LAWS

OF THE

STATE OF MAINE

AS PASSED BY THE

ONE HUNDRED AND TWENTY-SECOND LEGISLATURE

FIRST REGULAR SESSION
December 1, 2004 to March 30, 2005

FIRST SPECIAL SESSION
April 4, 2005 to June 18, 2005

THE GENERAL EFFECTIVE DATE FOR
FIRST REGULAR SESSION
NON-EMERGENCY LAWS IS
JUNE 29, 2005

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NON-EMERGENCY LAWS IS
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Penmor Lithographers
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2005

number of enrollees previously underinsured or uninsured, the number of enrollees previously insured, the number of individual enrollees and the number of enrollees enrolled through small employers;

(2) The total number of enrollees covered in health plans through large employers and self-insured employers;

(3) The number of employers, both small employers and large employers, who have ceased offering health insurance or contributing to the cost of health insurance for employees or who have begun offering coverage on a self-insured basis;

(4) The number of employers, both small employers and large employers, who have begun to offer health insurance or contribute to the cost of health insurance premiums for their employees;

(5) The number of new participating employers in the Dirigo Health ~~Insurance~~ Program;

(6) The number of employers ceasing to offer coverage through the Dirigo Health ~~Insurance~~ Program;

(7) The duration of employers participating in the Dirigo Health ~~Insurance~~ Program; and

(8) A comparison of actual enrollees in the Dirigo Health ~~Insurance~~ Program to the projected enrollees.

Sec. C-10. 24-A MRSA §6971, sub-§§2 and 3, as enacted by PL 2003, c. 469, Pt. A, §8, are amended to read:

2. Disease management. Dirigo Health shall develop appropriate disease management protocols, develop procedures for implementing those protocols and determine the manner in which disease management must be provided to plan enrollees in the high-risk pool. Dirigo Health may include disease management in its contract with participating carriers for the Dirigo Health ~~Insurance~~ Program pursuant to section 6910, contract separately with another entity for disease management services or provide disease management services directly through Dirigo Health.

3. Report. Dirigo Health shall submit a report, no later than January 1, 2006, outlining the disease management protocols, procedures and delivery mechanisms used to provide services to plan enrollees. The report must also include the number of plan enrollees in the high-risk pool, the types of diagnoses managed within the high-risk pool, the claims experience within the high-risk pool and the number and type of claims exceeding $100,000 for enrollees in the high-risk pool and for all enrollees in the Dirigo Health ~~Insurance~~ Program. The report must be submitted to the joint standing committee of the Legislature having jurisdiction over health insurance matters. The committee may make recommendations on the operation of the high-risk pool and may report out legislation to the Second Regular Session of the 122nd Legislature relating to the high-risk pool.

PART D

Sec. D-1. Appropriations and allocations. The following appropriations and allocations are made.

PROFESSIONAL AND FINANCIAL REGULATION, DEPARTMENT OF

Bureau of Insurance 0092

Initiative: Allocates funds for the costs of reviewing and analyzing the Board of Directors of Dirigo Health's filing of its determination as to the aggregate measurable cost savings from the operation of Dirigo Health and related MaineCare expansions.

OTHER SPECIAL REVENUE FUNDS	**2005-06**	**2006-07**
All Other	$50,000	$50,000
OTHER SPECIAL REVENUE FUNDS TOTAL	$50,000	$50,000

See title page for effective date.

CHAPTER 401

H.P. 924 - L.D. 1325

An Act To Ensure Continuity of Care Related to Implementation of the Federal Medicare Drug Benefit

Be it enacted by the People of the State of Maine as follows:

PART A

Sec. A-1. 22 MRSA §254, as amended by PL 2005, c. 12, Pt. KKK, §§1 to 3, is repealed.

Sec. A-2. 22 MRSA §254-D is enacted to read:

§254-D. Elderly low-cost drug program

The Department of Health and Human Services may conduct the elderly low-cost drug program to provide low-cost prescription and nonprescription

drugs, medication and medical supplies to disadvantaged, elderly and disabled individuals.

