


Getting There From Here


Maine's Legal Odyssey Toward Affordable Rx Drugs





*Maine thought it had found a way to make
prescription drugs more affordable for its senior citizens.
The pharmaceuticals industry had other ideas.*

By Bill Whitmore



AS WE SAY IN MAINE (OR AT LEAST PEOPLE FROM AWAY THINK WE DO): “YOU CAN’T GET THERE FROM HERE.” In the case that follows, the “there” Maine is trying to get to is affordable prescription drugs; the “here” Maine is traveling from is the current lack of access to affordable prescription drugs for all the elderly and the disadvantaged in Maine. While the national debate continues over what, if anything, to do about the ever increasing cost of prescription drugs, Maine continues to look for new ways to assist its citizens.

A combination of factors seems to make the cost of prescription drugs even more noticeable in Maine than in other states: the relatively low per capita income in Maine (ranked 35th in 2002 per capita personal income according to the U.S. Department of Commerce) coupled with the proximity to Canada and its lower-cost drugs.

Maine has a long history of attempting to alleviate the burden of costly prescription drugs for its senior citizens and low-income residents. Back in 1975, before the cost of prescription drugs was on anyone’s radar screen or political agenda, Maine launched the elderly low-cost drug program, aimed at helping senior citizens purchase prescription drugs.

Over the years this program has been amended frequently to update eligibility provisions and benefits. The current program covers approximately 36,000 elderly and disabled Maine residents with income levels below 185 percent of the federal poverty level (\$16,613 and \$22,422 per year for individuals and couples respectively). Also eligible are those with income levels 25 percent above these limits who spend 40 percent or more of their household income on prescription drugs.

The benefits of the program cover 80 percent of the cost of

any generic drug. (Enrollees pay the maximum of 20 percent or \$2.) Additionally, the program includes coverage for 80 percent of the cost of any brand-name or generic drug used in the treatment of any of the following illnesses: 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, or Lou Gehrig’s disease. For those who spend more than \$1,000 out of pocket on prescription drugs in a year, there’s a “catastrophic spending limit” that kicks in and covers 80 percent of all additional prescriptions for that year.

The program is funded “through appropriations from [Maine’s] general fund, dedicated revenue, federal or other grants, and other established and committed funding sources.” Additionally, the commissioner of the Department of Human Services “may accept, for the purposes of carrying out this program, federal funds appropriated under any federal laws relating to the furnishing, of low-cost drugs to disadvantaged, elderly, and disabled individuals . . . and may accept from any other agency of government, individual, group, or corporation

such funds as may be available.”

According to a recent research publication by the Rutgers Center for State Health Policy, there were 40,277 Maine citizens enrolled in the elderly low-cost drug program in the year 2000. This amounts to just under 50 percent of those income-eligible, non-Medicaid Medicare beneficiaries. Additionally, the research paper indicated that 24,618 enrollees actually filled a prescription with a total per enrollee expenditure of \$141.

The elderly low-cost drug program existed as a stand-alone law until June 2001, when it became Part II of the Healthy Maine Prescriptions program.

Healthy Maine Prescriptions

The Healthy Maine Prescriptions program came out of the 120th Maine legislature, was approved through a Medicaid waiver by Donna Shalala, then secretary of the U.S. Department of Health and Human Services, and was signed into law by Maine Governor Angus King in May 2001. The Drugs for the Elderly and Disabled program (DEL) was rolled into the Healthy Maine Prescriptions program as Part I.

The newly created section of Healthy Maine Prescriptions, Part II, targets low-income Maine residents earning less than 300 percent of the federal poverty level. Eligibility is based on income and requires that enrollees not have drug coverage through Medicaid, also known as MaineCare. Private insurance prescription drug coverage doesn't preclude enrollment in Healthy Maine Prescriptions.

The program was set up to offer discounted prescription drugs by forcing drug manufacturers to provide prescription drugs at Medicaid prices to those enrolled in Healthy Maine Prescriptions. It was estimated that initially about 225,000 Maine residents would be eligible; at its high point in the fall of 2002 enrollment reached approximately 115,000 (about 36,000 in Part I and 79,000 in Part II). The expected amount of discount was in the range of 20 percent to 25 percent, possibly higher for some drugs. A relatively short list of higher priced drugs requires prior approval from an enrollee's physician. Additionally, drug manufacturers not willing to extend Medicaid pricing to Healthy Maine Prescription enrollees risk having their drugs placed on the Medicaid prior approval list.

While Maine lawmakers were attacking the cost of prescription drugs from multiple directions, the Pharmaceutical Research and Manufacturers of America (PhRMA) filed a lawsuit, *PhRMA v. Thompson* (D.C. Cir. No. 02-5110), challenging the Medicaid waiver that allowed the formation of Healthy Maine Prescriptions. PhRMA's challenge was based on both clinical and legal grounds.

Clinically, PhRMA claimed, Maine's Medicaid patients would be harmed if drugs manufactured by companies not willing to extend Medicaid discounts to Healthy Maine Prescriptions enrollees were placed on the physician prior approval list. PhRMA suggested that this would limit access to these drugs.

Legally, PhRMA objected to Healthy Maine Prescriptions



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because it extended Medicaid discounts to a population when neither Maine nor the federal government contributed financially to the program, which is a legal requirement.

Additionally, PhRMA argued that the remaining cost of prescription drugs (approximately 80 percent on average) would be borne by enrollees in Healthy Maine Prescriptions—Maine residents—and these costs would exceed Medicaid guidelines limiting Medicaid member cost sharing to small amounts.

In an attempt to counter a portion of PhRMA's legal argument, Maine included in the law that created Healthy Maine Prescriptions a provision for a 2 percent contribution from the state for every prescription filled under the program.

On Dec. 24, 2002, the U.S. Court of Appeals found in favor of PhRMA. It ruled that Maine's Healthy Maine Prescriptions program was impermissible because there was no guarantee of any state contribution (Maine's 2 percent contribution wasn't approved by the secretary of DHHS in the original waiver) and there was also no provision for any federal financial involvement.

The state 2 percent subsidy was not ruled as being insufficient, however. Rather, the concern was that the subsidy wasn't approved in the Medicaid waiver. Judge Harry T. Edwards wrote that the law didn't specify an amount a state must contribute but noted that "the secretary has never formally considered or endorsed Maine's revised program that includes the 2 percent contribution."

On Dec. 26, 2002, Maine lawmakers and administrators announced that the Healthy Maine Prescriptions program would be suspended. The intent, however, was to move forward with an attempt to have Health and Human Services Secretary Tommy Thompson amend the earlier waiver approval to allow the 2 percent state contribution. As of October 2003, enrollment in DEL was at a level of approximately 28,000 with all enrollment removed from Part II of Healthy Maine Prescriptions.

Unintended Consequence

The inclusion of the DEL program within Healthy Maine Prescriptions created an uncertain future for a program that has existed since the 1970s. Healthy Maine Prescriptions offered a stronger, more formal discount program in place of the various individual

agreements with drug manufacturers that were the basis for DEL through the years. In April 2003, many of these agreements with drug manufacturers expired and weren't immediately replaced with new agreements, forcing some elderly patients in the DEL program to pay full cost for their prescriptions.

While some manufacturers have renewed their agreements, many didn't initially show interest in renewing the discounts that supported the DEL program in the past. The Maine Department of Human Services, however, is committed to persuading those still without an agreement to enter once again into discount contracts.

Concurrent with the short life span of the Healthy Maine Prescriptions program has been the legally challenged Maine Rx program. While Healthy Maine Prescriptions has been primarily targeted at the elderly and the poor, the Maine Rx program was born to help the uninsured purchase prescription drugs, regardless of their income level. Studies indicate that a large number of the uninsured are employed (or self-employed) by companies not offering health insurance coverage. Many of these uninsured are well enough employed to disqualify them from low-income assistance programs.

In August 2000, Maine Rx, authored by then state Sen. Chellie Pingree (now head of the advocacy group Common Cause after an unsuccessful run for the U.S. Senate in 2002) became law. Maine Rx's primary purpose and method of accomplishing that purpose were, in essence, quite simple: reduce prescription drug costs for Maine residents by negotiating rebates with drug manufacturers. Those drug manufacturers not willing to agree to rebates would have sales of their drugs to Medicaid patients subject to prior authorization.

The notable aspects of the Maine Rx program aren't found in a description of its benefits but rather in its protracted legal dispute and the fervor with which PhRMA battled to prevent Maine Rx from ever seeing the light of day.

Under the original law, any Maine resident lacking prescription drug insurance coverage would be eligible for discounts of up to 60 percent off generic drugs, and 15 percent off brand-name drugs. The state would make pharmacies whole by reimbursing them with rebates collected from drug manufacturers. The state's original estimate was that 325,000 Maine residents would be eligible.

The initial implementation was delayed on both logistical and legal fronts. The logistical difficulties were in the Maine Department of Human Services' attempts to sign rebate agreements with the drug manufacturers. While some agreements were signed, they were mostly with smaller drug manufacturers. In December 2000, it was announced that Maine Rx would not commence on Jan. 1, 2001, as originally planned.

At the same time Maine DHS was attempting to sign rebate agreements with drug manufacturers, PhRMA, representing these same manufacturers, was filing suit in federal district court to block the implementation of Maine Rx. PhRMA's primary contention was that the imposition of prior authorization

would impose a significant burden for Medicaid patients without any purpose to support Medicaid. PhRMA also argued that the law was an illegal regulation of out-of-state commerce. The district court ruled in favor of PhRMA and issued a preliminary injunction in October 2000. This was the beginning of a long legal odyssey for Maine Rx.

Legal Limbo

The case was appealed to the 1st Circuit U.S. Court of Appeals. In May 2001, the ruling of the Court of Appeals overturned the federal district court's earlier injunction of Maine Rx. The appeals court's ruling was based on its interpretation that Maine Rx wasn't at odds with "Medicaid's structure and purpose." Later in May 2001, PhRMA asked for reconsideration of the Court of Appeals decision. In June 2001, the request for reconsideration was denied, thus leading to the July 2001 PhRMA appeal to the U.S. Supreme Court. A stay of the court order reverted to the federal district court ruling until the U.S. Supreme Court's involvement was complete, thus putting Maine Rx indefinitely on hold.

Over the next year and a half, Maine Rx remained in a legal limbo while numerous briefs were filed with the Supreme Court. In May 2002, the U.S. solicitor general recommended the court not hear the case, which would have allowed the program to move forward. Contrary to the U.S. solicitor gen-



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eral, the Bush administration sided with PhRMA in objecting to Maine Rx. Ultimately the case was heard by the Supreme Court on Jan. 22, 2003. On May 19, 2003, the Supreme Court issued a ruling upholding the decision of the Court of Appeals and allowing Maine Rx to move forward.

The Supreme Court agreed with the Court of Appeals in its finding that Maine Rx did support the purpose of Medicaid. It went on to describe three ways in which it did so.

First, Maine Rx would provide benefits to the “medically needy even if they don't qualify for AFDC and SSI benefits.”

Second, the court noted, it was possible that “by enabling some borderline aged and infirm persons better access to prescription drugs earlier, Medicaid expenses will be reduced.” According to the court, expenses would be reduced because if “this borderline group are not able to purchase necessary prescription medicine, their conditions may worsen, causing further financial hardship and thus making it more likely they will end up in the Medicaid program and require more expensive treatment.”

Third, the court stated, the prior authorization requirement would produce cost savings, just as it does in managed care organizations. Thus, “avoiding unnecessary costs in the administration of a state's Medicaid program obviously serves the interests of both the federal government and the states that pay the cost of providing prescription drugs to Medicaid patients.”

There are two particularly interesting and possibly ironic aspects of the court's opinion. First, the court stated that the Maine Rx program would provide “better access” to prescription drugs. Since Maine Rx's primary purpose is creating greater affordability of prescription drugs, it appears that the court has defined “better access” also to mean less expensive.

Second, the court's belief that “better access” to prescription drugs may ultimately increase Medicaid savings through earlier treatment is the same argument the prescription drug industry uses in claiming that new expensive drugs actually save health care dollars by treating patients in a less expensive manner and avoiding, in many cases, costly hospitalization.

Maine Rx began on January 1, 2004, with the expanded name of Maine Rx Plus. The primary difference between Maine Rx Plus and the original law is the inclusion of income eligibility limits. Under the new law, anyone earning up to 350 percent of the federal poverty level (\$31,400 for an individual, \$42,420 for a family of two, and \$64,400 for a family of four) will qualify.

Additionally, any family with prescription drug expenses exceeding 5 percent of income or total medical expenses exceeding 15 percent of income will qualify, regardless of income. The state now estimates that 275,000 Maine residents are eligible, including those previously eligible for the Healthy Maine Prescriptions program.

While it's difficult to disagree with the intent of Maine's programs to provide affordable prescription drugs to its elderly

and impoverished citizens, it doesn't preclude one from raising some relevant points.

First, the primary goal of both programs described in this article is to lower the cost of prescription drugs. As any actuary knows, however, the overall cost of any medical service is driven by two components: the unit cost of services, coupled with the utilization of those services. Is it possible that Maine might be just as well served by investments in social programs that target the health of its citizens? Could reducing the need for drugs while simultaneously reducing their cost be more helpful in the long run?

This isn't to suggest that the state of Maine is sitting idly by while its citizens become sick. Maine has state-wide programs that attempt to reduce the prevalence of asthma, smoking, obesity, and other health concerns. By subsidizing prescription drug costs, is Maine (in some cases inadvertently) encouraging unhealthy behavior instead of working to improve health and change lifestyles? Or possibly utilization is better addressed though expanding supply and not attempting to limit demand. (Isn't supply and demand the only college economics lesson most of us remember?) The supply could be expanded through an increase in generic drug offerings, but this is a federal issue, not a state one.

Maine legislators didn't hang their collective hats on the legal outcome of Maine Rx. During the first regular session of the 121st Maine legislature in 2003, myriad bills related to pharmacy issues were passed and subsequently signed into law by the governor. Among them were:

- Prescription drug manufacturers or labelers whose drugs are dispensed in Maine will have to report annually on their expenditures for marketing their drugs.
- Prescription drug purchases must disclose in receipt the full retail price, patient cost, and third-party payer cost.
- Pharmacists are required to dispense a therapeutically equivalent generic drug if the prescribing physician doesn't specify that a particular brand-name drug must be dispensed.
- Pharmacy benefits managers must disclose all contractual agreements with drug manufacturers and pass on all benefits resulting from these agreements.

The Maine Rx Plus program may have determined how to get “there” (total access to affordable prescription drugs) from “here” (limited access to affordable drugs). But another old political saying often heard in Maine is: “As Maine goes, so goes the nation.” While this may no longer be the case politically, it does appear to be true in efforts to offer affordable prescription drugs. Many states are following Maine's lead and models in their own attempts at addressing this political, legal, and morally challenging issue. ●

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