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Final Report of the COMMISSION TO STUDY BULK PURCHASING OF PRESCRIPTION DRUGS AND MEDICAL SUPPLIES

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to the
JOINT STANDING COMMITTEE ON HEALTH AND HUMAN SERVICES

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Executive Summary

The Commission to Study Bulk Purchasing of Prescription Drugs and Medical Supplies, created by Resolve 1999, chapter 75, was established to address the increasing costs of prescription drugs and the lack of affordable access to insurance coverage for prescription drugs. The 12-member Commission met four times in October and November 1999, and explored information and proposals concerning prescription drug costs and expenditures. The Commission unanimously reached the following recommendations.

1. The Commission recommends that the State should not at this time pursue bulk purchasing of prescription drugs as a separate program.

2. The Commission recommends that the State expand educational outreach to inform Maine citizens about the many State, Federal and private programs available to reduce prescription costs.

3. The Commission recommends that the State investigate the feasibility of joining with other states, especially in local or regional affiliations, to lower prescription drug costs to consumers.

4. Recognizing that the Legislature and the Department of Human Services anticipate that the Maine Residents Low-Cost Drug Program will reduce prescription drug costs to consumers, the Commission recommends that the State move forward as rapidly as possible with the rule-making and legislative process to implement the program.

5. The Commission recommends that the availability of access to reduced-cost prescription drugs through the federal Office of Drug Pricing be explored more thoroughly to determine whether prescription drugs at a lower price can be made more available to programs providing services to Maine residents.

6. The Commission recommends that the State encourage a public-private partnership to generate, maintain and distribute a simple and coordinated therapeutic and pricing guideline for physicians and other prescribers.

7. The Commission recommends that the State encourage public-private partnerships for expanded purchasing volume, thereby increasing consumer's opportunity to purchase prescription drugs at lower prices.

8. The Commission recommends that the Department of Human Services continue to pursue the Medicaid waiver with the Health Care Financing Administration.

I Introduction

A. Inception of the study

During the First Regular Session of the 119th Legislature, the Joint Standing Committee on Health and Human Services was asked to find ways to address the increasing costs of prescription drugs and the lack of affordable access to insurance coverage for prescription drugs. Many legislative proposals made their way to the Committee. Several bills advocated modifications in the Elderly Low-Cost Drug Program. Other bills proposed establishing a purchasing consortium to make prescription drugs available at lower cost to low-income and elderly residents of the State. The Committee supported changes to the Elderly Low-Cost Drug Program (enacted as part of the Budget Bill, PL 1999, c. 401, Part KKK, as amended by PL 1999, c. 531, Part F), and created the Maine Resident Low-Cost Drug Program (PL 1999, c. 431, see Appendix D). In addition, the Committee recommended and the Legislature approved the creation of the Commission to Study Bulk Purchasing of Prescription Drugs and Medical Supplies, referred to in this report as "the Commission," initially proposed in LD 206 and finally passed as Resolve 1999, chapter 75.

B. Study charge

The Health and Human Services Committee determined that a comprehensive study of bulk purchasing of prescription drugs and medical supplies was needed to determine whether bulk purchasing could be used to provide Maine residents access to affordable prescription drugs and medical supplies. The Commission was directed to examine the need for a bulk purchasing mechanism, and to determine if there would be financial benefits and potential savings to private citizens, insurance carriers, self-insured employee health benefit plans and publicly funded health coverage. The charge also required the Commission to evaluate the potential impact of bulk purchasing on the State's economy and on pharmacies, hospitals and other health care facilities within the State. Resolve 1999, chapter 75, included as Appendix A, sets out the complete

charge to the Commission.

Early in its deliberations, the Commission determined that a broader focus was necessary, and that more ideas need to be explored in order to improve access to prescription drugs. It therefore interpreted its charge as a starting point, and used its meetings to examine additional approaches. The Commission also determined that its top priority was making prescription drugs more affordable, and therefore did not address durable medical equipment and medical supplies.

C. Study process

The Commission to Study Bulk Purchasing of Prescription Drugs and Medical Supplies consisted of 12 members, appointed by the Senate President, the Speaker of the House of Representatives and the Governor. In addition to six legislators representing both major political parties, the membership included the following persons: a member of a professional organization representing pharmaceutical manufacturers; a member of a statewide organization representing health care carriers regulated under Titles 24 and 24-A of the Maine Revised Statutes; a member from a statewide organization representing hospitals; a member of a statewide organization representing pharmacies; a member from a statewide organization representing pharmaceutical wholesalers; and the Director of the Bureau of Medical Services within the Department of Human Services, or the Director's designee. A list of the members is included as Appendix B.

The Commission met four times, as authorized by the enabling legislation, in October and November 1999 at the State House in Augusta. Interested parties attended the meetings, contributed ideas and participated in the Commission's discussion. The Commission members themselves brought an exceptional combination of personal and professional knowledge and experience, which allowed the discussion to start at a very high level and to progress from there.

The Commission examined the benefits and costs of the State's entering into the prescription drug market as a bulk purchaser. The discussion covered the following elements that

the State would have to include in its bulk purchasing distribution system: The ability to deliver prescription drugs to pharmacies throughout the state within hours of ordering; the ability to stock a large number of different drugs, including branded and generic; the storage requirements for some drugs, such as refrigeration; a large investment in technology; and the ability to track drugs throughout the distribution system to handle recalls or other problems. The existing distribution system contains all these elements; the State bulk purchasing program would have to duplicate each element. Another significant cost identified early in the discussion is the detrimental effect that such action may have on Maine businesses that are currently part of the wholesale and retail prescription drug business. For these reasons, the Commission agreed that it would also look beyond bulk purchasing to identify any other actions that would help the Legislature address the underlying problem of high prescription drug costs for those without any prescription drug coverage. The members and interested parties made additional suggestions. The Commission's recommendations are included in Part III of this report.

II Background

A. Prescription drugs

Prescription drugs are an integral component of today's health care system. Medications can be more cost-effective and less invasive than other forms of treatment, and they play important roles in the entire range of treatment, from saving lives to maintaining productive lives and lifestyles. Use of medications often results in lower overall health care costs for conditions such as asthma, AIDS, diabetes, heart disease, osteoporosis and stroke[1]. Taking prescription drugs does not eliminate visits to the health care provider – physicians and other prescribers still must ensure that the dosage is correct, determine whether the medication is having the desired effect and monitor the patient's condition and progress – but the resulting improvements they produce are significant.

Health care spending has been on the increase, and many studies have been undertaken to identify trends and factors. Just as prescription drugs are an important component in providing health care, they play an important role in costs, too. A study published by the National Institute for Health Care Management Foundation reported that total national health expenditures experienced an average annual percentage growth of 5.5% from 1992 to 1997. Prescription drug expenditures over the same period increased an average of 11.1% annually. This difference resulted in prescription drugs becoming a larger factor in total national health expenditures, increasing from 5.6% in 1992 to 7.2% of expenditures in 1997[2]. In Maine, Medicaid expenditures, after rebates, for outpatient prescription drugs increased by 9.5% from state fiscal year 1996-1997 to 1997-1998, and by 20.3% from 1997-1998 to 1998-1999[3]. The pharmaceutical industry figures paint a less stark picture: The Pharmaceutical Reseacrh and

[1] P*h*RMA, Backgrounder: The Myth of "Rising Drug Prices" Exposed, January 14, 1999, page 1.

[2] National Institute for Health Care Management, Factors Affecting the Growth of Prescription Drug Expenditures, Barents Group LLC, July 1999, page 1.

[3] Spreadsheet from Christopher Nolan, Department of Human Services, November 29, 1999, included as Appendix C.

Manufacturers of America (P*h*RMA) reports that the percentage of Gross Domestic Product (GDP) spent on prescription drugs has stayed at about one-half of one percent for the past 30 years, while the portion of GDP devoted to health care has increased from 7.4 % in 1970 to an estimated 14.4% in 1996[4].

A change in regulatory restrictions on print and television advertising has resulted in many new direct-to-consumer (DTC) advertising campaigns. About $1.3 billion was spent on DTC advertising in 1998[5]. The ten drugs most heavily advertised to consumers in 1998 accounted for $9.3 billion or about 22 percent of the total increase in drug spending between 1993 and 1998.

A portion of the increased expenditures on pharmaceuticals is related to rising drug prices. Several studies have pointed out large price increases for individual items[6]. One study attributes 64% of the increased spending to higher per prescription prices[7]; another study calculated that the prices for the 50 prescription drugs most frequently used by the elderly rose more than four times the rate of inflation during calendar year 1998[8]. Maine Medicaid prescription drug expenditures per prescription increased 22.8% from state fiscal year 1996-1997 to 1997-1998[9]. An additional reason that the average price per prescription has gone up so dramatically is the introduction of expensive new drugs that replace lower-cost existing medications. On average, the new drugs cost more than twice as much as older drugs[10].

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[4] P*h*RMA, Backgrounder: Prescription Drug Prices and Profits, page 4.

[5] National Institute for Health Care Management, Factors Affecting the Growth of Prescription Drug Expenditures, Barents Group LLC, July 1999, page 12.

[6] Families USA, Hard to Swallow, Rising Drug Price's for America's Seniors, November 1999; National Institute for Health Care Management, Factors Affecting the Growth of Prescription Drug Expenditures, Barents Group LLC, July 1999; Access and Affordability Monitoring Project, Boston University School of Public Health, Affordable Medications for Americans, Alan Sager, Ph.D., Deborah Socolar, M.P.H., July 1999.

[7] National Institute for Health Care Management, Factors Affecting the Growth of Prescription Drug Expenditures, Barents Group LLC, July 1999, page 15.

[8] Families USA, Hard to Swallow, Rising Drug Price's for America's Seniors, November 1999, page 2.

[9] Spreadsheet from Christopher Nolan, Department of Human Services, November 29, 1999, included as Appendix C.

[10] National Institute for Health Care Management, Factors Affecting the Growth of Prescription Drug

Rising drug expenditures are also attributable to greater drug utilization nationwide. The number of prescriptions filled increased from 1.9 billion in 1993 to 2.5 billion in 1998, a jump of 600 million prescriptions[11]. According to IMS Health, an organization that tracks pharmaceutical sales at the retail level, a large portion of the increase in expenditures for prescription drugs in 1998 is accounted for by the increased use of drugs, as well as the fact that doctors are more frequently prescribing newer, innovative and sometimes more costly medicines. For some leading therapeutic categories, the total utilization rate more than doubled between 1993 and 1998. For example, the number of prescriptions filled for oral antihistamines increased by 500% to 41 million prescriptions; the number filled for cholesterol-lowering medications increased by 162% to 68 million prescriptions, and for antidepressants, the number increased by 111% to 120 million. Also increasing is the number of prescriptions written and filled per person; therapies often include more than one medication to treat a particular illness or condition. Maine Medicaid outpatient prescription drug figures show a per person increase in the number of prescriptions of 5.6% from state fiscal year 1996-1997 to 1998-1999[12].

In addition, more drugs are being introduced to treat conditions that formerly were not treatable by medication. The increase in use of drugs rather than surgery or to prevent heart attacks and strokes, for example, results in greater expenditures for drugs, but greatly lowers or eliminates expenditures in other categories of health care. A recent study showed that a new medicine to prevent osteoporosis costs just $3,000 over 15 years – instead of $41,000 for hip replacement surgery[13]. New therapies are changing the quality of life, reducing the length of hospital stays and decreasing other, often more expensive and more invasive, components of medical care.

Expenditures, Barents Group LLC, July 1999, page 18.

[11] National Institute for Health Care Management, Factors Affecting the Growth of Prescription Drug Expenditures, Barents Group LLC, July 1999, page 21.

[12] Spreadsheet from Christopher Nolan, Department of Human Services, November 29, 1999, included as Appendix C.

[13] P*h*RMA, Backgrounder: Prescription Drug Prices and Profits, page 4.

B. Methods of paying for prescription drugs available in Maine

There are three ways Maine residents obtain their prescription drugs. Many have prescription drug coverage as part of a comprehensive health benefit program. These consist of both private and public programs, including private insurance programs, Medicaid and Cub Care, the state children's health care program established under Title XXI of the federal Social Security Act. Second, some receive benefits under stand-alone state drug benefit programs. The Elderly Low-Cost Drug Program is one such program, under which the participant receives drug benefits, but no other health benefits. Despite the availability of these programs, many consumers have no prescription drug insurance and do not qualify for any of the federal or state public programs that provide prescription drug benefits; they pay cash for their medications, or they do without. Although the Department of Human Services is in the process of determining a more accurate figure for who is not covered by any form of prescription drug program, there are estimates that as many as 20-25% of all Mainers fall into this category. Many of these consumers are elderly, on fixed incomes, or both, and, because no one negotiates price discounts for them, they usually pay the highest prices for prescription drugs. Prescription benefit managers negotiate with manufacturers for better prices for their insureds; the federal government obtains lower prices for huge purchasers such as the Department of Defense and the Veterans Administration; the federal government also mandates manufacturers' rebates for the Medicaid program through a statutory formula; the federal Office of Drug Pricing negotiates reduced prices for certain federal health care grant recipients. Some studies indicate that as the larger purchasers negotiate lower and lower prices, the costs of providing those lower prices are shifted to the cash-paying consumers, who usually end up paying the highest prices of all.

Perhaps the hardest hit are the elderly. Per capita, persons over 62 use more prescription drugs than any other segment of the population. They rely on medication to keep them out of hospitals and nursing homes, help them maintain their health and continue to be participating, productive members of the community. Many people do not have prescription drug benefits once

they retire, ironically the time in their lives when they could benefit most from the coverage. Although it is at the top of the list for Medicare reform, there is currently no prescription drug benefit for outpatients under Medicare. Medicare recipients who want prescription drug coverage have the option of purchasing on the private market different "Medi-gap" policies which may be cost prohibitive. It has been reported that, for some, although there is currently limited information about the number of such people in Maine, the cost of their prescription medications is so high that they must choose between paying their rent and filling their prescription. According to testimony presented at a joint public hearing of the Joint Standing Committees on Health and Human Services and Taxation on March 3, 1999, some elderly couples often have to choose whose prescription will be filled, because their limited income will not pay for all the medications they both need.

Some uninsureds have taken the step of traveling to where lower prescription drug prices are paid by the uninsured consumer. On more than one occasion, senior citizens in Maine have boarded buses for Quebec, where prices for prescription drugs that are on the Quebec formulary are as low as two-thirds the cost in the United States. One such trip was featured on *60 Minutes* in October 1999.

Individual research-based pharmaceutical manufacturers have developed prescription drug patient assistance programs. Each manufacturer designs and administers its own program. Through these programs manufacturers provide prescription medicines free of charge to physicians whose patients might not otherwise have access to necessary medicines. The duration of benefits varies by drug and manufacturer. P*h*RMA publishes a directory of these programs, and includes instructions on how to access the benefits. In 1998, P*h*RMA member company programs provided 2.8 million prescriptions for 1.5 million patients in the United States. The wholesale value of those drugs totaled $500 million. A more coordinated approach to these programs, recognizing anti-trust restrictions, could greatly benefit consumers; a single website on the Internet maintained by an independent entity may be extremely useful.

Maine law authorizes the voluntary establishment of private purchasing alliances. An

alliance is a nonprofit corporation licensed under the Insurance Code to provide health insurance to its members through multiple unaffiliated carriers. Alliances are authorized to set their own standards for membership in the alliance. These entities are designed to provide additional options for the purchase of insurance by small employers. Although the law became effective in July 1996 and the rules governing alliances were finally adopted in March 1997, there are no licensed purchasing alliances in the State. Employers and others may want to explore the establishment of private purchasing alliances to provide prescription drug coverage for their employees.

C. Maine prescription drug programs

Maine has established a number of programs under which participants receive prescription medication for no charge, for a co-pay or at a reduced price.

1. Medicaid. (22 MRSA §3174-G, subsection 1) In Maine, the Medicaid program is the largest payor for prescription medication, as well as for hospitalization and care by physicians and other providers. To qualify for Medicaid, a person must meet income criteria and be a member of a category covered by Medicaid, referred to as being "categorically eligible." In Maine Medicaid categories include:

a. Children up to age 12 months and pregnant women - both at family income levels up to 185% of the federal poverty level (fpl) ;

b. The elderly and the disabled - both at family incomes up to 100% fpl;

c. Children ages one through 18 - at family incomes up to 150% fpl; and

d. Families qualified to receive benefits under the Temporary Assistance to Needy Families (TANF) program under 22 MRSA chapter 1053-B.

The income limits have some flexibility for people who have high medical expenses, known as "spend down" eligibility. There are no co-pays for children. Adults may have a variable co-pay of up to $3 on some services. Co-pays are very limited by the federal

government.

2. Cub Care. (22 MRSA §3174-T) The Cub Care program provides health coverage for children ages one year through 19, at family incomes up to 200% of the federal poverty level. The income limit was increased from 185% on October 1, 1999 under the Commissioner's powers to increase or decrease the income limit to maximize coverage within the funding limits of the program under 22 MRSA §3174-T, subsection 2, paragraph A. It is anticipated that the increased coverage will be provided within the original Cub Care state and federal budget amounts during state fiscal year 1999-2000.

Beginning July 1, 2000 the income limit is raised to 200% of the federal poverty level (fpl) by statute, PL 1999, Chapter 401, Part QQ. Additional funding of $466,796 is provided from the Fund for a Healthy Maine (the national tobacco settlement money) for the cost of benefits. Also allocated from the Fund for a Healthy Maine during state fiscal year 2000-2001 is $29,587 for a staff person in the Department of Human Services (DHS) for Cub Care administration. Matching federal funds were allocated for both accounts.

Children age birth through age 12 months are covered under the Medicaid program, because persons eligible for Medicaid are required by federal law to be covered under that program. This creates a bit of a gap between the pregnant women and children to age 12 months, with incomes to 185% fpl, who are on Medicaid and the Cub Care children at 200% fpl. DHS is considering the challenge presented by this disparity.

The Cub Care program provides full health care benefits, including prescription medicines and supplies, exactly the same as the Medicaid program. There are no co-pays.

Families are required to pay contributions for coverage (premiums), depending on family income, calculated at 5% of benefit cost for families at 150-160% fpl, 10% of benefit cost for families at 160-170% fpl, and 15% of benefit cost for families at 170-185% fpl. There is a maximum (the base times 2) in each category of income. The benefit cost is an average for the

program, currently around $1200 per year per child. There is no statutory premium figure for children 185 to 200% fpl; DHS will presumably charge them the same as children with family incomes 170-185% fpl.

3. Elderly Low-Cost Drug Program. (22 MRSA 254, as amended by LD 617, PL 1999, chapter 401, Part KKK, as further amended by LD 2255, PL 1999, chapter 531, Part F)

a. The basic component. The basic component of the Elderly Low-Cost Drug Program (ELCDP) provides assistance with payment for prescription medicines for adults ages 62 and over and disabled adults for certain specified chronic medical conditions. The conditions covered include cardiac 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 amytrophic lateral sclerosis (Lou Gehrig's disease).

Beginning August 1, 1999, the existing ELCDP was revamped to increase the income level and designate it as the basic component of the ELCDP. The income level for the ELCDP increased from roughly 131% of the federal poverty level to 185%. Before August 1, 1999, the income level was determined by reference to the Maine Residents Property Tax Program (the "circuit breaker" program) and was not expressed as a percentage of the federal poverty level. Persons who pay more than 40% of their income for unreimbursed prescription drugs are eligible for the basic component up to an additional 25% of the applicable income levels. The co-pay is $2 or 20%, whichever is greater.

b. The supplemental component. The "supplemental component of the program" came into effect August 1, 1999. The supplemental component of the program covers all prescription drugs and medications provided under the Medicaid program with certain exceptions. Under the supplemental component of the program participating manufacturers will discount their drug prices by the same amount as the Medicaid discount.

DHS will pay $2 toward the cost of the prescription. The consumer will pay the remainder. The effect of the DHS $2 co-pay and the Medicaid level discount will be a discount to the consumer that is estimated to be about 20% off current prices paid by those without drug coverage.

No state funds were allocated or appropriated for the supplemental component of the program. It is intended to be self-sufficient, operating on the discounts and $2 DHS co-pay.

4. Maine Resident Low-Cost Prescription Drug Program. (22 MRSA §254-B, from LD 2082, Public Law 1999, chapter 431) Beginning February 1, 2000, or as soon thereafter as possible, a new program is scheduled to take effect: the Maine Resident Low-Cost Prescription Drug Program, MRLCPDP. Under this program manufacturers who choose to participate voluntarily pay rebates to DHS. DHS plans to set the voluntary rebates approximately the same amount as the Medicaid rebates (around 18-20% at present). According to DHS, a manufacturer who chooses to participate must participate for all drugs sold in the state.

When filling a prescription, the consumer picks whichever participating pharmacy he or she wishes and may perhaps have a choice of manufacturer. The pharmacist discounts the prescription from the pharmacy's normal price by the discount amount established by DHS (roughly the rebate amount). Except for applying the mandatory discount to drugs provided by a participating manufacturer, the pharmacy is free to set its own prices, so the consumer's price for a drug produced by a participating manufacturer may vary from pharmacy to pharmacy.

If the drug purchased is one for which a discount has been applied, the pharmacy notifies DHS and DHS pays the discount amount to the pharmacy weekly or biweekly. To qualify for MRLCPDP the consumer must be a Maine resident and have no 3rd party prescription drug coverage. There is no enrollment procedure or identification card. Eligibility is established by the pharmacist when the consumer fills the prescription.

DHS is preparing rules that should address many of the concerns raised during the

hearings before passage of LD 2082 and reiterated to the Commission. Those concerns include:

- The method by which DHS will calculate the discount per drug without revealing the amount of the Medicaid rebate paid for that drug;
- The way or ways by which pharmacies will be expected to determine whether an individual is a Maine resident and has no prescription drug coverage;
- How Maine residents will know which companies are participating in the program, and which drugs are produced by those companies;
- How Maine residents will know that the discount is paid by the manufacturer, and does not come from the State; and
- How DHS will implement the statutory requirement that the rules "promote the use of efficacious and lower-cost drugs."

MRLCPDP is self-funded by the voluntary rebates paid by participating manufacturers. There is no state appropriation to support this program. There are allocations of $2,500,000 in state fiscal year 1999-2000 and $10,000,000 in 2000-2001 from the rebate amounts paid in to DHS by the participating manufacturers.

The MRLCPDP will take effect only after DHS completes the rule-making process, which includes a public hearing on the proposed rules. Once the rules are provisionally adopted, they must be submitted to the Legislature for review and approval as "major substantive" rules.

5. Medicaid waiver drug program. (22 MRSA §3174-G, subsection 1-A, from LD 617, Public Law 1999, chapter 401, Part KKK, as amended by LD 2255, Public Law 1999, chapter 531, Part F) The statute directs DHS to apply for a Medicaid waiver to provide Medicaid prescription drug benefits as follows.

- Qualified persons ages 62 and over and disabled persons ages 19 and over are eligible for benefits. The family income limitation for both sets of persons is 185% fpl. Coverage under the Medicaid waiver drug program is contingent upon sufficient funds being appropriated and allocated to cover costs. If funding is insufficient, the income limit is to be decreased.

- The full range of drugs provided in the Medicaid program must be provided.
- There is no asset limitation.
- Co-payments are comparable to Medicaid co-payments.
- Coverage is required to begin July 1, 2000 or as soon thereafter as possible.

Funding is governed by 22 MRSA §3174-G, subsection 1-B and is to be provided by a combination of funds:

a. Funding appropriated to the Elderly Low-Cost Drug Program and any rebates paid under that program,

b. Funding of at least $5,000,000 in state fiscal year 2000-2001 from the Fund for a Healthy Maine, and

c. Allocated federal matching funds for state fiscal year 2000-2001 of $23,804,694.

Establishment of this Medicaid waiver drug program is contingent on approval of the waiver by the federal Health Care Financing Administration (HCFA).

The federal poverty levels for 1999 are:

	100%	150%	185%	200%
Family of one	$8240	$12,360	$15,244	$16,480
Family of two	$11,060	$16,590	$20,461	$22,120

D. Other prescription drug programs and proposals

1. Federal Office of Drug Pricing. The Office of Drug Pricing (ODP), part of the Bureau of Primary Health Care within the U.S. Department of Health and Human Services, is responsible for the implementation and management of Section 340B of the Public Health Service Act (enacted as part of the Veterans Health Care Act of 1992, PL 102-585). Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a

pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula. Although the price calculation is the same as the Medicaid rebate calculation, the purchasers under the 340B program pay the reduced cost upfront, rather than first paying full price and receiving a rebate later. The costs of drugs under the 340B program are generally, but not always, slightly higher than the Federal Supply Schedule.

An entity is eligible to take advantage of the 340B program prices if it falls within the program's definition of "covered entity." "Covered entities" are defined in the statute as follows.

- Federally-qualified health centers
- Entities receiving grants for health services for residents of public housing
- Qualified family planning projects
- HIV early intervention programs
- State-operated AIDS drug purchasing assistance programs
- Qualified black lung clinics
- Qualified comprehensive hemophilia diagnostic treatment centers
- Qualified Native Hawaiian Health Centers
- Qualified urban Indian organizations receiving funds under the Indian Health Care Improvement Act
- Qualified HIV health care services programs
- Entities receiving funds for treatment of sexually transmitted diseases or tuberculosis
- Qualified "subsection (d) hospitals"

Certain restrictions apply to the covered entities and their practices in order to maintain eligibility under the ODP program. The "Entity Guidelines" published in the Federal Register prohibit covered entities from reselling or otherwise transferring outpatient drugs purchased at the statutory discount to an individual who is not a patient of the covered entity. The ODP definition of a patient (see Federal Register Notice, "Patient and Entity Eligibility", October 24, 1996, p.55157, Item (C)) states: "An individual is a "patient" of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if: (1) the

covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care: and (2) the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains for the covered entity; and (3) the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement. An individual will not be considered a "patient" of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting. An individual registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHS Act will be considered a "patient" of the covered entity for purposes of this definition if so registered as eligible for the State program."

Entities in Maine listed in the ODP's database as participating the ODP programs are listed in Appendix E.

2. Canadian pricing Several studies have pointed out that prescription drug prices in Canada, as well as in other countries, are significantly lower than U.S. drug prices for the same medication[14]. The Canadian health department -- Health Canada -- regulates the price of patented drugs. Once a new prescription drug is approved for market by the Therapeutics Products Program of the Health Protection Branch of Health Canada, the maximum price the manufacturer can charge is established by the Patented Medicine Prices Review Board[15]. The mandate of the PMPRB is to ensure that the prices of patented medicines are not excessive. If the PMPRB determines that a manufacturer has charged excessive prices, it can recover double the excess revenues from the manufacturer. The PMPRB follows fairly extensive guidelines in establishing

[14] Congressional Research Service, Prescription Drug Price Comparisons: The United States, Canada and Mexico, David Cantor, January 23, 1998.

[15] Patented Medicine Prices Review Board, Health Canada, Compendium of Guidelines, Polices and Procedures,

prices and in determining whether excessive prices have been charged. In general, prices paid to the manufacturer are tied to the prices of other drugs in the same therapeutic class and the range of prices paid in seven other countries: France, Germany, Italy, Sweden, Switzerland, the United States and the United Kingdom. Price increases are tied to the Consumer Price Index.

After the PMPRB establishes the maximum price, each Province negotiates with the manufacturer for the price it will pay for the drug. As provincial plans cover about 44% of all prescription drug sales in Canada, each Province carries significant weight in the negotiations. Private insurers can also negotiate with the manufacturers for the best price under their plans, but in practice that price is the same as the price established for the provincial plans.

3. Other states' approaches. The Commission looked at how other states have approached the increasing lack of affordability of prescription drugs. Nevada has enacted a program to pay up to $480 of prescription drug insurance premiums for seniors without such coverage. New Hampshire has established a plan for seniors which is administered by a private entity and under which the private entity negotiates lower prices with manufacturers. Missouri established a state annual income tax credit of up to $750 for pharmaceutical costs incurred by qualified seniors and disabled veterans. California recently passed legislation directing pharmacies that participate in the California Medicaid program to also offer a discount to all Medicare beneficiaries[16].

www.pmprb-cepmb.gc.ca/comp-in-e html.

[16] National Conference of State Legislatures, "Making Medicines Affordable," Richard Cauchi, State Legislatures, December 1999, pp. 10-11.

III Findings and Recommendations

A. Findings. The Commission makes the following findings.

1. Prescription medications are essential to the life and health of Maine residents, while remaining unaffordable to some, particularly the elderly.

2. About 25% of Maine residents are on their own when purchasing prescription medicines because they do not have private medication insurance, do not qualify for state or federal assistance programs, cannot afford to purchase drug coverage insurance, or, lastly, although they can afford them, choose not to purchase a drug insurance program.

3. Maine residents who have no prescription drug coverage pay the full retail price for prescription drugs. Those who are covered by a prescription drug program benefit from the volume purchases of prescription medications made by their health insurance provider, the state Medicaid Program, the federal Office of Drug Pricing, private Pharmacy Benefit Managers or other private health care providers, and usually pay a co-pay on a negotiated discounted price.

4. Although large volume purchasers can often negotiate lower prescription drug costs, and competition at the retail level may result in savings to the consumer, there are many other factors which also affect the cost of prescription drugs.

5. The State has considerable clout in negotiating volume discounts, as indicated by the establishment both components of the ELCDP, the Maine Medicaid Program and General Assistance. Without detailed investigation, the implementation of a separate distribution system appears very costly,

which may negate any savings that the State could achieve through bulk purchasing.

6. The 119th Maine Legislature approved the Maine Residents Low-Cost Drug Program, which is scheduled to begin in 2000, and significantly expanded the Elderly Low-Cost Drug Program.

7. Maine prescribers, pharmacists and other health care professionals want to help their patients acquire effective prescription medications at reasonable prices.

8. The affordability of prescription drugs is a national issue, not unique to Maine.

B. Recommendations. The following are unanimous recommendations of the Commission.

1. The Commission recommends that the State should not at this time pursue bulk purchasing of prescription drugs as a separate program.

2. The Commission recommends that the State expand educational outreach to inform Maine citizens about the many State, Federal and private programs available to reduce prescription costs.

3. The Commission recommends that the State investigate the possibility of joining with other states, especially in local or regional affiliations, to lower prescription drug costs to consumers.

4. Recognizing that the Legislature and the Department of Human Services anticipate that the Maine Residents Low-Cost Drug Program will reduce

prescription drug costs to consumers, the Commission recommends that the State move forward as rapidly as possible with the rule-making and legislative process to implement the program.

5. The Commission recommends that the availability of access to reduced-cost prescription drugs through the federal Office of Drug Pricing be explored more thoroughly to determine whether prescription drugs at a lower price can be made more available to programs providing services to Maine residents.

6. The Commission recommends that the State encourage a public-private partnership to generate, maintain and distribute a simple and coordinated therapeutic and pricing guideline for physicians and other prescribers.

7. The Commission recommends that the State encourage public-private partnerships for expanded purchasing volume, thereby increasing ability to purchase prescription drugs at lower prices.

8. The Commission recommends that the Department of Human Services continue to pursue the Medicaid waiver with the Health Care Financing Administration.

APPENDIX A

ENABLING LEGISLATION

APPROVED
JUN 17 '99
BY GOVERNOR

CHAPTER
75
RESOLVES

STATE OF MAINE

IN THE YEAR OF OUR LORD
NINETEEN HUNDRED AND NINETY-NINE

H.P. 144 - L.D. 206

Resolve, to Establish the Commission to Study Bulk Purchasing of Prescription Drugs and Medical Supplies

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

Whereas, a comprehensive study of bulk purchasing of prescription drugs and medical supplies is needed to determine whether bulk purchasing could be used to provide Maine residents access to affordable prescription drugs and medical supplies, such a study to be undertaken during the summer and fall of 1999; 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

Sec. 1. Commission established. Resolved: That there is established the Commission to Study Bulk Purchasing of Prescription Drugs and Medical Supplies, referred to in this resolve as the "commission"; and be it further

Sec. 2. Membership. Resolved: That the commission consists of 12 members appointed as follows:

1. The President of the Senate shall appoint 5 members as follows:

A. Two Senators, one from each major political party. The first-named Senator is the Senate chair;

B. One person from a professional organization representing pharmaceutical manufacturers;

C. One person from a statewide organization representing health care carriers regulated under the Maine Revised Statutes, Titles 24 and 24-A; and

D. One person from a statewide organization representing hospitals;

2. The Speaker of the House of Representatives shall appoint 5 members as follows:

A. Four Representatives, 2 from each major political party. The first-named Representative is the House chair; and

B. One person from a statewide organization representing pharmacies; and

3. The Governor shall appoint 2 members as follows:

A. The Director of the Bureau of Medical Services within the Department of Human Services or the director's designee; and

B. One person from a statewide organization representing pharmaceutical wholesalers; and be it further

Sec. 3. Appointments; meetings. Resolved: That all appointments must be made no later than 30 days following the effective date of this resolve. The appointing authorities shall notify the Executive Director of the Legislative Council upon making their appointments. When the appointment of all members is complete, the chairs shall call and convene the first meeting of the commission no later than July 30, 1999; and be it further

Sec. 4. Duties. Resolved: That the commission shall study bulk purchasing of prescription drugs and medical supplies. The commission shall study the need for a bulk purchasing mechanism and the financial benefits and potential savings to private citizens, insurance carriers, self-insured employee health benefit plans and publicly funded health coverage. The commission shall evaluate the potential impact of bulk purchasing on the State's economy and on pharmacies, hospitals and other health care facilities within the State. In its report, the commission shall propose a plan for bulk purchasing that

represents the best judgment of a majority of the members of the commission for a bulk purchasing mechanism for the State.

In examining the issue of bulk purchasing of prescription drugs and medical supplies, the commission may examine bulk purchasing mechanisms in use in other states and countries and shall consult with interested parties representing a broad range of views.

The commission is authorized to meet as necessary to complete its work, up to a maximum of 4 meetings of the commission; and be it further

Sec. 5. Staff assistance. Resolved: That the commission may request staffing and clerical assistance from the Legislative Council; and be it further

Sec. 6. Compensation. Resolved: That the commission members who are Legislators are entitled to receive the legislative per diem, as defined in the Maine Revised Statutes, Title 3, section 2, for each day's attendance at meetings of the commission and are entitled to reimbursement for travel and other necessary expenses, upon application to the Legislative Council. The Executive Director of the Legislative Council shall administer the commission's budget; and be it further

Sec. 7. Report. Resolved: That the commission shall submit its report with any accompanying legislation to the Joint Standing Committee on Health and Human Services by December 1, 1999. If the commission requires a limited extension of time to conclude its work and make its report, it may apply to the Legislative Council, which may grant the extension. Upon submission of its required reports, the work of the commission terminates; and be it further

Sec. 8. Appropriation. Resolved: That the following funds are appropriated from the General Fund to carry out the purposes of this resolve.

1999-00

LEGISLATURE

Commission to Study Bulk Purchasing of Prescription Drugs and Medical Supplies

Personal Services	$1,320
All Other	1,700

Provides funds for the per

diem and expenses of legislative members for 4 meetings of the Commission to Study Bulk Purchasing of Prescription Drugs and Medical Supplies and to print the required report.

LEGISLATURE TOTAL	$3,020

Emergency clause. In view of the emergency cited in the preamble, this resolve takes effect when approved.

APPENDIX B

LIST OF COMMISSION MEMBERS

Commission to Study Bulk Purchasing of Prescription Drugs and Medical Supplies
Resolve 1999, Chapter 75

Appointments by the Governor

- Robert E. Carroll, Jr., R.Ph.
  Department of Professional and Financial Regulation

- William Griffin
  Bindley Western, Goold Division

Appointments by the President of the Senate

- Senator Peggy A Pendleton, R.N., Chair
  Senate District 31 (Cumberland County)

- Senator I. Joel Abromson
  Senate District 27 (Cumberland County)

- Bruce Daniels, R.Ph., MBA
  MaineGeneral Medical Center
  (representing a statewide organization representing hospitals)

- David L. Massanari, M.D.
  Harvard Pilgrim Health Care
  (representing a statewide organization representing health care carriers)

- Marjorie E. Powell, Esq.
  Pharmaceutical Research and Manufacturers of America (P*h*RMA)
  (representing a professional organization representing pharmaceutical manufacturers)

Appointments by the Speaker of the House of Representatives

- Representative Elaine Fuller, R.N., Chair
  House District 80 (Manchester)

- Representative Joseph Bruno, R.Ph.
  House District 38 (Raymond)

- Representative David G. Lemoine
  House District 20 (Old Orchard Beach)

- Representative Christine Savage
  House District 60 (Union)

- Reginald S. Gracie, Jr., R.Ph.
  Rite-Aid Corporation; Maine Pharmacy Association
  (representing a statewide organization representing pharmacies)

APPENDIX C

MAINE MEDICAID OUTPATIENT PRESCRIPTION DRUG SPENDING

Medicaid Outpatient Prescription Drug Spending

	SFY 97	SFY 98	Chg	SFY 99	Chg
Gross Expenditures	$98,964,628	$109,697,688	10.8%	$135,493,928	23.5%
Drug Rebates	-$17,206,484	-$20,206,046	17.4%	-$27,957,863	38.4%
Net Expenditures	$81,758,144	$89,491,642	9.5%	$107,536,065	20.2%
Drug Rebate Percentage	17.4%	18.4%		20.6%	
Number of Drug Recipients	141,220	144,205	2.1%	148,654	3.1%
Gross Exp Per Recipient	$700.78	$760.71	8.6%	$911.47	19.8%
Net Exp Per Recipient	$578.94	$620.59	7.2%	$723.40	16.6%
Number of Prescriptions	2,793,666	2,870,422	2.7%	3,114,155	8.5%
Prescriptions per Recipient	19.8	19.9	0.6%	20.9	5.2%
Expenditures per Prescription	$35.42	$38.22	7.9%	$43.51	13.8%

November 29, 1999, Christopher Nolan, Bureau of Medical Services, Department of Human Services

APPENDIX D

MAINE RESIDENT LOW-COST PRESCRIPTION DRUG PROGRAM

APPROVED	CHAPTER
JUN 07 '99	43 1
STATE OF MAINE BY GOVERNOR	PUBLIC LAW

IN THE YEAR OF OUR LORD
NINETEEN HUNDRED AND NINETY-NINE

S.P. 732 - L.D. 2082

An Act to Reduce the Cost of Prescription Drugs to Qualifying Residents of the State

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

Sec. 1. 22 MRSA §254-B is enacted to read:

§254-B. Maine resident low-cost prescription drug program

The department shall conduct a program, referred to in this section as the "Maine resident low-cost prescription drug program" or the "program," to provide low-cost prescription drugs to qualifying residents of this State.

1. Agreement. A drug manufacturer that sells prescription drugs in this State may voluntarily elect to enter into a rebate agreement with the department. The agreement must be modeled after Section 1927 of the United States Social Security Act and must include the requirement that the manufacturer make rebate payments to the State each calendar quarter or according to a schedule established by the department.

2. Rebate amount. The rebate amount required from a manufacturer to the State is equivalent to the rebate amount calculated under the Medicaid Rebate Program pursuant to 42 United States Code, Section 1396r-8.

3. Discount to qualifying residents. Any participating retail pharmacy that sells drugs covered by an agreement pursuant to subsection 1 shall discount the retail price of those drugs sold to qualifying residents. The department shall adopt rules to establish discounts for covered drugs and rules that promote

the use of efficacious and lower-cost drugs. The amount of the discount for covered drugs must be determined by considering an average of all rebates provided pursuant to subsection 2, weighted by sales of drugs subject to these rebates over the most recent 12-month period for which the information is available. The total aggregate discount amount for all covered drugs must be equivalent to the total aggregate rebate amount for all covered drugs sold, less the administrative costs of the program pursuant to subsection 6.

4. Operation of program. Participating retail pharmacies shall submit claims to the department to verify the amount of discount due the resident. The department may not impose charges on retail pharmacies that submit claims or receive payments under the program. The retail pharmacies shall charge residents the current retail price charged by each retail pharmacy for that prescription drug to persons purchasing that drug who are not covered by insurance or 3rd-party payor plans, less the discount amount, pursuant to subsection 3.

The amount of the discount must be indicated on the resident's receipt. On a weekly or biweekly basis, the retail pharmacy must be reimbursed by the department for drug discounts provided to residents. The department shall collect the necessary utilization data from the retail pharmacies submitting claims in order to comply with 42 United States Code, Section 1396r-8. The department shall protect the confidentiality of all information subject to confidentiality protection under state and federal law, rule or regulation.

5. Discrepancies in rebate amounts. Discrepancies in rebate amounts must be resolved using the process established in this subsection.

A. If there is a discrepancy in the manufacturer's favor between the amount claimed by a pharmacy and the amount rebated by the manufacturer, the department, at the department's expense, may hire a mutually agreed-upon independent auditor. Following the audit, if a discrepancy still exists, the manufacturer shall justify the reason for the discrepancy or make payment to the department for any additional amount due.

B. If there is a discrepancy against the interest of the manufacturer in the information provided by the department to the manufacturer regarding the manufacturer's rebate, the manufacturer, at the manufacturer's expense, may hire a mutually agreed-upon independent auditor to verify the accuracy of the data supplied to the department. Following the audit, if a discrepancy still exists, the department

shall justify the reason for the discrepancy or refund to the manufacturer any excess payment made by the manufacturer.

C. Following the procedures established in paragraph A or B, either the department or the manufacturer may request a hearing before the Administrative Hearings Unit. Supporting documentation must accompany the request for a hearing.

6. Administrative and associated computer costs for program. Administrative and computer costs for the program must be funded solely from the rebates received from the pharmaceutical manufacturers. The department may not spend more for the administrative costs and associated computer costs of this program than it spends on the elderly low-cost drug program.

7. Obligation of retail pharmacies in State. The obligation of retail pharmacies to discount drugs to qualifying residents begins 3 months after the drug manufacturer begins to pay the rebate to the department.

8. Dedicated fund. There is established the Prescription Drug Dedicated Fund, referred to in this section as the "fund," to receive revenue from manufacturers who pay rebates as provided in subsection 1, to reimburse retail pharmacies for discounts provided to residents pursuant to subsections 3 and 4, to reimburse the department for administrative and associated computer costs and to pay other reasonable program costs. The fund is a nonlapsing dedicated fund. Interest on fund balances accrues to the fund. Surplus funds in the fund must be used to increase the amount of discounts given to residents under the program.

9. Annual summary report. The department shall report the status of the program to the Legislature on an annual basis. The report must include information on changes in 3rd-party prescription drug coverage and the financial status of the program.

10. Qualifying resident. Qualifying resident, also referred to in this section as a "resident," means a legal resident of this State who does not have 3rd-party prescription drug coverage.

11. Participating retail pharmacy. Participating retail pharmacy, also referred to in this section as a "retail pharmacy," means a retail pharmacy located in this State, or another business licensed to dispense prescription drugs in this State, that voluntarily elects to participate in the program and that provides discounts to residents as provided in subsection 3.

12. Rulemaking. The department shall adopt rules to implement the provisions of this section. Rules adopted pursuant to this subsection are major substantive rules as defined in Title 5, chapter 375, subchapter II-A.

Sec. 2. Authorization. The Department of Human Services is authorized to receive rebates from drug manufacturers under the Maine resident low-cost prescription drug program, Maine Revised Statutes, Title 22, section 254-B, beginning February 1, 2000 or as soon thereafter as rules are adopted to implement the program.

Sec. 3. Allocation. The following funds are allocated from Other Special Revenue funds to carry out the purposes of this Act.

	1999-00	**2000-01**
HUMAN SERVICES, DEPARTMENT OF		
Prescription Drug Dedicated Fund		
All Other	$2,500,000	$10,000,000

Provides funds to establish a program to provide low-cost prescription drugs to Maine residents who are not covered by 3rd-party prescription drug plans.

APPENDIX E

OFFICE OF DRUG PRICING: MAINE PARTICIPANTS

Federal Office of Drug Pricing

Entities in Maine listed in the Office of Drug Pricing's database as participating the ODP programs include:

- Bucksport Regional Health Center
- Regional Medical Center at Lubec
- Health Care for Portland's Homeless Project
- Tri-County Health Services, Farmington Family Planning Clinic
- Rumford Family Planning Clinic
- Machias Family Planning Clinic
- Health 1st Family Planning Clinic (Fort Kent)
- Midcoast Clinic (Belfast)
- Skowhegan Family Planning Clinic, Michelle Boulette Center
- Planned Parenthood of Northern New England (Portland)
- Planned Parenthood of Northern New England (Biddeford))
- Planned Parenthood of Northern New England (Brunswick)
- Planned Parenthood of Northern New England (Sanford)
- Portland Division of Public Health
- Maine Department of Human Services, Bureau of Health, HIV/STD Program
- Penquis health Services (Bangor)
- Dexter Family Planning Clinic
- Guilford Family Planning Clinic
- Lincoln Family Planning Clinic
- City of Portland, Public Health Division
- Millinocket Family Planning Clinic
- Milo Family Planning Clinic
- Sacopee Valley Health Center, Family Planning Clinic
- Auburn Family Planning Clinic
- Norway Family Planning Clinic

- Calais Family Planning Clinic
- Arthur Jewell Community Health Center, Reynolds Road Brooks)
- Health 1st, Houlton Family Planning Clinic
- Health 1st Family Planning (Madawaska)
- Midcoast Family Planning Clinic (Damariscotta)
- Midcoast Family Planning Clinic (Rockland)
- Health 1st, Patten Family Planning
- KVCAP Family Planning (Jackman)
- Pittsfield Family Planning Clinic
- KVCAP family Planning (Hinckley)
- Health 1st Family Planning Program (Presque Isle)
- Kennebec Family Planning (Augusta)
- Downeast Health Services, Inc., Family Planning Clinic (Ellsworth)
- Kennebec Valley Community Action (Waterville)
- Penquis Community Action Program (Bangor)
- Western Maine Community Action (East Wilton)
- Aroostook County Action Program (Presque Isle)
- Penobscot Bay Medical Center
- Family Planning Association of Maine, Inc. (Augusta)
- Maine Department of Human Services

APPENDIX F

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