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HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH CARE SERVICES
ANALYSIS

BILL #: HB 2049

RELATING TO: Medicaid Prescribed Drug Services

SPONSOR(S): Representative Kelly

TIED BILL(S):

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

(1) HEALTH CARE SERVICES
(2) HEALTH & HUMAN SERVICES APPROPRIATIONS
(3)
(4)
(5)

I. SUMMARY:

HB 2049 relates to Medicaid prescribed drug services. The bill:

- Directs the Agency for Health Care Administration to establish a preferred drug designation program, built upon specified parameters relating to the requirement that a prescribing physician shall be required to consult with another physician prior to prescribing a drug that has not received preferred drug designation. This is to be implemented with the advice of the Pharmacy and Therapeutics Committee.

- Authorizes the agency to implement prescribed drug cost-containment initiatives, which can include specified parameters.

- Directs the agency to maintain an open formulary consistent with these provisions.

- Requires the agency to file a report with the Governor and Legislative leadership each January 1, regarding progress made in controlling Medicaid prescribed drug costs.

- Creates a nine-member Pharmacy and Therapeutics Committee, with specified membership, duties, including advising the agency on the preferred drug designation program. Authorizes travel and per diem reimbursement for committee members specific to committee functions.

The bill's effective date is July 1, 2000.

The agency estimates that the drug designation program and the committee will cost $1.8 million, while the cost containment measures will save $185.8 million, for a net savings of $184 in the Medicaid prescribed drug program.

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

1.	Less Government	Yes []	No [x]	N/A []
2.	Lower Taxes	Yes []	No []	N/A [x]
3.	Individual Freedom	Yes []	No [x]	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:

1. In creating the preferred drug designation program and the associated Pharmacy and Therapeutics Committee, the bill creates more functions for the Florida Medicaid program.

3. In specifying the use of a preferred drug approach to Medicaid prescribed drugs, Medicaid recipients and their prescribing providers will have diminished freedom compared to the current absolutely open formulary under Medicaid.

B. PRESENT SITUATION:

Medicaid

Medicaid is a medical assistance program that pays for health care for the poor and disabled. The program is jointly funded by the federal government, the state, and the counties. The federal government, through law and regulations, has established extensive requirements for the Medicaid program. The Agency for Health Care Administration is the single state agency responsible for administering the Florida Medicaid program. The statutory provisions for the Medicaid program appear in ss. 409.901 through 409.9205, F.S. Section 409.905, F.S., specifies the 12 required services under the Florida Medicaid program, per federal Medicaid regulations. Section 409.906, F.S., lists the 24 “optional” service categories that the State of Florida has chosen to include in the Florida Medicaid program. Among the latter is prescribed drug services, s. 409.906(20), F.S.

The state budget for the program for the current fiscal year is $7,416,045,061, and the program anticipates serving 1,607,144 clients this year.

Medicaid Prescribed Drug Program

Currently, Medicaid uses an open drug formulary, where recipients may obtain most prescription drugs without restriction. Adult recipients are limited to six prescriptions per month, but additional prescriptions are readily obtained if medically necessary. Many utilization limits are in place to prevent overuse or misuse, but most brand and generic drugs are available within their medically-accepted standards. Medicaid does not employ a Pharmacy and Therapeutics Committee to determine the most cost-effective drugs to include in a Medicaid formulary. In addition, nursing home patients now receive all prescription drugs through the fee-for-service system and are limited to eight drugs per

month, with an exception process identical to that used for community residents. Neither the nursing home nor the pharmacy has a financial stake in controlling the costs or utilization of prescriptions by Medicaid recipients.

While the number of recipients and provider reimbursement levels have been relatively stable over the past three years, Medicaid spending for prescription drugs has increased at an annual rate of over 20 percent. The cost of new drugs, effects of direct-to-consumer advertising for new drugs, and increases in utilization are the three pertinent factors to this increase. The increase in cost is being experienced by other states' Medicaid programs. Without intervention, Florida's Medicaid spending for prescription drugs will increase by over $600 million to $2 billion in 2000. Prescription drugs will surpass hospital inpatient expenditures as the second most expensive component of the Medicaid budget in FY 1999-2000, and will be second only to nursing homes. (Source: Social Services Estimating Conference, November 1999).

While the prescription drug benefit is not a federal required service for Medicaid programs, all states provide this benefit as an important part of their overall health care programs. Some states impose a monthly "hard cap" limit, with exceptions, for prescription drugs. For example, Texas has a three prescription cap; California's program is based on a closed formulary with a six prescription limit; and Georgia limits prescriptions to five per month. Prescription costs per member and overall program costs per member are lower than Florida's for all three of these states. (Source: Health Care Financing Administration 64 and 2082 reports, FY 1997).