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Beneficiary under Medicare Part D" means a person who is enrolled in Medicare Part D.

B. "Enrollee" means a person who receives benefits under the program.

C. "Household income" means family income as defined by the department for the purposes of this section.

D. "MaineCare member" means a person who receives benefits under the MaineCare program under chapter 855.

E. "Manufacturer" means a manufacturer of prescription drugs and includes a subsidiary or affiliate of the manufacturer or a person or entity that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 207.20 (1999).

F. "Medicare Part D" means the prescription drug benefit program provided under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173.

G. "Program" means the elderly low-cost drug program authorized in this section.

H. "Wholesale price" means the average price paid by a wholesaler to a manufacturer for a product distributed for retail sale. "Wholesale price" includes a deduction for any customary prompt payment discounts.

2. Administration. The commissioner shall provide sufficient personnel to ensure efficient administration of the program. The commissioner shall determine the extent and the magnitude of the program on the basis of the calculated need of the recipient population and the available funds. The department may not spend more on this program than is available through appropriations from the General Fund, dedicated revenue, federal or other grants and other established and committed funding sources. The commissioner may accept, for the purposes of carrying out this program, federal funds appropriated under any federal law relating to the furnishing of free or low-cost drugs to disadvantaged, elderly or disabled individuals and may take such action as is necessary for the purposes of carrying out that federal law and may accept from any other agency of government, individual, group or corporation such funds as may be available to carry out this chapter. The department may establish priorities of coverage and cost-sharing with available funds. Funds appropriated from the General Fund to carry out the purposes of this section may not lapse but must carry from year to year.

3. Applications. The commissioner shall make available suitable applications for benefits under the program with instructions for applicants. Individuals who are eligible for benefits under both MaineCare and Medicare Part D may be deemed eligible for the program without the need for application.

4. Conduct of program. This subsection governs the conduct of the program, including the basic, supplemental and catastrophic components, by the department.

A. Prescription and nonprescription drugs, medications and medical supplies of manufacturers that enter into rebate agreements pursuant to paragraph H may be available under the program. The department may create and implement a preferred drug list. Drugs may be made available through the operation of the basic and supplemental components of the program as follows.

(1) The basic component of the program must provide drugs and medications for cardiac conditions and high blood pressure, diabetes, arthritis, anticoagulation, hyperlipidemia, osteoporosis, chronic obstructive pulmonary disease and asthma, incontinence, thyroid diseases, glaucoma, parkinson's disease, multiple sclerosis and amyotrophic lateral sclerosis. The basic component must also provide over-the-counter medications that are prescribed by a health care provider and approved as cost-effective by the department.

(2) The supplemental component of the program must provide all prescription drugs and medications of manufacturers that enter into rebate agreements pursuant to paragraph H other than those prescription drugs and medications provided under subparagraph (1).

B. An individual is eligible for the program if that individual:

(1) Is a legal resident of the State;

(2) Meets the income eligibility criteria set forth in this section or is eligible for both MaineCare and Medicare Part D;

(3) Does not receive full MaineCare pharmaceutical benefits; and

(4) Is at least 62 years of age, or is 19 years of age or older and determined to be disabled by the standards of the federal social security program. A person who was eligible for the program at any time from August 1, 1998 to July 31, 1999 and who does not meet the requirements of this subparagraph at the time of application or renewal retains eligibility for the program if that person is a member of a household of an eligible person.

C. The department may require that an enrollee or applicant for the program who is otherwise eligible for Medicare Part D become a beneficiary under Medicare Part D unless the department determines that good cause exists for the person not to participate in Medicare Part D.

D. Income eligibility of individuals must be determined by this paragraph and by reference to the federal poverty guidelines for the 48 contiguous states and the District of Columbia, as defined by the federal Office of Management and Budget and revised annually in accordance with the United States Omnibus Budget Reconciliation Act of 1981, Section 673, Subsection 2, Public Law 97-35, reauthorized by Public Law 105-285, Section 201 (1998). If the household income is not more than 185% of the federal poverty guideline applicable to the household, the individual is eligible for the basic program and the supplemental program. Individuals are also eligible for the basic and the supplemental program if the household spends at least 40% of its income on unreimbursed direct medical expenses for prescription drugs and medications and the household income is not more than 25% higher than the levels specified in this paragraph. For the purposes of this paragraph, the cost of drugs provided to a household under this section is considered a cost incurred by the household for eligibility determination purposes.

