The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Health Regulation Committee

BILL:	SB 2242
INTRODUCER:	Senator Oelrich
SUBJECT:	Dispensing of Drugs
DATE:	April 4, 2008
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HR	**Pre-meeting**
2.			HA	
3.				
4.				
5.				
6.				

I. Summary:

The bill prohibits a pharmacist from dispensing a drug for immunosuppressive therapy following a transplant procedure which is not the specific formulation or which is not manufactured by the specific manufacturer as prescribed by the prescribing practitioner.

The bill authorizes a pharmacist to substitute a drug product that is generically equivalent to the drug prescribed for immunosuppressive therapy following a transplant only if, before making the substitution, the pharmacist obtains written or oral authorization from the prescribing practitioner.

This bill creates section 765.5225, Florida Statutes.

II. Present Situation:

Immunosuppressive Drug Therapy

Organ procurement is the process of surgically removing an organ or tissue from one person (the donor) and placing it into another person (the recipient). Transplantation is necessary because the recipient's organ has failed or has been damaged by disease or injury. Organ transplantation is one of the great advances in modern medicine. Unfortunately, the need for organ donors is much greater than the number of people who actually donate. Every day in the United States 17 people die waiting for an organ and more than 80,000 men, women, and children await life-saving organ transplants. Organs and tissues that can be transplanted include liver, kidney, pancreas, heart, lung, intestine, cornea, middle ear, skin, bone, bone marrow, heart valves and connective tissue.

Immunosuppressive drugs suppress the body's immune response. Immunosuppressive drug therapy is often a necessary component of organ transplantation. Immunosuppressive drugs are used to prevent the body from rejecting a transplanted organ. When an organ is transplanted from a donor into the recipient, rejection may occur. The immune system of the recipient may trigger the same response against the new organ that it would have to any foreign material, and thereby damage the transplanted organ. Rejection may occur rapidly (acute rejection), or over a long period of time (chronic rejection). Rejection may occur despite close matching of the donated organ and the transplant patient. Immunosuppressant drugs greatly decrease the risks of rejection, protecting the new organ and preserving its function.

The following drugs have been used to provide immunosuppression in organ transplantation:

- Prograf® (tacrolimus) is indicated for the prophylaxis of organ rejection in patients receiving liver, kidney, or heart transplants.[1]
- Rapmune® (sirolimus), is used with kidney transplants.[2]
- Neoral® (Cyclosporine) is used with liver, kidney, or heart transplants.
- Myfortic® (Mycophenolic Acid) is used with kidney and other organ transplants.[3]
- Sandimmune® (cyclosporine) is used with kidney, liver, and heart transplants.
- Imuran® (Azathioprine) is used with kidney transplants.
- Prednisone a corticosteroid hormone is also used with organ transplants.

The use of generic immunosuppressants continues to remain a controversial subject. Many participants who are examining the use of generic substitution of the brand name formulation of immunosuppressive drugs agree that generic substitution may provide immunosuppression in low-risk transplant patients but a minority are still concerned with the use of generic formulations with transplant recipients whose risks have not yet been quantified.[4]

Generic Drug Substitution

Florida law 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.[5] A "generically equivalent drug product" is defined to mean a drug product with the same active ingredient, finished dosage form, and strength. The generic substitution law only applies to drugs that are prescribed by brand name. If the prescription is written for a drug identified by its generic name, the pharmacist may use her or his professional judgment to select any drug product with the same active ingredients, including a brand-name drug product. The pharmacist must maintain a record of any drug substitution. Florida law governing the Medicaid program also requires generic substitution of brand-name drug products.[6]

[1] The patent for Prograf® is scheduled to expire on April 8, 2008.
[2] The patent for Rapmune® is scheduled to expire on July 7, 2013.
[3] The patent for Myfortic® is scheduled to expire on April 1, 2017.
[4] See Alloway, Rita, et. al., "Report of the American Society of Transplantation Conference on Immunosuppressive Drugs and the Use of Generic Immunosuppressants" American Journal of Transplantation 3:1211-1215 (2003).
[5] See s. 465.025, F.S.
[6] See s. 409.908(14), F.S., which requires Medicaid providers to 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

Pharmacy Practice

Chapter 465, F.S., governs the practice of the profession of pharmacy. 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.

III. Effect of Proposed Changes:

The bill creates s. 765.5225, F.S., to prohibit a pharmacist from dispensing a drug for immunosuppressive therapy following a transplant procedure which is not the specific formulation or which is not manufactured by the specific manufacturer as prescribed by the prescribing practitioner.

The bill authorizes a pharmacist to substitute a drug product that is generically equivalent to the drug prescribed for immunosuppressive therapy following a transplant only if, before making the substitution, the pharmacist obtains written or oral authorization from the prescribing practitioner.

The bill provides an effective date upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

prescriber has requested and received approval to require the branded product. See also 42 CFR 447.331(c) relating to the Medicaid program, which provides that certain payment limitations do not apply if "a physician certifies in *his or her own handwriting* that a specific brand is medically necessary for a particular patient."

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The bill may result in higher costs to individuals, commercial health plans, managed care organizations, and others who must purchase immunosuppressive drugs.

C. Government Sector Impact:

For immunosuppressive drugs, the Florida Medicaid program, is currently filling about half the prescriptions for these drugs with brand name products. If the Medicaid program is subject to the bill's requirements, officials at the Agency for Health Care Administration (agency) have indicated that the cost difference between what Medicaid reimbursed for the generic prescriptions and the highest brand cost would have been $28,215 for immunosuppressive drugs during calendar year 2007. Staff at the agency indicate that although the cost of the bill's requirement to the Medicaid program is insubstantial, the reimbursement for brand name drugs represents 80 percent of the program's drug costs.

The Medicaid program staff estimate the annual fiscal impact of the bill to be approximately $28,215 at current claim levels.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill appears to be in conflict with s. 465.025, F.S., relating to generic substitution and s. 409.908(14), F.S., relating to the Medicaid Program's policy on coverage of brand name drug products. Although the Legislature itself cannot, by law, bind a future Legislature, it may be prudent to provide a "notwithstanding clause" for these sections of law to recognize the conflict in statute.[7]

In addition, the agency staff reports that the bill may conflict with s. 409.912(39)(a)16, F.S., which requires a Medicaid recipient to use medication that is on the preferred drug list (PDL) prior to an alternative medication that is not listed, unless additional documentation is provided by the prescriber. Section 409.912(39)(a)16., F.S., requires prescribers of an immunosuppressive drug that has been excluded from the PDL to satisfy the step-therapy prior authorization requirements. The bill would require a pharmacist to dispense the originally prescribed drug absent the prescriber's authorization to do otherwise

[7] See *Neu v. Miami Herald Pub. Co*., 462 So.2d 821 (Fla. 1985).

The bill may inadvertently impose additional liabilities on pharmacists and pharmacies that dispense immunosupressive drugs by not providing immunity from liability in any action for loss, damage, injury, or death to any person occasioned by or arising from the use or nonuse of the drugs. The generic drug substitution law grants immunity from civil liability for the dispensing of a generic substitution for the brand name drug product listed in a prescription.[8]

The bill may result in delays and inconvenience for patients seeking immunosuppressive drugs as a part of their post-transplant regimen to avoid rejection. It may take some time for the pharmacist to obtain oral or written authorization from the prescribing practitioner. If the pharmacist is unable to communicate with the prescribing practitioner, the delay could be life-threatening.

The bill imposes requirements on a class of immunosupressive drugs, that may be prescribed for a number of uses such as cancer treatment, in addition to an adjunct therapy for organ transplants.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

[8] See 465.025(8), F.S., which provides that the standard of care to be applied to the acts of any pharmacist performing professional services in compliance with this section when a substitution is made by said pharmacist shall be that which would apply to the performance of professional services in the dispensing of a prescription order prescribing a drug by generic name. In no event when a pharmacist substitutes a drug shall the prescriber be liable in any action for loss, damage, injury, or death to any person occasioned by or arising from the use or nonuse of the substituted drug, unless the original drug was incorrectly prescribed.