SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based only on the provisions contained in the legislation as of the latest date listed below.)

BILL: CS/SB 940

SPONSOR: Health, Aging and Long-Term Care Committee, Senator Lee and others

SUBJECT: Health Care/Prescription Drugs

DATE: March 15, 2000 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Liem	Wilson	HC	Favorable/CS
2.			FP	
3.				
4.				
5.				

I. Summary:

The Committee Substitute for Senate Bill 940 creates a catastrophic pharmaceutical expense assistance program for individuals over the age of 65 who have an income at or below 250 percent of the Federal Poverty Level and who have out-of-pocket prescription expenses that exceed or are projected to exceed 10 percent of their incomes. The program is not an entitlement and is to be administered by the Agency for Health Care Administration (AHCA) in consultation with the Department of Elderly Affairs (DOEA). The bill requires that, to the extent possible, administration of the program (including eligibility determination, claim processing, and reporting) use existing administrative mechanisms such as the Medicaid fiscal agent and area agencies on aging.

The bill requires AHCA to make payments for prescription drugs on behalf of eligible individuals, and AHCA and DOEA to develop a single-page application for the catastrophic pharmaceutical expense program. AHCA is required to by rule establish eligibility requirements, limits on participation, benefit limitations, a requirement for generic drug substitution and other program parameters comparable to Medicaid for the program. AHCA is to report annually to the Legislature on the operation of the program.

The bill requires that, as a condition of participation in the Medicaid program and the catastrophic pharmaceutical expense program, a pharmacy must agree that the charge to any Medicare beneficiary who presents a Medicare card be no greater than the Medicaid rate for ingredients and dispensing fees, plus 2.5% of the Medicaid ingredient payment.

The bill finds that physicians and other health care professionals have a fiduciary responsibility to act in the best interests of their patients and requires the Board of Medicine, the Board of Osteopathic Medicine, the Board of Podiatric Medicine and the Board of Dentistry to adopt by rule, guidelines to discourage health care practitioners under their jurisdictions from accepting gifts, payments, subsidies or other financial inducements from pharmaceutical manufacturers which may undermine the practitioners independent judgement. Complimentary samples of drugs

are not included as gifts, payments, subsidies or financial inducements. The bill mandates that each of these boards require the practitioners under their jurisdiction to disclose gifts, subsidies payments and other financial inducements from manufacturers which conflict with the practitioners duty of loyalty to his or her patients.

The bill provides an appropriation to the Agency for Health Care Administration to provide Medicaid services for persons whose incomes are between 90 and 100 percent of the Federal poverty Level, to implement the catastrophic pharmaceutical expense assistance program, and to develop a computerized system to allow participating pharmacies to determine the maximum allowable charge for prescription drugs sold to Medicare beneficiaries.

The bill creates an undesignated section of law.

II. Present Situation:

Outpatient prescription drugs, which are not covered by Medicare, represent a substantial out-of-pocket burden for many elderly persons. This lack is often cited as a major shortcoming of the Medicare program, the federal health insurance program for older and disabled Americans.

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 Elder 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 disease, 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 these benefits 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 (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 $1250 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 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 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 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.

Fourteen 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).

Pharmacy Manufacturer Gifts to Physicians

A controversy exists over the regular contact that physicians have with the pharmaceutical industry and its sales representatives, who spend a large sum of money each year promoting their products to physicians by way of gifts, free meals, travel subsidies, sponsored teachings, and symposia. A recent article, "Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?" *Journal of the American Medical Association*, Vol. 283, No. 3 (January 19, 2000) identified the extent of and attitudes toward the relationship between the pharmaceutical industry and its representatives and physicians and the impcat of such relationships on the knowledge, attitude and behavior of physicians. The researcher reviewed 29 studies published since 1994 and found that meetings between doctors and drug company representatives correlated with "nonrational" prescribing habits, such as increased requests to add drugs to hospital formularies, increased prescription rates and prescription of more expensive drugs rather than generic equivalents. According to the researcher's calculations, meetings between drug company representatives and physicians typically begin during medical school and subsequently occur on average four times per month, with companies spending between $8,000 and $13,000 per physician in promotions annually.