E. Specifications for the administration and management of the program may include, but are not limited to, program objectives, accounting and handling practices, supervisory authority and evaluation methodology.

F. The method of prescribing or ordering the drugs under paragraph A may include, but is not limited to, the use of standard or larger prescription refill sizes so as to minimize operational costs and to maximize economy. Unless the prescribing physician indicates otherwise or the department determines that it would not be cost-effective, the use of generic or chemically equivalent drugs is required, as long as these drugs are of the same quality and have the same mode of delivery as is provided to the general public, consistent with good pharmaceutical practice.

G. The commissioner may establish the amount of payment to be made by the program and by enrollees toward the cost of drugs and medications furnished under the program, including covered prescription and nonprescription drugs, medications and medical supplies, under the following terms.

(1) For the basic component of the program, the total cost to an enrollee for the purchase of any covered drug or medication may not exceed the sum of $2 plus 20% of the price allowed for that drug or medication under program rules.

(2) For the supplemental component of the program, the total cost to an enrollee for the purchase of any covered drug or medication may not exceed:

(a) For a brand name drug or medication, the cost to the program for that drug or medication minus the $2 paid by the program; and

(b) For a generic drug or medication, the sum of $2 plus 20% of the price allowed for that drug or medication under program rules.

(3) For the catastrophic component of the program, the commissioner shall establish annual limits on the costs incurred by enrollees for drugs and medications covered under the program on or prior to May 31, 2001. After the limit is reached, the program must pay 80% of the cost of each drug and medication covered by the supplemental component of the program on May 31, 2001 minus $2. Any remaining amount is paid by the enrollee. The limits must be set by the commissioner by rule as necessary to operate the program within the program budget.

H. Payment must be denied for drugs from manufacturers that do not enter into a rebate agreement with the department.

(1) Each agreement must provide that the manufacturer make rebate payments for both the basic and supplemental components of the program to the department according to the following schedule.

(a) From October 1, 1992 to October 1, 1998, the rebate percentage is equal to the percentage recommended by the federal Center for Medicare and Medicaid Services of the manufacturer's wholesale price for the total number of dosage units of each form and strength of a prescription drug that the department reports as reimbursed to providers of prescription drugs, provided payments are not due until 30 days following the manufacturer's receipt of utilization data supplied by the department, including the number of dosage units reimbursed to providers of prescription drugs during the period for which payments are due.

(b) Beginning October 1, 1998, the department shall seek to achieve an aggregate rebate amount from all rebate agreements that is 6 percentage points higher than that required by subdivision (a), provided such rebates result in a net increase in the rebate revenue available to the elderly low-cost drug program.

(2) Upon receipt of data from the department, the manufacturer shall calculate the quarterly payment.

(a) If a discrepancy is discovered, the department may, at its expense, hire a mutually agreed-upon independent auditor to verify the manufacturer's calculation.

(b) If a discrepancy is still found, the manufacturer shall justify its calculation or make payment to the department for any additional amount due.

(c) The manufacturer may, at its expense, hire a mutually agreed-upon independent auditor to verify the accuracy of the utilization data provided by the department. If a discrepancy is discovered, the department shall justify its data or refund any excess payment to the manufacturer.

(d) If the dispute over the rebate amount is not resolved, a request for a hearing with supporting documentation must be submitted to the department's office of administrative hearings. Failure to resolve the dispute may be cause for terminating the drug rebate agreement and denying payment to the manufacturer for any drugs.

(3) A prescription drug of a manufacturer that does not enter into an agreement pursuant to this paragraph is reimbursable only if the department determines the prescription drug is essential.

