

STORAGE NAME: h0769p1.hcs

DATE: March 22, 2000

**HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH CARE SERVICES
ANALYSIS**

BILL #: PCS/HB 769

RELATING TO: Pharmacy Benefit Program

SPONSOR(S): Representatives Argenziano, Byrd, and others

TIED BILL(S):

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

- (1) HEALTH CARE SERVICES
 - (2) ELDER AFFAIRS AND LONG-TERM CARE
 - (3) GOVERNMENT RULES AND REGULATIONS
 - (4) HEALTH AND HUMAN SERVICES APPROPRIATIONS
 - (5)
-

I. SUMMARY:

Proposed Committee Substitute for HB 769 provides for:

- A pharmacy assistance program for very low-income elders, targeting those with incomes between 90 and 100 percent of the federal poverty level, the so-called qualified Medicare beneficiaries (QMBs); and those with incomes between 100 and 120 percent of the federal poverty level, the so-called special low-income Medicare beneficiaries (SLMBs);
- Reduced prescribed drug costs for Medicare beneficiaries by requiring that, as a condition of participation in the Florida Medicaid program and the pharmacy benefit program, a pharmacy must agree that the charge to any Medicare beneficiary who presents a Medicare card when presenting a prescription be equal to the amount paid to that pharmacy for filling a prescription under Medicaid;
- A pharmacy benefit counseling and assistance program as part of the Office of Volunteer Community Service within the Department of Elderly Affairs;
- A Medication Cost-Reduction Program, which provides for the aggregated purchase of the 25 most frequently prescribed drugs for elders and for the disabled by the state as a most favored customer, with administrative costs to be paid by those who participate in the program.
- Authorization for the Agency for Health Care Administration (AHCA) to pursue a federal waiver designed to target any available federal financial participation for the new benefit program and counseling services; and
- Specific appropriations from General Revenue of \$40 million to AHCA to fund the pharmacy assistance program, and of \$250,000 to AHCA to implement the Medicaid cost-reduction program as provided in the bill.

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

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

- | | | | |
|-----------------------------------|------------------------------|--|---|
| 1. <u>Less Government</u> | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 2. <u>Lower Taxes</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 3. <u>Individual Freedom</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 4. <u>Personal Responsibility</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 5. <u>Family Empowerment</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |

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

In creating the Pharmacy Benefit Program, the pharmacy benefit counseling and assistance program, and the medication cost reduction program, the bill requires the establishment of expanded government functions.

B. PRESENT SITUATION:

Outpatient prescription drugs, which are not covered by Medicare, represent a substantial out-of-pocket burden for many elderly and disabled persons. This lack is often cited as a major shortcoming of the Medicare program, the federal health insurance program for older and disabled Americans. On average, elderly people spend just over \$2,000 on medical care and prescription drugs, almost twenty percent of their annual income, even though most are on Medicare and have some type of private insurance as well, according to a recent study by the American Association of Retired Persons. The Commonwealth Fund estimates that 11 percent of Medicare beneficiaries spend more than \$100 per month on prescription drugs.

Florida is home to approximately 2.5 million elderly Medicare beneficiaries. Over 90 percent of these elders take one prescribed drug daily, while the average take 7 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. According to the Department of Elderly Affairs, over 15 percent of older people keep their expenses down by taking less medication than prescribed, or by going without their medications altogether. This strategy compromises the effectiveness of controlling the progression of chronic diseases, resulting in a greater likelihood that these elders will use hospital emergency rooms or other urgent care.

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 (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 prescription drug benefits under Medicare HMOs is uncertain.

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% of the federal poverty level. Medicaid will also pay some medical expenses not covered by Medicare, generally up to Medicaid limits for these individuals.

Medicare Supplement Policies

Part VIII of ch. 627, F.S., establishes regulatory requirements for Medicare supplement policies. Approximately 13 percent of seniors with drug coverage have purchased individual Medicare supplement policies (known as "Medigap" policies) which cover medical services not covered by Medicare. These supplement policies are labeled by the Department of Insurance, in terms of coverage packages offered, as plans A thru J. Plans labeled H, I, and J provide coverage for prescription medications. Plans H and I pay 50 percent of charges for prescription drugs with a maximum benefit of \$1,250 per year. Plan J pays 50 percent of charges for prescription drugs up to \$3,000 per year. All Medigap drug plans have a \$250 deductible, and pay 50 percent of the cost of the prescription. The cost of supplemental coverage for Medicare beneficiaries may range from \$132 to \$324 per month, depending on the extent of coverage in the plan selected, age, health status, and other factors.

