

FIRST EXTRAORDINARY SESSION
SENATE COMMITTEE SUBSTITUTE FOR

SENATE BILLS NOS. 4, 1, 5 & 6

91ST GENERAL ASSEMBLY

Reported from the Committee on Public Health and Welfare, September 6, 2001, with recommendation that the Senate Committee Substitute do pass.

2418S.05C

TERRY L. SPIELER, Secretary.

AN ACT

To repeal section 135.095, RSMo, relating to a Missouri Senior Rx Program, and to enact in lieu thereof ten new sections relating to the same subject, with a contingent effective date for a certain section and an emergency clause.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Section 135.095, RSMo, is repealed and ten new sections enacted in lieu thereof, to be known as sections 135.094, 135.095, 208.550, 208.553, 208.556, 208.559, 208.562, 208.565, 208.568 and 208.571, to read as follows:

135.094. For all tax years beginning on or after January 1, 2002, but before January 1, 2003, a claimant who has attained sixty-five years of age on or before the last day of the tax year shall be allowed, for the purpose of offsetting the cost of legend drugs, a maximum credit against the tax otherwise due pursuant to chapter 143, RSMo, not including sections 143.191 to 143.265, RSMo, of two hundred dollars. For the purpose of this section, a "claimant" is defined as a person or persons claiming a credit under section 135.010. If two claimants are eligible to file a joint federal income tax return and reside at the same address at any time during the taxable year, then the credit may only be allowed if claimed on a combined Missouri income tax return or a combined claim return reporting their combined incomes and property taxes. A claimant shall not be allowed a credit unless the claimant or spouse has attained the age of sixty-five on or before the last day of the calendar year and the claimant or spouse was a resident of Missouri for the entire year during which the credit is claimed. A claimant must apply for his or her own credit. A claimant shall be entitled to the maximum credit allowed by this section if the claimant has an income as defined

EXPLANATION--Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.

in section 135.010 of fifteen thousand dollars or less; provided that, no claimant who meets the income criteria for Medicaid eligibility, or has coverage for pharmaceutical benefits through a health benefit plan as defined in section 376.1350, RSMo, including a Medicare supplement or Medicare+Choice plan, or through a self-funded employee benefit plan shall qualify for the credit allowed pursuant to this section unless a claimant's pharmaceutical expenses exceed the claimant's coverage, in which case, a claimant may qualify for a credit for the additional expenses, up to two hundred dollars. No claimant who is a resident of a local, state or federally funded facility shall qualify for the credit allowed pursuant to this section. The credit shall be claimed as prescribed by the director of the department of revenue, however, the claim must be accompanied by proof of a claimant's pharmaceutical expenses. The department of social services shall develop methods of verification of expenses by rule for use by the department of revenue. Such credit shall be considered an overpayment of tax and shall be refundable even if the amount of the credit exceeds a claimant's tax liability. A credit may not be claimed pursuant to this section for any tax year ending after December 31, 2002, or any tax year during which an equivalent pharmaceutical benefits program is implemented, whichever is later. The provisions of this section shall only be effective if the provisions of sections 208.550 to 208.571, RSMo, are not fully operational by December 31, 2002. For purposes of this section the term "fully operational" shall be defined by the commission for the Missouri senior Rx program established pursuant to section 208.553, RSMo.

135.095. For all tax years beginning on or after January 1, 1999, but before [January 1, 2005] **December 31, 2001**, a resident individual who has attained sixty-five years of age on or before the last day of the tax year shall be allowed, for the purpose of offsetting the cost of legend drugs, a maximum credit against the tax otherwise due pursuant to chapter 143, RSMo, not including sections 143.191 to 143.265, RSMo, of two hundred dollars. An individual shall be entitled to the maximum credit allowed by this section if the individual has a Missouri adjusted gross income of fifteen thousand dollars or less; provided that, no individual who receives full reimbursement for the cost of legend drugs from Medicare or Medicaid, or who is a resident of a local, state or federally funded facility shall qualify for the credit allowed pursuant to this section. If an individual's Missouri adjusted gross income is greater than fifteen thousand dollars, such individual shall be entitled to a credit equal to the greater of zero or the maximum credit allowed by this section reduced by two dollars for every hundred dollars such individual's income exceeds fifteen thousand dollars. The credit shall be claimed as prescribed by the director of the department of revenue. Such credit shall be considered an overpayment of tax and shall be refundable even if the amount of the credit exceeds an individual's tax liability.

