SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

BILL: CS/SB 2098

SPONSOR: Health, Aging, and Long-Term Care Committee and Senator Wasserman Schultz

SUBJECT: Prescription Drugs

DATE: April 21, 2003 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Parham	Wilson	HC	Favorable/CS
2.			AHS	
3.			AP	
4.				
5.				
6.				

I. Summary:

This bill creates a prescription drug purchase assistance program, called the LifeSaver Rx program, by expanding Medicaid eligibility through a federal waiver to provide partial coverage of a prescription-drug-only benefit. This benefit is limited to residents of the state who are age 65 or older, with net family incomes at or below 200 percent of the federal poverty level (FPL) in year one and at or below 300 percent in year two and thereafter, who participate in Medicare, and who have exhausted all third-party prescription coverage. An annual enrollment fee will be required to offset administrative costs. Medicaid pricing, manufacturer rebates, and a state subsidy (matched with federal funds) will be used to generate cost savings to enrollees in the program.

The bill requires the Agency for Health Care Administration (Agency) to publish on its website the most recent average wholesale prices for the 200 drugs most frequently dispensed to the elderly and to provide a mechanism for consumers to calculate the retail price that should be paid under the Medicare prescription discount program. The Agency is required to submit a report by January 1, 2004, regarding alternatives to using the average wholesale price in pricing drugs purchased by the Medicaid program.

This bill amends s. 409.9066, F.S., and creates ss. 409.960, 409.962, 409.964, 409.966, 409.968, 409.970, 409.972, 409.974, 409.976, 409.978, 409.980, and 409.982, F.S., and four undesignated sections of law.

II. Present Situation:

The costs of 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. 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.

As a direct result of high out-of-pocket costs of drugs, many people do not ask doctors for the prescriptions they need, do not fill the prescriptions they are given, use lower doses of drugs than those prescribed and take their drugs less often than they should. The higher a person's out-of-pocket costs for drugs, the more likely they are to be noncompliant. This compromises the effectiveness of controlling the progression of chronic disease, resulting in greater use of 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 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. Some Medicare beneficiaries with prescription drug coverage are members of Medicare HMOs. The scope and availability of Medicare HMO prescription drug coverage varies widely within and across market areas. Approximately 10 percent of Florida Medicare beneficiaries have coverage through the Medicaid program.

Out-of-Pocket Spending on Prescription Drugs 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 fees charged by pharmacists. Individuals rarely have the ability to influence either of these prices, and therefore are subject to cost-shifting from groups with more purchasing power.

Pharmaceutical Pricing

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

Cash customers are generally individuals who either lack prescription drug coverage and therefore pay out of their own pockets, or have indemnity-type insurance that reimburses them after they have made their cash purchases. Cash customers generally pay the highest prices for drugs because they lack the opportunity, let alone the bargaining power, to negotiate discounts from either the retail pharmacy or the manufacturer. They generally pay at or above a drug's average wholesale price (AWP), which is the manufacturer's list price.

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

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

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

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

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

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

To qualify for the drug pricing program, the covered entity must be a federal purchaser or federally-funded grantee recognized under section 340B of the Public Health Service Act.

Florida Department of Health Pharmacy Purchasing - Section 381.0203, Florida Statutes, authorizes the Florida Department of Health to contract on a statewide basis for the purchase of drugs, to be used by state agencies and political subdivisions. The Office of Pharmacy Services within the Department of Health contracts for the purchase of drugs for use by state agencies and political subdivisions. Under this program, the state negotiates a discounted price with drug manufacturers currently for county health departments, the Department of Corrections, and the Department of Children and Families. The negotiated contract language customarily contains a provision that limits the use of the discounted drugs purchased by the state for clients or patients of the state.

Medicaid Pharmacy Reimbursement

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

Florida Medicaid Pharmacy Services is responsible for managing the $1.87 billion drug program for the Florida Medicaid Program. Over the past three years there have been many new initiatives implemented to reduce the growth in drug expenditures. Those initiatives implemented over the past two years - the four-brand limit, clinical prior authorizations, the Preferred Drug Program and related initiatives - have saved the Agency and the State of Florida nearly $500 million.

Medicaid reimburses for prescribed drug services for all Medicaid recipients, except for those in limited programs, such as the Qualified Medicare Beneficiary (QMB) program and aliens. Medicaid reimbursement for prescribed drugs is the lowest of: 1) the estimated acquisition cost of the drug, plus the dispensing fee; 2) the Federal or state maximum-allowable cost, plus the dispensing fee; 3) the wholesaler Acquisition Cost plus seven percent; 4) the average wholesale price less 13.25 percent plus the dispensing fee; or 5) the amount billed by the pharmacy, which cannot exceed the pharmacy's usual and customary charge for the prescription.

Prescription Assistance

The Florida Legislature passed the Senior Prescription Affordability Act on July 1, 2000, allowing Florida residents with Medicare cards to receive discount prescription prices. The Act

primarily helps individuals who do not have prescription drug coverage or those who have reached their prescription limit. Part one became effective July 1, 2000, and allows Florida residents with Medicare cards to purchase their prescription drugs at a Medicaid-participating pharmacy and receive a discounted prescription price. Individuals do not have to be Medicaid-eligible.

The second part became effective January 1, 2001, and provides financial assistance to those senior citizens who are eligible to receive both Medicare and Medicaid. To qualify for the program, a beneficiary must: 1) be a Florida resident age 65 or over, 2) be eligible for both Medicare and Medicaid, but not be enrolled in a Medicare HMO that provides a pharmacy benefit, and 3) have income between 90-120 percent of the FPL. Monthly benefits are limited to $80 and there is a 10 percent co-payment requirement.

In 2000, the Florida Legislature also enacted a program to require that, as a condition of participation in the Medicaid program or the pharmaceutical expense assistance program, a pharmacy must agree to charge any Medicare beneficiary, who presents a Medicare card when they present a prescription, a price no greater than the cost of ingredients equal to the average wholesale price minus 9 percent, and a dispensing fee of $4.50. In lieu of this requirement, and as a condition of participation in the Medicaid program or the pharmaceutical expense assistance program, a pharmacy must agree to provide a private, voluntary prescription discount program to state residents who are Medicare beneficiaries or accept a private voluntary discount prescription program from state residents who are Medicare beneficiaries. This discount must be at least as great as the above discount. Many Medicare beneficiaries have complained that they have no way to verify that they are getting the full discount.

The Senior Prescription Affordability Act was expanded in 2002 and named the "Ron Silver Senior Drug Program." The program was implemented in August, 2002. The current statute (s. 409.9065, F.S.) for the Silver Saver prescription drug program limits the number of persons who can receive assistance from the program. Eligibility for the program is 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 or Medicare coverage does not include any pharmacy benefit. This program allows individuals 65 years of age and older, with incomes between 88 and 120 percent of the FPL, to receive a $160 monthly benefit toward prescription drug costs. No premium or deductible is applied; however, a small co-payment is required: $2 for a generic drug prescription, $5 for a brand name preferred drug, or $15 for a non-preferred drug. Preferred drugs are found on the Medicaid Preferred Drug List. The waiver, approved by the federal government, includes an enrollment cap. To date, the Agency has been able to serve 100 percent of the approved applicants and has not utilized a waiting list.

Medicaid Co-Payments for Prescribed Drugs

The Code of Federal Regulations (42 CFR 447.50-447.56) establishes limits on the cost sharing requirements of Medicaid beneficiaries. Federal regulations limit cost sharing to nominal amounts ($.50-$3.00) and require that certain populations be exempt from cost sharing. Federal Medicaid regulations (CFR 447.54) describe these limits and specifically exempt the following categories: children (under age 21 or under age 18 at the state's option), pregnant women,

institutionalized recipients, emergency services, family planning services, and HMO enrollees (42 CFR 447.53). Co-payments are limited to a maximum of $3.00 (42 CFR 447.54(a)(3)) or, if a state chooses to use a coinsurance requirement, the amount cannot exceed five percent of the state contribution.

III. Effect of Proposed Changes:

The bill creates a new Medicaid benefit category that would ensure discounted prescription drug costs for participants at any participating pharmacy in Florida. Beneficiaries would receive discounted Medicaid pricing and credit for manufacturer rebates, creating cost reductions amounting to approximately 30 percent below standard retail pricing. Persons without adequate drug coverage, whose family incomes are at or below 200 percent of the FPL in year one and 300 percent of the FPL in year two and thereafter, would be eligible to voluntarily enroll in the program.

Section 1. Creates s. 409.960, F.S., providing the name "LifeSaver Rx Program" for the program.

Section 2. Creates s. 409.962, F.S., describing legislative findings and the purpose of the program. The bill states that one in four Florida residents have no prescription drug insurance or inadequate prescription drug insurance and that they pay higher prices for prescriptions than do insurance plans, HMOs, and government supported programs. In many cases, this causes denial of access that can result in more expensive encounters with the health care delivery system through emergency room and hospital visits. Many other individuals enter into institutions because they are unable to pay for the drugs that could support them outside the institution. The state medical assistance programs, such as Medicaid, pay for these individuals to receive treatment from hospitals and institutions.

The bill proposes that a state government program, such as Medicaid, can and should act as a prescription benefit manager to negotiate price reductions and rebates for the Medicaid population. The language establishes the LifeSaver Rx program in the Agency as an expansion of the Medicaid program, which would use enrollment fees and manufacturer rebates to fund cost reductions and administer the program. This expansion would allow the state to provide prescription drug benefits to a larger eligible population. Individuals enrolled in the program would receive a discount on all prescription drugs that the Medicaid program covers.

Section 3. Creates s. 409.964, F.S., defining terms used in the bill.

Section 4. Creates s. 409.966, F.S., directing the Agency to operate the program as a state pharmaceutical assistance program under 42 U.S.C. s. 1396r-8(c)(1)(C)(i)(III). The Secretary of the Agency is directed to negotiate discount prices or rebates from drug manufacturers and labelers and contract with retail pharmacies that will honor the discounted prices for the program.

When negotiating discounts or rebates, the Secretary of the Agency must consider: 1) the Medicaid calculated rebate according to 42 U.S.C. s. 1396r-8, 2) prices provided to eligible entities under 42 U.S.C. s. 256b, and 3) other available information on drug prices and discounts.

Negotiations of supplemental rebates pursuant to s. 409.912(38)(a)7, F.S., may also be considered. Discounts for the program participants will be calculated by the Secretary on a quarterly basis.

Section 5. Creates s. 409.968, F.S., specifying that participants in the program will be required to pay an amount equal to the Medicaid allowable charge for a prescription, minus the amount paid by the Agency for the prescription. The Agency will pay an amount equal to the estimated manufacturer rebate, plus a state subsidy from general revenue of the prescription, plus the federal match of the state's contribution for the prescription.

Participating retail pharmacies must charge the Medicaid allowable charge for prescriptions sold to individuals enrolled in this program. The pharmacies will be reimbursed the amount of the Agency's estimated manufacturer rebate.

This benefit is not an entitlement.

Section 6. Creates s. 409.970, F.S., setting forth eligibility requirements for the program. To be eligible, an individual must: 1) be a Florida resident, 2) be a Medicare participant age 65 or older, 3) have a net family income at or below 200 percent of the FPL in year one and at or below 300 percent of the FPL in year two and thereafter, 4) have exhausted all third-party prescription benefits, and 5) request to be enrolled in the program. Individuals eligible for assistance under the state's Medicaid program are not eligible to participate in this program.

This section instructs the Agency to establish enrollment procedures, permits an annual enrollment fee of up to $50 per enrollee, and requires the Agency to undertake outreach efforts to build public awareness and maximize enrollment of the program.

Revenues from rebates and enrollment fees may be used for, but are not limited to, offsetting the cost to the state to administer the program, the purchase of prescription drugs, and promoting public awareness.

Section 7. Creates s. 409.972, F.S., specifying program operation. The Board of Pharmacy, created by s. 465.004, F.S., is authorized, in consultation with the Agency, to adopt rules pursuant to ss. 120.536(1) and 120.54, F.S., for pharmacies on disclosure of savings resulting from the program to program participants. Proprietary information must be protected by these rules.

The Agency must reimburse pharmacies weekly or biweekly or pay in advance for program discounts in accordance with contracts between the Agency and such businesses.

The Agency will collect utilization data from participating pharmacies that is necessary to calculate the manufacturer or labeler rebate amount. The Agency must protect the confidentiality of information subject to protection under state and federal laws, rules, and regulations.

Section 8. Creates s. 409.974, F.S., specifying the resolution process for rebate disputes with manufacturers. If a discrepancy exists in the manufacturer's or labeler's favor concerning the amount claimed by a participating pharmacy and the amount of the rebate, the Agency, at its own

expense, may hire a mutually agreed-upon independent auditor. If the auditor is not able to justify the discrepancy, the manufacturer or labeler must justify the reason concerning the discrepancy or pay the additional amount due to the Agency.

If a discrepancy exists against the manufacturer's or labeler's interest concerning the information provided by the Agency to the manufacturer or labeler regarding the rebate, the manufacturer or labeler, at its own expense, may hire a mutually agreed-upon independent auditor. If the auditor is not able to justify the discrepancy, the Agency must justify the reason concerning the discrepancy or refund the manufacturer or labeler.

If an auditor is unable to settle the discrepancy, the Agency, manufacturer, or labeler may request a hearing pursuant to s. 120.569, F.S., and s. 120.57, F.S. Supporting documentation must be included in the request for a hearing.

Section 9. Creates s. 409.976, F.S., requiring the Agency to provide a report to the executive and legislative branches, in January of each year, on the enrollment and financial status of the program.

Section 10. Creates s. 409.978, F.S., permitting the Secretary of the Agency to coordinate drug pricing and rebate negotiations with other programs when the Secretary determines it is beneficial.

Section 11. Creates s. 409.980, F.S., providing rulemaking authority for the Agency to implement this program. The rules must be in accordance with ss. 120.536(1) and 120.54, F.S. Rules must include eligibility requirements, limits on participation and benefits, generic drug substitution requirements, as well as other parameters comparable to the Medicaid program.

Section 12. Creates s. 409.982, F.S., authorizing the Agency to seek any waivers of federal law, rule, or regulation necessary to implement this act in year one and to seek any additional waivers in year two and thereafter.

Section 13. Provides that the Agency will contribute a percent of the cost of prescriptions purchased under the program.

Section 14. Amends s. 409.9066, F.S., adding subsection (3), providing that the Agency shall publish, on a free website available to the public, the most recent average wholesale prices for the 200 drugs most frequently dispensed to the elderly, and shall provide a mechanism that consumers may use to calculate the retail price that should be paid under the Medicare prescription discount program.

Section 15. Directs the Agency to submit a report to the Legislature regarding the cost effectiveness of, and alternatives to, using the average wholesale price in the pricing of pharmaceutical products purchased by the Medicaid program by January 1, 2004.

Section 16. Provides that the Legislature shall appropriate general revenue funds to the Agency in an amount sufficient to implement this act.

Section 17. Provides severability for the various sections of this act.

Section 18. Provides that the act is effective 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 Art. I, s. 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:

The bill permits an annual enrollment fee of up to $50 per enrollee.

B. Private Sector Impact:

Pharmacies may be paid less for drugs for enrollees in the program compared to payment at standard retail prices. An enrollee's payment will be based on the Medicaid allowable reimbursement for a drug less the total of the anticipated rebate, a state subsidy of the Medicaid allowable reimbursement, and the federal matching payments for the state subsidy. The Agency will reimburse the pharmacy for the sum of the anticipated rebate, the state-funded subsidy, and the federal matching funds for the state subsidy.

Enrolled individuals will pay less for their prescriptions.

C. Government Sector Impact:

Local Governments
This act would reduce spending requirements for those local governments that provide this assistance to residents.

Department of Children and Families
The Department of Children and Families indicates that this program would require modifications to the current eligibility determination systems.

	Amount Year 1 (FY 03-04)	Amount Year 2 (FY 04-05)
1. Non-Recurring Impact:		
Administrative Trust Fund (State)	$311,986	$3,061
Administrative Trust Fund (Federal)	$311,987	$3,061
Non-Recurring Expenditures	**$623,973**	**$6,122**
2. Recurring Impact:		
Administrative Trust Fund (State)	$500,748	$544,073
Administrative Trust Fund (Federal)	$500,749	$544,074
Total Recurring Expenditures	**$1,001,497**	**$1,088,147**
Administrative Trust Fund (State)	$812,735	$547,134
Administrative Trust Fund (Federal)	$812,735	$547,135
Total Non-Recurring & Recurring Expenditures-DCF	**$1,625,470**	**$1,094,269**

Agency for Health Care Administration
Section 6 of this bill specifies that individuals are not eligible to participate in the Lifesaver Rx program unless they have exhausted all third party prescription coverage and are not eligible to participate in Medicaid. This analysis assumes that individuals with incomes between 88 to120 percent of the FPL qualify for Medicaid pharmacy benefits through the current Silver Saver prescription program; however, 20 percent of this population exhausts their Silver Saver benefit on a monthly basis. These individuals would then be allowed to use the Lifesaver benefit after their Silver Saver benefit has been exhausted.