Out-of-Pocket Spending on Prescription Drug by Seniors

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 services 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.

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 the Florida Medicaid program. The statutory provisions for the Medicaid program appear in ss. 409.901 through 409.9205, F.S. Individuals who are elderly or disabled, whose incomes are under 100 percent of the federal poverty level (FPL) are an optional coverage group eligible for Medicaid under the provisions of s. 409.904(1), F.S. Payments for services to individuals in the optional categories are subject to the availability of monies and any limitations established by the General Appropriations Act or chapter 216, F.S. In the 1992 special session of the Legislature, proviso language in the amended General Appropriations Act reduced Medicaid eligibility from 100 percent FPL to 90 percent FPL.

Medicaid spent approximately \$249 million on prescriptions for 170,000 aged persons in 1998, an average of approximately \$1,465 per person.

Certain Medicare beneficiaries have incomes low enough to qualify for limited Medicaid benefits--currently between 90 percent and 120 percent of the federal poverty level--but Medicaid does not pay for any outpatient prescription drugs for these individuals. Medicaid only covers Medicare premiums, deductibles, or copayments for these individuals. These individuals are responsible for the costs of their own prescriptions.

Department of Elderly Affairs--Volunteer Programs

The Office of Volunteer and Community Services was created within the Department of Elderly Affairs when the department was created in 1991, as s. 430.07, F.S. The office annually compiles an inventory of services needed yet not currently received by elders which can be provided by elders acting as volunteers. In addition, the office: identifies state rules and policies which restrict volunteer service by and for elders and proposes corrective action in a report to the Legislature; identifies methods of promoting volunteer service by and for older persons; develops volunteer programs that include individuals of all ages while drawing on the strengths and skills of Florida's elders; and encourages contributions and grants through private, state, and federal sources to promote, implement, and evaluate volunteer programs by elders. This program has fostered large increases in the volunteer numbers and hours of service. In addition to volunteer programs, the Information Clearinghouse, as authorized in s. 430.04(4), F.S., is also located in the office and receives thousands of calls and requests annually for information.

SHINE (Serving Health Insurance Needs of Elders) is a free, volunteer-based health insurance counseling program administered by the Florida Department of Elderly Affairs, Office of Volunteer and Community Services. SHINE is an award-winning program geared toward helping elders navigate through the complicated health insurance system. For two consecutive years, SHINE earned the Davis Productivity Award from Florida TaxWatch for teamwork and initiative in enhancing the services provided to Florida's elders. Volunteer counselors offer expertise on Medicare, Medicaid, long-term care insurance, and health maintenance organizations (HMOs). SHINE volunteers can help with understanding health care choices under the Medicare+Choice program and other changes brought about by the Balanced Budget Amendment of 1997. SHINE has a network of over 600 volunteer counselors in 55 counties. More than 30,000 clients were assisted by SHINE during the 1997/1998 grant year, the most recent year for which complete information is available.

Drug Manufacturers' Patient Assistance Programs

Uninsured individuals, including the elderly whose prescription drug costs are not otherwise covered, may obtain some drugs through the drug manufacturers' patient assistance programs that are available for limited periods of time, and only available via direct intervention by a treating physician. The lack of a central point of contact for this activity, the time limited nature of such coverage, differing eligibility criteria, and a cumbersome application process create frustration and discourage patient and physician participation. Even so, Pfizer, one of the large drug manufacturers, reported that in 1998 it provided \$8.6 million in indigent drug assistance via over 111,000 prescriptions to just under 50,000 patients through more than 2,300 health care providers in the State of Florida during 1998.