208.550. As used in sections 208.550 to 208.571, the following terms mean:

(1) "Clearinghouse", the Missouri senior Rx clearinghouse established in section 208.571;

(2) "Commission", the commission for the Missouri senior Rx program established in section 208.553;

(3) "Direct seller", any person, partnership, corporation, institution or entity engaged in the selling of pharmaceutical products directly to consumers in this state;

(4) "Distributor", a private entity under contract with the original labeler or holder of the national code number to manufacture, package or market the covered prescription drug;

(5) "Division", the division of aging within the department of health and senior services;

(6) "FDA", the Food and Drug Administration of the Public Health Services of the Department of Health and Human Services;

(7) "Fully operational", shall be defined by the commission for the Missouri senior Rx program established in section 208.553;

(8) "Household income", the amount of income as defined in section 135.010, RSMo. For purposes of this section, household income shall be the household income of the applicant for the previous calendar year;

(9) "Innovator multiple-source drugs", a multiple-source drug that was originally marketed under a new drug application approved by the FDA. The term includes:

(a) Covered prescription drugs approved under Product License Approval (PLA), Establishment Licenses Approval (ELA), or Antibiotic Drug Approval (ADA); and

(b) A covered prescription drug marketed by a cross-licensed producer or distributor under the Approved New Drug Application (ANDA) when the drug product meets this definition;

(10) "Manufacturer", shall include:

(a) An entity which is engaged in any of the following:

a. The production, preparation, propagation, compounding, conversion or processing of prescription drug products:

(i) Directly or indirectly by extraction from substances of natural origin;

(ii) Independently by means of chemical synthesis; or

(iii) By a combination of extraction and chemical synthesis;

b. The packaging, repackaging, labeling or relabeling, or distribution of prescription drug products;

(b) The entity holding legal title to or possession of the national drug code number for the covered prescription drug;

(c) The term does not include a wholesale distributor of drugs, drugstore chain organization or retail pharmacy licensed by the state;

(11) "Medicaid", the program for medical assistance established pursuant to Title XIX of the federal Social Security Act and administered by the department of social services;

(12) "Missouri resident", an individual who establishes residence for a period of twelve months in a settled or permanent home or domicile within the state of Missouri with the intention of remaining in this state. An individual is a resident of this state until the individual establishes a permanent residence outside this state;

(13) "National drug code number", the identifying drug number maintained by the FDA. The complete eleven-digit number must include the labeler code, product code and package size code;

(14) "New drug", a covered prescription drug approved as a new drug under section 201(p) of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, 21 U.S.C. S 321(p));

(15) "Noninnovator multiple-source drug", a covered prescription drug which is not an innovator multiple-source drug approved under an Abbreviated New Drug Application (ANDA) or an Amended Antibiotic Drug Approval (AADA);

(16) "Prescription drug", a prescription drug as defined in 13 CSR 70-20. The current limitations or restrictions placed on certain pharmaceuticals by the department of social services shall remain and the department may define additional restrictions by rule;

(17) "Program", the Missouri senior Rx program established pursuant to section 208.556;

(18) "Single-source drugs", legend drug products for which the FDA has not approved on Abbreviated New Drug Application (ANDA);

(19) "Third-party administrator", a private party contracted to administer the Missouri senior Rx program established in section 208.556, with duties that may include, but shall not be limited to, devising applications, enrolling members, administration of prescription drug benefits, and implementation of cost-control measures, including such programs as disease management programs, early refill edits, and fraud and abuse detection system and auditing programs;

(20) "Unit", a drug unit in the lowest identifiable amount, such as tablet or capsule for solid dosage forms, milliliter for liquid forms and gram for ointments or creams. The manufacturer shall specify the unit for each dosage form and strength of each covered prescription drug in accordance with the instructions developed by the Center for Medicare and Medicaid Services (CMS) for purposes of the Federal Medicaid Rebate Program under section 1927 of Title XIX of the Social Security Act (49 Stat. 620, 42 U.S.C. section 301 et seq.);

(21) "Wholesaler", any person, partnership, corporation, institution or entity to

which the manufacturer sells the covered prescription drug, including a pharmacy or chain of pharmacies.