(4) All prescription drugs of a manufacturer that enters into an agreement pursuant to this paragraph that appear on the list of approved drugs under the program must be immediately available and the cost of the drugs must be reimbursed except as provided in this paragraph. The commissioner may impose prior authorization requirements on drugs under the program. If the commissioner establishes maximum retail prices for prescription drugs pursuant to section 2693, the department shall adopt rules for the program requiring the use of a drug formulary and prior authorization for the dispensing of certain drugs to be listed on a formulary.

(5) The names of manufacturers who do and do not enter into rebate agreements pursuant to this paragraph are public information. The department shall release this information to health care providers and the public on a regular basis and shall publicize participation by manufacturers that is of particular benefit to the public.

I. The eligibility determination made by the department is final, subject to appeal in accordance with the appeal process established in the MaineCare program.

5. Relationship to federal Medicare program. To the extent permitted by federal law and to the extent that funds are available, the department may:

A. Serve as the authorized representative for enrollees for the purpose of enrollment in a Medicare Part D plan;

B. Apply for Medicare Part D benefits and subsidies on behalf of enrollees;

C. Establish rules by which enrollees may opt out of the procedures under paragraphs A and B;

D. At its discretion, file exceptions and appeals pertaining to Medicare Part D eligibility or benefits on behalf of enrollees who are beneficiaries under Medicare Part D. The department may identify a designee for this function;

E. Identify objective criteria for evaluating Medicare Part D plans for the purposes of assisting or enrolling persons in those plans;

F. Deem eligible for and enroll in the program without the need for application individuals who are eligible for both MaineCare and Medicare Part D;

G. For enrollees who are also beneficiaries under or eligible for Medicare Part D:

(1) Provide coverage of drugs to the same extent that coverage is available to enrollees who are not eligible for Medicare Part D; and

(2) Provide assistance with premiums and other cost-sharing requirements of Medicare Part D; and

H. For enrollees who are MaineCare members and who are also beneficiaries under or eligible for Medicare Part D:

(1) Provide coverage of drugs to the same extent that coverage is available to enrollees who are MaineCare members who are not eligible for Medicare Part D; and

(2) Provide assistance with the cost of prescription drugs and premiums and other cost-sharing requirements of Medicare Part D.

6. Education, outreach and materials to increase access. The department shall provide education and outreach services to applicants and enrollees in the program, MaineCare members and beneficiaries under Medicare Part D to increase access to needed prescription and nonprescription drugs and fully use other private, state and federal programs. The department shall provide materials, which must cover the availability of benefits and the application process, must include brochures, posters for pharmacies and flyers for pharmacists to distribute with prescription drug purchases.

7. Rulemaking. The commissioner may adopt rules to implement the program. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

Sec. A-3. Emergency rules. Because of concerns regarding the anticipated scope of benefits and other factors that might limit access to medically necessary drugs provided under the federal Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the challenge of coordination of benefits under federal and state laws, the Department of Health and Human Services and the Governor shall convene a group of stakeholders of not more than 10 persons, appointed by the Commissioner of Health and Human Services, to advise and report to the department. After receiving the report of the stakeholders group and no later than January 1, 2006, the department shall adopt emergency rules for the elderly low-cost drug program under the Maine Revised Statutes, Title 22, section 254-D and the MaineCare program to implement the provisions of this Part. Rules adopted pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

PART B

Sec. B-1. 22 MRSA §§3174-HH and 3174-II are enacted to read:

§3174-HH. Coordination of services

For the purposes of maximizing coverage for prescription drugs for members who are enrolled in the MaineCare program, the department may provide prescription drug services for MaineCare members through the elderly low-cost drug program established under section 254-D.

§3174-II. Relationship to federal Medicare program

1. Authorization. To the extent permitted by federal law, with regard to the Medicare Part D benefit established in the federal Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, the department may:

A. Serve as an authorized representative for MaineCare members for the purpose of enrollment into a Medicare Part D plan;

B. Apply for Medicare Part D benefits and subsidies on behalf of MaineCare members;

C. Establish rules by which MaineCare members may opt out of the procedures under paragraphs A and B;

D. At its discretion, file exceptions and appeals on behalf of MaineCare members who are beneficiaries under Medicare Part D. The department may identify a designee for this function; and

E. Identify objective criteria for evaluating Medicare Part D plans for the purposes of assisting or enrolling MaineCare members in Medicare Part D plans.

