HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 361 Medicaid/Wholesale Drug Prices
SPONSOR(S): Vana and others
TIED BILLS: None. **IDEN./SIM. BILLS:** CS/SB 320 (s)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Services (Sub)	8 Y, 0 N	Mitchell	Collins
2) Health Care			
3) Health Appropriations (Sub)			
4) Appropriations			
5)			

SUMMARY ANALYSIS

HB 361 amends s. 409.9066, F.S., relating to the Medicaid Prescription Discount program, to require drug manufacturers that participate in the program to disclose the average wholesale price of all prescription drugs eligible for sale in the Medicaid or pharmaceutical expense assistance programs. The bill requires manufacturers to disclose the price information at least once every six months and requires the Agency for Health Care Administration (AHCA) to publish the information on a free website available to the public.

During the 2000 Florida legislative session, the Legislature enacted a program provided for by s. 409.9066, F.S., to require that, as a condition of participation in the Medicaid program or the pharmaceutical expense assistance program, a pharmacy must agree to charge any Medicare beneficiary a price no greater than the cost of ingredients equal to the average wholesale price minus 9 percent, and a dispensing fee of $4.50.

In lieu of the requirement, a pharmacy must either provide or accept a private, voluntary prescription discount program to Medicare beneficiaries, as a condition of participation in the Medicaid program or the pharmaceutical expense assistance program. These discounts must be at least as great as the discount provided above equal to the average wholesale price minus 9 percent, and a dispensing fee of $4.50.

Many Medicare beneficiaries have complained that they have no way to verify that they are getting the full discount. The bill provides a mechanism for elder consumers to confirm the price they should be paying for medications. The bill will help address the high costs of prescription drugs that are not covered by Medicare and represent a substantial out-of-pocket burden for many elder persons.

The effective date of the bill is July 1, 2003.

According to the Agency for Health Care Administration, it will cost $50,351 for the first year and $46,726 for the second and subsequent years for the agency to collect and publish the information on the website. These costs will be 50% federally reimbursable with a Medicaid administrative match, thereby costing the agency $25,176 for the first year and $23,363 for the second and subsequent years.

On April 2, 2003, the Health Services Subcommittee adopted a “strike-all” amendment to the bill and reported the bill favorably to the Health Care Committee. See: Section IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES for details.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

1. Reduce government?	Yes[]	No[X]	N/A[]
2. Lower taxes?	Yes[]	No[]	N/A[X]
3. Expand individual freedom?	Yes[]	No[]	N/A[X]
4. Increase personal responsibility?	Yes[]	No[]	N/A[X]
5. Empower families?	Yes[X]	No[]	N/A[]

For any principle that received a "no" above, please explain:

The bill requires certain drug manufacturers to report additional information to a government agency.

B. EFFECT OF PROPOSED CHANGES:

HB 361 amends s. 409.9066, F.S., relating to the Medicaid Prescription Discount program to require drug manufacturers that participate in the program to disclose at least once every six months the average wholesale price of all prescription drugs eligible for sale in the Medicaid or pharmaceutical expense assistance programs. The bill requires the Agency for Health Care Administration to publish the price information on a free website available to the public.

The effective date of the bill is July 1, 2003.

CURRENT SITUATION

Medicare Prescription Discount Program
During the 2000 Florida legislative session, the Legislature enacted a program established in s. 409.9066, F.S., that requires a pharmacy to agree to charge any Medicare beneficiary a price no greater than the cost of ingredients equal to the average wholesale price, minus 9 percent, and a dispensing fee of $4.50, as a condition of participation in the Medicaid program or the pharmaceutical expense assistance program.

In lieu of the requirement, a pharmacy must either provide or accept a private, voluntary prescription discount program to Medicare beneficiaries, as a condition of participation in the Medicaid program or the pharmaceutical expense assistance program. These discounts must be at least as great as the discount provided above equal to the average wholesale price minus 9 percent, and a dispensing fee of $4.50.

Many Medicare beneficiaries have complained that they have no way to verify that they are getting the full discount.

High Cost of Prescription Drugs
The purpose of this bill is to address the high costs of prescription drugs that represent a substantial out-of-pocket burden for many elderly persons. Outpatient prescription drugs are not covered by Medicare. This lack of prescription drug coverage is often cited as a major shortcoming of the Medicare program, the federal health insurance program for older and disabled Americans.

Nationwide, Medicare beneficiaries spend an average of $415 per year on prescription drugs. Individuals who are older, who have poor health status, or who have limitations on their activities, spend twice the average amount per year.

Seniors, as individual purchasers of prescription drugs, tend to be charged higher prices than group purchasers, due in large part to the ability of large group purchasers to shop for and negotiate better prices for both the prescription drug and dispensing fees charged by pharmacists. Individuals rarely have the ability to influence either of these prices, and therefore are subject to cost-shifting from groups with more purchasing power.

Florida is home to approximately 2.6 million elderly Medicare beneficiaries. Over 90 percent of these elders take one prescribed drug. On average, a Medicare recipient takes seven different medications. There is a direct correlation between advancing age and the number of prescription drugs taken. Although Americans over 65 make up only 12 percent of the population, they take 25 percent of all prescribed drugs sold in the United States.

Prescription Drug Coverage
Approximately 65 percent of non-institutionalized Medicare beneficiaries have some form of prescription drug coverage; however, the level of this coverage varies. Most (59 percent) of these individuals with prescription drug coverage receive their drug coverage through private supplemental insurance, either through employer-sponsored plans or individually purchased private policies. About one-fifth of Medicare beneficiaries with prescription drug coverage are members of Medicare HMOs, which, in an effort to attract seniors, have offered various levels of prescription drug coverage at no additional cost to the enrollee. The scope and availability of Medicare HMO prescription drug coverage varies widely within and across market areas. A number of HMO plans responded to the federal rate changes under the Balanced Budget Act of 1997 by ceasing operations in some counties in Florida, reducing coverage for some benefits, often prescription drug benefits, or raising prices in areas where the HMO plan determined that rates were inadequate to meet their operational costs. The future of these benefits is uncertain.

Medicaid Prescription Coverage
Approximately 10 percent of Florida Medicare beneficiaries have coverage through the Medicaid program. Medicaid covers prescription medications for elderly and disabled individuals whose incomes are under 90 percent of the federal poverty level. Medicaid will also pay some medical expenses not covered by Medicare, generally up to Medicaid limits for these individuals.

Wholesale Drug Prices
The average wholesale price for prescription drugs is established by either the manufacturer or one of the three major wholesale drug companies and published in trade literature such as The Red Book, wholesale catalogues, databases or on microfiche and distributed to trading partners in the industry. Public access to these prices is not generally available. Similarly, access to wholesale prices for other products such as groceries or electrical supplies is not generally available.

According to AHCA, it currently purchases pricing information from a commercial marketer, First DataBank. This pricing information is, in most cases, obtained through wholesaler surveys and not from manufacturers. In addition, this information is considered proprietary by First DataBank's contract with the Medicaid fiscal agent. The agency was denied permission in 1999 to publish current pricing data by First DataBank but was granted approval to publish partial information provided it was at least 90 days out of date.

Pharmaceutical Pricing
Pharmaceutical pricing in the United States is the product of a complex system of marketing and purchasing arrangements, government controls and competitive pressures. Pricing of a given drug eventually dispensed to a consumer is generally a factor of the distribution channel the drug in question flows through and the presence or absence of government regulation and control.

Cash customers are generally individuals who either lack prescription drug coverage and therefore pay out of their own pockets, or have indemnity-type insurance that reimburses them after they have made their cash purchases. Cash customers generally pay the highest prices for drugs because they

lack the opportunity and bargaining power to negotiate discounts from either the retail pharmacy or the manufacturer. They generally pay at or above a drug's average wholesale price (AWP), which is the manufacturer's list price.

Pharmacy Benefit Managers (PBM) are private third parties that manage drug benefits for large groups of individuals, such as enrollees in an insurance plan or employees of a self-insured company. By negotiating both discounts from participating pharmacies and rebates from preferred manufacturers, PBM customers typically pay less than a drug's average manufacturer price (AMP) – which is about 20 percent below AWP – and as low as 40 percent below AWP.

Institutional Purchasers - Hospitals and group or staff model health maintenance organizations, that own and operate their own pharmacies generally receive favorable pricing from manufacturers because they do not have to buy through retail channels and can negotiate directly with manufacturers, either individually or as part of a group purchasing organization. Negotiated discounts for the purchase of drugs are subject to the requirements of the Robinson-Patman Price Discrimination Act. In 1936, Congress passed the Robinson-Patman Price Discrimination Act, which provides that price savings on quantity purchases must relate to quantitative differences and nothing more. The Robinson-Patman Price Discrimination Act provides exemptions to purchases of supplies by schools, churches, hospitals, public libraries, and other nonprofit institutions when those supplies are for the "use of the institution." The United States Supreme Court has held that the purchase of discounted drugs by a nonprofit hospital are exempt from the Robinson-Patman Price Discrimination Act if the drug purchases are for the institution's own use and intended for the entity's operation in the care of individuals who are its patients - Abbott Laboratories et al v. Portland Retail Druggists Association, 425 U.S. 1 (1976).

340B Program - Many federally-funded clinics, health departments and hospitals are eligible for below-market discounts under section 340B of the Public Health Service Act. This act provides these clinics and hospitals with the same price discounts as Medicaid. However, 340B providers usually pay less than the Medicaid net price because they are able to negotiate sub-ceiling prices. They also save by not paying drug mark-ups and dispensing fees to retail pharmacies.

Federal Supply Schedule (FSS) - The FSS is a schedule of contracts and prices for frequently used supplies and services available for purchasing by federal agencies and other entities such as the U.S. territories and tribal governments. There are no statutory ceilings on prices, but the government often uses a "most favored customer" price as a starting point in negotiations to obtain below-market prices. FSS prices are on average slightly above 340B prices.

Federal Ceiling Price - The Veterans Administration, Department of Defense, Public Health Service, and Coast Guard often get pricing below FSS on brand name drugs because these drugs are subject to a maximum statutory price called the federal ceiling price (FCP). FCP is set at 24 percent below the non-federal average manufacturer price, or AMP, often referred to as non-FAMP. FCP prices are on average slightly below 340B prices.

VA Contract - In 1992, Congress enacted the Veterans Health Care Act (s. 602, P.L. 102-585) allowing certain federal, state, and local government agencies to purchase prescription drugs at discounted public health service prices. Under this law, a drug manufacturer must enter into discount pricing agreements with the Department of Veterans Affairs and with covered entities funded by the Public Health Service in order to have its drugs covered by Medicaid. Covered entities include certain disproportionate share hospitals, federally qualified health centers, AIDS and tuberculosis clinics, and other outpatient clinics funded under the Public Health Service Act. To qualify for the drug pricing program, the covered entity must be a federal purchaser or federally-funded grantee recognized under section 340B of the Public Health Service Act.

Department of Health Pharmacy Purchasing - Section 381.0203, Florida Statutes, authorizes the Florida Department of Health to contract on a statewide basis for the purchase of drugs, to be used by state agencies and political subdivisions. The Office of Pharmacy Services within the Florida

Department of Health contracts for the purchase of drugs for use by state agencies and political subdivisions. Under this program, the state negotiates a discounted price with drug manufacturers currently for county health departments, the Department of Corrections, and the Department of Children and Families. The negotiated contract language customarily contains a provision that limits the use of the discounted drugs purchased by the state for clients or patients of the state.

Medicaid Rebate Program - Federal Medicaid law requires drug manufacturers to pay state Medicaid agencies a quarterly rebate on brand name drugs equal to 15.1 percent off of AMP or the manufacturer's best price, whichever is lower, plus an additional rebate if the price of the drug has risen faster than the rate of inflation. The Medicaid net price is the effective price paid after the minimum price is reduced further by either the best price or inflationary adjustment, or both. Because Medicaid is entitled to a manufacturer's best price or better, the Medicaid net price will almost always be as good as or better than the best prices negotiated in the private sector (whether by a PBM, health maintenance organization, group purchasing organization or other private purchaser.) The Florida Medicaid program, in addition, has the authority to negotiate state supplemental rebates. Florida Medicaid, in its claims processing, tests the price a pharmacy submits against a logic routine which pays the lesser of AWP minus 13.25 percent, the wholesale acquisition cost plus 7 percent, the federal ceiling price, or the usual and customary charge. The system pays whichever is the lowest price, plus a dispensing fee.

C. SECTION DIRECTORY:

Section 1. Amends s. 409.9066, F.S., relating to the Medicare prescription discount program to require drug manufacturers to disclose their average wholesale prices and the Agency for Health Care Administration to publish the information on a free web site, available to the public.

Section 2. Provides an effective date of July 1, 2003.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   See Fiscal Comments.

2. Expenditures:

   See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

There will be a fiscal impact on some manufacturers due to the requirement that they designate an average wholesale price for products currently priced only at "direct sale" or "wholesaler" cost. They will be required to distribute that information to AHCA bi-annually. Manufacturers that already provide a suggested average wholesale price will simply be required to ensure this information is transmitted to AHCA two times per year.

D. FISCAL COMMENTS:

The Agency for Health Care Administration reports that there will be a fiscal impact on the agency for collecting and publishing pricing information from more than 400 manufacturers on more than 35,000 individual prescription drug products/packages reimbursable by Medicaid on a bi-annual basis. The agency expects that, based on past experience, there will be a large number of inquiries from the public seeking follow-up information.

According to the agency, collecting the information required by the bill and publishing such information on a web page will require additional staff resources equivalent to one FTE. The agency states that the costs will be $50,351 for the first year and $46,726 for the second and subsequent years. These costs will be 50 percent federally reimbursable with a Medicaid administrative match. Accordingly, the agency states it will incur a fiscal impact of $25,176 for the first year and $23,363 for the second and subsequent years.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

According to AHCA, an administrative rule will be necessary to implement the provisions of this bill. The agency reports it has authority to promulgate administrative rules related to pharmacy providers but does not have authority to promulgate a rule requiring actions by pharmaceutical manufacturers other than obliquely through coverage and limitations within the pharmacy provider manual.

C. DRAFTING ISSUES OR OTHER COMMENTS:

According to AHCA, businesses that publish average wholesale price information for the pharmaceutical industry may object to the legislation on several grounds. The lack of a clear definition of “average wholesale price” may result in allegations that the legislation is unconstitutionally vague.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On April 2, 2003, the Health Services Subcommittee adopted a “strike-all” amendment and reported the bill favorably to the Health Care Committee:

Amendment 1 requires the Agency for Health Care Administration to publish on a website, the average wholesale price of the 200 drugs most frequently dispensed to the elderly and to report to the Legislature on the cost effectiveness and alternatives to using average wholesale prices for Medicaid purchasing.