208.553. 1. There is hereby established the "Commission for the Missouri Senior Rx Program" within the division of aging in the department of health and senior services to assist in the operation of the Missouri senior Rx program established in section 208.556. The commission shall consist of the following thirteen members:

(1) Two members of the senate, with one member from the majority party appointed by the president pro tem of the senate and one member of the minority party appointed by the president pro tem of the senate with the concurrence of the minority floor leader of the senate;

(2) Two members of the house of representatives, with one member from the majority party appointed by the speaker of the house of representatives and one member of the minority party appointed by the speaker of the house of representatives with the concurrence of the minority floor leader of the house of representatives;

(3) The director of the department of social services or his or her designee;

(4) The director of the department of health and senior services or his or her designee;

(5) The following four members appointed by the governor with the advice and consent of the senate:

(a) A pharmacist;

(b) A physician;

(c) A representative from a senior advocacy group; and

(d) A representative from an area agency on aging;

(6) A representative from the Pharmaceutical Manufacturers Association as a nonvoting member appointed by the president pro tem of the senate and the speaker of the house of representatives;

(7) One public member appointed by the president pro tem of the senate; and

(8) One public member appointed by the speaker of the house of representatives.

The commission shall elect a chair and may employ an executive director and such professional, clerical, and research personnel as may be necessary to assist in the performance of the commission's duties.

2. The commission:

(1) May establish guidelines, policies, and procedures necessary to establish the Missouri senior Rx program;

(2) Shall hold quarterly meetings within fifteen days of the submission of each quarterly report required in subsection 14 of section 208.556, and other meetings as deemed necessary to make recommendations to the division for appropriate cost-control measures;

(3) May establish guidelines and collect information and data to promote and facilitate the program;

(4) May, after implementation of the program, evaluate and make recommendations regarding the creation of a senior prescription drug benefit available to seniors who are not eligible for the program due to income that does not meet the program requirements.

3. The members of the commission shall receive no compensation for their service on the commission, but shall be reimbursed for ordinary and necessary expenses incurred in the performance of their duties as a member of the commission.

4. If the provisions of sections 208.550 to 208.571 are not fully operational by December 31, 2002, then the provisions of section 135.094, RSMo, shall be effective for the tax year ending December 31, 2002.

208.556. 1. There is hereby established the "Missouri Senior Rx Program" within the division of aging in the department of health and senior services to help defray the costs of prescription drugs for elderly Missouri residents. The program shall be governed by the commission for the Missouri senior Rx program established in section 208.553. The commission shall solicit requests for proposal from private contractors for the third-party administration of the program; except that the commission shall either administer the rebate program established in section 208.565 or contract with the division of medical services for the rebate program established in section 208.565.

2. Before December 31, 2002, the commission shall also solicit requests for proposal from private contractors for an insurance-based program to provide prescription drug coverage to individuals eligible under this program.

3. Administration of the program shall include, but not be limited to, devising program applications, enrolling participants, administration of prescription drug benefits, and implementation of cost-control measures, including such strategies as disease management programs, early refill edits, fraud and abuse detection system, and auditing programs. The commission shall select a bid from the requests for proposal; however, if no bids are received, the program shall be administered collaboratively by the department of health and senior services and the department of social services.

4. Any Missouri resident sixty-five years of age or older, who has not had access to employer-subsidized health care insurance that offers a pharmacy benefit for six months prior to application, who is not currently ineligible pursuant to subsection 6 of this section, and who has a household income at or below twelve thousand dollars for an individual or at or below seventeen thousand dollars for a married couple is eligible to participate in the program.

5. Upon available funding and subject to appropriations, any Missouri resident sixty-five years of age or older, who has not had access to employer-subsidized health

care insurance that offers a pharmacy benefit for six months prior to application, who is not currently ineligible pursuant to subsection 6 of this section, and who has a household income at or below seventeen thousand dollars for an individual or at or below twenty-three thousand dollars for a married couple is eligible to participate in the program. If full funding for the program is not available, then participants at the income levels established pursuant to subsection 4 of this section shall be given priority.

6. Any person who is receiving Medicaid benefits shall not be eligible to participate in the program. The Missouri senior Rx program is a payer of last resort. If a senior has coverage for pharmaceutical benefits through a health benefit plan, as defined in section 376.1350, RSMo, including a Medicare supplement or Medicare+Choice plan, or through a self-funded employee benefit plan, the Missouri senior Rx program shall pay only for eligible costs not provided by such coverage.

7. Applicants for the program shall submit an annual application to the division, or the division's designee, that attests to the age, residence, and annual household income for an individual or couple, if married. The third-party administrator shall prescribe the form of the application for enrollment in the program, which shall be approved by the division. The commission shall develop a means test by which applicants must demonstrate that they meet the income requirement of the program.

8. Nothing in this section shall be construed as requiring an applicant to accept Medicaid benefits in lieu of participation in this program.

9. The following deductibles shall apply to enrollees in the program:

(1) For an individual with a household income at or below twelve thousand dollars, two hundred fifty dollars;

(2) For a married couple with a household income at or below seventeen thousand dollars, two hundred fifty dollars for each person;

(3) Pursuant to subsection 5 of this section, for an individual with a household income between twelve thousand one dollars and seventeen thousand dollars, five hundred dollars; and

(4) Pursuant to subsection 5 of this section, for a married couple with a household income between seventeen thousand one dollars and twenty-three thousand dollars, five hundred dollars for each person.

10. For prescription drugs, participants shall pay a forty percent coinsurance. The division may implement a higher coinsurance at the recommendation of the commission. Such coinsurance may be adjusted annually by the general assembly through the appropriation process and shall be used to reduce the state's cost for the program. In addition, each enrollee with an annual household income at or below twelve thousand dollars for an individual or at or below seventeen thousand

dollars for a married couple shall pay an annual twenty-five dollar enrollment fee and each enrollee with a household income between twelve thousand one dollars and seventeen thousand dollars for an individual or at or below between seventeen thousand one dollars and twenty-three thousand dollars for a married couple shall pay an annual thirty-five dollar enrollment fee to offset the administrative costs of the program.

11. The total expenditures for each enrollee under this program may be up to but shall not exceed five thousand dollars for each participant.

12. In providing program benefits, the department may enter into a contract with a private individual, corporation or agency to implement the program.

13. The division shall utilize area agencies on aging, senior citizens centers, and other senior focused entities to provide outreach, enrollment referral assistance, and education services to potentially eligible seniors for the pharmaceutical investment program for seniors. The division and third-party administrators shall be responsible for informing eligible seniors on the availability of and providing information about pharmaceutical company benefits which may be applicable.

14. The commission shall submit quarterly reports to the governor, the senate appropriations committee, the house of representatives budget committee, the speaker of the house of representatives, the president pro tem of the senate, and the division that include:

- (1) Quantified data as to the number of program applicants;
- (2) An estimate of whether the current rate of expenditures will exceed the existing appropriation for the program in the current fiscal year; and
- (3) Information regarding the commission's recommendations for changes to enrollment fees, coinsurance, deductibles, and benefit caps for enrollees in the program.

15. The program established in this section is not an entitlement. Benefits shall be limited to the level supported by the moneys explicitly appropriated pursuant to this section. If in any fiscal year the commission projects that the total cost of the program will exceed the amount currently appropriated for the program, the commission shall implement cost-control measures to reduce the projected cost. Such cost-control measures may include, but are not limited to, increasing the coinsurance or enrollment fee outlined in subsection 10 of this section. The Missouri senior Rx program is a payer of last resort. If the federal government establishes a pharmaceutical assistance program that covers program eligible seniors under Medicare or another program, the Missouri senior Rx program shall cover only eligible costs not covered by the federal program.

16. Any rule or portion of a rule, as that term is defined in section 536.010, RSMo, that is created under the authority delegated in sections 208.550 to 208.571 shall become

effective only if it complies with and is subject to all of the provisions of chapter 536, RSMo, and, if applicable, section 536.028, RSMo. Sections 208.550 to 208.571 and chapter 536, RSMo, are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536, RSMo, to review, to delay the effective date or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2002, shall be invalid and void.

208.559. 1. The Missouri senior Rx program shall be fully operational no later than July 1, 2002. The division shall accept applications for enrollment during an initial open enrollment period from April 1, 2002, through May 30, 2002. Beginning with the enrollment period for calendar year 2004, open enrollment periods for the program shall be held from November first through December fifteenth of the calendar year immediately preceding the calendar year for which participation is sought.

2. A person may apply for participation in the program outside the enrollment periods listed in subsection 1 of this section within thirty days of such person attaining the age and income eligibility requirements of the program established in section 208.556.

208.562. 1. Generic prescription drugs shall be used for the program when available. An enrollee may receive a name brand drug when a generic drug is available only if both the physician and enrollee request that the name brand drug be dispensed and the enrollee pays the coinsurance on the generic drug plus the difference in cost between the name brand drug and the generic drug.

2. Pharmacists participating in the pharmaceutical investment program for seniors shall be reimbursed for the price of prescription drugs based on the following formula:

(1) For generic prescription drugs, the average wholesale price minus twenty percent, plus a four dollar and nine cent dispensing fee; and

(2) For name brand prescription drugs, the average wholesale price minus ten and forty-three one hundredths percent, plus a four dollar and nine cent dispensing fee.

208.565. 1. The division shall issue a certificate of participation to pharmaceutical manufacturers participating in the Missouri senior Rx program. A pharmaceutical manufacturer may apply for participation in the program with an application form prescribed by the commission.

2. The division shall negotiate annually with participating manufacturers for the amount of rebates. The rebate amount for each brand name drug shall be fifteen percent of the average manufacturers' price as defined pursuant to 42 U.S.C. 1396r-8(k)(1). No other discounts shall apply. The rebate amount for each generic drug shall be eleven percent. No other discounts shall apply. In order to receive a certificate of

participation a manufacturer or distributor participating in the Missouri senior Rx program shall provide the division of aging the average manufacturers' price for their contracted products. The following shall apply to the providing of average manufacturers' price information to the division of aging:

(1) Any manufacturer or distributor with an agreement under this section that knowingly provides false information is subject to a civil penalty in an amount not to exceed one hundred thousand dollars for each provision of false information. Such penalties shall be in addition to other penalties as prescribed by law;

(2) Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers pursuant to this subsection or under an agreement with the division pursuant to section 208.565 is confidential and shall not be disclosed by the division in any form which discloses the identity of a specific manufacturer or wholesaler or prices charged for drugs by such manufacturer or wholesaler, except to permit the state auditor to review the information provided.

3. All rebates received through the program shall be used toward refunding the program. If a pharmaceutical manufacturer refuses to participate in the rebate program, such refusal shall not affect the manufacturer's status under the current Medicaid program. There shall be no drug formulary, prior or retroactive approval system, or any similar restriction imposed on the coverage of outpatient drugs made by pharmaceutical manufacturers who have agreements to pay rebates for drugs utilized in the Missouri senior Rx program, provided that such outpatient drugs were approved for marketing by the Food and Drug Administration.

4. Any prescription drug of a manufacturer that does not participate in the program shall not be reimbursable.

208.568. 1. There is hereby created in the state treasury the "Missouri Senior Rx Fund", which shall consist of all moneys deposited in the fund pursuant to sections 208.550 to 208.565 and all moneys which may be appropriated to it by the general assembly, from federal or other sources.

2. The state treasurer shall administer the fund and credit all interest to the fund and the moneys in the fund shall be used solely by the commission for Missouri senior Rx program and the division of aging for the implementation of the pharmaceutical investment program for seniors established in sections 208.550 to 208.571.

3. Notwithstanding the provisions of section 33.080, RSMo, to the contrary, moneys in the fund shall not revert to the credit of the general revenue fund at the end of the biennium.

208.571. 1. There is hereby established the "Missouri Senior Rx Clearinghouse" within the Missouri senior Rx commission established pursuant to section 208.553. The

commission shall submit requests for proposal from private contractors for the third-party administration of the clearinghouse. The third-party administrator of the Missouri senior Rx program may submit a request for proposal for administration of the clearinghouse. The clearinghouse shall be a quasi-public agency created to:

- (1) Assist all Missouri residents in accessing prescription drug programs;**
- (2) Educate the public on quality drug programs and cost containment strategies;**

- (3) Serve as a resource for pharmaceutical benefit issues.**

2. The purpose of the clearinghouse shall include, but not be limited to:

- (1) Promoting competition for customer service and consumer choice;**
- (2) Scaling existing programs according to budgetary needs;**
- (3) Providing meaningful assistance for Medicare beneficiaries and the general public through discounts and subsidies; and**
- (4) Integrating subsidy programs into the mainstream.**

Section B. Because immediate action is necessary to ensure the timely provision of prescription drugs to the elderly, this act is deemed necessary for the immediate preservation of the public health, welfare, peace, and safety, and is hereby declared to be an emergency act within the meaning of the constitution, and this act shall be in full force and effect upon its passage and approval.

Bill

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