By Representative Kosmas

A bill to be entitled

An act relating to Medicaid prescription drugs; amending s. 409.91195, F.S.; providing for the development of a restricted drug formulary by the Medicaid Pharmaceutical and Therapeutics Committee; revising membership of the committee; requiring the Agency for Health Care Administration to establish a restricted drug formulary upon recommendation by the committee; providing for revisions to the formulary by the committee and the agency; requiring the agency to publish and disseminate the formulary to all Medicaid providers in the state; amending s. 409.912, F.S.; revising the method of determining reimbursement to pharmacies for Medicaid-prescribed drugs under the Medicaid-prescribed drug spending-control program implemented by the agency; authorizing the agency to establish a restricted formulary and to negotiate supplemental rebates from manufacturers; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 409.91195, Florida Statutes, is amended to read:

409.91195 Medicaid Pharmaceutical and Therapeutics Committee.--There is created a Medicaid Pharmaceutical and Therapeutics Committee <u>for the purpose of developing a restricted drug formulary</u>. ~~The committee shall develop and implement a voluntary Medicaid preferred prescribed drug~~

~~designation program.~~The program shall provide information to Medicaid providers on medically appropriate and cost-efficient prescription drug therapies through the development and publication of a restricted drug formulary ~~voluntary Medicaid preferred prescribed-drug list~~.

(1) The Medicaid Pharmaceutical and Therapeutics Committee shall be comprised of nine members as specified in 42 U.S.C. s. 1396.~~appointed as follows: one practicing physician licensed under chapter 458, appointed by the Speaker of the House of Representatives from a list of recommendations from the Florida Medical Association; one practicing physician licensed under chapter 459, appointed by the Speaker of the House of Representatives from a list of recommendations from the Florida Osteopathic Medical Association; one practicing physician licensed under chapter 458, appointed by the President of the Senate from a list of recommendations from the Florida Academy of Family Physicians; one practicing podiatric physician licensed under chapter 461, appointed by the President of the Senate from a list of recommendations from the Florida Podiatric Medical Association; one trauma surgeon licensed under chapter 458, appointed by the Speaker of the House of Representatives from a list of recommendations from the American College of Surgeons; one practicing dentist licensed under chapter 466, appointed by the President of the Senate from a list of recommendations from the Florida Dental Association; one practicing pharmacist licensed under chapter 465, appointed by the Governor from a list of recommendations from the Florida Pharmacy Association; one practicing pharmacist licensed under chapter 465, appointed by the Governor from a list of recommendations from the Florida Society of Health System Pharmacists; and one health care~~

~~professional with expertise in clinical pharmacology appointed by the Governor from a list of recommendations from the Pharmaceutical Research and Manufacturers Association.~~The members shall be appointed to serve for terms of 2 years from the date of their appointment. Members may be appointed to more than one term. The Agency for Health Care Administration shall serve as staff for the committee and assist them with all ministerial duties.

(2) Upon recommendation by the committee, the Agency for Health Care Administration shall establish a restricted drug formulary ~~the voluntary Medicaid preferred prescribed-drug list. Upon further recommendation by the committee, the agency shall add to, delete from, or modify the list~~. The committee shall also review requests for additions to, deletions from, or modifications of the formulary as presented to it by the agency, and upon further recommendation by the committee, the agency shall add to, delete from, or modify the list as appropriate ~~list~~. ~~The list shall be adopted by the committee in consultation with medical specialists, when appropriate, using the following criteria: use of the list shall be voluntary by providers and the list must provide for medically appropriate drug therapies for Medicaid patients which achieve cost savings in the Medicaid program.~~

(3) The Agency for Health Care Administration shall publish and disseminate the Medicaid restricted drug formulary ~~voluntary Medicaid preferred prescribed drug list~~ to all Medicaid providers in the state.

Section 2. Paragraph (a) of subsection (37) of section 409.912, Florida Statutes, is amended to read:

409.912 Cost-effective purchasing of health care.--The agency shall purchase goods and services for Medicaid

recipients in the most cost-effective manner consistent with the delivery of quality medical care. The agency shall maximize the use of prepaid per capita and prepaid aggregate fixed-sum basis services when appropriate and other alternative service delivery and reimbursement methodologies, including competitive bidding pursuant to s. 287.057, designed to facilitate the cost-effective purchase of a case-managed continuum of care. The agency shall also require providers to minimize the exposure of recipients to the need for acute inpatient, custodial, and other institutional care and the inappropriate or unnecessary use of high-cost services.

(37)(a) The agency shall implement a Medicaid prescribed-drug spending-control program that includes the following components:

1. Medicaid prescribed-drug coverage for brand-name drugs for adult Medicaid recipients not residing in nursing homes or other institutions is limited to the dispensing of four brand-name drugs per month per recipient. Children and institutionalized adults are exempt from this restriction. Antiretroviral agents are excluded from this limitation. No requirements for prior authorization or other restrictions on medications used to treat mental illnesses such as schizophrenia, severe depression, or bipolar disorder may be imposed on Medicaid recipients. Medications that will be available without restriction for persons with mental illnesses include atypical antipsychotic medications, conventional antipsychotic medications, selective serotonin reuptake inhibitors, and other medications used for the treatment of serious mental illnesses. The agency shall also limit the amount of a prescribed drug dispensed to no more than a 34-day supply. The agency shall continue to provide

unlimited generic drugs, contraceptive drugs and items, and diabetic supplies. The agency may authorize exceptions to the brand-name-drug restriction, based upon the treatment needs of the patients, only when such exceptions are based on prior consultation provided by the agency or an agency contractor, but the agency must establish procedures to ensure that:

a. There will be a response to a request for prior consultation by telephone or other telecommunication device within 24 hours after receipt of a request for prior consultation; and

b. A 72-hour supply of the drug prescribed will be provided in an emergency or when the agency does not provide a response within 24 hours as required by sub-subparagraph a.

2. Reimbursement to pharmacies for Medicaid prescribed drugs shall be set at the lower of the average wholesale price less 13.25 percent, wholesaler acquisition costs plus 7 percent, federal or state pricing limits, or the provider's usual and customary charge.

3. The agency shall develop and implement a process for managing the drug therapies of Medicaid recipients who are using significant numbers of prescribed drugs each month. The management process may include, but is not limited to, comprehensive, physician-directed medical-record reviews, claims analyses, and case evaluations to determine the medical necessity and appropriateness of a patient's treatment plan and drug therapies. The agency may contract with a private organization to provide drug-program-management services.

4. The agency may limit the size of its pharmacy network based on need, competitive bidding, price negotiations, credentialing, or similar criteria. The agency shall give special consideration to rural areas in determining

the size and location of pharmacies included in the Medicaid pharmacy network. A pharmacy credentialing process may include criteria such as a pharmacy's full-service status, location, size, patient educational programs, patient consultation, disease-management services, and other characteristics. The agency may impose a moratorium on Medicaid pharmacy enrollment when it is determined that it has a sufficient number of Medicaid-participating providers.

5. The agency shall develop and implement a program that requires Medicaid practitioners who prescribe drugs to use a counterfeit-proof prescription pad for Medicaid prescriptions. The agency shall require the use of standardized counterfeit-proof prescription pads by Medicaid-participating prescribers. The agency may implement the program in targeted geographic areas or statewide.

6. The agency may enter into arrangements that require manufacturers of generic drugs prescribed to Medicaid recipients to provide rebates of at least 15.1 percent of the average manufacturer price for the manufacturer's generic products. These arrangements shall require that if a generic-drug manufacturer pays federal rebates for Medicaid-reimbursed drugs at a level below 15.1 percent, the manufacturer must provide a supplemental rebate to the state in an amount necessary to achieve a 15.1-percent rebate level. If a generic-drug manufacturer raises its price in excess of the Consumer Price Index (Urban), the excess amount shall be included in the supplemental rebate to the state.

7. The agency may establish a restricted formulary in accordance with 42 U.S.C. s. 1396r, and pursuant to the establishment of such formulary, is authorized to negotiate supplemental rebates from manufacturers at no less than 10

percent of the average wholesale price on the last day of each quarter. State supplemental manufacturer rebates will be invoiced concurrently with federal rebates.

Section 3. This act shall take effect July 1, 2001.

****

HOUSE SUMMARY

With respect to the regulation of prescription drugs under the Medicaid program, provides for the development of a restricted drug formulary by the Medicaid Pharmaceutical and Therapeutics Committee. Replaces the voluntary Medicaid preferred prescribed drug designation program with the restricted drug formulary. Revises membership of the committee. Requires the Agency for Health Care Administration to establish a restricted drug formulary upon recommendation by the committee. Provides for revisions to the formulary by the committee and the agency. Requires the agency to publish and disseminate the formulary to all Medicaid providers in the state.

Revises the method of determining reimbursement to pharmacies for Medicaid-prescribed drugs under the Medicaid-prescribed drug spending-control program implemented by the agency. Authorizes the agency to establish a restricted formulary and to negotiate supplemental rebates from manufacturers.