The Agency estimates that 1.4 million Florida residents age 65 or older have incomes between 120-300 percent of the FPL and approximately 68,731 individuals have incomes below 88 percent of the FPL that do not qualify for Medicaid benefits. Based on national studies, an estimated 25 percent of these populations (350,000 individuals) lack prescription drug coverage and would be eligible for this program. With an estimated implementation date of January 1, 2004, it is assumed that approximately 100,000 individuals will enroll in the program in the first year, and an additional 100,000 individuals will enroll in the second year.

The bill allows a $50 annual enrollment fee, which if all estimated eligibles enroll would yield revenues of $5 million in the first year and $10 million in the second year to reduce the administrative costs of the program in the Agency. The fiscal analysis is based on a five percent state subsidy.

Total Recurring & Non-Recurring Revenues and Expenditures-AHCA:

	Amount Year 1 (FY 03-04)	Amount Year 2 (FY 04-05)
Sub-Total Non-Recurring Revenues	$ 0	$ 0
Sub-Total Recurring Revenues	$30,306,637	$110,113,541
Total Revenues	**$30,306,637**	**$110,113,541**
Sub-Total Non-Recurring Expenditures	$784,265	$6,122
Sub-Total Recurring Expenditures	$34,976,026	$127,088,726
Total Expenditures	**$35,760,291**	**$127,094,848**

Difference (Total Revenues minus Total Expenditures)-AHCA:

	($5,453,654)	**($16,981,307)**

This analysis assumes that approximately one third (100,000) of the eligible population will enroll in the program each year. The following table shows an estimated cost based on an estimate of 100,000 new individuals enrolled into the program each year. The estimated costs assume that a federal waiver will be approved that will allow federal matching funds to be used for the program.

COST FOR DRUG EXPENDITURES ASSUMING 100,000 BENEFICIARIES IN FY 2003-04 (January 01, 2004 Start Date) AND 200,000 BENEFICIARIES IN FY 2004-05

	FY 2003-04	FY 2004-05
Estimated Enrollment	100,000	200,000
Average Prescriptions per Month	3.5	3.5
Average Cost per Script	$34.37	$36.00
Total Annual Cost for Drugs	**$72,177,000**	**$302,400,000**
Enrollment Fee ($50 per year)	$5,000,000	$10,000,000
Manufacturer Rebates (Assume 25%)	$18,044,250	$75,600,000
State Share (5% of Total)	$3,608,850	$15,120,000
Federal Share (Assume 58.92% of Total State/Federal)	$5,176,082	$21,686,232
Total State and Federal Share	**$8,784,932**	**$36,806,232**
Recipient Share	$40,347,818	$297,400,000
Fiscal Agent Claims Processing		
Estimated Total Prescriptions	2,100,000	8,400,000
Estimated Cost per Claim	$0.23	$0.23
State	$120,750	$483,000
Federal	$362,250	$1,449,000
Total Cost for Claims Processing	**$483,000**	**$1,932,000**

According to the Agency, collecting the information in the bill and publishing such information on a web page will require additional staff resources. These costs will be 50 percent federally-reimbursable as Medicaid administrative match.

VI. Technical Deficiencies:

None.

VII. Related Issues:

In order to obtain Federal matching funds for this program, the Agency will have to obtain an 1115 waiver from CMS. Currently, CMS only allows an 1115 waiver to provide assistance to individuals up to 200 percent of the FPL. However, the language in this bill suggests an upper income limit at 300 percent of the FPL in year two and thereafter. Through past discussions with CMS concerning prescription drug program expansions, CMS have indicated that income limits can go as high as 300 percent of the FPL. The state must demonstrate, however, that focusing resources on populations below 200 percent of the FPL is unnecessary because the state already has high coverage rates in this income range, and covering individuals above 200 percent of the FPL under the demonstration will not induce individuals with private health insurance coverage to drop their current coverage.

