

**STORAGE NAME:** h1087s1.grr

**DATE:** April 7, 2000

**HOUSE OF REPRESENTATIVES  
AS FURTHER REVISED BY THE COMMITTEE ON  
GOVERNMENTAL RULES & REGULATIONS  
ANALYSIS**

**BILL #:** CS/HB 1087

**RELATING TO:** Delivery of Health Care Services/Elder Pharmacy Assistance

**SPONSOR(S):** Committee on Health Care Services and Representatives Pruitt, Goode, and others

**TIED BILL(S):**

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

- (1) HEALTH CARE SERVICES YEAS 17 NAYS 0
- (2) ELDER AFFAIRS & LONG TERM CARE YEAS 11 NAYS 0
- (3) GOVERNMENTAL RULES & REGULATIONS
- (4) HEALTH AND HUMAN SERVICES APPROPRIATIONS
- (5)

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**I. SUMMARY:**

CS/HB 1087 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, after payments by other liable entities are deducted. 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 administration of the program, to the extent possible, to include the 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; with DOEA, to develop a single-page application for the program; establish, by rule, eligibility requirements, limits on participation, benefit limitations, a requirement for generic drug substitution, and other program parameters comparable to Medicaid for the program; and 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 when presenting a prescription be no greater than the Medicaid rate for ingredients and dispensing fees, plus 2.5 percent of the Medicaid ingredient payment.

The bill provides Legislative findings regarding the nature of the relationship between the patient and practitioner, and the underlying trust in that relationship, prompting 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, and specifies that accepting such gifts, payments, subsidies, or other financial inducements which do not primarily entail a benefit to patients, are of substantial value, and undermine the practitioner's judgment or which conflict with the practitioner's duty of loyalty to patients shall be grounds for disciplinary action.

The bill appropriates \$54,755,800 from General Revenue and \$15,244,200 from the Medical Care Trust Fund 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; implement the catastrophic pharmaceutical expense assistance program; and develop a computerized system to allow participating pharmacies to determine the maximum allowable charge for prescription drugs sold to Medicare beneficiaries.

The act takes effect upon becoming a law, and there is one amendment traveling with the bill.

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 checked="" type="checkbox"/> | No <input type="checkbox"/>            | N/A <input type="checkbox"/>            |
| 4. <u>Personal Responsibility</u> | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/>            | N/A <input type="checkbox"/>            |
| 5. <u>Family Empowerment</u>      | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/>            | N/A <input type="checkbox"/>            |

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

Less Government

In creating the Catastrophic Pharmaceutical Expense Program, the bill requires the establishment of an expanded government function relating to eligibility for and operation of the program.

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 20 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 (AARP). 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 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 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 - 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.

### **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 111,00 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.

### **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 impact 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 of Health. 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 profession. 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.

### **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>100% of FPL</u>	<u>250% of FPL</u>
1	\$8,350	\$20,875
2	\$11,250	\$28,125
3	\$14,150	\$35,375
4	\$17,050	\$42,625

### **C. EFFECT OF PROPOSED CHANGES:**

CS/HB 1087 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, after payments by other liable entities are deducted. 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 administration of the program, to the extent possible, to include the 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; with DOEA, to develop a single-page application for the program; establish, by rule, eligibility requirements, limits on participation, benefit limitations, a requirement for generic drug substitution, and other program parameters comparable to Medicaid for the program; and 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 when presenting a prescription be no greater than the Medicaid rate for ingredients and dispensing fees, plus 2.5 percent of the Medicaid ingredient payment.

The bill provides Legislative findings regarding the nature of the relationship between the patient and practitioner, and the underlying trust in that relationship, prompting 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, and specifies that accepting gifts, payments, subsidies, or other financial inducements from pharmaceutical manufacturers which do not primarily entail a benefit to patients, are of substantial value, and undermine the practitioner's independent professional judgment or which conflict with the practitioner's duty of loyalty to patients shall be grounds for disciplinary action.

The bill appropriates \$54,755,800 from General Revenue and \$15,244,200 from the Medical Care Trust Fund 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; implement the catastrophic pharmaceutical expense assistance program; and develop a computerized system to allow participating pharmacies to determine the maximum allowable charge for prescription drugs sold to Medicare beneficiaries.

**D. SECTION-BY-SECTION ANALYSIS:**

**Section 1.** Creates a catastrophic pharmaceutical expense assistance program consisting of the following subsections:

Subsection (1) establishes the program to provide financial assistance to low-income elderly individuals with catastrophic pharmaceutical expenses.

Subsection (2) limits eligibility to those individuals who do not qualify for assistance under Medicaid, who are 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 after payments by other liable entities are deducted.

Subsection (3) specifies that the benefits under the program are those covered by the Medicaid program under s. 409.906(20), F.S. It also specifies that payments shall be for the total amount of prescription drug expenses above 10 percent of an individual's annual income.

Subsection (4) provides for the program to be administered by the Agency for Health Care Administration, in consultation with the Department of Elderly Affairs. The bill requires: that, to the extent possible, administration of the program, including eligibility determination, claims processing, and reporting shall use existing administrative mechanisms, including the Medicaid fiscal agent system and area agencies on aging; AHCA to make payments for prescription drugs on behalf of eligible individuals; AHCA and DOEA to develop a single-page application for the catastrophic pharmaceutical expense assistance program; AHCA to, by rule, establish eligibility requirements, limits on participation, benefit limitations, a requirement for generic drug substitution and other program parameters comparable to those of the Florida Medicaid program for this program; and an annual report to the Legislature on the operation of the program.

Subsection (5) states that the program is not an entitlement, and is the payer of last resort.

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

**Section 3.** Provides Legislative findings regarding the nature of the relationship between the patient and practitioner, and the underlying trust in that relationship, prompting 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.

**Section 4.** Effective October 1, 2000, amends s. 455.624(1), F.S., relating to the grounds for disciplinary action under the Division of Medical Quality Assurance, to add as a new paragraph (y) that accepting gifts, payments, subsidies, or other financial inducements from pharmaceutical manufacturers which do not primarily entail a benefit to patients, are of substantial value, and undermine the practitioner's independent professional judgment or which conflict with the practitioner's duty of loyalty to patients shall be grounds for disciplinary action.

**Section 5.** 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 s. 409.904(1), F.S., whose incomes are between 90 and 100 percent of the federal poverty level.

**Section 6.** Appropriates \$42 million from the General Revenue Fund to the Agency for Health Care Administration to implement the catastrophic pharmaceutical expense assistance program.

**Section 7.** Appropriates \$1 million from the General Revenue Fund 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 8.** Provides for the act to take effect upon becoming a law, except as otherwise provided.

### III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

#### A. FISCAL IMPACT ON STATE GOVERNMENT:

##### 1. Revenues:

N/A

##### 2. Expenditures:

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. By component, these funds are to be expended as follows:



- \$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 s. 409.904(1), F.S., whose incomes are between 90 and 100 percent of the federal poverty level.
- \$42 million from the General Revenue Fund to the Agency for Health Care Administration to implement the catastrophic pharmaceutical expense assistance program.
- \$1 million from the General Revenue Fund 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.

**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 that provides 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 program 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:**

While the bill, in section 5, provides an appropriation of \$27 million for the extension of Medicaid benefits to those age 65 and over and disabled with incomes between 90 and 100 percent of the federal poverty level, AHCA estimates a need of \$55.4 million to fully fund this coverage category, or a difference of \$28.4 million from the appropriated amount. Because Medicaid is an entitlement program, a deficit will be created if this expansion is not fully funded.

In its review of the bill, the Department of Elder Affairs indicated that, even though the bill does not provide direct appropriation to that agency, DOEA will incur expenses relating to its collaborative involvement in the development and operation of this new 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:

Subsection (4) of section 1 of the bill grants rulemaking authority to AHCA for establishment of eligibility requirements, limits on participation, benefit limitations, a requirement for generic drug substitution, and other program parameters comparable to those of the Medicaid program for the catastrophic pharmaceutical expense assistance program.

C. OTHER COMMENTS:

Comments by the Committee on Health Care Services

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 program will be coordinated with the Medicaid Medically Needy Program. That program is designed as a catastrophic coverage option based on month-to-month eligibility via spend-down. The new catastrophic pharmacy assistance program, as specified in subsection (5) of section 1 of the bill, is the payor of last resort; so is the Medicaid program generally. This issue needs to be resolved.

Subsection (4) of section 1 of the bill seems to grant almost unlimited authority to AHCA as to program parameters and administration. This may be overly broad for Legislative delegation and rule-making authority.

In its review of the bill, the Department of Elder Affairs indicated that, even though the bill does not provide direct appropriation to that agency, DOEA will incur expenses relating to its collaborative involvement in the development and operation of this new program.

Another issue raised by DOEA relates to the requirement that a single-page application be utilized for program eligibility purposes. Questions were raised relating to whether such eligibility determination is to be based upon a self-declaration made by the applicant or whether there is to be a verification process. Because the program will not be an entitlement and is limited in the amount of appropriation, this important factor needs to be considered as there are likely to be many more applicants for the program than can be covered.

Also related to the eligibility process, consideration will need to be given to the expediency of self-determination versus the administrative costs and potential fraud avoided with some type of verification process.

**VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:**

When the bill was heard by the Committee on Health Care Services on March 23, 2000, the committee adopted an amendment which: modified Legislative findings to delete specific reference to physicians; deleted rulemaking for guidelines and disclosure of gifts by practitioners; and amended s. 455.624(1), F.S., to add as a grounds for disciplinary action the acceptance of gifts to the detriment of patients. The bill as amended was unanimously approved as a committee substitute.

The Committee on Elder Affairs & Long Term Care heard the bill on April 5, 2000, and adopted one amendment. The amendment revised the eligibility criteria for the catastrophic pharmaceutical expense program providing that to be eligible for benefits, individuals with income between 100 percent and 185 percent of the federal poverty level shall have out-of-pocket prescription drug costs that are five percent of their annual income or more, after payments from other liable entities are deducted. Others must spend 10% of income before becoming eligible for benefits.

**VII. SIGNATURES:**

**COMMITTEE ON HEALTH CARE SERVICES:**

Prepared by:

Phil E. Williams

Staff Director:

Phil E. Williams

**AS REVISED BY THE COMMITTEE ON ELDER AFFAIRS & LONG TERM CARE:**

Prepared by:

Tom Batchelor, Ph.D.

Staff Director:

Tom Batchelor, Ph.D.

**STORAGE NAME:** h1087s1.grr

**DATE:** April 7, 2000

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AS FURTHER REVISED BY THE COMMITTEE ON GOVERNMENTAL RULES &  
REGULATIONS:

Prepared by:

Staff Director:

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Shari Z. Whittier

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David M. Greenbaum