Part II, ch. 455, F.S., provides the general regulatory provisions for health care professions licensed by the department. Section 455.624, F.S., provides grounds for which licensed health care professionals may be disciplined by the Department of Health or the regulatory board which has jurisdiction over the professional. Licensed health care professionals may be disciplined for exercising influence on a patient or client for the purpose of financial gain of the licensee or a third party. The practice of medicine is regulated by the Board of Medicine within the Department of Health. The Board of Medicine may discipline medical physicians who violate applicable practice standards, including those listed in ch. 455, F.S., or the medical practice act. The practices of osteopathic medicine, podiatry, and dentistry are similarly regulated within the Department of Health.

III. Effect of Proposed Changes:

Section 1. Creates a catastrophic pharmaceutical expense assistance program for individuals over the age of 65 who have an income at or below 250 percent of the Federal Poverty Level and have out-of-pocket prescription expenses that exceed or are projected to exceed 10 percent of their incomes. The program is to be administered by the Agency for Health Care Administration, in consultation with the Department of Elderly Affairs. The benefits under the program are those covered by the Medicaid program in s. 409.906(20), F.S. The bill requires that, to the extent possible, administration of the program including eligibility determination, claim processing, and reporting, use existing administrative mechanisms such as the Medicaid fiscal agent and area agencies on aging.

The bill requires AHCA to make payments for prescription drugs on behalf of eligible individuals, and AHCA and DOEA to develop a single-page application for the catastrophic pharmaceutical expense program.

The bill requires AHCA to by rule establish eligibility requirements, limits on participation, benefit limitations, a requirement for generic drug substitution and other program parameters comparable to Medicaid for the catastrophic pharmaceutical expense program.

The bill requires an annual report to the Legislature on the operation of the program and states that the program is not an entitlement.

Section 2. Requires that as a condition of participation in the Medicaid program and the catastrophic pharmaceutical expense program, a pharmacy must agree that the charge to any Medicare beneficiary who presents a Medicare card be no greater than the Medicaid rate for ingredients and dispensing fees, plus 2.5% of the Medicaid ingredient payment.

Section 3. Provides that the nature of the relationship between the patient and practitioner and the underlying trust in that relationship prompt the need for guidelines to avoid the receipt by health care practitioners of gifts, payments, subsidies or other financial inducements from pharmaceutical manufacturers which adversely shape the health care practitioners' independent professional judgment and which undermine their patients' access to treatment, course of care, and clinical outcomes. The Board of Medicine, the Board of Osteopathic Medicine, the Board of Podiatric Medicine, and the Board of Dentistry must adopt, by rule, guidelines to discourage health care practitioners under their respective jurisdictions from accepting gifts, payments, subsidies, or other financial inducements from pharmaceutical manufacturers which may undermine the practitioners' independent professional judgment. Any gift, payment, or other financial inducement that a health care practitioner receives from a pharmaceutical manufacturer should primarily entail a benefit to his or her patients and should not be of substantial value. Complimentary samples of medicinal drugs are excluded from the requirements of this section.

Section 4. Appropriates $15,244,200 from the Medical Care Trust fund and $11,755,800 from the General Revenue Fund to the Agency for Health Care Administration to provide Medicaid services for persons who are eligible under section 409.904(1), F.S., whose incomes are between 90 and 100 percent of the Federal Poverty Level.

Section 5. Appropriates $42 million from the General Revenue Fund to the Agency for Health Care Administration to implement the catastrophic pharmaceutical expense assistance program.

Section 6. Appropriates $1 million from the General Revenue Fund to the to the Agency for Health Care Administration to develop a computerized system that allows participating pharmacies to determine allowable maximum payments for prescription drugs under section 2 of the bill.

Section 7. The act takes effect upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Subsections 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The requirement for discount prescription pricing for Medicare beneficiaries who are not covered by the program created in the bill will reduce revenues to pharmacies and pharmaceutical manufacturers.

C. Government Sector Impact:

The bill appropriates $54,755,800 from the General Revenue Fund and $15,244,200 from the Medical Care Trust Fund to the Agency for Health Care Administration.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.