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HOUSE OF REPRESENTATIVES AS FURTHER REVISED BY THE COMMITTEE ON HEALTH AND HUMAN SERVICES APPROPRIATIONS ANALYSIS

BILL #: CS/CS/HB 769 & 1087

RELATING TO: Pharmacy Benefit Program

SPONSOR(S): Committee on Health & Human Services Appropriations, Health Care Services,

Representatives Argenziano, Byrd, Pruitt, Goode and others

TIED BILL(S):

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

(1) HEALTH CARE SERVICES YEAS 16 NAYS 0

- (2) ELDER AFFAIRS & LONG TERM CARE YEAS 11 NAYS 0
- (3) GOVERNMENTAL RULES & REGULATIONS YEAS 7 NAYS 0
- (4) HEALTH AND HUMAN SERVICES APPROPRIATIONS YEAS 8 NAYS 0

(5)

I. SUMMARY:

Committee Substitute for 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);
- A Medication Purchasing Cooperative to assist qualified individuals with the purchase of prescribed drugs at the best possible price;
- Specific appropriations from General Revenue of \$15 million to AHCA to fund the pharmacy assistance program, and of \$250,000 to AHCA to implement the Medication Purchasing Cooperative as provided in the bill.

The bill's effective date is upon becoming law.

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II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

1.	Less Government	Yes []	No [x]	N/A []
2.	Lower Taxes	Yes []	No []	N/A [x]
3.	Individual Freedom	Yes []	No []	N/A [x]
4.	Personal Responsibility	Yes []	No []	N/A [x]
5.	Family Empowerment	Yes []	No []	N/A [x]

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

Less Government

In creating the Pharmacy Benefit Program and the Medication Purchasing Cooperative, 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 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 (AARP) 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

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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

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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 in 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 111,00 prescriptions to just under 50,000 patients through more than 2,300 health care providers in the State of Florida during 1998.

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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, also known as the "Anti-Chain-Store 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.

The class of trade known as for "own use" is generally comprised of government entities, HMOs, hospitals, and other health care entities eligible to purchase the same drug at a lower price than the manufacturer offers at retail without violating antitrust laws. For this reason, the price paid for prescription drugs for an institution's own use should always be less expensive than retail. All drugs purchased using the statewide pharmaceutical contracts are intended for an entity's own use.

The Department of General Services contracts with a pharmacy benefit manager to purchase prescription drug services for state employees. The prescription benefits vary depending upon the individual plan. Plans that offer prescription benefits through retail pharmacies cost more than plans that serve their clients through closed HMO pharmacies because of the drug cost differential between the two classes of trade.

Other States' Programs Providing Pharmaceutical Assistance to the Elderly

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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 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:

Size of Family Unit	90% of FPL	100% of FPL	120% of FPL
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:

CS/CS/HB 769 provides for: a pharmacy assistance program for very low-income elders; reduced prescribed drug costs for Medicare beneficiaries; the Medication Purchasing Cooperative; and specific appropriations. See the SECTION-BY-SECTION ANALYSIS which follows for additional detail.

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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 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. Creates the Medication Purchasing Cooperative consisting of the following subsections:

Subsection (1) requires the Agency for Health Care Administration, in consultation with the Department of Health, the Department of Elder Affairs, and the Department of Management Services to establish a Medication Purchasing Cooperative.

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Subsection (2) states the Agency for Health Care Administration shall administer the Medication Purchasing Cooperative.

Subsection (3) authorizes the agency to adopt rules to implement this section.

Subsection (4) provides for program eligibility, limited to those individuals who are residents of the state who are 65 years of age or older, or disabled as defined s. 415.102, F.S. and have incomes at or below 250% of the federal poverty level.

Subsection (5) requires the cooperative to solicit bids annually from pharmacies to obtain discounts on all prescribed medicines for cooperative members.

Subsection (6) allows the agency to charge individuals enrolled in the cooperative a monthly membership fee to fully offset the administrative costs of the cooperative. It also requires the cooperative to issue identification cards to cooperative members to present to pharmacies for purposes of member identification.

Subsection (7) requires participating pharmacies to guarantee the member a discount on a prescribed drug at the rate quoted in their contract with the state.

Subsection (8) requires the agency to submit an annual report to the Speaker of the House of Representatives, the President of the Senate regarding the status of the cooperative.