PART C

Sec. C-1. 22 MRSA §254-A, as amended by PL 2001, c. 691, §2 and affected by §6, is repealed.

Sec. C-2. 22 MRSA §258, sub-§1, ¶A, as enacted by PL 2001, c. 293, §5, is amended to read:

A. "Elderly low-cost drug program" means the program established as part of the Healthy Maine Prescription Program pursuant to section ~~254~~ 254-D.

Sec. C-3. 22 MRSA §2681, sub-§3, as enacted by PL 1999, c. 786, Pt. A, §3, is amended to read:

3. Rebate agreement. A drug manufacturer or labeler that sells prescription drugs in this State through the elderly low-cost drug program under section ~~254~~ 254-D or any other publicly supported pharmaceutical assistance program shall enter into a rebate agreement with the department for this program. The rebate agreement must require the manufacturer or labeler to make rebate payments to the State each calendar quarter or according to a schedule established by the department.

Sec. C-4. 22 MRSA §2681, sub-§9, as amended by PL 2003, c. 494, §8, is further amended to read:

9. Dedicated fund. The Maine Rx Plus Dedicated Fund, referred to in this section as the "fund," is established to receive revenue from manufacturers and labelers who pay rebates as provided in subsection 4 and any appropriations or allocations designated for the fund. The purposes of the fund are to reimburse retail pharmacies for discounted prices provided to qualified residents pursuant to subsection 5; to reimburse the department for contracted services including pharmacy claims processing fees, administrative and associated computer costs and other reasonable program costs; and to benefit the elderly low-cost drug program under section ~~254~~ 254-D. The fund is a nonlapsing dedicated fund. Interest on fund balances accrues to the fund. Surplus funds in the fund must be used for the benefit of the program. Notwithstanding Title 5, section 1585, surplus funds may also be transferred to the elderly low-cost drug program established under section ~~254~~ 254-D.

Sec. C-5. 22 MRSA §3174-G, sub-§1-B, as amended by PL 2001, c. 650, §2, is further amended to read:

1-B. Funding. State funds necessary to implement subsection 1-C must include General Fund appropriations and Other Special Revenue allocations from the Fund for a Healthy Maine to the elderly low-cost drug program operated pursuant to section ~~254~~ 254-D, including rebates received in that program from pharmaceutical manufacturers, that are no longer needed in that program as a result of the Medicaid waiver obtained pursuant to subsection 1-C.

Sec. C-6. 22 MRSA §3174-G, sub-§1-C, as enacted by PL 2001, c. 650, §3, is amended to read:

1-C. Prescription drug waiver program. Except as provided in paragraph G, the department shall apply to the federal Centers for Medicare and Medicaid Services for a waiver or amend a pending or current waiver under the Medicaid program authorizing the department to use federal matching dollars to enhance the prescription drug benefits available to persons who qualify for the elderly low-cost drug program established under section ~~254~~ 254-D. The program created pursuant to the waiver is the prescription drug waiver program, referred to in this subsection as the "program."

A. As funds permit, the department has the authority to establish income eligibility levels for the program up to and including 200% of the federal nonfarm income official poverty level, except that for individuals in households that spend at least 40% of income on unreimbursed direct medical expenses for prescription medications, the income eligibility level is increased by 25%.

B. To the extent reasonably achievable under the federal waiver process, the program must include the full range of prescription drugs provided under the Medicaid program on the effective date of this subsection and must limit copayments and cost sharing for participants. If cost sharing above the nominal cost sharing for the Medicaid program is determined to be necessary, the department may use a sliding scale to minimize the financial burden on lower-income participants.

C. Coverage under the program may not be less beneficial to persons who meet the qualifications of former section 254 than the coverage available under that section on September 30, 2001.