Medicaid Drug Rebate Program

The Omnibus Budget Reconciliation Act of 1990 requires a pharmaceutical company to pay a rebate on its drug products in order to receive reimbursement by the Medicaid program. This law requires drug manufacturers that participate in the Medicaid program to enter into a national rebate contract with the Secretary of the Department of Health and Human Services for states to receive federal funding for outpatient drugs dispensed to Medicaid patients. The rebate program requires drug manufacturers to pay state Medicaid programs, for each of a manufacturer's pharmaceutical products, the higher of a basic percentage rebate or a rebate equivalent to the best price the manufacturer offers a non-government customer. Manufacturers must pay an additional rebate if the price of any product has increased faster than the Consumer Price Index since the fourth quarter of 1990. These rebates apply only to state Medicaid programs and are not available to the general public.

Medicaid Pharmacy Pricing

Medicaid uses a complex algorithm to determine the price it will pay for a specific drug at a given time. The maximum Medicaid will pay is the lesser of the Average Wholesale price of the drug less 11.5 percent, the wholesale acquisition cost of the drug plus 7 percent, the Federal maximum allowable cost, the state maximum cost, or the amount billed. The pricing system edits a claim which has been billed to Medicaid, and therefore does not apply to non-Medicaid transactions.

Negotiated Drug Discounts

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 were 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.

Other States' Programs Providing Pharmaceutical Assistance to the Elderly

A number of states have implemented, or are implementing, programs or exploring policy options that involve: 1) assisting elderly and disabled individuals in gaining access to the prescription drug discounts and rebates enjoyed by government; or 2) developing a state-funded program which would provide either coverage or access to prescription medications for the elderly. Sources of funds for these programs include: the state general fund, tobacco tax, tobacco settlements, sales tax, rebate revenue, trust funds, lottery and casino revenues, and participant fees.

According to an April 1999 report from the AARP, 14 states have implemented programs to provide pharmaceutical coverage for low-income elderly persons or persons with disabilities who do not qualify for Medicaid. The 14 states that have implemented such programs are: Maine and New Jersey (1975); Maryland (1979); Delaware (1981); Pennsylvania (1984); Illinois and Rhode Island (1985); Connecticut (1986); New York (1987); Wyoming (1988); Vermont (1989); Michigan (1994); Massachusetts (1996); and Minnesota (1999).

Information available from the Pharmaceutical Research and Manufacturers of America (PHARMA) in August 1999 indicated that 15 states had a state pharmaceutical assistance program for low-income elderly. Compared to the AARP list of 14 states, the PHARMA data included Missouri and Nevada, but did not include Wyoming. As of November 1999, the National Conference of State Legislatures reported that a total of 16 states had adopted elder pharmacy assistance programs, with North Carolina being the newest. Another five states considered but did not adopt such programs as part of 1999 legislative deliberations, according to PHARMA. As of early February 2000, the National Conference of State Legislatures reported that, so far, 29 states have senior pharmaceutical assistance programs on the agenda for 2000.

Federal Poverty Level

The federal Department of Health and Human Services annually updates the federal poverty guidelines used as the basis for eligibility for a variety of federal and state programs. These data, generally referred to as the "federal poverty level" are published in the *Federal Register*. As published on February 15, 2000, the federal poverty level for the indicated family sizes and percentage levels for the year 2000 are as follows:

<u>Size of Family Unit</u>	<u>90% of FPL</u>	<u>100% of FPL</u>	<u>120% of FPL</u>
1	\$7,515	\$8,350	\$10,020
2	\$10,125	\$11,250	\$13,500
3	\$12,735	\$14,150	\$16,980
4	\$15,345	\$17,050	\$20,460

C. EFFECT OF PROPOSED CHANGES:

PCS/HB 769 provides for: a pharmacy assistance program for very low-income elders; reduced prescribed drug costs for Medicare beneficiaries; a pharmacy benefit counseling and assistance program; the Medication Cost-Reduction Program; federal waiver authorization; and specific appropriations. See the SECTION-BY-SECTION ANALYSIS which follows for additional detail.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Creates the pharmacy benefit program consisting of the following subsections:

Subsection (1) provides legislative intent relating to the focus of the program on very low income people, and leveraging maximum pharmaceutical manufacturer participation in the program.

Subsection (2) provides for the establishment of the pharmacy benefit program, designed to provide prescription drug coverage to a limited group of the most needy individuals. The program is to be administered by the Agency for Health Care Administration in conjunction with the Department of Elderly Affairs.

Subsection (3) provides for program eligibility, limited to those individuals who qualify for limited assistance under the Florida Medicaid program as a result of being dually eligible for both Medicare and Medicaid, but whose limited assistance does not include any pharmacy benefit. Specifically eligible are the following low-income senior citizens:

those with incomes between 90 and 100 percent of the federal poverty level, the so-called qualified Medicare beneficiaries (QMBs); and those with incomes between 100 and 120 percent of the federal poverty level, the so-called special low-income Medicare beneficiaries (SLMBs).

Subsection (4) specifies program parameters. The program must include the Medicaid open formulary of prescribed drugs, with generics used when available and appropriate. The agency is directed to, by rule, determine an eligibility process, a 20 percent copayment requirement, an annual limit of \$1,000 per beneficiary, and other program parameters as necessary. The Medicaid fiscal agent or a separately contracted pharmacy benefits manager, or both, are to be used for the processing and payment of claims.

Subsection (5) requires pharmaceutical manufacturers, in order to have a drug covered under this program, to: provide the maximum rebate to the state as authorized in federal Medicaid regulations and other applicable federal regulations or guidelines; make the drug available to the program for the best price that the manufacturer makes the drug available under any purchasing arrangement; agree to actively participate in Florida with the Indigent Drug Program of the Pharmaceutical Research and Manufacturers of America and the pharmacy benefit counseling and assistance program as established by the bill.

Subsection (6) authorizes the agency to petition the U.S. Food and Drug Administration for approval to purchase otherwise prohibited medications from foreign sources for purposes of distribution under the program.

Subsection (7) authorizes the agency to adopt rules to implement this section.

Section 2. Requires that as a condition of participation in the Florida Medicaid program and the pharmacy benefit program, a pharmacy must agree that the charge to any Medicare beneficiary who presents a Medicare card when presenting a prescription be equal to the amount paid to that pharmacy for filling a prescription under Medicaid.

Section 3. Creates s. 430.072, F.S., relating to the pharmacy benefit counseling and assistance program.

Subsection (1) creates the program within the Office of Volunteer Community Services within the Department of Elderly Affairs, for the purpose of assisting elderly persons in obtaining prescription medications that they would otherwise not be able to afford. The new office is to implement, monitor, and evaluate the delivery or counseling services under the program. Other specific duties are provided, including: service delivery through specific types of volunteers; collaboration with other entities; and contributions and grants.

Subsection (2) provides for family unit assessment according to specified guidelines developed to determine need for pharmacy services. Assessment elements include ability to pay and dependence upon prescription medication. "Family unit" is defined in this context.

Subsection (4) directs DOEA to accept and encourage contributions and grants for funding counseling services.

Subsection (5) requires the director of Health Care Administration and the Secretary of Health to assign staff with expertise in the areas of pharmacy benefit management and chronic disease management to assist the DOEA Office of Volunteer Community Service with this program, and AHCA is directed to assign a pharmacist, from existing resources, to this program to assist with establishing and operating this program.

Subsection (6) directs DOEA to adopt rules to implement this section.

Section 4. Establishes the Medication Cost-Reduction Program, consisting of the following provisions:

Subsection (1) directs the Director of the Agency for Health Care Administration, in consultation with the Secretary of Health, the Secretary of the Department of Elderly Affairs, and the director of the Division of State Group Insurance of the Department of Management Services, within 180 days after the effective date of this act, to: develop a program to aggregate the purchase of prescription drugs for residents of the state who are 65 years of age and older, or who are disabled as defined in s. 415.102, F.S.; to provide for qualification of the state as a most favored customer in the purchase of prescription drugs; and to pass the cost savings resulting from this most favored customer status on to such state residents.

Subsection (2) directs the program to provide for the distribution of prescription drugs to residents of this state who age 65 years of age and older or disabled, at the most favored customer status rate, limited to those 25 drugs most prescribed to elders and those 25 drugs most prescribed to the disabled, with an annual review of these drugs.

Subsection (3) specifies that administrative costs associated with this program shall be covered by participation or membership charge to those elderly or disabled persons participating in the program.

Subsection (4) authorizes the AHCA director to enter into an agreement with one or more not-for-profit entities for the purpose of developing and managing this program, through a request for proposals process, based on specified selection criteria.

Subsection (5) requires the AHCA director to document certain cost savings and public benefits prior to accepting a proposal for these benefit management services, and report certain information to legislative leadership. Saves from termination any existing contract of any impacted agency or program.

Section 5. Directs AHCA to pursue with the federal Health Care Financing Administration any possible waivers that might be used to obtain federal matching funds for any aspects of the pharmacy benefit program or the counseling program.

Section 6. Appropriates from General Revenue to AHCA \$40 million to fund the pharmacy assistance program.

Section 7. Appropriates from General Revenue to AHCA \$250,000 for implementation of the Medicaid cost-reduction program as created by the bill.

Section 8. Provides a July 1, 2000, effective date.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

N/A

2. Expenditures:

The bill appropriates from General Revenue to AHCA \$40 million to fund the pharmacy assistance program, and from General Revenue to AHCA \$250,000 for the Medicaid cost-reduction program.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

N/A

2. Expenditures:

To the extent that local governments may be providing funds to a local effort to provide pharmacy assistance to local elderly residents, such counties may see a decrease in demand for any such program.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The requirement for discount prescription pricing for Medicare beneficiaries who are not covered by the programs created in the bill will reduce revenues to pharmacies serving Medicare beneficiaries.

The bill will, for the first time, impose price controls on pharmacies in Florida. Industry reaction to this proposal is not expected to be favorable.

D. FISCAL COMMENTS:

To the extent that the two groups specifically targeted for the pharmacy benefit program, namely those very low-income elders with incomes between 90 and 120 percent of the federal poverty level, are already known to Medicaid because of the limited benefits they receive as dually eligible for Medicare and Medicaid, the administrative costs of identifying these individuals will be minimal.

While the bill provides no specific appropriation to the Department of Elderly Affairs, the department indicates a need for \$643,719 to fund the Pharmacy Benefit Counseling and Assistance Program.

In its bill analysis, AHCA indicated a need for \$50.6 million to implement the provisions of the pharmacy benefit program.

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 expend funds or to take action requiring the expenditure of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

This 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 state tax shared with counties or municipalities.

V. COMMENTS:

A. CONSTITUTIONAL ISSUES:

Although section 2 of this bill may have an impact on interstate commerce, as a general rule, if Congress has not enacted laws in a subject area to the contrary, the states may regulate local aspects of interstate commerce. The courts generally apply a balancing test. Only if the regulations seriously impede commerce and produce little local benefit will the courts invalidate the state action. If the state provisions regulate even-handedly to effectuate a legitimate local public interest and their effects on interstate commerce are only incidental, the state regulation is generally upheld.

B. RULE-MAKING AUTHORITY:

N/A

C. OTHER COMMENTS:

A technical correction is needed on page 10, line 11. The appropriation section inadvertently refers to the *Medicaid* Cost-Reduction Program, not the *Medication* Cost-Reduction Program as created by section 4 of the bill.

Since issues relating to pharmacy assistance under Medicare are pending in Congress, consideration may need to be given to a "sunset" of this bill's provisions if comparable provisions are adopted federally.

There is no indication in the bill how benefits under the new pharmacy benefit program will be coordinated with the Medicaid Medically Needy Program, which is designed as a catastrophic coverage option based on month-to-month eligibility via spend-down.

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In its review of the bill, the Department of Health provided the following comments regarding subsection (6) of section 1. The bill authorizes AHCA to petition the federal Food and Drug Administration for approval to purchase otherwise prohibited medications from foreign sources for purposes of distribution under the program. The Prescription Drug Marketing Act of 1987 (PDMA) prohibits the re-importation of drugs intended for sale in foreign countries. This act was passed partially as a result of frauds perpetrated against American manufacturers and also because it provided cover for the importation of foreign counterfeit drugs. The PDMA does provide for reimportation, under FDA authorization, for emergency medical care, but it is inconceivable to assume the provisions of this bill meet this requirement.

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