HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 433 Purchasing of Medicaid Prescribed Drugs
SPONSOR(S): Roberson
TIED BILLS: **IDEN./SIM. BILLS:** SB 894

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee		Holt	Calamas
2)	Health & Family Services Policy Council			
3)	Health Care Appropriations Committee			
4)	Full Appropriations Council on General Government & Health Care			
5)				

SUMMARY ANALYSIS

The bill requires a provider of prescribed drugs to give preference in the purchasing of Medicaid prescribed drugs, including generic drugs, to drugs that are manufactured or repackaged at a "qualified facility" located in this state. A "qualified facility" is defined as a new or expanding facility located in this state at which prescription drugs are manufactured or repackaged. A manufacturer or repackaging facility *may* apply to the Department of Health for a permit recognizing them as a "qualified facility".

The Department of Health is directed to adopt rules prescribing a permit application form, procedures, and criteria for recognizing a qualified facility. Once a "qualified facility" is permitted they are eligible for Medicaid drug purchasing preference.

The fiscal impact to the Medicaid program is indeterminate. The Department of Health believes that no additional staff would be needed and they could perform the duties outlined in the bill within existing resources.

The bill takes effect July 1, 2009.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background:

Medicaid Preferred Drug List

The 2001 Florida Legislature significantly expanded its efforts to control pharmaceutical costs in the state's Medicaid program by enacting a program called the preferred drug list (PDL).[1] Under this law, Medicaid prescribing practitioners are required to prescribe the medications on the PDL, or must obtain prior authorization from the Agency for Health Care Administration ("agency") to prescribe a medication not on the PDL, in order for Medicaid to pay for the prescription.

In order for a drug manufacturer to have its medications considered for inclusion on the PDL, it must agree to provide the state both federally-mandated rebates and state-mandated supplemental rebates. Since rebate negotiations involve disclosure by pharmaceutical manufacturers of proprietary information regarding the elements of their wholesale pricing, federal law prohibits disclosure of information received by Medicaid agencies from manufacturers that discloses identities of manufacturers or wholesalers or the prices charged by these manufacturers or wholesalers.[2] The federal prohibition applies to the U.S. Secretary of the Department of Health and Human Services, the U.S. Secretary of Veterans Affairs, and state Medicaid agencies and their contractors.

To address the federal confidentiality requirements and to ensure the use of this pricing information for negotiating state supplemental rebate agreements, the 2001 Legislature enacted a public records and public meetings exemption related to rebate negotiations.[3] Trade secrets, rebate amount, percent of rebate, manufacturer's pricing, and supplemental rebates with respect to supplemental rebate negotiations are confidential and exempt from public records requirements.

Minnesota Multistate Contracting Alliance for Pharmacy

Currently, the Department of Health and the Department of Corrections purchase their drugs through the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP).[4] The MMCAP was created in 1985 as a free voluntary group purchasing organization operated and managed by the Materials

[1] Chapter 2001-104, L.O.F.
[2] 42 U.S.C. 1396r 8
[3] Chapter 2001 216, L.O.F.; codified in s. 409.91196, F.S.
[4] Email from the Department of Health on file with the Health Care Regulation Policy Committee.

Management Division of the State of Minnesota's Department of Administration for government healthcare facilities. MMCAP is currently encompasses 45 member states that purchase over $1 billion per year and have national account status with all of the major brand name and generic pharmaceutical manufacturers.[5]

MMCAP's primary function is to provide a full range of pharmaceuticals to its participating facilities. But also has contracts for vials and containers, medical supplies, drug testing, returned goods processing, influenza vaccine, and dental supplies. MMCAP does not establish a formulary, but compiles a list of frequently used drugs from its facilities. Participating facilities are encouraged, but not required, to exclusively use MMCAP contracts and contract pricing, since it creates the volume that results in the best value for all members.[6]

Effects of the Bill

The bill requires a provider of prescribed drugs to receive preference in the purchasing of Medicaid prescribed drugs, including generic drugs, to drugs that are manufactured or repackaged at a "qualified facility" located in this state. A "qualified facility" is defined as a new or expanding facility located in this state at which prescription drugs are manufactured or repackaged. A manufacturer or repackaging facility *may* apply to the Department of Health for a permit recognizing them as a "qualified facility".

According to the Agency for Health Care Administration, this language is in conflict with federal fair trade laws, and is in conflict with federal requirements and state statutes regarding reimbursement to Medicaid providers of prescribed drugs. The bill would eliminate the pricing competition that is the basis for the equitable reimbursement of Medicaid pharmacy providers, which references the acquisition cost for products. Medicaid pharmacy providers in the state are subject to federal upper limit pricing for many drugs, and if limited to obtaining their inventory from suppliers in the state, they could potentially have acquisition costs higher than the allowable reimbursement. Both state and federal maximum allowable reimbursement is based upon free competition among all suppliers, and this language would give "qualifying facilities" an unfair advantage for market share along with freedom from competition.[7]

In addition, according to the Agency for Health Care Administration, restricting the purchasing function of Florida pharmacies subject to federal and state reimbursement limits based on competitive market prices would place Florida Medicaid pharmacy providers at a disadvantage, and places them at risk of providing services at less than their costs. Independent pharmacies, which typically operate on smaller earnings margins than larger chain drug stores, may be more significantly impacted. Access to prescribed drug services for Medicaid recipients may be negatively impacted if pharmacies cannot remain sufficiently profitable to continue to provide services for Medicaid recipients.[8]

The bill directs the Department of Health to adopt rules prescribing a permit application form, procedures, and criteria for recognizing a qualified facility. Once a "qualified facility" is permitted it is eligible for Medicaid drug purchasing preference.

B. SECTION DIRECTORY:

Section 1. Amends s. 409.908, F.S., relating to the reimbursement of Medicaid providers.
Section 2. Creates s s. 499.01205, F.S., relating to the recognition of qualifying facility for Medicaid purchasing preference.
Section 3. Provides that the bill takes effect July 1, 2009.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

[5] Minnesota Multistate Contracting Alliance for Pharmacy, What is MMCP and Membership. Available online at: http://www.mmd.admin.state.mn.us/mmcap/background.htm (last viewed March 15, 2009).
[6] *Id.*
[7] See generally, Agency for Health Care Administration Bill Analysis, HB 433, March 15, 2009.
[8] *Id*.

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   Not applicable.

2. Expenditures:

   See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   Not applicable.

2. Expenditures:

   Not applicable.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Manufacturers and repackagers of prescription drugs located in the State of Florida who receive recognition as "qualifying facilities" will obtain preference when purchasing Medicaid prescribed drugs.

D. FISCAL COMMENTS:

The bill has no specific definitions, provisions, or parameters that would allow quantification of the fiscal impact to the Medicaid program. However, the bill potentially creates a pricing environment that reduces price competition in the marketplace, thereby placing Medicaid at a disadvantage.

The Department of Health projects that that approximately 96 prescription drug manufacturers and 15 prescription drug repackagers will apply for recognition as a "qualifying facility", which would increase the workload for staff in the Drugs, Devices, and Cosmetics Program to process an additional application type. However, the Department of Health believes that no additional staff would be needed and they could perform the duties outlined in the bill within existing resources.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. This bill does not appear to: require counties or municipalities to spend funds or take an action requiring the expenditure of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of a state tax sharing with counties or municipalities.

2. Other:

   The bill may implicate the Clayton Antitrust Act[9], by eliminating the pricing competition that is the basis for the equitable reimbursement of Medicaid pharmacy providers, which references the acquisition cost for products. The Clayton Antitrust Act specifically prohibits any person engaged in commerce, either directly or indirectly, to discriminate in price of items of like grade and quality, if such discrimination substantially lessens competition or tends to create a monopoly in any line of commerce, or to injure, destroy, or prevent competition with any person who either grants of knowingly receives the benefit of such discrimination.[10]

[9] 15 USC 1 § 13, 13a.
[10] *Ibid.*

The bill may implicate Section 3, Article II, of the Florida Constitution, providing for the separation of powers. As interpreted by the Florida Supreme Court, that section prohibits delegation of legislative authority to the other branches of government. The Florida Supreme Court has opined: "[w]here the Legislature makes the fundamental policy decision and delegates to some other body the task of implementing that policy under adequate safeguards, there is no violation of the [Delegation of Powers] doctrine." *Askew v. Cross Key Waterways*, 372 So.2d 913 at 921. (Fla.1978). The bill may not provide sufficient guidance to the Department of Health as to the criteria for recognizing a "qualified facility". Similarly, the bill may not provide sufficient guidance to the Agency for Health Care Administration on what constitutes a "purchasing preference".

The bill may implicate Section 8, Article I, of the United States Constitution, granting Congress the power to regulate commerce among the states. Federal cases addressing legitimate state objectives may be persuasive, including *Department of Revenue of Kentucky v. Davis*, 128 S.Ct. 1801 (2008); *United Haulers Association v. Oneida-Herkimer Solid Waste Management Authority*, 127 S.Ct. 1786 (2007); *Granhelm v. Heald* 544 U.S. 460 (2005); *Oregon Waste Systems, Inc., v. Dept. of Environmental Quality of Ore.*, 511 U.S. 93 (1994); and *New Energy Co. of Ind. V. Limbach*, 486 U.S. 269 (1988).

B. RULE-MAKING AUTHORITY:

The bill authorizes the Department of Health to adopt rules to prescribe a permit application, approval procedures, and criteria for recognizing a "qualifying facility".

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill states that pharmacies must "give preference in the purchasing of Medicaid prescribed drugs", it is not clear whether a pharmacy must maintain two separate inventories in the event that inventory purchases were made elsewhere for non-Medicaid customers. Furthermore, the term "preference" is not defined.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES