of life-long [brand-name] immunosupressants diminishes the quality of life for successful long-term solid organ transplant recipients."[26]

The participants in the conference reached several consensus points regarding the use of generic immunosuppressive drugs after a transplant[27], including:

---

[17] *See* "Generic Competition and Drug Prices," U.S. Food And Drug Administration, Center for Drug Evaluation and Research; located on February 27, 2008 at http://www.fda.gov/cder/ogd/generic_competition.htm.
[18] *Id.*
[19] See "Generic Drug Prices in the U.S. are Lower Than Drug Prices in Canada," United States Food and Drug Administration,Office of Planning, White Paper (November 2003); located on February 27, 2008 at http://www.fda.gov/oc/whitepapers/drugprices.html.
[20] *Id.*
[21] *Id.*
[22] s. 465.025, F.S.
[23] *Id.*
[24] *Id.*
[25] *Id.*
[26] "Report of the American Society of Transplantation Conference on Immunosuppressive Drugs and the Use of Generic Immunosuppressants," American Journal of Transplantation 2003; 3:1211-1215 at p. 1211; located on February 27, 2008 at http://www.blackwell-synergy.com/doi/pdf/10.1046/j.1600-6143.2003.00212.x?cookieSet=1.
[27] *Id.* at p. 1214.

- Support for the availability of generic immunosuppressive drugs, as medication costs may be a contributing factor in a transplant recipient's non-compliance with prescribed medical regimens.[28]
- That, with appropriate monitoring, FDA approved generic narrow therapeutic index immunosuppressive agents appear to provide adequate immunosuppression to low-risk transplant recipients; however, there is insufficient data regarding the risks of using generic immunosuppressive drugs on particularly at-risk patient populations, such as African-American or pediatric patients. As such, the conference participants recommended that "demonstrations of bioequivalence in at-risk populations should be incorporated into the generic drug approval process."[29]

Similarly, other organizations that have evaluated the use of generic immunosuppressive drugs on transplant recipients have criticized the FDA's current bioequivalence standards--single-dose studies in small numbers volunteers that are fasting, healthy, and often homogeneous in terms of age and gender.[30]

Pharmacy Practice

Chapter 465, F.S., governs the practice of the pharmacy profession. The Board of Pharmacy within the Department of Health is authorized to adopt rules for duties conferred upon it under the Pharmacy Practice Act. Section 465.003, F.S., defines the "practice of the profession of pharmacy" to include compounding, dispensing and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent and proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and other pharmaceutical services.

Effect of Proposed Changes

The bill requires that pharmacists dispense the "original specifically prescribed drug," in lieu of a generic equivalent, to patients prescribed immunosuppressive therapy drugs following an organ transplant. "Original specifically prescribed drug" is not defined in the bill or elsewhere in law. The bill creates an exception to the brand-only dispensing requirement, allowing a pharmacist to dispense a generic equivalent drug when the pharmacist obtains written or oral authorization from the prescribing practitioner to do so.

The bill does not create or address any record keeping requirements for pharmacists under this section, including how records are to be created or retained to establish that an "oral authorization" was received by the pharmacist.

The new section of law created by this bill places these requirements in chapter 765, which concerns anatomical gifts. However, chapter 465 governs the regulation of pharmacists. The bill makes no

[28] For example, during the first year following a kidney transplant, the cost of drugs make up approximately 15-25 percent of the transplant related expenditures billed to Medicaid, with that number increasing to 30-90% in subsequent years. *Id.* at 1213 (citing Alloway RR. "Generic Immunosuppressant Use in Solid Organ Transplantation." Transplant Proc. 1999; 31(3A (Suppl.): 6S).

[29] *See supra* note 26 at 1214.

[30] *See, e.g.*, "Issues in Bioequivalence and Generic Substitution for Antiarrythmic Drugs," American Heart Association; located on February 28, 2008 at http://www.americanheart.org/presenter.jhtml?identifier=3015266; "Drug Substitution in Transplantation," National Kidney Foundation; located on February 28, 2008 at http://www.transweb.org/reference/articles/drugs/drug_substitution.htm (recognizing that "[b]ecause safe and effective generic immunosuppressive drugs may have potential cost-related benefits, the conference participants welcomed their introduction in the field of transplantation. However…it is recommended that the FDA hold narrow therapeutic drug range drugs to more stringent standards of bioequivalence assessment than those used for other therapeutic classes, requiring that the drug manufacturer conduct replicate studies of intrasubject variability and subject-by formulation interactions in addition to conventional bioavailability studies").

cross-references to chapter 465 or other regulatory requirements created in the bill. It is uncertain what, if any, enforcement power the Board of Pharmacy will have to ensure pharmacists comply with this provision.

C. SECTION DIRECTORY:

Section 1. Creates s. 765.5225, F.S.: relating to preservation of donated organs.

Section 2. Provides an effective date of July 1, 2008.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

2008-09	2009-10
$15,648	$15,648

2. Expenditures:

The estimated fiscal impact for the current Florida Medicaid fee-for-service population would be $28,215 annually, at current claim levels for this limited group of drugs. The state share would be $12,567 and the federal share would be $15,648. This amount is the difference between the highest claim brand price and the generic claim price multiplied by the number of generic brand claims for January through December 2007.

The estimated fiscal impact on the State Employees' Group Health Self-Insurance program is $73,080. The Department of Management Services typically issues notification to plan enrollees for any benefit changes. Such notification may result in additional administrative processes and unbudgeted costs for the department if such notification cannot be included in the regular annual open enrollment period documentation. Historically, the annual open enrollment period is mid-September though mid-October. The additional member notification estimate would be a nonrecurring or start-up cost of $73,080 and is based on an approximate health insurance enrollment of 174,000 and a production/rate mailing cost of $0.42 per piece of mail.

	2008-09	2009-10
Medicaid Expenditures	$28,215	$28,215
State Employee Health Insurance Mailings	$73,080	$ 0
Total Expenditures	$101,295	$28,215
General Revenue Fund	$85,647	$12,567
Medical Care Trust Fund	$15,648	$15,648

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

Locally funded health plans will likely experience increased costs.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

If name-brand drugs cannot be substituted with generic drugs, individual and employer sponsored insurance plans may incur additional costs through increased claims costs that will be passed on to policyholders in the form of increased premiums.

D. FISCAL COMMENTS:

The Agency indicates that if numerous exemptions or a reversal of the Florida generic substitution were implemented, the cost to the Medicaid program would be substantial for all payors: individuals, commercial health plans, and Florida Medicaid. Presently, approximately one-third of prescriptions reimbursed by Medicaid are for brand products, but these products account for more than 80 percent of expenditures. The average cost of a generic prescription is $21.09, while the average cost for a brand prescription is $183.96[31].

The Division of State Group Insurance indicates that by making it more difficult to access generic immunosuppressive drugs, the proposed legislation may negatively impact generic distribution which will reduce substitution savings to the self-insured State Employee Health Insurance program. This would have an indeterminate negative fiscal impact on the State Employees' Group Health Self-Insurance Trust Fund.[32]

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill creates this new regulation for pharmacists in the "anatomical gifts" chapter of law (chapter 765) in lieu of chapter 465, which governs the regulation of pharmacists. Given that there are no cross-references to Chapter 465 or other regulatory requirements created in the bill, it is uncertain what, if any, enforcement power the Board of Pharmacy will have to ensure pharmacists comply with this provision.

Additionally, the bill creates an exception for pharmacists who receive a "written or oral authorization" to use a generic immunosuppressive drug; however, the bill does not create or address any record keeping requirements for pharmacists to ensure compliance with this provision, including how records are to be created or retained to establish that an "oral authorization" was received by the pharmacist.

[31] Agency for Health Care Administration 2008 Bill Analysis and Economic Impact Statement.
[32] Department of Management Services 2008 Bill Analysis.

In line 16, the bill references “originally specifically prescribed drug;” however, “originally specifically prescribed drug” is not defined in the bill or elsewhere in law. Section 465.025, F.S., which concerns the substitution of drugs, defines “brand name” as “the registered trademark name given to a drug product by its manufacturer, labeler, or distributor. Within the context of the bill, the “original specifically prescribed drug” appears to have the same or a similar meaning to the “brand name” drug which may be prescribed by a treating practitioner.

According to AHCA, the proposed legislation may conflict with s. 409.912(39)(a)16, F.S., which requires Medicaid recipients’ use of medication included on the preferred drug list prior to an alternative medication that is not listed, unless additional documentation is provided by the prescriber.[33]

D. STATEMENT OF THE SPONSOR

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

[33] Agency for Health Care Administration 2008 Bill Analysis and Economic Impact Statement.