Section 3. Appropriates from General Revenue to AHCA \$15.2 million to fund the pharmacy assistance program.

Section 4. Appropriates from General Revenue to AHCA \$250,000 for implementation of the Medication Purchasing Cooperative as created by the bill.

Section 5. Provides for the repeal of this legislation upon federal enactment of pharmaceutical benefits through the Medicare Program.

Section 6. Provides an effective date of upon becoming law.

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 \$15.2 million to fund the pharmacy assistance program, and from General Revenue to AHCA \$250,000 for the Medication Purchasing Cooperative.

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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:

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.

The annualized cost of the program would be about \$30 million for the 30,000 eligibles in the 28 counties that do not have a participating Medicare HMO.

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:

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A. CONSTITUTIONAL ISSUES:

N/A

B. RULE-MAKING AUTHORITY:

The Agency for Health Care Administration is given rulemaking authorization for implementing the provisions of this legislation.

C. OTHER COMMENTS:

Comments by the Committee on Health Care Services to the original 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.

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 re-importation, under FDA authorization, for emergency medical care, but it is inconceivable to assume the provisions of this bill meet this requirement.

The Department of Health also noted that drugs purchased under the class of trade known as "own use" cannot lawfully be sold or transferred to the retail market to reduce drug costs for state employees. The interpretation of the words "for their own use" was the major issue in a landmark lawsuit involving the Robinson-Patman Price Discrimination Act (1936). In Abbott Laboratories et al v. Portland Retail Druggists Association Inc., 425 U.S. 1, 47 L.Ed.2nd 537, 96 S.Ct.1305 (1976), the U.S. Supreme Court held that not all of a nonprofit hospital's purchases are exempt from the provisions of the Robinson-Patman Act. The Court ruled that there must be a continuing relationship between the hospital and the patient. State-purchased drugs are intended solely for consumption in traditional government functions as interpreted by the Court in Jefferson County Retail Druggist Association, Inc., v. Abbott Laboratories, et al., 460 U.S. 150, 74 L.Ed.2nd 882, 103 S.Ct. 1011 (1983). A Federal Trade Commission Staff Advisory Opinion relating to Henry County Memorial Hospital, dated April 10, 1997, indicated a continuing reliance on these court cases for guidance in this area.

State law cannot supersede federal law. As the above-referenced cases and opinion indicate, pooling the purchase of certain drugs for elders and the disabled as proposed in section 4 of this bill could prove to be difficult.

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VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

When the Committee on Health Care Services heard this bill on March 23, 2000, the committee approved a committee substitute which: deleted reference to the Commission on Pharmaceutical Benefits for Elderly and Disabled Persons and the aggregation of purchasing of prescribed drugs by all state entities involved in drug purchasing; and created the Medication Cost-Reduction Program.

The Committee on Elder Affairs & Long Term Care heard the bill on April 5, 2000, and adopted two amendments. The first amendment revised the eligibility standard for the Pharmacy Benefit Program, raising the income limit from 120% to 150% of the federal poverty guidelines.

The second amendment reduced the participants' copayment from 20 percent to 5 percent.

On April 12, 2000, the Committee on Governmental Rules & Regulations adopted the following amendment and passed the bill favorably, as amended:

Amendment 1 - Removed language "the so-called specified low-income Medicare beneficiaries" for those with incomes between 100% and 150% of the federal poverty level.

The Committee on Health and Human Services Appropriations met on April 18, 2000, and approved a committee substitute which combined CS/HB 769 and HB 1087. It approved only a pharmacy benefit program for the elderly and most in need and a medication purchasing cooperative and appropriations for each.

VII. SIGNATURES:

COMMITTEE ON HEALTH CARE SERVICES: Prepared by:	Staff Director:		
Phil E. Williams	Phil E. Williams		
AS REVISED BY THE COMMITTEE ON ELDER AFFAIRS & LONG TERM CARE: Prepared by: Staff Director:			
Tom Batchelor, Ph.D.	Tom Batchelor, Ph.D.		
AS FURTHER REVISED BY THE COMMITTEE ON GOVERNMENTAL RULES & REGULATIONS: Prepared by: Staff Director:			
Shari 7. Whittier	David M. Greenbaum		

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AS FURTHER REVISED APPROPRIATIONS:	BY THE COMMITTEE ON HEALTH AND HUMAN SERVICES
Prepared by:	Staff Director:

Lynn Dixon

Lynn Dixon