CMS requires that 1115 waivers be budget neutral, that is, they can not result in an increase in federal costs compared to costs in the absence of the demonstration. As a means to obtain budget neutrality the state must show a savings in Medicaid to offset expenditures for an expansion under the waiver. According to the Agency, there is insufficient evidence of individuals between 200 and 300 percent of the FPL spending down to Medicaid in order to "prove" budget neutrality. Therefore, in all likelihood, CMS would not accept the expansion up to 300 percent of the FPL.

Several court cases have sought to alter Maine's prescription drug policies, which are similar to what this bill proposes.

The Maine Rx Program was created in 2000, providing a discounted price for any eligible resident who enrolls in the program. The program relies on state-based manufacturer rebates to achieve the lower price. It also provides authorization for the Commissioner of Human Services to establish maximum retail prices effective July 2003 if prices paid under the Maine Rx program for the most common drugs are not reasonably comparable to the lowest prices paid in the state. This law is not an entitlement program.

In 2001, Maine's subsidy and discount programs were merged into the expanded and renamed Healthy Maine Prescriptions Program (separate from the Maine Rx program). The Healthy Maine program, which allowed seniors to purchase prescriptions through a Medicaid waiver, was halted by a U.S. Court of Appeals ruling on December 24, 2002. The program used a waiver to pass the discount prices obtained by the state Medicaid program on to seniors with incomes up to 300% of FPL. The ruling affects most of the 110,000 people already enrolled in Maine; it also may delay or affect 2002 laws enacted in Hawaii, New Mexico and Vermont (and considered in several others). As of September 1, 2002, there were 115,000 residents enrolled in the subsidy

and discount components of "Healthy Maine Prescriptions," with 36,000 receiving subsidies and the balance of 79,000 receiving the discount-only benefit.

In Pharmaceutical Research and Manufacturers of America v. Thompson, 313 F.3d 600 (D.C. Cir. 2002), the court found that the Healthy Maine Program, approved by the federal Department of Health and Human Services, which allowed Maine to extend Medicaid's rebate requirements to drugs purchased by low-income individuals who were not otherwise covered by Medicaid, violates the Social Security Act. The D.C. Circuit had previously declared unlawful a Vermont discount prescription drug program on which Maine had modeled its program (See Pharmaceutical Research and Manufacturers of America v. Thompson, 251 F.3d 219 [D.C. Circuit 2001]). The court held that Vermont's program was impermissible under the Act, because there was no net expenditure of funds for Medicaid purposes in an amount determined independently of the amount of the rebates.

The ruling does not directly invalidate state laws; it focuses on the limitations of the federal Department of Health and Human Services to approve a program that does not guarantee any specified state financial contribution. Indeed, Maine's law, passed five months after the waiver approval, provides a two percent state contribution. However, Maine's state contribution cannot be matched with federal funds. The court ruling states that this financial revision "has yet to be considered or approved by the Secretary." The court did not rule on whether the two percent subsidy is enough to prompt the rebate obligations under the Social Security Act. This ruling has no impact on "Pharmacy Plus" waivers, where state and federal financial contributions are clearly defined.

In a separate case, the U.S. Supreme Court is considering the validity of the 2001 Maine Rx law. The Court heard arguments in the Maine Rx case on January 22, 2003. This law authorized a discounted price for any eligible Maine resident who enrolls in the program. The program relies on state-based manufacturer rebates to achieve the lower price. Maine Rx is not a Medicaid program, and is legally separate from the 2001 statute that established Healthy Maine Prescriptions.

Hawaii is the only other state to have an enacted law using key elements from the Maine Rx program. In 2002, New Mexico, Ohio, and Vermont also enacted discount programs, but these use different legal structures that may not be affected by the Maine court challenge.

The D.C. Circuit did not address whether a state's contribution of two percent of the cost of the discount drug program constitutes sufficient payment to satisfy the Social Security Act since the subsidy was not part of the program formally endorsed by the Secretary of Health and Human Services that was before the court for review.

VIII. Amendments:

None.