D. In determining enrollee benefits under the program, to the extent possible, the department shall give equitable treatment to coverage of prescription medications for cancer, Alzheimer's disease and behavioral health.

E. The department is authorized to provide funding for the program by using funds appropriated or allocated to provide prescription drugs under sections ~~254~~ 254-D and 258.

Sec. C-7. 24-A MRSA §5002-B, sub-§2-A, as enacted by PL 2001, c. 410, Pt. B, §7, is amended to read:

2-A. Low-cost drugs for the elderly or disabled program. An issuer that offers standardized plans that include prescription drug benefits shall permit an insured who has a plan from the same issuer

without prescription drug benefits to purchase a plan with prescription drug benefits under the following circumstances:

A. The insured was covered under the low-cost drugs for the elderly or disabled program established by Title 22, former section 254 or section 254-D;

B. The insured applies for a plan with prescription drug coverage within 90 days after losing eligibility for the low-cost drugs for the elderly or disabled program established by Title 22, former section 254 or section 254-D; and

C. The insured either:

(1) Had a Medicare supplement plan with prescription drug benefits from the same issuer prior to enrolling in the low-cost drugs for the elderly or disabled program established by Title 22, former section 254 or section 254-D; or

(2) Is entitled to continuity of coverage pursuant to subsection 1 and has had prescription drug benefits, through either a Medicare supplement plan or the low-cost drugs for the elderly or disabled program established by Title 22, section ~~254~~ 254-D, since the insured's open enrollment period with no gap in prescription drug coverage in excess of 90 days.

The purchase of a plan with prescription drug benefits by an insured pursuant to this subsection does not affect eligibility for coverage under the low-cost drugs for the elderly or disabled program established by Title 22, section ~~254~~ 254-D if the insured is not covered by a Medicare supplement plan with prescription drug benefits at the time of reapplying for coverage under the low-cost drugs for the elderly or disabled program established by Title 22, section ~~254~~ 254-D.

See title page for effective date.

CHAPTER 402

S.P. 536 - L.D. 1541

An Act Pertaining to Disclosure of Prescription Drug Prices

Emergency preamble. Whereas, acts of the Legislature do not become effective until 90 days after adjournment unless enacted as emergencies; and

Whereas, the 121st Legislature in the Second Special Session enacted legislation requiring pharmaceutical manufacturers to report certain pricing information to the Department of Health and Human Services; and

Whereas, certain provisions of those reporting requirements require clarification or are duplicative of data otherwise available to the department; and

Whereas, clarification of those provisions is necessary in order to amend the law as close as possible in time to the first reporting date; and

Whereas, the reportable information constitutes trade secrets, and the existing confidentiality protection afforded to the reported information is not adequate; and

Whereas, in the judgment of the Legislature, these facts create an emergency within the meaning of the Constitution of Maine and require the following legislation as immediately necessary for the preservation of the public peace, health and safety; now, therefore,

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA §2698-B, sub-§1, as enacted by PL 2003, c. 667, §1 and affected by §2, is amended to read:

1. Quarterly report. A manufacturer of prescription drugs dispensed in this State under a health program directed or administered by the State shall, on a quarterly basis, report by National Drug Code the following pharmaceutical pricing criteria to the commissioner for each of its drugs:

~~A. The average wholesale price;~~

~~B. The wholesale acquisition cost;~~

C. The average manufacturer price as defined in 42 United States Code, Section 1396r-8(k); and

D. The best price as defined in Section 1927 of the Social Security Act, 42 United States Code, Section 1396r-8(c)(1)(C) as in effect on January 1, 2005.

The pricing information required under this subsection is for drugs defined under the Medicaid drug rebate program.

Sec. 2. 22 MRSA §2698-B, sub-§2, as enacted by PL 2003, c. 667, §1 and affected by §2, is repealed.

Sec. 3. 22 MRSA §2698-B, sub-§§3, 4 and 5, as enacted by PL 2003, c. 667, §1 and affected by §2, are amended to read: