By Senator Diaz de la Portilla

34-1480-00 See HB 611

A bill to be entitled

An act relating to elderly pharmaceutical insurance coverage; providing a short title; providing definitions; providing a program for pharmaceutical insurance coverage for elderly persons; providing for program eligibility; providing for pharmaceutical insurance contracts; providing criteria and requirements; providing contractor responsibilities; providing for contractor's reports; establishing an elderly pharmaceutical insurance coverage board; providing for membership; providing duties of the board; requiring reports; providing for an advisory committee to the board; providing for membership of the committee; providing for an executive director of the board; providing for a salary; providing duties of the executive director; specifying program rule requirements; providing dispensation limitations; providing eligibility requirements for program participants who qualify by paying an application fee or meeting a deductible; specifying the amount of the fee or deductible for certain persons; providing for copayments; providing for annual determinations by the board of increases in covered amounts; providing for participating provider pharmacies; providing for reimbursement to provider pharmacies; providing penalties for fraud and abuse; providing procedures for

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determinations by the Department of Health relating to package or form of dosage or administration of certain drugs as excluded from the program as covered drugs; providing an exception; providing for use of out of state pharmacies; providing criteria and procedures; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. (1) SHORT TITLE.--This act may be cited as the "Elderly Pharmaceutical Insurance Coverage Act".

(2) DEFINITIONS.--For purposes of this act, the term:

(a) "Annual coverage period" means the period of 12 consecutive calendar months for which an eligible program participant has met the application fee or deductible requirements of subsections (8) and (9).

(b) "Board" means the Elderly Pharmaceutical Insurance Coverage Board established under subsection (5).

(c) "Contractor" means a private not-for-profit or proprietary corporation that has entered into a contractual arrangement with this state to carry out the provisions of subsection (4).

(d) "Covered drug" means a drug dispensed subject to a legally authorized prescription pursuant to chapter 465, Florida Statutes, or chapter 893, Florida Statutes, and insulin, an insulin syringe, or an insulin needle. Such term does not include:

1. Any drug determined by the Commissioner of the Federal Food and Drug Administration to be ineffective or unsafe.

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2. Any drug dispensed in a package, or form of dosage or administration, which the Secretary of Health finally determines pursuant to subsection (13) does not constitute a covered drug for purposes of this act.

3. Any device for the aid or correction of vision or any drug, including vitamins, which is generally available without a physician's prescription.

(e) "Executive director" means the executive director of the board established under subsection (5).

(f) "Income" means "adjusted gross income" as defined in section 420.0004, Florida Statutes, but includes only the income of program applicants and spouses and excludes the income of other members of the household.

(g) "Provider pharmacy" means a pharmacy registered in this state pursuant to chapter 465, Florida Statutes, or a pharmacy registered in a state bordering this state when certified as necessary by the executive director pursuant to subsection (14), for which an agreement to provide pharmacy services for purposes of the program pursuant to subsection (10) is in effect.

(h) "Program year" means a year beginning on October 1 and ending the following September 30.

(i) "Resident" means an individual legally domiciled within this state.

(j) "Secretary" means the secretary of the Department of Health.

(3) PROGRAM ELIGIBILITY.--

(a) Persons eligible for coverage under subsection (8) include:

1. Any unmarried resident who is at least 65 years of age and whose income for the calendar year immediately

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preceding the effective date of the annual coverage period is less than or equal to $12,000.

2. Any married resident who is at least 65 years of age and whose income for the calendar year immediately preceding the effective date of the annual coverage period when combined with the income in the same calendar year of such married person's spouse is less than or equal to $15,000 dollars.

After the initial determination of eligibility, each eligible individual must be redetermined eligible at least every 24 months.

(b) Persons eligible for coverage under subsection (9) include:

1. Any unmarried resident who is at least 65 years of age and whose income for the calendar year immediately preceding the effective date of the annual coverage period is more than $12,000 and less than $18,000.

2. Any married resident who is at least 65 years of age and whose income for the calendar year immediately preceding the effective date of the annual coverage period when combined with the income in the same calendar year of such married person's spouse is more than $15,000 and less than $23,000.

After the initial determination of eligibility, each eligible individual must be redetermined eligible at least every 24 months.

(c)1. Eligibility for assistance under this act shall not be granted to any person who, at the time an application is made, is receiving medical assistance under any other

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provision of law of this state or to any person receiving equivalent or better coverage from any other public or private third-party payment source or insurance plan than those benefits provided for under this act.

2. An individual who is determined eligible for assistance under this act whose prescription costs are covered in part by any public or private plan may receive reduced assistance under this act. In such cases, benefits provided through this act shall be considered payments of last resort.

3. The fact that some of an individual's prescription drug expenses are paid or reimbursable under Medicare shall not disqualify an individual, if he or she is otherwise eligible, from receiving assistance under this act. In such cases, the state shall pay the portion of the cost of those prescriptions for qualified drugs for which no payment or reimbursement is made by Medicare, less the participant's copayment required on the amount not paid by Medicare.

(4) PHARMACEUTICAL INSURANCE CONTRACT.--

(a) The board established under subsection (5) shall, subject to the approval of the Governor, enter into a contract with one or more contractors to assist in carrying out the provisions of this act. Such contractual arrangements shall be made subject to a competitive bidding process and shall ensure that state payments for the contractor's necessary and legitimate expenses for the administration of this program are limited to the amount specified in advance, and that such payments shall not exceed the amount appropriated for such expenses in any fiscal year. The board shall, at each of its regularly scheduled meetings, review the contract pricing provisions to assure that the level of contract payments are in the best interest of the state, giving consideration to the

total level of participant enrollment achieved, the volume of claims processed, and such other factors as may be relevant in order to contain state expenditures. If the board determines that the contract payment provisions do not protect the interests of the state, the executive director shall initiate contract negotiations for the purpose of modifying contract payments or scope requirements.

(b) The responsibilities of any contractor shall include, but need not be limited to:

1. Providing for a method of determining, on an annual basis and upon application by any person, the eligibility of persons pursuant to subsection (3) within a reasonable period of time, including alternative methods for such determination of eligibility, including, but not limited to, through the mail or home visits, where reasonable or necessary, and for notifying applicants of such eligibility determinations.

2. Notifying each eligible program participant in writing prior to the commencement of the annual coverage period of such participant's cost-sharing responsibilities pursuant to subsections (8) and (9). The contractor shall also notify each eligible program participant of any adjustment of the copayment schedule by mail no less than 30 days prior to the effective date of such adjustment and shall inform such eligible program participants of the date such adjustment shall take effect.

3. Issuing an identification card to each program participant who is eligible to purchase prescribed covered drugs for an amount specified pursuant to paragraph (8)(c) or paragraph (9)(c). Cards shall be issued to participants meeting application fee or deductible requirements on or before the effective date of the card. The dates of the annual

coverage period shall be printed on the card. When an eligible program participant meets the annual limits on point of sale copayments set forth in paragraph (8)(d) or paragraph (9)(d), new identification cards shall be issued to such participant indicating waiver of such copayment requirements for the remainder of the annual coverage period or the contractor shall develop and implement an alternative method to permit the purchase of covered drugs without a copayment requirement. Such participant shall be provided a means of recovering any excess copayments made prior to their receipt of such new identification cards or prior to the implementation of any such alternative method.

4. Developing and implementing the system for those individuals electing the deductible option to record their personal covered drug expenditures in accordance with paragraph (9)(c). Such recordkeeping system shall be provided to each such participant at a nominal charge which shall be subject to the approval of the board. The contractor shall also reimburse participants for personal covered drug expenditures made in excess of their deductible requirements, less the copayments required by paragraph (9)(d), made prior to their receipt of an identification card issued in accordance with subparagraph 3.

5. Processing of claims for reimbursement to participating provider pharmacies pursuant to subsection (11).

6. Performing or causing to be performed utilization reviews for such purposes as may be required by the board.

7. Conducting audits and surveys of participating provider pharmacies as specified pursuant to the terms and conditions of the contract.

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8. Coordinating coverage with insurance companies and other public and private organizations offering such coverage for those eligible program participants having partial coverage for covered drugs through third-party sources, and providing for recoupment of any duplicate reimbursement paid by the state on behalf of such eligible program participants.

(c) The contractor or contractors shall be required to provide such reports as may be deemed necessary by the board and shall maintain files in a manner and format approved by the executive director.

(d) The contractor or contractors may contract with private not-for-profit or proprietary corporations, or with entities of local government within this state, to perform such obligations of the contractor or contractors as the board shall permit.

(5) ELDERLY PHARMACEUTICAL INSURANCE COVERAGE BOARD.--

(a) The Elderly Pharmaceutical Insurance Coverage Board is hereby established within the Executive Office of the Governor.

(b) The board shall consist of the Commissioner of Education, the Secretary of Health, the Insurance Commissioner, the Secretary of Elderly Affairs, and the Secretary of Management Services. Each board member may designate an officer of his or her respective department to represent and exercise all the powers of such board member as the case may be at all meetings of the board from which such board member may be absent.

(c) The Secretary of Elderly Affairs and Secretary of Health shall serve as co-chairs of the board.

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(d) The board shall meet at such times as may be requested by the co-chairs, provided that the board shall meet at least four times each year.

(e) The board shall:

1. Subject to the approval of the Governor, adopt program rules pursuant to subsection (7).

2. Determine the annual schedule of cost-sharing responsibilities of eligible program participants pursuant to subsections (8) and (9).

3. Enter into contracts pursuant to subsection (4).

4. Recommend and implement alternative program improvements for the efficient and effective operation of the program in accordance with the provisions of this act.

5. Establish or contract for a therapeutic drug monitoring program. Such program shall monitor therapeutic drug use of eligible program participants in an effort to prevent the incorrect or unnecessary consumption of such therapeutic drugs.

6. Develop and implement, in cooperation with area offices for the aging, an outreach program to inform the elderly of benefits they may be entitled to pursuant to this act and to make available information concerning the program for elderly pharmaceutical insurance coverage.

7. Prepare an annual report and submit such report to the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than the first day of January of each year, beginning January 1, 2002. The board shall include in the report a summary of the administrative-cost-containment initiatives completed during the year. Such report shall, at a minimum, contain annual statistical information regarding the number of persons

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enrolled in the program by marital status and income level; the total and per capita number of prescriptions filled and total state reimbursement and participant copayment expenditures, by income levels; the total numbers of prescriptions filled with generic drugs, brand name drugs, and sole source drugs; the authorization and substitution rate for the total numbers of prescriptions filled with generic, brand name, and sole source drugs; the distribution of the top 300 most commonly used drugs by volume and cost; a distribution of all prescriptions by volume and price; the annual percentage increase in the cost of such drugs, numbers of participating provider pharmacies, recipients, and payments by county; the amount of cost recoveries for the period covered in the report; projections of program costs for the following 2 years; and an evaluation of the performance of the program contractor or contractors and of the cost-effectiveness of all outreach efforts.

8. Prepare an evaluation report on the experience of the program for the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than October 1, 2001. Such report shall include the recommendations of the board concerning the continuation of the program.

(f) Board members shall receive no compensation for their services as board members.

(g) There shall be an advisory committee to the board comprised of twelve persons. Four members shall be appointed by the Governor, three members shall be appointed by the President of the Senate, one member shall be appointed by the minority leader of the Senate, three members shall be appointed by the Speaker of the House of Representatives, and

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one member shall be appointed by the minority leader of the House of Representatives. The committee members shall be representatives of consumers, pharmacists, pharmaceutical drug manufacturers, and pharmaceutical wholesalers. No less than 50 percent of the committee membership shall represent the consumers of this state. The executive director shall consult the advisory committee and consider its recommendations concerning the implementation of this program and the policies governing the continued operation of this program. Committee members shall receive no compensation for their services but shall be allowed their actual and necessary expenses incurred in the performance of their duties.

(6) EXECUTIVE DIRECTOR.--Upon the recommendation of the co-chairs, the Governor shall appoint an executive director of the board. The executive director shall receive an annual salary fixed by the Governor within the amount available therefor by appropriation and shall be entitled to reimbursement for reasonable expenses incurred in connection with the performance of his or her duties. The executive director shall:

(a) Monitor the provision of services pursuant to contractual arrangements entered into pursuant to subsection (4) and examine and review all documents and other information to assure compliance with all provisions of this act, whether such documents or other information are under the control of a contractor or a participating provider pharmacy.

(b) Appoint staff and request the assistance of any department or other agency of the state in performing such functions as may be necessary to carry out the provisions of this act.

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(c) Perform such other functions as may be specifically required by this act, as assigned by the board, or necessary to ensure the efficient operation of the program.

(7) RULES.--

(a) The board shall adopt program rules that shall:

1. Provide for a process of determining and redetermining eligibility for participation in the program, including provisions for submission of proof of income, age, and residency and information on existing complete or partial coverage of prescription drug expenses under a third-party assistance or insurance plan.

2. Provide for a fair-hearing process pursuant to an agreement with the Department of Health for individuals and participating provider pharmacies to appeal determinations or actions of the contractors.

3. Establish procedures for the state to recover the value of benefits or payments made under this act, if any, which were based on applications or claims submitted in violation of any provision of this act.

(b) For purposes of this act, except as otherwise provided in this act, a covered drug shall be dispensed in quantities no greater than a 30-day supply or 100 units, whichever is greater. In the case of a drug dispensed in a form of administration other than a tablet or capsule, the maximum allowed quantity shall be a 30-day supply. The board is authorized to approve exceptions to such limits for specific products following consideration of recommendations from pharmaceutical or medical experts regarding commonly packaged quantities, unusual forms of administration, length of treatment, or cost-effectiveness.

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(8) ELIGIBILITY REQUIREMENTS FOR PARTICIPANTS QUALIFYING BY PAYMENT OF AN APPLICATION FEE.--

(a) Each eligible individual meeting the application fee requirements of this subsection may purchase covered drugs for an amount specified by paragraph (c).

(b) An eligible individual electing to meet the requirements of this subsection shall pay a one-time application fee of $10 in a manner and form determined by the executive director prior to the beginning of a participant's first annual coverage period.

(c)1.a. Upon payment of the application fee pursuant to paragraph (b), an eligible program participant shall, at the time of each purchase of a covered drug, pay the lesser of a point-of-sale copayment as set forth in sub-subparagraph b. or the actual cost of the drug purchased. Such copayment shall not be waived or reduced in whole or in part, subject to the limits provided by paragraph (d).

b. The point-of-sale copayment amounts that are to be charged eligible program participants shall be in accordance with the following schedule:

(I) For each purchase of a covered drug costing $29.99 or less, $6.00.

(II) For each purchase of a covered drug costing $30.00 or more, $15.00.

For the purposes of such schedule of point-of-sale copayments, "costing" means the amount of reimbursement which shall be paid by the state to a participating provider pharmacy in accordance with subsection (11) plus the point-of-sale copayment, calculated as of the date of sale.

2. Commencing October 1, 2001, and every year thereafter, the board shall determine the percentage increase in the average wholesale price per unit of medication for approved claims for the top 500 drugs most commonly used during the prior program year, weighted for volume of claims. If the increase in the average wholesale price, as determined by the board, is greater than the percentage increase in the prescription drug component of the consumer price index measured for the same period, the board may increase the point-of-sale copayment per purchase of a covered drug set forth in this subdivision, or the corresponding ranges of program prices in effect at the time such adjustment is made, or both, by an amount not to exceed the lesser of the percentage increase in:

a. The average wholesale price per unit weighted for volume of claim approved during the previous program year; or

b. The prescription drug component of the consumer price index during the previous program year.

The determination to increase the amount of point of sale copayments or corresponding range of program prices in effect shall follow a review of such factors as the relative financial capacity of the state and such eligible program participants to support such adjustments and changes in the cost-of-living adjustment made in social security benefits. Such increase shall not take effect sooner than 60 days after the board makes such determination. Notwithstanding any inconsistent provision of this subparagraph, the board may adjust the point-of-sale copayment schedule to reflect the relative financial capacity of the state, and in no event shall such adjustment reduce the state share of the cost of

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covered drugs at the time of purchase to an average amount of less than 65 percent.

(d) During each annual coverage period, no point-of-sale copayment as set forth in paragraph (c) shall be required to be made for the remainder of such period by any eligible program participant who has already incurred copayments in excess of the following limits:

1. On copayments by an unmarried individual who is an eligible program participant:

a. Individual income of $5,000 or less, no more than $400.

b. Individual income of $5,001 to $6,000, no more than $480.

c. Individual income of $6,001 to $7,000, no more than $560.

d. Individual income of $7,001 to $8,000, no more than $640.

e. Individual income of $8,001 to $9,000, no more than $720.

f. Individual income of $9,001 to $10,000, no more than $800.

g. Individual income of $10,001 to $11,000, no more than $880.

h. Individual income of $11,001 to $12,000, no more than $960.

2. On copayments by each married individual who is an eligible program participant:

a. Joint income of $5,000 or less, no more than $300.

b. Joint income of $5,001 to $6,000, no more than $360.

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c. Joint income of $6,001 to $7,000, no more than $420.

d. Joint income of $7,001 to $8,000, no more than $480.

e. Joint income of $8,001 to $9,000, no more than $540.

f. Joint income of $9,001 to $10,000, no more than $600.

g. Joint income of $10,001 to $11,000, no more than $660.

h. Joint income of $11,001 to $12,000, no more than $720.

i. Joint income of $12,001 to $13,000, no more than $780.

j. Joint income of $13,001 to $14,000, no more than $840.

k. Joint income of $14,001 to $15,000, no more than $900.

(9) ELIGIBILITY REQUIREMENT FOR PARTICIPANTS QUALIFYING BY MEETING A DEDUCTIBLE.--

(a) Each eligible individual meeting the deductible requirements of this subsection may purchase covered drugs for an amount specified by paragraph (c).

(b) Each eligible individual approved for coverage under this subsection who shall incur during any annual coverage period $150 of personal covered drug expenditures that are not reimbursed by any other public or private third-party payment source or insurance plan shall be deemed to have met his or her deductible requirements for the remainder of such annual coverage period.

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(c)1.a. Upon satisfaction of the deductible requirements of paragraph (b), an eligible program participant shall, at the time of each purchase of a covered drug, pay the lesser of a point-of-sale copayment as set forth in sub-subparagraph b. or the actual cost of the drug purchased. Such copayment shall not be waived or reduced in whole or in part, subject to the limits provided by paragraph (d).

b. The point-of-sale copayment amounts that are to be charged eligible program participants shall be in accordance with the following schedule:

(I) For each purchase of a covered drug costing $29.99 or less, $6.

(II) For each purchase of a covered drug costing $30 or more, $15.

For purposes of such schedule, "costing" means the amount of reimbursement which shall be paid by the state to a participating provider pharmacy in accordance with subsection (11) plus the point-of-sale copayment, calculated as of the date of sale.

2. Commencing October 1, 2001, and every year thereafter, the board shall determine the percentage increase in the average wholesale price per unit of medication for approved claims for the top 500 drugs most commonly used during the prior program year, weighted for volume of claims. If the increase in the average wholesale price, as determined by the board, is greater than the percentage increase in the prescription drug component of the consumer price index measured for the same period, the board may increase the point of sale copayment per purchase of a covered drug set forth in this paragraph, or the corresponding ranges of program prices

in effect at the time such adjustment is made, or both, by an amount not to exceed the lesser of the percentage increase in:

a. The average wholesale price per unit weighted for volume of claims approved during the previous program year; or

b. The prescription drug component of the consumer price index during the previous program year.

The determination to increase the amount of point-of-sale copayments or corresponding range of program prices in effect shall follow a review of such factors as the relative financial capacity of this state and such eligible program participants to support such adjustments and changes in the cost-of-living adjustment made in social security benefits. Such increase shall not take effect sooner than 60 days after the board makes such determination. Notwithstanding any inconsistent provision of this subparagraph, the board may adjust the point-of-sale copayment schedule to reflect the relative financial capacity of the state, and in no event shall such adjustment reduce the state share of the cost of covered drugs at the time of purchase to an average amount of less than 65 percent.

(d) During each annual coverage period, no point-of-sale copayments as set forth in paragraph (c) shall be required to be made for the remainder of such period by any eligible program participant meeting the personal covered drug expenditure requirements of paragraph (b) in excess of the following limits:

1. On copayments by each unmarried individual who is an eligible program participant:

a. Individual income of $10,000 or less, no more than $575.

b. Individual income of $10,001 to $11,000, no more than $633.

c. Individual income of $11,001 to $12,000, no more than $690.

d. Individual income of $12,001 to $13,000, no more than $748.

e. Individual income of $13,001 to $14,000, no more than $805.

f. Individual income of $14,001 to $15,000, no more than $863.

g. Individual income of $15,001 to $16,000, no more than $920.

h. Individual income of $16,001 to $17,000, no more than $978.

i. Individual income of $17,001 to $18,000, no more than $1035.

2. On copayments by each married individual who is an eligible program participant:

a. Joint income of $13,000 or less, no more than $561.

b. Joint income of $13,001 to $14,000, no more than $603.50.

c. Joint income of $14,001 to $15,000, no more than $647.

d. Joint income of $15,001 to $16,000, no more than $690.

e. Joint income of $16,001 to $17,000, no more than $733.

f. Joint income of $17,001 to $18,000, no more than $776.50.

g. Joint income of $18,001 to $19,000, no more than $819.50.

h. Joint income of $19,001 to $20,000, no more than $862.50.

i. Joint income of $20,001 to $21,000, no more than $906.

j. Joint income of $21,001 to $22,000, no more than $949.

k. Joint income of $22,001 to $23,000, no more than $992.

(10) PARTICIPATING PROVIDER PHARMACIES.--

(a) The state shall offer an opportunity to participate in this program to all pharmacies as defined in subsection (2).

(b) To participate in this program, a pharmacy shall be required to enter into a provider agreement and shall abide by such terms and conditions as shall be prescribed in the agreement, including the release of financial information for the purpose of program audits and surveys.

(11) REIMBURSEMENT TO PARTICIPATING PROVIDER PHARMACIES.--

(a) The amount of reimbursement which shall be paid by the state to a participating provider pharmacy for any covered drug filled or refilled for any eligible program participant shall be equal to the lower of:

1. The usual and customary charge of the pharmacy for such drugs minus the point-of-sale copayment as required by subsections (8) and (9);

2. The pharmacy's charge to the general public at the time of purchase, taking into consideration any quantity and promotional discounts, minus the point-of-sale copayment as required by subsections (8) and (9); or

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3. The average wholesale price based on the quantities participating pharmacies buy most frequently, provided such average wholesale prices shall be discounted by 5 percent for any participating provider pharmacy or group of provider pharmacies with common ownership whose total prescription volume for the preceding calendar year was at least 100,000 prescriptions dispensed,

plus a dispensing fee of $2.75, except that such dispensing fee shall be $3 for participating provider pharmacies that provide 24-hour emergency prescription service, emergency delivery service at no cost to the consumer, and direct patient consultation with each prescription and that maintain a patient drug profile card on each eligible program participant, and minus the point-of-sale copayment as required by subsections (8) and (9).

(b) For purposes of determining the amount of reimbursement which shall be paid to a participating provider pharmacy, the board shall determine or cause to be determined, through a statistically valid survey, the quantities of each covered drug which participating provider pharmacies buy most frequently. Using the results of such survey, the contractor shall update every 30 days the list of average wholesale prices upon which such reimbursement is determined, using nationally recognized and most recently revised sources. Such price revisions shall be made available to all participating provider pharmacies. The pharmacist shall be reimbursed based on the price in effect at the time the covered drug is dispensed.

(c)1. Notwithstanding any inconsistent provision of law, if a manufacturer, as defined in s. 1927 of the Federal

Social Security Act, has entered into a rebate agreement with the Department of Health or with the Federal Secretary of Health and Human Services on behalf of the Department of Health under s. 1927 of the Federal Social Security Act, the program for elderly pharmaceutical insurance coverage shall reimburse for covered drugs that are dispensed under the program by a provider pharmacy only pursuant to the terms of the rebate agreement between the program and such manufacturer; however, the program may reimburse for any covered drugs pursuant to paragraphs (a) and (b) which are rated 1-A by the Federal Food and Drug Administration and which are determined by the board to be essential to the health of persons participating in the program.

2. The rebate agreement between such manufacturer and the program for elderly pharmaceutical insurance coverage shall use for covered single-source drugs and innovator multiple-source drugs the identical formula used to determine the basic rebate for federal financial participation for single-source drugs and innovator multiple-source drugs, pursuant to s. 1927(c)(1) of the Federal Social Security Act, to determine the amount of the rebate pursuant to this paragraph. The rebate agreement between such manufacturer and the program for elderly pharmaceutical insurance coverage shall use for non-innovator multiple-source drugs, the identical formula used to determine the basic rebate for federal financial participation for non-innovator multiple-source drugs, pursuant to s. 1927(c)(3) of the Federal Social Security Act, to determine the amount of the rebate pursuant to this subparagraph. The amount of rebate shall be calculated by multiplying the required rebate formulas by the total number of units of each dosage form and

strength dispensed. The rebate agreement shall also provide for periodic payment of the rebate, provision of information to the program, audits, verification of data, and confidentiality of information.

3. The program, in providing utilization data to a manufacturer as provided for under s. 1927(b) of the Federal Social Security Act, shall provide such data by zip code, if requested, for the top 300 most commonly used drugs by volume covered under a rebate agreement.

4. Any funds collected pursuant to any rebate agreements entered into with a manufacturer pursuant to this paragraph shall be deposited into the General Revenue Fund.

(12) PENALTIES FOR FRAUD AND ABUSE.--

(a) Any person who knowingly makes a false statement or representation, or who, by deliberate concealment of any material fact or by impersonation or other fraudulent device, obtains or attempts to obtain or aids or abets any person to obtain any benefit under this act to which he or she is not entitled, commits a misdemeanor of the first degree, punishable as provided in section 775.082 or section 775.083, Florida Statutes.

(b) Any person who, having made application to receive any benefit under this act for the use and benefit of another and having received such benefit, knowingly and willfully converts such benefit or any part of such benefit to a use other than for the use and benefit of such other person commits a misdemeanor of the first degree, punishable as provided in section 775.082 or section 775.083, Florida Statutes.

(c) Any person who, with intent to defraud, presents for allowance or payment any false or fraudulent claim for

furnishing services or merchandise, or knowingly submits false information for the purpose of obtaining greater compensation than that to which such person is legally entitled for furnishing services or merchandise, or knowingly submits false information for the purpose of obtaining authorization for furnishing services or merchandise under this act commits a misdemeanor of the first degree, punishable as provided in section 775.082 or section 775.083, Florida Statutes.

(13) PROCEDURES FOR DETERMINATIONS RELATING TO PACKAGE, OR FORM OF DOSAGE OR ADMINISTRATION, OF CERTAIN DRUGS.--

(a) If the Secretary of Health makes an initial determination that a particular package, or form of dosage or administration, of a drug does not constitute a covered drug for purposes of this act due to the availability of a less expensive package, or form of dosage or administration, that is pharmaceutically equivalent and equivalent in its therapeutic effect for the general health characteristics of the eligible program participant population, the department shall notify the manufacturer of such drug product that the department intends to exclude such package, or form of dosage or administration, from the program and shall provide such manufacturer with the reasons for such exclusion together with the facts that the department relies upon to support its initial determination. The manufacturer shall have 15 days after receiving such exclusion notice to notify the department of an intent to appeal the decision. If the manufacturer fails to notify the department of an intent to appeal within the time specified in this subsection, the Secretary of Health shall immediately thereafter determine whether the package, or form of dosage or administration, shall be excluded from the

program. If the manufacturer notifies the department of an intent to appeal, the manufacturer shall submit to the department, within 45 days after receiving such exclusion notice, the basis of the manufacturer's appeal. Within 15 days after receiving such submission from the manufacturer, the department shall provide to the manufacturer any additional facts concerning the drug product which the department relies upon to support its initial determination. Within 10 days after receiving such facts, the manufacturer may submit additional facts concerning the drug package, or form of dosage or administration. Based on the facts submitted pursuant to this subsection, the Secretary of Health shall make a final determination as to whether or not the package, or form of dosage or administration, of the drug product constitutes a covered drug for the purposes of this act. A determination that a drug package, or form of dosage or administration, does not constitute a covered drug for purposes of this act is subject to judicial review.

(b) Notwithstanding paragraph (a), the Department of Health shall establish by rule an appropriate process for allowing drug packages, or forms of dosage or administration, finally determined under this subsection not to be covered drugs for the purposes of this act to be dispensed to program participants for whom such drug packages, or forms of dosage or administration, are medically indicated as certified to by a physician treating such participant. Any such drug package, or form of dosage or administration, so certified as medically indicated for a specific participant in accordance with such rules shall be a covered drug for the purpose of this act.

(14) USE OF OUT-OF-STATE PROVIDER PHARMACIES; NECESSITY AND CONVENIENCE.--

(a) In counties having a population of 75,000 or less which are in close proximity to Alabama or Georgia and which are determined by the executive director to be inadequately served by provider pharmacies registered in this state, the executive director may approve as provider pharmacies, pharmacies located in Alabama or Georgia. Such approvals may be made only after:

1. Consideration of the convenience and necessity of residents of this state in the rural areas served by such pharmacies.

2. Consideration of the quality of service of such pharmacies and the standing of such pharmacies with the governmental board or agency of the state in which the pharmacy is located.

3. The executive director has given all licensed pharmacies within the county notice of his intention to approve such out-of-state provider pharmacies.

4. The executive director has held a public hearing at which he or she has determined factually that the licensed pharmacies within such county are not adequately serving as provider pharmacies.

(b) The executive director shall investigate and determine within 90 days after the filing of an application for certification by the governing body of any municipality claiming to be lacking adequate pharmaceutical service within a county determined by the executive director to be not adequately served by provider pharmacies registered in this state pursuant to paragraph (a) whether to grant certification.

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

(c) Each certification granted pursuant to this subsection shall expire not more than 5 years after its date of issuance.

Section 2. This act shall take effect October 1, 2000.

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LEGISLATIVE SUMMARY

Provides a program for pharmaceutical insurance coverage for elderly persons. Provides for eligibility, pharmaceutical insurance contracts, an elderly pharmaceutical insurance coverage board and an advisory committee to the board, program requirements, eligibility requirements for program participants, participating provider pharmacies, penalties for fraud and abuse, procedures for determinations by the Department of Health relating to package or form of dosage or administration of drugs as excluded drugs, and use of out-of-state pharmacies. (See bill for details.)

CODING: Words ~~stricken~~ are deletions; words underlined are additions.