Title XIX, Section 1927, of the Social Security Act states that a prior authorization program established by a state under paragraph (5) is not a formulary subject to the requirements of a Pharmacy and Therapeutics Committee.

Medicaid Cost Containment Initiatives

Medicaid cost containment initiatives have primarily focused on two fronts: disease management and fraud and abuse initiatives. Beginning in 1997, the Legislature directed the Agency for Health Care Administration to establish disease management programs under the Medicaid program. Initially targeted were disease management programs specific to Medicaid recipients with a diagnosis of diabetes, hemophilia, asthma, and HIV/AIDS. In 1998, the Legislature added end stage renal disease, congestive heart failure, cancer, sickle cell anemia, and hypertension to the targeted disease list. In 1999, legislation was adopted to permit implementation of disease management programs for any condition. The Medicaid budget has already been reduced by $42 million in anticipation of savings resulting fro implementation of the disease management initiative.

The Legislature, the Attorney General's Office, and specifically the Medicaid Fraud Control Unit under the Attorney General, the Agency for Health Care Administration, the Office of Statewide Prosecutor, and the federal government have taken numerous steps over the past several years to combat fraud and abuse within the Florida Medicaid program. Past initiatives have included: claims payment analyses and controls, provider surety bonds and financial background checks, on-site provider visits, Level I and Level II criminal background checks, additional Medicaid Management Information System edits, and improved interagency coordination. Current initiatives include: pharmacy audits, including on-site audits and audits specific to overpayments, an explanation of medical benefits mailing to some recipients; pharmacy lock-in, whereby a federal waiver has been obtained to permit the state to lock-in an abusive Medicaid recipient to a single pharmacy; recipient fingerprinting demonstration project, at approximately 200 pharmacies to ensure that only

the eligible recipient or an authorized representative is picking up prescribed drugs; enhanced claims analysis and automated fraud and abuse detection capabilities; additional pharmacy fraud and abuse controls, including surety bonds and on-site inspections prior to entering provider agreements; fraud detection system enhancements to identify patterns of fraud; and Physician Practice Pattern review, including drug usage evaluation, prescribing profiles, physician education, and outcomes analysis. Budget reductions of $75 million have already been made in expectation of savings from the various fraud and abuse activities and the Practice Pattern Review program.

Medicaid Formulary Study Panel

The 1999 Florida Legislature established the Medicaid Formulary Study Panel by budget proviso to prepare recommendations on the advisability, feasibility, and cost-effectiveness of implementing an appropriate formulary for the Medicaid prescribed drug program. The panel consisted of nine members, three members each appointed by the Governor, the Speaker of the House of Representatives, and the President of the Senate. The Executive Director of the Agency for Health Care Administration served as the panel's chairperson.

The panel's findings were based on its evaluation of reports, Medicaid program data, and information provided by experts and public testimony.

- Since the mid-1990s the rate of increase in overall Medicaid expenditures has not exceeded 6 percent per year. However, the rate of increase for prescribed drugs has continued to grow at double-digit levels. In FY 1999-2000, the rate of increase for the entire Medicaid program will be 6 percent compared to 16.9 percent for prescribed medicines.

- Medicaid prescription drug costs are projected to reach $1.2 billion in FY 1999-2000. Left unchecked, by FY 2000-2001, the prescribed drug line item could exceed $1.5 billion -- outstripping hospital inpatient expenditures for the first time in the program's history, second only to nursing home costs.

- Florida has one of the highest drug costs per person in the country, $999 per drug recipient in 1999.

- Some factors that contribute to increasing costs include direct marketing to consumers, increased marketing to providers, new and more expensive drug therapies for chronic illnesses, higher ingredient costs, multiple drug therapies, an aging population, recognition of new diseases, new uses of existing drugs, and changes in patient demographics.

- The use of formularies is a common practice in the private sector.

- Medicaid is a primary payer of care for severly impaired individuals and people with serious chronic illnesses. Ten percent of Medicaid beneficiaries account for nearly 70 percent of total program expenditures.

The panel considered the following formulary-based and non-formulary-based options during its deliberations:

<u>Formulary-Based Options</u>

- Establish a preferred drug list (formulary) for all major drugs.

- Establish a preferred drug list (formulary) for a select group of therapeutic categories.
- Establish a selective preferred drug list.
- Establish a state drug manufacturer rebate program in conjunction with a preferred drug list.

Non-Formulary-Based Options

- Establish a monthly “hard” limit on *all* drugs for non-institutionalized, adult Medicaid patients.
- Establish a monthly “hard” limit on *brand name* drugs for non-institutionalized, adult Medicaid patients.
- Modify ingredient cost pricing.
- Require a state supplemental rebate in the form of product at best price from manufacturers and based on market share of Medicaid patients by therapeutic class.
- Maintain an open formulary for Medicaid prescribed medicines and strengthen disease management initiatives to control overall health care costs, including prescription drug expenditures.

The panel supported the option to maintain an open formulary for Medicaid prescribed medicines, and to enhance disease management initiatives to control prescription drug expenditures.

The panel voted not to recommend the adoption of any type of preferred drug list for the Florida Medicaid prescribed medicine program by a vote of 6 to 3. Panel mambers who voted against any of the preferred drug list approaches cited concerns raised during the public testimony and other arguments against these measures as reasons for their decision. Although the panel did not endorse a preferred drug list, they prepared an implementation plan describing how a preferred drug list could be implemented should the Legislature decide to adopt one of the Medicaid program.

C. EFFECT OF PROPOSED CHANGES:

HB 2049 directs the Agency for Health Care Administration to establish a preferred drug designation program, with specific advice and input from a nine-member Pharmacy and Therapeutics Committee. The parameters of the program are specified, as are duties for the committee. The bill also: authorizes the agency to implement prescribed drug cost-containment initiatives, which can include specified parameters; directs the agency to maintain an open formulary consistent with these provisions; and requires the agency to file a report with the Governor and Legislative leadership each January 1, regarding progress made in controlling Medicaid prescribed drug costs.

See the following SECTION-BY-SECTION ANALYSIS for additional details.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Amends s. 409.912, F.S., relating to cost-effective purchasing of health care under the Medicaid program, to add as a new subsection (37) relating to various aspects of Medicaid’s prescribed drug program, as follows:

Paragraph (a) provides authority for AHCA to develop and implement a Medicaid preferred prescribed drug designation program. Prescribing of a drug that does not have a preferred drug designation under the program would require a prior consultation with another physician. The Pharmacy and Therapeutics Committee established under

s. 409.91203, F.S., by section 2 of the bill, will advise the agency in the development and implementation of the program.

Paragraph (b) authorizes the agency to implement prescribed drugs cost containment initiatives, including, but not limited to:

- Limiting the number of name-brand prescriptions available to adult Medicaid recipients on a monthly basis;
- Capitation of the prescribed drug benefit for nursing home residents or alternative cost control measures;
- Negotiating and controlling additional supplemental rebates from pharmaceutical manufacturers; and
- Other cost-effective purchasing of prescribed drugs, in accordance with federal law.

Paragraph (c) directs the Medicaid program to maintain an open formulary consistent with the provisions of this subsection.

Paragraph (d) requires the agency to submit a report to the Governor and Legislative leaders by January 15 of each year, addressing, but not limited to, the progress that has been made to control costs in Medicaid prescribed drug services.

Section 2. Creates s. 409.91203, F.S., relating to the Pharmacy and Therapeutics Committee to advise the agency and provide guidance in the development and implementation of the Medicaid preferred prescribed drug designation program. Staff support for the committee is to come from AHCA. The following subsections are created:

Subsection (1) specifies that the committee be composed of nine members as required by federal law, each of whom will be appointed by the Governor or his or her designee for a four-year term. The members are as follows: four Florida-physicians licensed, one of whom must have experience in managing a preferred prescribed drug designation program; four Florida-licensed pharmacists; and a consumer representative. The bill provides immunity from liability for committee members in the conduct of their duties.

Subsection (2) specifies to following duties for the committee:

- Recommending the initial prescribed drugs for program designation based on specific criteria relating to: Medicaid participating physician and pharmacist preference, effectiveness, safety, misuse potential, essentialness, therapeutic comparisons and advantages, impact on Medicaid spending, and manufacturers' existing or proposed discounts and disease management participation and funding.
- Ongoing review and recommendations regarding drug designation, either additions or deletions.
- Evaluation adequacy of preferred prescribed drug designations, based on specified criteria.

- Assisting in the development of clinical guidelines, especially for prescribed drugs.

Subsection (3) specifies that members serve without compensation, except for allowable travel and per diem expenses

Section 3. Provides for a July 1, 2000, effective date.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

Though technically not revenues, the agency estimates the following cost avoidance associated with the identified aspects of this bill:

Savings from Preferred Drug Designation
(projected amount dependent on classes chosen by Pharmacy and Therapeutics, which drugs designated as preferred in those classes, and protocols or mechanisms for obtaining non-preferreds, lapsed 6 months)

General Revenue	($17,886,553)	($ 35,773,106)
Grants and Donations Trust Fund	($ 9,030,167)	($ 18,060,334)
Medical Care Trust Fund	($23,250,874)	($ 46,501,747)
Total Expenditure Reduction	($50,167,594)	($100,335,187)

Savings from Brand Name Drug Limit
(projected limit of 4 RX/month/adult, no lapse)

General Revenue	($ 46,929,215)	($ 46,929,215)
Grants and Donations Trust Fund	($ 23,692,583)	($ 23,692,583)
Medical Care Trust Fund	($ 61,003,662)	($ 61,003,662)
Total Expenditure Reduction	($131,625,460)	($131,625,460)

Savings from Capitation of NH RX
(expected 8% savings of $100 million annual expenditures, lapsed 6 months)

General Revenue	($1,426,144)	($2,852,288)
Grants and Donations Trust Fund	($ 720,000)	($1,440,000)
Medical Care Trust Fund	($1,853,856)	($3,707,712)
Total Expenditure Reduction	($4,000,000)	($8,000,000)
General Revenue	($ 66,241,912)	($ 85,554,609)
Grants and Donations Trust Fund	($ 33,442,750)	($ 43,192,917)
Medical Care Trust Fund	($ 86,108,392)	($111,213,121)
Total Prescribed Drug Reduction	($185,793,054)	($239,960,647)

2. Expenditures:

   The agency also estimates costs of $1.8 million associated with the preferred prescribed drug designation program and the Pharmacy and Therapeutics Committee.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   N/A

2. Expenditures:

   N/A

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Pharmaceutical manufacturers may experience a different mix of drug sales to the Medicaid population, not necessarily fewer drugs, but more generics and fewer high-cost brand name drugs. The manufacturers may also pay slightly more rebates to Medicaid than they do now.

Pharmacies would experience the same change in the mix of drugs provided to Medicaid recipients; however, the pharmacies' profit margins may not be affected or may increase as generics generally allow a higher profit to the pharmacy.

Doctors would have to alter their prescribing patterns to adopt the "preferred drugs" for prescriptions are not automatically covered by Medicaid.

D. FISCAL COMMENTS:

Given the estimated revenues and expenditures above, AHCA indicates a net savings under the Medicaid prescribed drug program of $184 million.

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 action requiring the expenditure of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

The bill does not reduce the authority that counties or municipalities 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:

A. CONSTITUTIONAL ISSUES:

N/A

B. RULE-MAKING AUTHORITY:

N/A

C. OTHER COMMENTS:

The provisions of this bill appear to conflict with, or at least run counter to, the provisions of HB 2145, the House General Appeopriations bill, and HB 2151, a related bill specific to Medicaid prescribed drug cost reductions, both of which were approved on second reading by the House on March 31, 2000.

This bill is directly counter to the recommendations of the Legislatively created Medicaid Formulary Study Panel report issued on March 3, 2000. See the PRESENT SITUATION portion of this analysis for an overview of the panel's report recommendations.

In its analysis of this bill, the Agency for Health Care Administration noted:

> In creating the 9-member Pharmacy and Therapeutics Committee, the bill references a federal requirement relating to this membership (page 3, lines 7-8). This is not accurate. Only if a state Medicaid program adopts a formulary under its Medicaid program is it required to have a 9-member pharmacy and therapeutics committee. Since the bill does not set up a specific formulary, no such advisory body is required by federal Medicaid regulations.
>
> Regarding litigation potential, AHCA noted that since the bill will reduce expenditures in the Medicaid prescribed drug program by creating a "cap" on monthly brand prescriptions, or by reducing access to drugs that are not designated as "preferred," many Medicaid recipients will see this as a reduction in their benefits. As a result, these recipients may exercise their right to appeal any reduction in benefits, generating many appeal hearings. In addition, if a manufacturer's drug is denied the "preferred drug" designation, the manufacturer may request an administrative hearing to review the Agency or the Pharmacy and Therapeutics Committee's decision.

Title XIX, Section 1927, of the Social Security Act states that a prior authorization program established by a state under paragraph (5) is *not* a formulary subject to the requirement of a pharmacy and therapeutics committee. Since this bill proposes to maintain an open formulary, including appointment of a pharmacy and therapeutics committee is an unnecessary and government-increasing part of the bill that could be eliminated.

The agency has the authority to implement and administer a preferred drug list with prior authorization, and all other practical effects of this bill. The present Drug Utilization Review

Board and or Practice Pattern Review Panel, each composed of practicing physicians and pharmacists, are available to provide input and review of the proposed preferred drug list. These groups are presently meeting concurrently on a quarterly basis, and have developed methods for review of appropriate therapies including those criteria outlined in this bill. The preferred-drug designation program could be implemented immediately upon passage of the bill.

A suggestion would be to amend subsection (37)(a) to state that the agency will implement a Medicaid preferred-drug designation program, with advice of the Drug Utilization Review Board and Prescribing Pattern Review Panel. Eliminate the unnecessary creation of a new pharmacy and therapeutics committee (Section 2.), but require (d), submission of an annual report to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

N/A

VII. SIGNATURES:

COMMITTEE ON HEALTH CARE SERVICES:

Prepared by: Staff Director:

Phil E. Williams Phil E. Williams