ounty forums address drug costs

By Beurmond Banville Of the NEWS Staff M.DAWASKA — Annette Gagnon rose from her seat, walked to the front table where legislators were sitting, slowly took six prescription medications out of her purse and placed them on the table.

On of the medications alone, she said, cost her \$100 for a month's supply at a Maine drugstore. When she can get it in Canada, the same prescription costs \$43 for a two-month supply.

costs \$43 for a two-monin suppy.

"I don't have a choice, I have to take all of these since I had my heart surgery," the 79-year-old told legislators here during an Emergency Forum on Prescription Drugs. "It doesn't leave much on my Social Security check."

Several other senior citizens in Madawaska also told lawmakers of the hardships the high price of prescription drugs places on them and their limited incomes.

Americans who have doctors licensed in Canada can get their prescriptions filled in Canada, where the American-produced drugs cost an average of 33 percent less. In Britain, the difference is even more extreme with American-made drugs costing 66

the United States, legislators said.

Dr. Andre Loiselle, a Madawaska physician licensed to practice in Maine and New Brunswick, said about 20 percent of his patients fill their prescriptions in Canada.

"It's too bad not all people realize they can do this," Loiselle said at the forum. "About 20 percent of my patients tell me they can't afford their prescriptions, and we try to find ways to help them."

The prescription drug forum held Saturday in Madawaska and a similar one in Presque Isle the same day were sponsored by the Maine State Employees Association. Both sessions were attended by a handhul of Democratic legislators pushing for support of LD 4030, An Act to Establish Fairer Prescription Drug Prices.

About 65 people from St. Francis to Van Buren attended the session in Madawaska. As many were at the Presque Isle hearing, Sen. Judy Paradis, D-Frenchville, said.

"We must bring down the high cost of drugs because some people have to make choices [between] buying their drugs, food or home fuel," said Dana Graham, vice president of the MSEA. "Some people, especially among the

elderly in Maine, are going without the drugs they need."

"Its outrageous," Senate President Mark Lawrence told the Madawaska audience. "People elsewhere in the world can buy prescription drugs for one-third to one-half the costs of the drugs in the United States, and they are manufactured here.

"The prices are so severe that even government programs are not enough for some of our people, especially the elderly," Lawrence said. "This legislation is an attempt to get to the root of the problem here in Maine."

Sen. Chellie Pingree, D-North Haven, and sponsor of the legislation, said the bill would help establish price controls, if pharmaceutical companies don't bring the price of prescription drugs down to the prices in Canada.

A hearing is scheduled on the bill

March 8. Legislators in Madawaska said they expect the pharmaceutical industry will lotby state legislators hard on the bill, for fear of losing exorbitant profits.

Speaker of the House Steven

Speaker of the House Steven Rowe told the Madawaska group, "Pharmaceutical industry profits — \$24 billion last year — are out

"No other business in the world

is as profitable," Rowe said.
"Even the way they are, they still spend 30 percent of every dollar people pay for prescriptions for advertising."

Other countries, people were told negotiate prices that can be charged for drugs with pharmaceutical companies.

Senior citizens, who are 12 percent of Maine's population, consums 33 percent of prescription drugs. On average, prescription users in the United States pay 30 percent more for drugs than people do in Canada and 60 percent more than people do in England, according to information passed out at the forum.

out at the forum.

The bill in Maine would not affect local pharmacies, legislators said. The prices would be lowered by the pharmaceutical comments to denostores.

lowered by the pharmaceutical companies to drugstores.
Rep. John L. Martin, D-Eagle Lake, and Rep. Douglas Ahearne, D-Madawaska, urged residents to call their federal legislators and Gov Angus King with their concerns about drug prices.

Cettis about the factor call us."

"You don't need to call us."

Martin said pointing at himself,

Ahearne and Paradis, because
they support this legislation.

they support this legislation.
"Some others don't support this kind of effort," Martin said.

DANGUR DAILI NEWS - IDURSDAI, DEDIL 19, 2000

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Price controls

he key question lawmakers needed to ask when they were told by the pharmaceutical industry that "price controls do not work" is, "Do not work for whom?" Because for all the bluster about state and federal bills that seek lower drug prices for the public, negotiated prices are commonplace in the industry.

A bill supported overwhelmingly by the Legislature would set Maine drug prices here according to the much lower prices in Quebec. They are lower in Quebec because Canada, like many industrialized nations, negotiates prices with the industry, just as health maintenance organizations do in the United States. The transaction gives manufacturers access to a market in exchange for lower prices to individuals in that market. Such exchanges are common in business, and are the basis for everything from group insurance rates to discount packages on tour buses.

The federal Department of Health and Human Services this week found that Medicare recipients who lack drug coverage — nearly half the total in rural areas — pay about 15 percent more for their drugs, when they can afford them, than those with coverage. With manufacturers' rebates to insurers, the gap grows to 40 percent or more. That is, some seniors have drug coverage because insurers representing them negotiated lower prices with drug manufacturers. The manufacturers regain some of their lost profit by charging higher prices to those without coverage.

Rep. Tom Allen of Maine's 1st District has been trying for a couple of years to secure similar negotiated prices for Medicare recipients without drug coverage, but he has been stopped in Congress thus far because of the price-controls argument. This has sufficiently frustrated statelevel politicians to submit the Quebec pricing system in the Legislature and send Gov. Angus King to meet with other New England governors to find a way to simply shop for pharmaceuticals in Canada.

Drug manufacturers do not oppose the reduced pricing system merely out of pique. They say higher costs for drugs allow for more research and better distribution of groundbreaking cures, thereby saving or improving lives. Another reason also is evident if you are a manufacturer and you find it necessary to spend 25 percent or 30 percent of your revenues on advertising: lower prices cut into profits record profits, it turns out, for the pharmaceutical industry these days. And while no one ought to trim profits simply because they have achieved records, there is the issue of Maine people who cannot afford to buy drugs, or cannot afford to buy both drugs and food, and so fall sicker or, for that matter, die.

The drug proposal from the Legislature is appropriate reaction to a system that enforces wide price disparities on essential products. It is not a system that can last for very long, given overall increases in costs to consumers, and Gov. King should make that point clear in his support of this plan.

The New York Times

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WEDNESDAY, APRIL 12, 2000

MAINE PASSES LAW TO SET DRUG PRICES

Groundbreaking Measure Uses
Canada's Rates as Yardstick

By CAREY GOLDBERG

In a slap to the pharmaceutical industry and a rebuke to Congress, the Maine Legislature on Tuesday became the first in the country to approve a bill that would clamp sweeping price controls on medications sold in the state.

The Act to Establish Fairer Prescription Drug Prices would immediately establish a pricing board to set suggested lower prices. If the prices did not fall, then as of Oct. 1, 2001, the board would mandate that all drugs sold in the state cost no more than they would in Canada.

The bill must still go to the govermor, Angus S. King Jr., an independent who has remained neutral on it, but it passed today by veto-proof margins in both chambers, 23 to 9 in the Senate and 102 to 47 in the House. is expected to face legal challenges, in particular on the grounds that it hinders interstate commerce, but the state attorney general has testified that he believes the bill can withstand them, in part because the commerce clause in the United States Constitution allows an exception for states protecting the basic health and safety of their citizens.

"This makes Maine the first state to say, 'Americans shouldn't be subsidizing low prices for prescription drugs around the world,' "Senator Chellie Pingree, the Senate's Democratic majority leader and the bill's primary sponsor, said. "The pharmaceutical industry worked extra hard against this bill, but they had no argument and this is a huge national

Continued on Page A21

Maine Legislature Approves Law to Control Drug Prices

Continued From Page Al

issue.

The rising cost of medications is particularly an issue in border states like Maine. There, residents can cross into Canada, which has national health insurance, and reap the benefits of the discount the Canadian government negotiates with drug companies, saving as much as 60 percent or 70 percent on some drugs.

The Vermont State Senate recently passed a similar bill with "fair pricing of prescription drugs" in its title, though it has yet to be voted on in the State House of Representatives. The New England states have also formed a coalition to try to present a united front on drug prices, whether through local price controls or the pooling of their residents to demand mass discounts. The legislative leaders in the coalition argue that virtually every other country negotiates a low price for their drugs with the industry, so Americans end up footing the bill for all the research that benefits everyone.

"Our goal," said Peter Shumlin, president pro tem of the Vermont Senate, "Is to have a number of states move forward simultaneously to send a message to the pharmaceutical industry that people in New England are sick and tired of paying a 60 to 80 percent premium for drugs made in America, and — I think we share this view with our friends in Maine — as long as the pharmaceutical industry remains the top donor to members in both parties in Congress, not much will happen there; it's going to have to happen state by

To backers of the pharmaceutical industry, that goal is deeply misguided, as is the Maine bill.

"It sounds like they're claiming this is a win for the Legislature, but I think it's a detrimental blow to pattents in Maine who need access to medicine," said Gabrielle Williams, a spokeswoman for Pharmaceutical Research and Manufacturers of America, the trade association, based in Washington. "It could have significant impacts on access to certain medications in Maine."

Delays in setting prices could bring delays in access to new drugs, she said. Also, price controls remove the financial incentive for research and development to create new drugs, she added.

some tear that manufacturers

would refuse to sell drugs in Maine. But the bill's backers say that would be a public relations disaster for the companies.

There has been plenty of local opposition to the bill in Maine as well. On Monday, a group of doctors, biotechnology backers and senior, citizens' groups held a news conference, saying they worried that pricescontrols might restrict access to drugs. They called for changes in insurance programs to make drugs more affordable for older people rather than for universal price controls.

Others sounded like Clyde E. Dyar, the economic and community development director for the town of Fairfield, Me., who worried that the bill would chill investment in the state's small biotechnology industry. "If we put price controls on in

"If we put price controls on in Maine, and we don't do it nationally, then it puts an onus on companies not to do business in Maine," he said in a telephone interview "Why don't we start in Louisiana? Why don't we start in Texas? Why don't we don't me national level, where it belongs? Why do we impose a hardship on Maine? It's tough enough as it is to do economic development in Maine. This puts another cross upon is to carry."

When the bill came to the floor of both chambers today, Senators Pingree said, the debate was lengthy largely because so many lawmakers wanted to share what they and their constituents had experienced being medicine. Ultimately, support for the bill crossed party lines. Also bolstering the vote was testimony from hundreds of elderly Mainers at a public hearing last month; many described choosing between paying for their medication or basics like food and rent.

The Maine bill sets aside \$20,000 for its legal defense. It lays out the composition of an 11-member pricing board, which would include a senior citizen and a disabled person. It also lays out several interim meadures meant to reduce prices, such as increased prescription drug benefits for low-income seniors, potential purchasing alliances with other states and incentive payments to health care providers to encourage them to prescribe cheaper products. The state-mandated pricing is not to come into effect if prices can be lowered by those other means.

$Another\ Viewpoint$

Maine Has to Stand Up for Itself

By Chellie Pingree

torial in the April 20 edition of The Drug Prices." The only argument I read against this bill is that the Act to (sic) access for Mainers to existing and newly developed drugs." I was disappointed to read the ed-Ellsworth American titled "Fixing Establish Fairer Prescription Drug Prices may "...delay (sic) or diminish

dom. Their good fortune is the result of the work done by governments who niors, and all other Maine citizens pay the highest prices in the world for prescription drugs. Our costs average one-third more than those paid by Canadian citizens and two-thirds negotiate a lower price. Studies conducted by the federal committee on Government Reform and Oversight show the nearly unbelievable differ-The statistics are shocking. Semore than those in the United King-

ences. Relafen, a common arthritis medication, can be purchased for \$59.55 for 100 reat your pet and \$25.65 to treat yourself. The ablets in Canada while Maine citizens pay \$116. Lanoxin heart medication will cost you \$6.36 to examples are endless.

reductions would leave them with no money to In spite of the fact that this is the most profion in profits last year, they have been spreading a message of fear in Maine by telling us that price continue research and development for new products. However, a Merrill Lynch study from September 1999 shows that with price reductable industry in the world, netting over \$24 biltions, the increased volume of utilization of phar-

development of new drugs, while much of the maceuticals will offset any perceived profit loss. Further, we know that the American axpayers are paying for 57 percent of the research and manufacturer's money is invested into manufac-



turing and marketing nonessential and lifestyle enhancing, high-profit drugs. We have a health-care system where medications are used to keep people living healthier and longer ives. We are very fortunate that new drugs are developed everyday and are the pharmaceutical industry. Howcare systems that does not sit at the grateful for the contributions made by ever, we continue to allow the industry to be the one player in the healthable to negotiate.

scription drugs has doubled in the past six years. Not only are low-incial sacurity benefits would be enough for a comfortable retirement quickly soon find that their prescripcome seniors affected, but also so are Unfortunately, the cost of prethose that thought their pension or sotion drug bills leave them broke.

tional problem." There is no question that this bill is far reaching, but with the inactivity of the federal government to act, states, including Maine, have to take it upon themselves to stand up to a power industry. The proposals Congress is considering will not help all The editorial states that price fixing will not solve a "difficult and complex na-

ourselves: the industry spends gress. Despite Congressman Allen's bill attracting national \$78 million a year to lobby Con-Senator Snowe's bill would hand even more taxpayer dollars over to this incredibly proftable industry. Even the procitizens, and especially, not all senior citizens. Let's not fool attention, he continues to struggle to even get a floor debate.

posed, and long overdue, Medicare expansion is unlikely to go beyond covering the lowest income citizens because of the high price tag.

quires us to continue to assist needy seniors, ask the federal government for more assistance, and examine regional purchasing alliances, and more. scription drugs in Maine are not as low as they are across the border, we plan to negotiate prices so Mainers are not forced to chocse between purchasing their medications or groceries. And, we are already working with other New England states. In fact, nearly the same bill has passed the Jermont Senate, and other bills have been introduced in Connecticut, New York, Pennsylvania However, by October 2001, if the costs of pre-The bill that passed the Maine legislature reand California

The industry counters by saying that if we sary medications to sick Maine residents with no them, but more importantly, shame on us if we are too afraid to call their bluff. not be available. Do we believe the pharmaceutical industry would actually refuse to send necesmore argument than a few less dollars for Wall Street investors? If they did this, then shame on take action in Maine, lifesaving medications will

fort in a state where virtually every lawmaker has expressed a deep concern for this issue. Not so The bill before us, LD 2599, is a bipartisan eflong ago a proposal to sue the tobacco industry

ment. Some day we may look back I am grateful to all the Maine shown the courage to stand up for our citizens. I am sorry to find this editorial writer is unwilling to Eventually, we all joined in and filawmakers who have already nally, so did the federal governon this effort in a very similar way. began in a few courageous states.

Chellie Pingree of North Haven is the Senate Majority Leader stand with us.



Drug bill passes easily

The lopsided vote in both chambers indicates the importance of the prescription price issue to Mainers.

> BY BONNIE WASHUK Staff Writer

AUGUSTA - The Senate and House overwhelmingly passed a bill Thursday that will seek to lower the prices of drug prescriptions by forming a "Maine Rx" program.

By using the power of thousands of consumers to negotiate for lower prices, the state will get prescrip-

discounts from the drug industry for citizens beginning in January.

lopsided vote in both chambers indicated how

important the issue of prescription prices is to Mainers.

The Senate vote was an unusual. unanimous 30-0. The House vote was 133-12. The bill was zoomed to Gov. Angus King's desk late Thursday and King signed it.

During floor debate some Republicans, who opposed the earlier drug bill, embraced the new compromise and heaped praise on King for the changes.

Sen. Jane Amero, R-Cape Elizabeth, said the earlier bill did not provide relief soon enough, and tied price controls to Canada's market, which would make it illegal. The new bill corrects both problems. It is a better solution "and a good beginning to address this problem," Amero said.

Sen. Richard Bennett, R-Norway, agreed. There are some problems in the bill such as a section dealing with profiteering, and the bill could be challenged in court, he. said. "But it's a very good idea to use the market approach to solving this problem. ... How will my constituents spell relief? M-A-I-N-E

Rx. Democrats the bill is necessary to stop seniors from making impossible choices of buying food, oil or medicine.

or taking a pill every other day to cut costs. Democrats warned the bill will be stiffly opposed by the pharmaceutical industry.

Sen. John Nutting, D-Leeds, said that is already happening. Several of his constituents received false information through phone calls that's making "the hair on my neck



DARYN SLOVER/SUN JOURNAL

support group; Mary Bessey, left, and Barbara Nelson, both of Livermore Falls, and members of Seniors Plus of Wilton, attend Thursday's rally in support of lowering prescription costs in Maine. Sitting next to Nelson are Cecile Lecialr and Gabrielle Labrecque of Lewiston.

stand up." People were told if the bill passed, "not a single prescription would be written in the state of Maine." Nutting said he corrected the information and explained to his constituents what the bill

Now there is profiteering going on in Maine from the industry, he said. Medicine he buys for his dairy cows is far cheaper than the

same medicine sold to humans. Nutting said. "This industry has no conscience. That's exhibited by what they're telling my constituents."

In the House, Speaker Steven Rowe, D.Portland, urged members to pass the bill, explaining the state will first try using the power of the

PLEASE SEE BILL PAGE A11

Bill

CONTINUED FROM PAGE A1

market to lower prices, and only if that fails will the state set prices. Rowe said he doubted the state would have to resort to price controls.

The 325,000 Mainers without drug insurance now "pay the highest drug prices in the state." That isn't fair, he said. The discounts at first will be 15 percent. "That won't be substantial, but it is a discount." Rowe said, adding the hope is as the program grows so will the dis-

Rep. John Buck, R-Yarmouth, asked what would prevent a drug manufacturer from not seiling medicine in Maine. Rowe answered there is language in the bill that prevents a company now selling in Maine from "retaliating" by

'Maine Rx'

The Pingree-King bill will first use the power of the market to lower prices, if that fails, the state will implement price controls based on what the industry is already charging in Maine.

Thursday's House and Senate votes mean a new drug program called "Maine Rx" will be created and the state will become a pharmacy benefits manager for 325,000 Mainers without prescription insurance now paying high prescription prices. Most of those are the elderly on Medicare.

By representing large numbers of people in Maine Rx, the state will force the industry to give discounts. If the industry's discounts are not comparable to some of the cheapest prices paid in the state by 2003, the state will set price controls.

stopping sales. "The prices aren't going to come down by them-selves," Rowe said. "We've got to get this jump-started." If the industry can give low prices to some, such as the Togus Veterans hospital, "why can't they do that for all?" Rowe asked

A handful of conservative Republicans urged defeat of the bill.

Rep. Tarren Bragdon, R-Bangor, said the amendment represents

"the worst kind of public policy." and that legislators are "demonizing an entire industry." Many people are alive today because of research and development by drug manufacturers. Rep. Debra Plowman, R-Hampden, agreed. "We're looking for a bad guy and we found one." The day she cannot get a prescription filled "because the state of Maine meddled" is the day she won't be happy, Plowman said.

Sun-Journal 5/12

AFFORDABLE PRESCRIPTIONS

Pingree-King accord will lower drug prices

 As with any deal, the results aren't perfect, but they're better than the alternatives.

egislators, activists and senior citizens who backed a bill to regulate the high costs of prescription medicine should have no problem rallying around a compromise bill worked out with Gov. King this week.

The new plan, unveiled Wednesday afternoon, is the fruit of 10 days of artful negotiation between the bill's sponsor, State Sen. Chellie Pingree, D-North Haven, and members of King's Cabinet. It reflects a shared commitment to achieve a first-in-the-nation mechanism to control the rising price of drugs, relying on a market approach rather than strong-armed regulatory practices to help Maine's senior citizens get a better deal on life-saving medication.

"We're playing their game," said King, who noted that he would have vetoed Pingree's original bill because of constitutional concerns. "The drug companies are merging to achieve market leverage, and we're saying we can do that too."

THE PINGREE-KING compromise would create a drug purchasing group for the 20 percent of Maine citizens who currently have no pharmaceutical benefit. Combined with the 30 percent of residents who currently have a drug benefit through the state's Medicaid program, the group would harness the purchasing power of half of Maine's population to negotiate lower prices from pharmaceutical companies, much as private insurance companies and the Veterans Administration do now.

Mainers covered under the plan would receive a "Maine Rx" card entitling them to discounted prices on prescription drugs at participating pharmacies. King predicts that the state, playing the role of a pharmacy benefits manager, could lower drug prices 15 percent by next January, and 30 to 35 percent in the following year.

If group purchasing alone fails to lower prices sufficiently, the bill includes a progressively severe set of economic and legal sanctions against recalcitrant drug manufacturers. For instance, the state has the power to require the use of inexpensive generic drugs when a doctor writes a prescription for a Medicaid beneficiary, but King says the state does not now invoke it. If a drug maker refuses to

negotiate with the state to provide lower prices for participants in the Maine Rx program, the Department of Human Services could simply begin to require the generic alternative.

THE BILL WOULD also allow the state to assess civil penalties (of up to \$100,000) against companies that charge excessive prices or restrict supplies. In addition, it would create a 12-member advisory commission made up of senior citizens, medical professionals and administrators to ensure that pharmaceutical companies maintain the availability of needed drugs, and that the prices are comparable to the lowest paid by any other group in the state.

Finally, if prices aren't brought down to a comparable level, the Legislature would be empowered to set maximum prices by 2003.

Despite its obvious advantages over the original bill, the compromise is not flawless. It relies on World War I-era profiteering laws to punish manufacturers who decide to stop providing drugs in Maine rather than sell at the lower price. That's a risky strategy that could involve expensive litigation. Merely from a practical perspective, it seems hard to levy fines against companies that don't do business in your state, whatever their

reasons.

Creating a purchasing group too large to ignore, rather than rattling rusty statutory sabers, is a better strategy to guarantee access. That's why we were encouraged to see that the Pingree-King compromise also authorizes the state to enter into agreements with other governments and purchasing cooperatives. King said he planned to invite Gov. Sheehan of New Hampshire and Gov. Dean of Vermont to join the effort, increasing the market clout of the plan.

KING AND PINGREE deserve credit for their willingness to set aside politics and work collaboratively toward a solution to the prescription drug crisis. The compromise they developed over the last 10 days may not produce the dramatic relief promised in the original legislation – at least at first – but neither will it run into the legal barriers and distribution concerns that Pingree's bill seemed certain to confront.

Lawmakers should proudly vote in favor of the revamped bill and make Maine a leader in the effort to make prescription drugs affordable to all.

Maine
2/132/01 Beth Ketch - Bureau & Medical Services
207-287-4078
Marie Rx - is now on hard re appeal - is to be heard in
Marie Rx - is now on hord reappeal - is to be heard in march 5
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STATE OF WISCONSIN – LEGISLATIVE REFERENCE BUREAU – LEGAL SECTION (608–266–3561)

1/11/01 Meeting w/Rep Coggo, Dave de Felice, Dick Sweet
Rep Coges: Wonts Maine biel with comes ruled unconstitutional (10/26/2000 ruling) removed +
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Specified parts from SB ! included (see Model Bill)
Specified parts from SBI incended (see Model Bill) Wants prior authornation" language retained, with a justification
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Prescription Drug Fair Pricing

Summary

- Prescription drug prices are out of control, rising twice as fast as inflation
- One in four Americans—70 million—do not have insurance covering prescription drugs.
- Uninsured seniors are especially at risk because they consume one-third of all prescription drugs.
- The prices uninsured Americans pay for prescriptions are about twice what the federal government pays for the same drugs under the Federal Supply Schedule.
- Americans pay 30% to 70% more than Canadians and Mexicans for the same prescriptions.
- Often pet medications cost much less than the exact same drugs when prescribed for humans.
- The uninsured have no leverage to negotiate better prices from the pharmaceutical industry.
- At the same time, the pharmaceutical industry is the most profitable industry in the world.
- State leaders across the nation are now proposing legislation to lower prescription drug prices.
- Like the new law in Maine, these proposals direct states to use their bulk purchasing power to negotiate fair drug prices for the uninsured.

A health crisis is sweeping this country, threatening the lives and well-being of millions of Americans—soaring prices for prescription drugs. Drug prices are out of control, rising twice as fast as the inflation rate. At the same time, the number of Americans with health insurance covering prescription drugs is declining by a million people per year. The problem is literally an epidemic because many Americans, especially seniors on a fixed income, are forced to risk their health by sharing drugs, skipping doses or doing without medicine altogether because it is simply too expensive.

One in four Americans—70 million—do not have insurance covering prescription drugs.

Medicare does not cover outpatient prescriptions, and older Americans desperately need these medicines. Because they have more medical concerns, seniors—representing only 12 percent of the population—consume one-third of all prescription drugs. More than 10 million children are also among the uninsured.

average, the prices paid by the uninsured for their prescriptions are about twice as much as the federal government pays for the same drugs under the Federal Supply Schedule. Uninsured families are charged far more for prescriptions than their insured neighbors, even in the same pharmacy. Similarly, uninsured Americans pay 30 percent to 70 percent more than Canadians and Mexicans pay for identical prescriptions. Even household pets get better drug prices than the uninsured—often veterinary medications sell for less than half of what they cost pet owners for the exact same drug.

By themselves, uninsured Americans have no ability to negotiate better prices.

Individual retail prescription customers are powerless in the marketplace, so the drug companies charge as much as they think they can. These same drug companies are reaping record profits—in fact, more than triple the profit of other industries, according to a *Fortune 500* ranking.

Uninsured Americans pay unconscionably high prices for their prescription drugs. O_n

The Prescription Drug Fair Pricing Act is based on a law just enacted in Maine. The legislation directs the state government to use its bulk purchasing power to negotiate steep discounts and pass the savings on to those who have no prescription drug insurance coverage, including retirees who rely on Medicare. Specifically, this legislation:

- 1. Provides a state prescription card to all residents who do not have prescription drug coverage under a public or private health insurance plan, approximately one-fourth of all residents.
- 2. Gives the state government the responsibility to negotiate substantial rebates from drug companies and discounts from drug retailers, then passes the savings along to participants, and
- Provides the state with tools to help persuade drug companies to negotiate in good faith, including public disclosure of uncooperative companies, outreach to health professionals, and the option to use prior authorization or formularies to encourage the use of lower-priced prescription drugs.

The Prescription Drug Fair Pricing Act received bipartisan support in Maine. The State Senate approved the law unanimously, the House vote was 133 to 11, and it was signed by Governor Angus King, an Independent. Democrats in the legislature unanimously supported the bill and Republicans voted for it by a margin of 68 to 11. House GOP Leader Thomas W. Murphy, Jr. said: "We hope that other states will follow our lead and that Congress will recognize this as a national problem...." Governor King declared the drug industry's charges that Maine was "anti-business" were "utter nonsense." He added, "I'll be surprised if many other states don't

was led by Senate Majority Leader Chellie Pingree, a member of the Board of the Center for Policy Alternatives and a 1996 graduate of CPA's Flemming Fellows Leadership Institute.

follow this lead." The bipartisan consensus

The Prescription Drug Fair Pricing Act does not cost taxpayers a dime. Like every health insurance plan, administrative costs will be paid out of the rebates negotiated from drug companies.

The drug industry asserts that, if they give fair prices to the uninsured, they will not have enough money to research and develop new drugs. This claim is simply absurd. The drug companies don't need to gouge the uninsured to pay for their research, because:

- 1. The pharmaceutical industry is already the most profitable industry in the world, earning profits of 18.3 percent compared to an average profit of five percent for other industries.
- 2. The top ten drug companies spent two and a half times more on marketing, public relations and administration than they did on research and development in 1999. The drug companies spent nearly \$2 billion on direct advertisements to the public last year.
- 3. A very large percentage of pharmaceutical research is financed with government money. The public deserves fair drug prices in return for its investment.
- 4. A reduction in prescription drug prices will be offset by an increase in the volume of sales, according to a study by Merrill Lynch.
- 5. The Prescription Drug Fair Pricing Act does not alter or affect the incentive for aggressive drug research and development. Because of patent protections, new drugs are sold at the highest prices and are extremely profitable. If anything, lowering prices for the uninsured will encourage drug companies to increase research to enhance their profits.

Prescription Drug Fair Pricing Act

Modeled after Maine's \$.1026, signed into law on May 11, 2000.

Summary: The Prescription Drug Fair Pricing Act creates a state "Rx Program" which provides a prescription card to state residents who do not have prescription drug insurance coverage or are underinsured; directs the state government to negotiate on behalf of the uninsured for substantial rebates from drug companies and discounts from retail pharmacies; and passes the savings along to Rx Program participants.

SECTION 1. SHORT TITLE

This Act shall be called the "(STATE) Prescription Drug Fair Pricing Act."

SECTION 2. FINDINGS AND PURPOSE

(A) FINDINGS—The legislature finds that:

- 1. Approximately one in four residents of (STATE) have no or wholly inadequate prescription drug insurance coverage.
- 2. These uninsured residents pay excessive prices for prescription drugs, far higher prices than are paid by managed care organizations, insurance companies and the federal government for the same medicines and dosages. In many cases, these excessive drug prices have the effect of denying residents access to medically necessary care, and thereby threatening their health and safety.
- 3. Many residents require repeated doctor or medical clinic appointments, having gotten sicker because they cannot afford to take the prescriptions prescribed for them. Many residents are admitted to or treated at hospitals each year because they cannot afford the drugs prescribed for them that could have prevented the need for hospitalization. Many others enter expensive institutional care settings because they cannot afford their necessary prescription drugs that could have supported them outside of an institution. In each of these circumstances, state medical assistance programs, including the Medicaid program, literally pay the price.
- 4. One major reason uninsured residents pay so much for prescription drugs is that, unlike insured residents, they have no prescription benefits manager negotiating a fair price with the drug companies on their behalf.
- 5. The state government is the only agent that, as a practical matter, can play an effective role as a market participant on behalf of all residents who are uninsured or underinsured. The state can and should act as a prescription benefit manager, negotiating voluntary drug rebates and using these funds to reimburse retail pharmacies for offering lower drug prices.
- (B) PURPOSE—This law is enacted by the legislature to create a program whereby the state acts as a participant in the prescription drug marketplace, negotiating voluntary rebates from drug companies and using the funds to make prescription drugs more affordable to (STATE) residents. Such a program will improve public health and welfare, promote the economic strength of our society, and substantially benefit state health assistance programs, including the Medicaid program.

SECTION 3. FAIR PRESCRIPTION DRUG PRICES

After section XXX, the following new section XXX shall be inserted:

(A) DEFINITIONS—in this section:

- 1. "Secretary" means the Secretary of the Department of (HEALTH), or the Secretary's designee(s).
- 2. "Department" means the Department of (HEALTH).

- 3. "Manufacturer" means a manufacturer of prescription drugs and includes a subsidiary or affiliate of a manufacturer.
- 4. "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale, and that has a labeler code from the Federal Food and Drug Administration under 21 Code of Federal Regulations, 207.20 (1999).
- 5. "Retail Pharmacy" means a retail pharmacy or other business licensed to dispense prescription drugs in this state.

(B) Rx PROGRAM

- 1. **Program established.** The Rx Program is established within the department to lower prescription drug prices for uninsured and underinsured residents of the state.
- 2. Rebate agreement. A drug manufacturer or labeler that sells prescription drugs in the state may voluntarily elect to enter into a rebate agreement with the department.
- 3. Rebate amount. The Secretary shall negotiate the terms of the rebate from a manufacturer or labeler, taking into consideration the rebate calculated under the Medicaid Rebate Program pursuant to 42 United States Code, Section 1396r-8, the average wholesale price of prescription drugs, and any other available information on prescription drug prices and price discounts.

 Shall review these manufacturer's products for prior authority.
- We do pres New this info l'augus doc
- Failure to agree. If a drug manufacturer or labeler elects not to agree to a rebate, the Secretary may place those manufacturer's or labeler's products on the prior authorization list for the state Medicaid program pursuant to (SECTION), and take similar actions involving prior authorization or formularies for any other state-funded prescription drug program. The Secretary shall promulgate rules creating clear procedures for the implementation of this paragraph. The names of manufacturers and labelers that do not enter into rebate agreements are public information and the department shall release this information to the public. The Secretary shall also publicize to doctors, pharmacists, and other health professionals information about the relative cost of drugs produced by manufacturers and labelers that enter into rebate agreements compared to those who do not enter into rebate agreements.
 - 5. Discounted prices for Rx Program participants. A retail pharmacy shall discount the price of prescription drugs sold to Rx Program participants.
 - a The department shall establish discounted prices for drugs covered by a rebate agreement and shall promote the use of efficacious and reduced-cost drugs, taking into consideration reduced prices for state and federally capped drug programs, differential dispensing fees, administrative overhead, and incentive payments.
 - b. Beginning July 1, 2001, a retail pharmacy shall offer prescription drugs at or below the average wholesale price, minus 6%, plus a dispensing fee designated by the Secretary. These initial price levels shall be calculated by the Secretary and the dispensing fee shall not be less than that provided under the state Medicaid program. The average wholesale price is the wholesale price charged on a specific commodity that is assigned by the drug manufacturer and is listed in a nationally recognized drug pricing file.
 - c. No later than January 1, 2002, a retail pharmacy shall offer prescription drugs at or below the initial price levels specified in paragraph (b) minus the amount of any rebate paid by the state to the retail pharmacy. These discounted price levels shall be calculated by the Secretary. In determining the discounted price levels, the Secretary shall consider an average of all rebates weighted by sales of drugs subject to these rebates over the most recent 12-month period for which the information is available.
 - 6. Eligibility for individuals to participate in the Rx Program. All residents of the state are eligible to participate in the Rx Program. The department shall establish simplified procedures for issuing Rx Program enrollment cards to eligible residents. The department shall undertake outreach efforts to build public awareness of the Rx Program and maximize enrollment by eligible residents.

CENTER FOR POLICY ALTERNATIVES

Operation of the Rx Program.

- The (BOARD OF PHARMACY) shall adopt rules requiring disclosure by retail pharmacies to Rx Program participants of the amount of savings provided as a result of the Rx Program. The rules must protect information that is proprietary in nature.
 - The department may not impose transaction charges on retail pharmacies that submit claims or receive payments b. under the Rx Program.
 - A retail pharmacy shall submit claims to the department to verify the amount charged to Rx Program participants.
 - On a weekly or biweekly basis, the department shall reimburse a retail pharmacy for discounted prices provided d. to Rx Program participants and dispensing fees set by the Secretary.
 - The department shall collect from the retail pharmacies utilization data necessary to calculate the amount of the e. rebate from the manufacturer or labeler. The department shall protect the confidentiality of all information subject to confidentiality protection under state or federal law, rule or regulation.
- Discrepancies in rebate amounts. Discrepancies in rebate amounts must be resolved using the process established in this subsection.
 - If there is a discrepancy in the manufacturer's or labeler's favor between the amount claimed by a pharmacy and the amount rebated by the manufacturer or labeler, the department, at the department's expense, may hire a mutually agreed-upon independent auditor. If a discrepancy still exists following the audit, the manufacturer or labeler 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 or labeler in the information provided by the department to the manufacturer or labeler regarding the manufacturer's or labeler's rebate, the manufacturer or labeler, at the manufacturer's or labeler's expense, may hire a mutually agreed-upon independent auditor to verify the accuracy of the data supplied to the department. If a discrepancy still exists following the audit, the department shall justify the reason for the discrepancy or refund to the manufacturer any excess payment made by the manufacturer or labeler.
 - Following the procedures established in paragraph (a) or (b), either the department or the manufacturer or labeler may request a hearing. Supporting documentation must accompany the request for a hearing.
 - Rx Dedicated Fund. The Rx Dedicated Fund is established to receive revenue from manufacturers and labelers who pay rebates and any appropriations or allocations designated for the fund. The purposes of the fund are to reimburse retail pharmacies for discounted prices provided to Rx Program participants, and reimburse the department for the costs of administering the program, including contracted services, computer costs, professional fees paid to retail pharmacies, and other reasonable program costs. The Rx Dedicated Fund is a non-lapsing dedicated fund. Interest on Rx Dedicated Fund balances accrues to the Fund.
 - 10. Annual summary report. The department shall report the enrollment and financial status of the Rx Program to the legislature by the 2nd week in January each year.
 - 11. Coordination with other programs. In implementing this section, the department shall coordinate with other governmental programs to increase efficiency and, where it is beneficial to another state program, combine drug pricing negotiations to maximize drug rebates for this and other programs, including the state Medicaid program.
 - 12. Rulemaking. The department may adopt rules to implement the provisions of this section.
 - 13. Waivers. The department may seek any waivers of federal law, rule or regulation necessary to implement the provisions of this section.

SECTION 4. SEVERABILITY

(INSERT STANDARD SEVERABILITY CLAUSE FOR YOUR STATE)

SECTION 5. EFFECTIVE DATE—This act shall take effect on July 1, 2001.



Explanation of Legal Issues in the Prescription Drug Fair Pricing Act

The model Prescription Drug Fair Pricing Act has been modified from the Maine law to address constitutional objections. On October 26, 2000, U.S. District Judge D. Brock Hornby ruled that key parts of the Maine law violated the U.S. Constitution. The Judge's objections rested on two legal arguments: that the regulatory scheme effectively controlled prices outside the state of Maine, and therefore violated the Commerce Clause, and that the prior authorization requirement was inconsistent with the congressional statutory intent for the Medicaid program, and therefore violated the Supremacy Clause. The newly revised policy model called the "Prescription Drug Fair Pricing Act" has been modified to overcome these constitutional arguments.

Two provisions which arguably violate the Commerce Clause have been deleted from the latest policy model. The Maine legislation has two sections which raised the biggest constitutional issues: one which requires the state to determine within three years whether the negotiated drug prices are low enough, and if not, to set maximum prices for specific drugs; the other, which imposes penalties up to \$100,000 per violation on drug manufacturers and marketers who "profiteer" by charging excessive prices or restricting the supply of drugs to the state. Both of these provisions have been removed from the policy model because, with strong tools to negotiate prices in the marketplace, the state will be able to lower prescription drug prices without resorting to such regulatory controls.

Clause, has been strengthened in the latest policy model. In his ruling, Judge Hornby said that "The State makes no argument that the new condition of prior approval serves any purpose of the Medicaid program." He argued, in large part, that the Medicaid program cannot be used for a purpose that does not serve Medicaid beneficiaries. In response to this constitutional objection, the latest policy model makes it clear that the new Rx Program in general, and the prior authorization provision in particular, will directly benefit the Medicaid program by:

(1) keeping residents who cannot afford the price of their prescriptions from getting sicker, getting poorer and requiring expensive Medicaid services; and (2) lowering some drug prices that the Medicaid program pays. In light of these additional provisions, the Judge's suggestion that the program does not serve "any purpose of the Medicaid program" becomes inapplicable and his preemption argument loses its strength. Finally, the policy model specifies in Section 13 that the state "may seek any waivers of federal law, rule or regulation necessary to implement the provisions of this section," so any further preemption argument can be handled by obtaining such a waiver.

This is the justification

DAK

Prescription Drugs

POLICY SUMMARY

Prescription Drug Fair Pricing

Summary

- Prescription drug prices are out of control, rising twice as fast as inflation.
- One in four Americans—70 million—do not have insurance covering prescription drugs.
- Uninsured seniors are especially at risk, because they consume one-third of all prescription drugs.
- The prices uninsured Americans pay for prescriptions are about twice what the federal government pays for the same drugs under the Federal Supply Schedule.
- Americans pay 30% to 70% more than Canadians and Mexicans for the same prescriptions.
- Often, pet medications cost much less than the exact same drugs when prescribed for humans.
- The uninsured have no leverage to negotiate better prices from the pharmaceutical industry.
- At the same time, the pharmaceutical industry is the most profitable industry in the world.
- State leaders across the nation are now proposing legislation to lower prescription drug prices.
- Like the new law in Maine, these proposals direct states to use their bulk purchasing power to negotiate fair drug prices for the uninsured.

A health crisis is sweeping this country, threatening the lives and well-being of millions of Americans—soaring prices for prescription drugs. Drug prices are out of control, rising twice as fast as the inflation rate. At the same time, the number of Americans with health insurance covering prescription drugs is declining by a million people per year. The problem is literally an epidemic, because many Americans, especially seniors on fixed incomes, are forced to risk their health by sharing drugs, skipping doses or doing without medicine altogether because it is simply too expensive.

One in four Americans—70 million—do not have insurance covering prescription drugs.

Medicare does not cover outpatient prescriptions, and older Americans desperately need these medicines. Because they have more medical concerns, seniors—representing only 12 percent of the population—consume one-third of all prescription drugs. More than 10 million children are also among the uninsured.

Uninsured Americans pay unconscionably high prices for their prescription drugs. On

average, the prices paid by the uninsured for their prescriptions are about twice as much as the federal government pays for the same drugs under the Federal Supply Schedule. Uninsured families are charged far more for prescriptions than their insured neighbors, even in the same pharmacy. Similarly, uninsured Americans pay 30 percent to 70 percent more than Canadians and Mexicans pay for identical prescriptions. Even household pets get better drug prices than the uninsured—often veterinary medications sell for less than half of what they cost pet owners for the exact same drug.

By themselves, uninsured Americans have no ability to negotiate better prices.

Individual retail prescription customers are powerless in the marketplace, so the drug companies charge as much as they think they can. These same drug companies are reaping record profits—in fact, more than triple the profit of other industries, according to a *Fortune 500* ranking.

The Prescription Drug Fair Pricing Act is based on a law just enacted in Maine. The legislation directs the state government to use its bulk purchasing power to negotiate steep discounts and pass the savings on to those who have no prescription drug insurance coverage, including retirees who rely on Medicare. Specifically, this legislation:

- Provides a state prescription card to all residents who do not have prescription drug coverage under a public or private health insurance plan or are grossly underinsured, approximately onefourth of all residents.
- Gives the state government the responsibility to negotiate substantial rebates from drug companies and discounts from drug retailers, then passes the savings along to participants, and
- 3. Provides the state with tools to help persuade drug companies to negotiate in good faith, including public disclosure of uncooperative companies, outreach to health professionals, and the option to use prior authorization or formularies to encourage the use of lower-priced prescription drugs.

The Prescription Drug Fair Pricing Act received bipartisan support in Maine. The State Senate approved the law unanimously, the House vote was 133 to 11, and it was signed by Governor Angus King, an Independent. Democrats in the legislature unanimously supported the bill, and Republicans voted for it by a margin of 68 to 11. House GOP Leader Thomas W. Murphy, Jr. said: "We hope that other states will follow our lead and that Congress will recognize this as a national problem." Governor King declared that the drug industry's charges that Maine was "anti-business" were "utter nonsense." He added, "I'll be surprised if many other states don't follow this lead." The bipartisan consensus

was led by Senate Majority Leader Chellie Pingree, a member of the Board of the Center for Policy Alternatives and a 1996 graduate of CPA's Flemming Fellows Leadership Institute.

The Prescription Drug Fair Pricing Act does not cost taxpayers a dime. Like every health insurance plan, administrative costs will be paid out of the rebates negotiated from drug companies.

The drug industry asserts that, if they give fair prices to the uninsured, they will not have enough money to research and develop new drugs. This claim is simply absurd. The drug companies don't need to gouge the uninsured to pay for their research, because:

- 1. The pharmaceutical industry is already the most profitable industry in the world, earning profits of 18.3 percent, compared to an average profit of five percent for other industries.
- 2. The top ten drug companies spent two and a half times more on marketing, public relations and administration than they did on research and development in 1999. The drug companies spent nearly \$2 billion on direct advertisements to the public last year.
- A very large percentage of pharmaceutical research is financed with government money.
 The public deserves fair drug prices in return for its investment.
- A reduction in prescription drug prices will be offset by an increase in the volume of sales, according to a study by Merrill Lynch.
- 5. The Prescription Drug Fair Pricing Act does not alter or affect the incentive for aggressive drug research and development. Because of patent protections, new drugs are sold at the highest prices, and are extremely profitable. If anything, lowering prices for the uninsured will encourage drug companies to increase research to enhance their profits.

ontacts for Mare Information :

Center for Policy Alternatives

1875 Connecticut Avenue, NW, Suite 710 Washington, D.C. 20009 202-387-6030 www.stateaction.org

Public Citizen

215 Pennsylvania Avenue, SE Washington, D.C. 20003 202-546-4996 www.citizen.org

Families USA

1334 G Street, NW Washington, D.C. 20005 202-628-3030 www.familiesusa.org

Consumer Federation of America

1424 16th Street, NW, Suite 604 Washington, D.C. 20036 202-387-6121 www.consumerfed.org

American Association of Retired Persons (AARP)

601 E Street, NW Washington, D.C. 20049 202-434-2277 www.aarp.org

U.S. House of Representatives Prescription Drug Task Force

1113 Longworth HOB Washington, D.C. 20515 www.house.gov/berry/prescriptiondrugs

Northeast Legislators State Legislative Association on Prescription Drug Pricing

c/o State Senator Peter Shumlin President Pro Tempore 115 State Street—State House Montpelier, VT 05633 802-828-3806 lsanchez@leg.state.vt.us

POLICY MODEL

Prescription Drug Fair Pricing Act

Modeled after Maine's S.1026, signed into law on May 11, 2000.

Summary: The Prescription Drug Fair Pricing Act creates a state "Rx Program" which provides a prescription card to state residents who do not have prescription drug insurance coverage or are underinsured; directs the state government to negotiate on behalf of the uninsured for substantial rebates from drug companies and discounts from retail pharmacies; and passes the savings along to Rx Program participants.

SECTION 1. SHORT TITLE

This Act shall be called the "(STATE) Prescription Drug Fair Pricing Act."

SECTION 2. FINDINGS AND PURPOSE

(A) FINDINGS—The legislature finds that:

- 1. Approximately one in four residents of (STATE) have no or wholly inadequate prescription drug insurance coverage.
- 2. These uninsured residents pay excessive prices for prescription drugs, far higher prices than are paid by managed care organizations, insurance companies and the federal government for the same medicines and dosages. In many cases, these excessive drug prices have the effect of denying residents access to medically necessary care, and thereby threatening their health and safety.
- 3. Many residents require repeated doctor or medical clinic appointments, having gotten sicker because they cannot afford to take the prescriptions prescribed for them. Many residents are admitted to or treated at hospitals each year because they cannot afford the drugs prescribed for them that could have prevented the need for hospitalization. Many others enter expensive institutional care settings because they cannot afford their necessary prescription drugs that could have supported them outside of an institution. In each of these circumstances, state medical assistance programs, including the Medicaid program, literally pay the price.
- 4. One major reason uninsured residents pay so much for prescription drugs is that, unlike insured residents, they have no prescription benefits manager negotiating a fair price with the drug companies on their behalf.
- 5. The state government currently provides prescription drugs and acts as a prescription benefit manager through a variety of health plans and assistance programs.
- 6. The state government is the only agent that, as a practical matter, can play an effective role as a market participant on behalf of all residents who are uninsured or underinsured. The state can and should act as a prescription benefit manager, negotiating voluntary drug rebates and using these funds to reimburse retail pharmacies for offering lower drug prices.
- (B) PURPOSE—Recognizing that the state already acts as a prescription benefit manager for a variety of health plans and assistance programs, this law is enacted to cover new populations by expanding the state's role as a participant in the prescription drug marketplace, negotiating voluntary relates from drug companies and using the funds to make prescription drugs more affordable to (STATE) residents. Such a program will improve public health and welfare, promote the economic strength of our society, and substantially benefit state health assistance programs, including the Medicaid program.

SECTION 3. FAIR PRESCRIPTION DRUG PRICES

After section XXX, the following new section XXX shall be inserted:

(A) **DEFINITIONS**—in this section:

- 1. "Secretary" means the Secretary of the Department of (HEALTH), or the Secretary's designee(s).
- 2. "Department" means the Department of (HEALTH).
- 3. "Manufacturer" means a manufacturer of prescription drugs and includes a subsidiary or affiliate of a manufacturer.
- 4. "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale, and that has a labeler code from the Federal Food and Drug Administration under 21 Code of Federal Regulations, 207.20 (1999).
- 5. "Participating retail pharmacy" means a retail pharmacy or other business licensed to dispense prescription drugs in this state that (a) participates in the state Medicaid program, or (b) voluntarily agrees to participate in the Rx Program.

(B) Rx PROGRAM

- 1. **Program established.** The Rx Program is established within the department to lower prescription drug prices for uninsured and underinsured residents of the state.
- 2. Rebate agreement. A drug manufacturer or labeler that sells prescription drugs in the state may voluntarily elect to enter into a rebate agreement with the department.
- 3. Rebate amount. The Secretary shall negotiate the terms of the rebate from a manufacturer or labeler, taking into consideration the rebate calculated under the Medicaid Rebate Program pursuant to 42 United States Code, Section 1396r-8, the average wholesale price of prescription drugs, and any other available information on prescription drug prices and price discounts.
- 4. Failure to agree. If the Secretary and a drug manufacturer or labeler fail to reach agreement on the terms of a rebate, the Secretary shall prompt a review of whether to place those manufacturer's or labeler's products on the prior authorization list for the state Medicaid program in accordance with (SECTION), and take similar actions involving prior authorization or formularies for any other state-funded prescription drug program. The Secretary shall promulgate rules creating clear procedures for the implementation of this paragraph. The names of manufacturers and labelers that do not enter into rebate agreements are public information and the department shall release this information to the public. The Secretary shall also publicize to doctors, pharmacists, and other health professionals information about the relative cost of drugs produced by manufacturers and labelers that enter into rebate agreements compared to those who do not enter into rebate agreements.
- 5. Discounted prices for Rx Program participants. A participating retail pharmacy shall discount the price of prescription drugs sold to Rx Program participants.
 - a. The department shall establish discounted prices for drugs covered by a rebate agreement and shall promote the use of efficacious and reduced-cost drugs, taking into consideration reduced prices for state and federally capped drug programs, differential dispensing fees, administrative overhead, and incentive payments.
 - b. Beginning July 1, 2001, a participating retail pharmacy shall offer prescription drugs at or below the average wholesale price, minus 6%, plus a dispensing fee designated by the Secretary. These initial price levels shall be calculated by the Secretary and the dispensing fee shall not be less than that provided under the state Medicaid program. The average wholesale price is the wholesale

- price charged on a specific commodity that is assigned by the drug manufacturer and is listed in a nationally recognized drug pricing file.
- c. No later than January 1, 2002, a participating retail pharmacy shall offer prescription drugs at or below the initial price levels specified in paragraph (b) minus the amount of any rebate paid by the state to the retail pharmacy. These discounted price levels shall be calculated by the Secretary. In determining the discounted price levels, the Secretary shall consider an average of all rebates weighted by sales of drugs subject to these rebates over the most recent 12-month period for which the information is available.
- 6. Eligibility for individuals to participate in the Rx Program. All residents of the state are eligible to participate in the Rx Program. The department shall establish simplified procedures for issuing Rx Program enrollment cards to eligible residents. The department shall undertake outreach efforts to build public awareness of the Rx Program and maximize enrollment by eligible residents.

7. Operation of the Rx Program.

- a. The (BOARD OF PHARMACY) shall adopt rules requiring disclosure by retail pharmacies to Rx Program participants of the amount of savings provided as a result of the Rx Program. The rules must protect information that is proprietary in nature.
- b. The department may not impose transaction charges on retail pharmacies that submit claims or receive payments under the Rx Program.
- c. A retail pharmacy shall submit claims to the department to verify the amount charged to Rx Program participants.
- d. On a weekly or biweekly basis, the department shall reimburse a retail pharmacy for discounted prices provided to Rx Program participants and dispensing fees set by the Secretary.
- e. The department shall collect from the retail pharmacies utilization data necessary to calculate the amount of the rebate from the manufacturer or labeler. The department shall protect the confidentiality of all information subject to confidentiality protection under state or federal law, rule or regulation.
- 8. **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 or labeler's favor between the amount claimed by a pharmacy and the amount rebated by the manufacturer or labeler, the department, at the department's expense, may hire a mutually agreed-upon independent auditor. If a discrepancy still exists following the audit, the manufacturer or labeler 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 or labeler in the information provided by the department to the manufacturer or labeler regarding the manufacturer's or labeler's rebate, the manufacturer or labeler, at the manufacturer's or labeler's expense, may hire a mutually agreed-upon independent auditor to verify the accuracy of the data supplied to the department. If a discrepancy still exists following the audit, the department shall justify the reason for the discrepancy or refund to the manufacturer any excess payment made by the manufacturer or labeler.
 - c. Following the procedures established in paragraph (a) or (b), either the department or the manufacturer or labeler may request a hearing. Supporting documentation must accompany the request for a hearing.

- 9. Rx Dedicated Fund. The Rx Dedicated Fund is established to receive revenue from manufacturers and labelers who pay rebates and any appropriations or allocations designated for the fund. The purposes of the fund are to reimburse retail pharmacies for discounted prices provided to Rx Program participants, and reimburse the department for the costs of administering the program, including contracted services, computer costs, professional fees paid to retail pharmacies, and other reasonable program costs. The Rx Dedicated Fund is a non-lapsing dedicated fund. Interest on Rx Dedicated Fund balances accrues to the Fund.
- 10. Annual summary report. The department shall report the enrollment and financial status of the Rx Program to the legislature by the 2nd week in January each year.
- 11. Coordination with other programs. Where the Secretary finds that it is beneficial to both the Rx Program and another state program, including the state Medicaid program, to combine drug pricing negotiations to maximize drug rebates, the Secretary shall do so.
- 12. Rulemaking. The department may adopt rules to implement the provisions of this section.
- 13. Waivers. The department may seek any waivers of federal law, rule or regulation necessary to implement the provisions of this section.

SECTION 4. SEVERABILITY

(INSERT STANDARD SEVERABILITY CLAUSE FOR YOUR STATE)

SECTION 5. EFFECTIVE DATE—This act shall take effect on July 1, 2001.



To: Chris Rasch From: Wendy Ray

Re: Changes to Model State Rx Cost Containment Bill

Date: January 16, 2001

The following changes should be made to the draft model legislation that was provided to you.

Theme

• The focus of the legislation in the preamble and purpose should be on the state as a market participant. The existing draft does not emphasize this enough.

• As much as possible, frame the legislation as an extension of state's current roles as a market participant (e.g. Medicaid, benefits for state employees, etc.) The existing draft implies that the state is not already a market participant.

Leverage Mechanism

- In paragraph 4, change language to "shall review those manufacturer's products for prior authorization" from "may place those manufacturer's or labeler's products on the prior authorization list"
- Prior authorization should be qualified by the following exceptions:
 - In determining which drugs are placed on the prior approval list, have a reasonable definition of "equivalents" and only allow prior approval for classes of drugs when safety, efficacy, and disease management considerations are not compromised by substitution with an equivalent
 - If the doctor says a substitution is not acceptable, or cannot be reached immediately, allow the prescription the first month in order to allow a thorough prior approval process, allowing the doctor to provide justification that the particular brand is medically necessary (using the Medicaid definition).
 - Reasonable standards for state review of doctors' requests for drugs on the prior approval list must be set.
 - If the doctors' request is denied after the prior approval process, the state must continue covering the initial prescription until subsequent hearings and appeals are completed.
 - Other options:
 - Require registration of sales representatives (like lobbyists)
 - Require manufacturers report marketing and promotional expenditures, including amounts spent on samples, gifts, salaries and commissions.
 - Require that all prescription drugs sold or distributed in the state, and all materials distributed in the state promoting such drugs, prominently carry a warning label stating

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fax: 202-737-9197

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that the manufacturer has not agreed to a negotiated price and cautioning the consumer that s/he may be paying a higher price or that there may be less expensive alternatives.

Likely Impermissible/Unworkable Mechanisms

- The legislation probably won't pass legal muster if it directly regulates what wholesalers can charge.
- The state can regulate retailers directly, but retailers represent an important constituency whose support for the legislation will be lost if this route is pursued

Failure to Agree

In paragraph 4, Change language to "if Secretary and drug manufacturer cannot agree, the Secretary may place" (from "elects" language)

Coordination with Other Programs

Strengthen the language in the paragraph 11 on this. If possible, enumerate coordination with Medicaid, state hospitals, state employees, teachers, drug discount programs for seniors, etc. Allow leverage across groups for the best prices and terms.

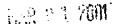
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Legislative Fiscal Bureau

One East Main, Suite 301 • Madison, WI 53703 • (608) 266-3847 • Fax: (608) 267-6873

February 28, 2001

TO:

Representative G. Spencer Coggs

Room 214 North, State Capitol

FROM:

Charles Morgan, Program Supervisor

SUBJECT: Prescription Drug Proposal

In response to your request, this memorandum provides an estimate on the number of persons who would be eligible for a prescription drug assistance program you have described to this office.

Under the proposal, all Wisconsin residents, regardless of age, would be eligible for the program if they: (a) are in households with income that does not exceed 300% of the federal poverty level (FPL); and (b) do not currently have coverage for prescription drugs. In 2001, 300% of the FPL is: (a) \$25,770 for an individual; (b) \$34,830 for a two-person family; (c) \$43,890 for a three-person family; and (d) \$52,950 for a four-person family.

The 1999-00 Blue Book indicates that the estimated population of Wisconsin in 1998 was 5,234,350. However, no information is available on the current income distribution of the Wisconsin population. Data from the 2000 U.S. Census on personal income is not yet available.

Some information from the 1990 U.S. Census could be used for developing this estimate. The 1990 census data suggests that approximately 28.14% of the Wisconsin population lived in households with income that did not exceed 200% of the FPL. To estimate the percent of the population in households with income up to 300% of the FPL, the estimated number of persons in households with income between 185% and 200% of the FPL was multiplied by 6.67 (15 x 6.67 = 100), and then added to the estimated population of persons in households with income up to 200% of the FPL. However, because it is likely that a greater number of persons are in these higher income ranges, this method gray probably underestimates the actual number of people in households with income under 300% of the FPL.

Based on this methodology, it is estimated that at least 2.5 million Wisconsin residents currently live in households with income up to 300% of the FPL.

In a national survey on prescription drugs conducted in 2000 as part of an ongoing partnership between the NewsHour with Jim Lehrer (a news program on National Public Television), the Kaiser Family Foundation and the Harvard School of Public Health, approximately 25% of respondents indicated that they had no coverage of prescription drugs. If this percentage is applied to the estimated 2.5 million Wisconsin residents who live in families with income up to 300% of the FPL, it is estimated that at least 625,000 Wisconsin residents would be eligible for the program.

The costs of providing discounts to enrollees, as well as program administration costs, would be entirely funded with rebate revenues contributed by manufacturers. It is not possible to estimate how much rebate revenue would be available to support these discounts and administrative costs, or what the average savings per enrollee would be.

I hope you find this information helpful. Please contact me if you require additional information on this matter.

CM/lah



State Representative

2/27/01

Committee on Census and Redistricting Committee on Corrections & the Courts Committee on Public Health Committee on Children and Families

Special Committee on State-Tribal Relations



Fair Pricing Prescription Drug Act - Eligibility Criteria

1. Eligibility Criteria

- No age limit
- Program open to those who do not have prescription drug
- insurance since 90 slaves before a fig. to many and the open to those with income at or below 300 percent of federal poverty level - but not MA or Badger lane eligible
- No enrollment fee
- No deductible
- No co-payments

2. Benefits of Eligibility Requirements

- Targets drug discounts to those that most need price relief
- Targeted relief makes it more attractive to drug companies
- Prevents "dumping" of policyholders by private employers

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Eligibility Criteria 2/27/2001

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36/01 Questions to ask Dans de Felice
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From Dave 3/13/01
(3) Program rate? - As in model bies (AWP- 690, plus dispensing)
A habeler - Is to participate
D'acciers - are for placing dongs under prior authorization

By Thursday 3/15, if possible

2001 - 2002 LEGISLATURE

D-NOTE

DAK: which

2001 ASSEMBLY BILL 120

February 13, 2001 – Introduced by Representatives Wieckert, Friske, Gronemus, Rhoades, Pettis, Krawczyk, Petrowski, Loeffelholz, D. Meyer, Leibham, V. Fitzgerald, Townsend Reynolds, Lippert, McCormick, Bies, Ainsworth, Albers, Freese, Gunderson, Gundrum, Hoven, Hundertmark, Jeskewitz, Johnsrud, Kauffert, Krstell, Kreibich, F. Lasee, M. Lehman, Musser, Nass, Olsen, Ott, Owens, Stratti, Skindrud, Stone, Sykora, Travis, Underheim, Urban, Vrakas, Wade and Ward, cosponsored by Senators Rosenzweig, Harsdorf, S. Fitzgerald, Darling, Schultz and Roessler. Referred to Committee on Health.

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AN ACT to amend 49.47 (4) (b) 2m. b., 49.47 (4) (b) 2r., 49.47 (4) (b) 2w., 49.47 (4) (b) 3., 49.47 (4) (c) 1., 49.47 (4) (c) 3. and 49.47 (4) (i) 2. (intro.); and to create 20.435 (4) (bv), 20.435 (4) (j), 20.435 (4) (jb), 49.45 (48), 49.47 (4) (aq) and 49.688 of the statutes; relating to: expanding medical assistance income eligibility.

requirements for elderly personal requiring pharmacies and pharmacists, as a condition of medical assistance participation, to charge eligibility low—income persons for prescription drugs no more than specific amounts; specifying requirements for rebate agreements between the department of health and family services and drug manufacturers; land prior authorization requirements under medical assistance; requiring the exercise of rule—making authority; making appropriation; and providing penalties.

Analysis by the Legislative Reference Bureau

Under current state law, pharmacies and pharmacists that are certified providers of medical assistance (MA) services are reimbursed, at a rate established by the department of health and family services (DHFS), for providing certain prescription drugs to MA recipients. Under the MA program, numerous prescription

ASSEMBLY BILL 120

drugs must be authorized by DHFS prior to being dispensed to MA recipients. Under current federal law, persons entitled to coverage under part B of medicare do not receive coverage for prescription drugs for outpatient care as a benefit.

Under current law, an individual who is 65 years of age or older, blind, or permanently disabled, is eligible to receive MA if he or she meets certain income and asset requirements. Currently, to satisfy the income requirements for MA eligibility, an individual who is 65 years of age or older, blind, or permanently disabled must have an income that does not exceed 133.33% of the maximum payment amount under the former and to families with dependent children (AFDC) program or the combined benefit amount available under the federal supplemental security income (SSI) program.

Beginning March 1, 2002, this bill increases to 100% of the federal poverty level the maximum income level for eligibility for MA for individuals who are 65 years of age or older, blind, or permanently disabled.

This bill provides that, beginning March 1, 2002, persons who have applied for and have been found by DHFS to be eligible for prescription drug assistance and who have paid an annual enfollment fee of \$25 may use a card, issued by DHFS, to obtain certain prescription drugs for outpatient care at a rate that is the average wholesale price minus 5% or the maximum allowable cost, as determined by DHFS, whichever is less, plus a pharmacy dispensing fee. After an eligible person has paid a deductible by expending \$840 in a 12-month period for prescription drugs at this reduced rate. the person may obtain additional prescription drugs in that period by paying a copayment of \$10 for each generic drug and a copayment of \$20 for each drug that is not a generic drug. Persons who are eligible to obtain prescription drugs for these reduced charges are state residents who are at least 65 years of age are not MA recipients, and have household incomes, as determined by DHFS, that do not exceed 185% of the federal poverty line for a family the size of the persons' eligible families. As a condition of participation by a pharmacy or pharmacist in the MA program, the pharmacy or pharmacist may not charge persons who are eligible for prescription drug assistance more than these amounts; as a part of the costs chargeable for the deductible, the pharmacy or pharmacist may include a dispensing fee but may not charge a dispensing fee after the deductible is met. If a person who is eligible has other available coverage for prescription drugs, the program does not apply to the costs for prescription drugs available under that other coverage.

Under the bill. DHFS or an entity with which DHFS contracts may enter with drug manufacturers into rebate agreements that are modeled on federal medicaid rebate agreements, under which the manufacturer must make payments to the state treasurer for deposit in the general fund for the manufacturer's drugs that are prescribed and purchased under the program. The amount of the rebate payment under the agreement is required to be determined by the method that is specified under federal medicaid rebate agreements. The amounts of the rebate payments must, in turn, together with general purpose revenues, be paid by DHFS to pharmacies or pharmacists that have reduced charges for prescription drugs for the eligible persons. Payment is at the average wholesale price minus 5% or the maximum allowable cost, as determined by DHFS, whichever is less, minus any

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ASSEMBLY BILL 120

copayment made, plus a dispensing fee. If a manufacturer enters into a rebate agreement, DHFS may not, after February 28, 2002, and before March 1, 2004, expand the prior authorization requirements under the MA program or under the prescription drug program created under the bill for prescription drugs manufactured by that manufacturer beyond those prior authorization requirements in effect under the MA program on March 1, 2002.

Under the bill, DHFS is authorized to enter into a contract with an entity to perform DHFS' duties and exercise its powers, other than rule making, under the prescription drug assistance program. DHFS must, under the bill, promulgate rules that specify the criteria to be used to determine household income for persons eligible for prescription drug assistance. Prescription drugs for which the reduced charges must be made are those that are available as an MA benefit and that are manufactured by a manufacturer that enters into a rebate agreement with DHFS. DHFS must calculate and transmit to pharmacies and pharmacists that participate in the MA program the prices at the discounted rate that must be charged to certain eligible persons in meeting the deductible for prescription drugs and must periodically update this information and transmit the updated information to pharmacies and pharmacists. DHFS must monitor compliance by pharmacies and pharmacists with the requirement to charge eligible persons for the specified prescription drugs at the reduced amounts and annually report to the legislature concerning the compliance. DHFS also must promulgate rules that establish prohibitions against fraud that are substantially similar to MA fraud provisions; the bill specifies penalties applicable to violations of these prohibitions. If federal law is changed to provide coverage for outpatient prescription drugs as a benefit under medicare or another program, DHFS must provide a report to the legislature that analyzes the differences between the federal program and the program under the bill and that provides recommendations concerning alignment, ikany, of the differences. The bill appropriates \$2,000,000 in general purpose revenues in fiscal year 2001-02 to the joint committee on finance and authorizes DHFS to submit a proposal for review and approval by the department of administration and by the joint committee on finance, for expenditure of these moneys for administration of the program.

INSERT

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The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

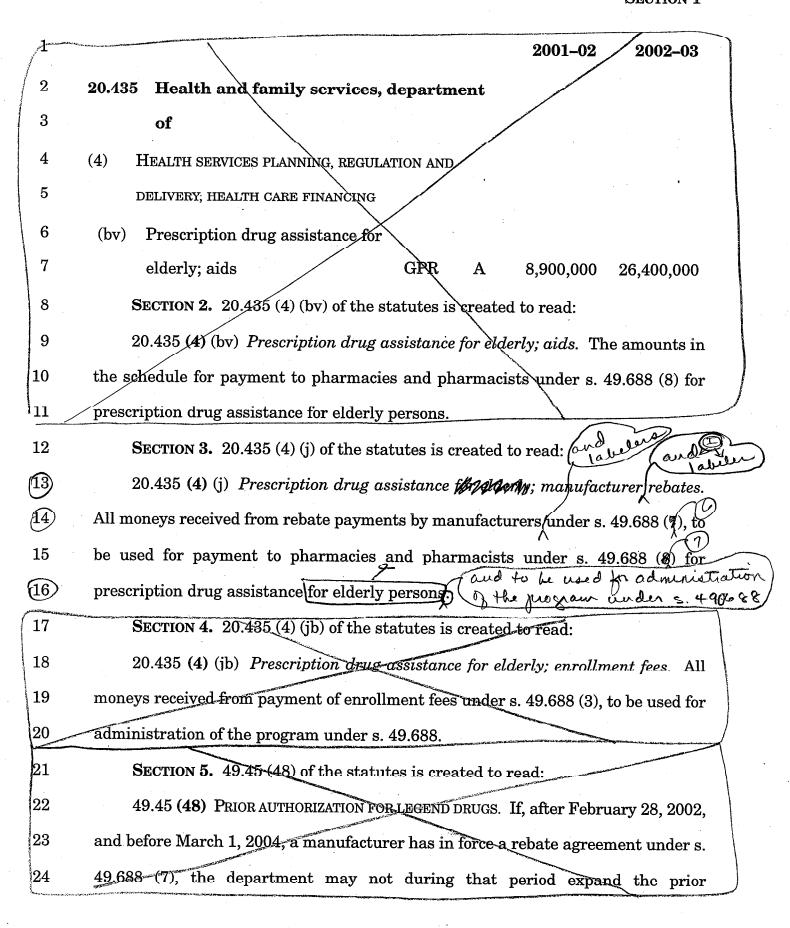
SECTION 1. 20.005 (3) (schedule) of the statutes: at the appropriate place, insert

For further information see the state and well fiscal estimate, which will be

2 the following amounts for the purposes indicated:

printed as an appendix to this bill.

ASSEMBLY BILL 120



, 1	authorization requirements for prescription drugs manufactured by the
2	manufacturer for which coverage is provided under s. 49.46 (2) (b) 6. h. beyond those
3	prior authorization requirements that are in effect on March 1, 2002
4	SECTION 6. 49.47 (4) (aq) of the statutes is created to read:
5	49.47 (4) (aq) 1. Subject to subd. 2., an individual who does not meet the
6	limitation on income under par. (c) is eligible for medical assistance if the individual's
7	income does not exceed 100% of the federal poverty level, and the individual is 65
8	years of age or older or is blind or totally and permanently disabled, as defined under
9	federal Title XVI.
10	2. If a federal waiver is necessary to provide medical assistance to individuals
11	specified in subd. 1., the department shall request a waiver from the secretary of the
12	federal department of health and human services before providing medical
13	assistance under this paragraph.
14	SECTION 7. 49.47 (4) (b) 2m. b. of the statutes is amended to read:
15	49.47 (4) (b) 2m. b. For persons who are eligible under par. (a) 3. or 4. or (aq),
16	motor vehicles are exempt from consideration as an asset to the same extent as
17	provided under 42 USC 1381 to 1385.
·18	SECTION 8. 49.47 (4) (b) 2r. of the statutes is amended to read:
19	49.47 (4) (b) 2r. For a person who is eligible under par. (a) 3. or 4. or (aq), the
20	value of any burial space or agreement representing the purchase of a burial space
21	held for the purpose of providing a place for the burial of the person or any member
22	of his or her immediate family.
23	SECTION 9. 49.47 (4) (b) 2w. of the statutes is amended to read:

25,

49.47 (4) (b) 2w. For a person who is eligible under par. (a) 3, or 4. or (aq), life insurance with cash surrender values if the total face value of all life insurance policies is not more than \$1,500.

SECTION 10. 49.47 (4) (b) 3. of the statutes is amended to read:

49.47 (4) (b) 3. For a person who is eligible under par. (a) 3. or 4. or (aq), funds set aside to meet the burial and related expenses of the person and his or her spouse in an amount not to exceed \$1,500 each, minus the sum of the cash value of any life insurance excluded under subd. 2w. and the amount in any irrevocable burial trust under s. 445.125 (1) (a).

SECTION 11. 49.47 (4) (c) 1. of the statutes is amended to read:

49.47 (4) (c) 1. Except as provided in par pars. (am) and (aq) and as limited by subd. 3., eligibility exists if income does not exceed 133 1/3% 133.33% of the maximum aid to families with dependent children payment under s. 49.19 (11) for the applicant's family size or the combined benefit amount available under supplemental security income under 42 USC 1381 to 1383c and state supplemental aid under s. 49.77 whichever is higher. In this subdivision "income" includes earned or unearned income that would be included in determining eligibility for the individual or family under s. 49.19 or 49.77, or for the aged, blind or disabled under 42 USC 1381 to 1385. "Income" does not include earned or unearned income which would be excluded in determining eligibility for the individual or family under s. 49.19 or 49.77, or for the aged, blind or disabled individual under 42 USC 1381 to 1385.

SECTION 12. 49.47 (4) (c) 3. of the statutes is amended to read:

49.47 (4) (c) 3. Except as provided in par. pars. (am) and (aq), no person is eligible for medical assistance under this section if the person's income exceeds the

NSERI

	1	maximum income levels that the U.S. department of health and human services sets
	2	for federal financial participation under 42 USC 1396b (f).
	3	SECTION 13. 49.47 (4) (i) 2. (intro.) of the statutes is amended to read:
	4	49.47 (4) (i) 2. (intro.) Notwithstanding par. (b) 2r. and 3., a person who is
	5	described in par. (a) 3. or 4. or (aq) is not eligible for benefits under this section if any
	6	of the following criteria is met:
NSER 7-6	7/7	SECTION 149.688 of the statutes is created to read:
	®	49.688 Prescription drug assistance for low-income Activity persons.
	9	(1) In this section:
INSER	110 V	(17(b).
7-10		(Poverty line" means the nonfarm federal poverty line for the continental
	12	United States, as defined by the federal department of labor under 42 USC 9902 (2).
	(13)	(Prescription drug" means a prescription drug, as defined in s. 450.01 (20),
	(14)	that is included in the drugs specified under s. 49.46 (2) (b) 6. h. and that is
	15	manufactured by a manufacturer that enters into a rebate agreement in force under
	<u>16</u>	have hearth
,	17)	"Prescription order" has the meaning given in s. 450.01 (21).
	18	(2) A person who is a resident, as defined in s. 27.01 (10) (a), of this state, with
	(19)	is at least 61 fears of age, who is not a recipient of medical assistance, whose annual
	20	household income, as determined by the department, does not exceed 185% of the 300%
	21	poverty line for a family the size of the person's eligible family, and who pays the
16	(22)	program enrollment fee specified in sublication is eligible to purchase a prescription
	23	drug at the amounts specified in sub. The person may apply to the
	(24)	department, on a form provided by the department together with proprets
		(Not) has not had insurance coverage for prescription drugs for outpatient care for at least 90 days prior to applying under this subsection

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\bigcirc 1	enrollment feel payment, for a determination of eligibility and issuance of a
2	prescription drug card for purchase of prescription drugs under this section.
3 ((3) (a) Program participants shall pay all of the following:)
4	1. For each 12-month benefit period, a program enrollment fee of \$25.
5	2. For each 12-month benefit period, a deductible for each person of \$840.
6	3. After payment of the deductible under subd. 2., all of the following:
7	a. A copayment of \$10 for each prescription drug that bears only a generic
8 .	name.
9	b A copayment of \$20 for each prescription drug that does not bear only a
10	generic name.
11	Notwithstanding s. 49.002, if a person who is eligible under this section has
12	other available coverage for payment of a prescription drug, this section applies only
13	to costs for prescription drugs for the person that are not covered under the person's
14	other available coverage.
15)	The department shall devise and distribute a form for application for the
16	program under sub. (2), shall determine eligibility for each 12-month benefit period
17	of applicants, and shall issue to eligible persons a prescription drug card for use in
18	purchasing prescription drugs, as specified in sub. (3). The department shall
19	$^{\wedge}$ promulgate rules that specify the criteria to be used to determine annual household
20	income under sub. (2).
21)	Beginning March 1, 2002, as a condition of participation by a pharmacy or
22	pharmacist in the program under ss. 49.45, 49.46, or 49.47, the pharmacy or
23	pharmacist may not charge a person who presents a valid prescription order and a
24	card indicating that he or she meets eligibility requirements under sub. (2) an

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(2), to the state treasurer to be credited to the appropriation under s. 20.435 (4) (j), 1 2 each calendar quarter or according to a schedule established by the department. (b) That the amount of the rebate payment such be determined by a method SERT revenue receive d'un der specified in 42 USC 18967-84cm From the appropriation accounts under s. 20.435 (4) March 1,2002, the department shall, under a schedule that is identical to that ased by the department for payment of pharmacy provider elaims under medical assistance provide to pharmacies and pharmacists payments for prescription drugs 8 sold by the pharmacies or pharmacista to persons eligible under sub. (2) who have **(10)** paid the deductible specified under sub. (3) (3) The payment for each prescription drug under this subsection shall be at the rate specified in sub. (6) (a), minusthe (12)of a copayment charged under sub. (6) (b) Applied addispensing feed as INSER $\widehat{13}$ The department shall devise and distribute a form for specified in sub. 267 2001. reports by pharmacies and pharmacists under this subsection and may limit 14 15 payment under this subsection to those prescription drugs for which payment claims are submitted by pharmacies or pharmacists directly to the department. 16 department may apply to the program under this section the same utilization and 17 cost control procedures that apply under rules promulgated by the department to 18 medical assistance under subch. IV. The department may not impose transaction **(19)** ses on Pharmacies or pharmacists that submit claims or receive payments The department shall, under methods promulgated by the department by unden Huis rule, monitor compliance by pharmacies and pharmacists that are certified providers 21 $\langle 22 \rangle$ of medical assistance with the requirements of sub. (*) and shall (annually report/to the legislature under s. 13.172 (2) concerning the compliance. The report shall 23

include information on any pharmacies or pharmacists that discontinue

1	participation as certified providers of medical assistance and the reasons given for
2 121)	the discontinuance.
3	(10) (a) The department shall promulgate rules relating to prohibitions on
4	fraud that are substantially similar to applicable provisions under s. 49.49 (1) (a).
5	(b) A person who is convicted of violating a rule promulgated by the department
6	under par. (a) in connection with that person's furnishing of prescription drugs under
7	this section may be fined not more than \$25,000, or imprisoned for not more than 7
8	years and 6 months, or both.
9	(c) A person other than a person specified in par. (b) who is convicted of violating
10	a rule promulgated by the department under par. (a) may be fined not more than
11	\$10,000, or imprisoned for not more than one year, or both.
12	(11) If federal law is amended to provide coverage for prescription drugs for
13	outpatient care as a benefit under medicare or to provide similar coverage under
14	another program, the department shall submit to appropriate standing committees
15	of the legislature under s. 13.172 (3) a report that contains an analysis of the
16	differences between such a federal program and the program under this section and
17	that provides recommendations concerning alignment, if any, of the differences.
18	(12) After February 28, 2002, and before March 1, 2004, the department may
19	not subject a manufacturer that enters into a rebate agreement under sub. (7) to prior

program on March 1, 2002.

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(6)(c) and (8)+0 (10)

Except as provided in subs. (9) to (12), and except for the department's rule-making requirements and authority, the department may enter into a contract

authorization requirements for a prescription drug under this section that are an

expansion of prior authorization requirements in effect under the medical assistance

with an entity to perform the duties and exercise the powers of the department under

this section.

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SECTION 15. Nonstatutory provisions.

(1) Prescription drug assistance for elderly; administration. Before July 1, 2001, the department of health and family services may develop and submit to the department of administration a proposal for expenditure of the funds appropriated under section 20.865 (4) (a) of the statutes for administration of the prescription drug assistance for elderly program under section 49.688 of the statutes, as created by this act. The department of administration may approve, disapprove, or modify and approve any proposal it receives under this subsection. If the department of administration approves the proposal, the department shall submit the proposal, together with any modifications, to the cochairpersons of the joint committee on finance. If the cochairpersons of the committee do not notify the secretaries of administration and health/and family services within 14 working days after receiving the proposal that the cochairpersons have scheduled a meeting for the purpose of reviewing the proposal, the secretary of administration may transfer from the appropriation under section 20.865 (4) of the statutes to the appropriation under section 20.435 (4) (a) of the statutes the amount specified in the proposal or any proposed modifications of the proposal for expenditure as specified in the proposal or any proposed modifications of the proposal and may approve any position authority specified in the proposal or any proposed modifications of the proposal. If, within 14 working days after receiving the proposal, the cochair persons notify the secretaries of administration and health and family services that the cochairpersons have scheduled a meeting for the purpose of reviewing the proposal, the secretary of administration may not transfer any amount specified in the proposal or any

	The state of the s
1	proposed modifications of the proposal from the appropriation under section 20.865
2	(4) of the statutes and may not approve any position authority specified in the
3	proposal or any proposed modifications of the proposal, except as approved by the
4	committee.
5	SECTION 16. Appropriation changes.
6	(1) Prescription drug assistance for exderly; administration. In the schedule
7	under section 20.005 (3) of the statutes for the appropriation to the joint committee
8	on finance under section 20.865 (4) (a) of the statutes, as affected by the acts of 1999,
9	the dollar amount is increased by \$2,000,000 for fiscal year 2001-02 to increase
10	funding for administration of the prescription drug assistance for elderly program
11	under section 49.608 of the statutes, as created by this act.
12	SECTION 17. Initial applicability.
13	(1) MEDICAL ASSISTANCE ELIGIBILITY. The treatment of section 49.47 (4) (aq), (b)
14	2m/b., 2r., 2w., and 3., (c) 1. and 3., and (i) 2. (intro.) of the statutes first applies to
15	eligibility determinations made for medical assistance on the effective date of this
16	subsection.
17	SECTION 18. Effective date. This act takes effect on the 2nd day after
(18)	2001-2003 públication of the biennial budget act prophastation
1907	(1) PRESCRIPTION DRUG ASSISTANCE FOR ELDERLY. The treatment of section 207438
202	(4) (bv) of the statutes takes effect on March 13 2002,
21	(2) MEDICAL ASSISTANCE ELIGIBILITY. The treatment of section 49.47 (4) (aq), (b)
22	2m. b., 2r., 2w., and 3., (c) 1. and 3., and (i) 2. (intro.) of the statutes and Section 17
23	(1) of this act take effect on March 1, 2002.
24	(END)

D-NOTE

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2001–2002 DRAFTING INSERT FROM THE LEGISLATIVE REFERENCE BUREAU

INSERT A

Under current law, pharmacies and pharmacists that are certified providers of medical assistance (MA) services are reimbursed, at a rate established by the department of health and family services (DHFS), for providing certain prescription drugs to MA recipients. Under the MA program, numerous prescription drugs are subject to prior authorization and must be authorized by DHFS prior to being dispensed to MA recipients.

This bill provides that, beginning March 1, 2003, persons who have applied for and have been found by DHFS to be eligible for prescription drug assistance may use a card, issued by DHFS, to obtain certain prescription drugs for outpatient care at a rate that is the average wholesale price minus 6% or the maximum allowable cost. as determined by DHFS, whichever is less, plus a pharmacy dispensing fee that is not less than the dispensing fee paid under MA. After September 30, 2003, an eligible person may obtain prescription drugs by paying this rate, plus the dispensing fee, minus the amount of any rebate amount received by DHFS under rebate agreements with drug manufacturers and repackagers of the drugs (labelers). In determining the amounts discounted by the rebate, DHFS must consider an average of all rebate payments made, as weighted by the sales of prescription drugs subject to the rebates over the most recent 12-month period for which the information is available. The pharmacy or pharmacist who sells the drug at these reduced prices receives reimbursement for the rebate amount from DHFS. Persons who are eligible to obtain prescription drugs for these reduced charges are state residents who are not MA recipients and do not have coverage under Badger Care; who have household incomes, as determined by DHFS, that do not exceed 300% of the federal poverty line for a family the size of the persons' eligible families; and who have not had insurance coverage for outpatient prescription drugs for at least 90 days prior to applying for the program.

Under the bill, DHFS or an entity with which DHFS contracts may enter with drug manufacturers or labelers into rebate agreements that take into consideration federal medicaid rebate agreements, the average wholesale price of prescription drugs, and any other available information on prescription drug prices and price discounts. Under the rebate agreement, the manufacturer or labeler must make payments to the state treasurer for deposit in the general fund for the manufacturer's or labeler's drugs that are prescribed and purchased under the program. DHFS must collect from pharmacies and pharmacists utilization data necessary to calculate the amounts to be rebated; patient-identifiable data that is collected must be treated by DHFS as a patient health care record for purposes of confidentiality. The amounts of the rebate payments must be paid to the state and, in turn, paid by DHFS to pharmacies or pharmacists that have reduced charges for prescription drugs for the eligible persons. If a manufacturer or labeler elects not to enter into a rebate agreement, DHFS must determine, under procedures that are required to be established by rule, whether to subject the manufacturer's or labeler's drugs to prior authorization requirements under MA. DHFS may disseminate to the

public information that specifies the names of manufacturers or labelers that elect not to enter into rebate agreements. In addition, DHFS must disseminate to health professionals information about the relative cost of prescription drugs of manufacturers or labelers that enter into rebate agreements in comparison with the cost of prescription drugs of manufacturers or labelers that do not enter into rebate agreements. Discrepancies in amounts claimed by pharmacies and amounts rebated by a manufacturer or labeler or in information provided by DHFS to the manufacturer or labeler regarding the rebate may be reviewed by independent auditors. If the discrepancy continues following the audit, additional amounts due must be paid, or DHFS must refund excess payment made, as appropriate. For further controversies, one of the parties may request an administrative hearing. DHFS must request from the secretary of the federal department of health and human services a waiver of any federal medicaid laws necessary to implement the bill's prior authorization requirements under MA.

Under the bill, DHFS must monitor compliance by pharmacies and pharmacists with the requirement to charge eligible persons for the specified prescription drugs at the reduced amounts and annually report to the legislature concerning the compliance. DHFS also must promulgate rules that establish prohibitions against fraud that are substantially similar to MA fraud provisions; the bill specifies penalties applicable to violations of these prohibitions.

The bill requires that DHFS promulgate as rules procedures for determining whether to subject drugs produced by a manufacturer or repackaged by a labeler to prior authorization requirements under MA. In addition, the pharmacy examining board must promulgate rules requiring disclosure by a pharmacist to a drug purchaser who is a participant under the program of the amount of the discount on the retail price of the drug that is provided to the participant under the program.

For further information see the **state** fiscal estimate, which will be printed as an appendix to this bill.

INSERT 7-6
SECTION 4. 49.45 (53) of the statutes is created to read:

49.45 (53) Prior authorization for Legend Drugs. (a) In this subsection:

1. "Labeler" means a person that receives prescription drugs from a manufacturer or wholesaler, repackages the prescription drugs for later retail sale, and has a labeler code issued by the federal food and drug administration under 21 CFR 207.20 (b).

3. 24 "Prescription drug" means a prescription drug, as defined in s. 450.01 (20),

that is included in the drugs specified under s. 49.46 (2) (b) 6. h.

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- *Manufacturer" means a manufacturer of prescription drugs and includes a subsidiary or affiliate of the manufacturer.
- (b) The department shall promulgate as rules procedures for determining, under s. 49.688 (7) (c), whether to subject all prescription drugs produced by a manufacturer or repackaged by a labeler to prior authorization requirements under medical assistance. The rules shall include all of the following:
- 1. Authorization to subject a prescription drug to prior authorization requirements only if considerations relating to safety, efficacy, and disease management are not compromised by denial of the prior authorization or substitution of the drug with an equivalent.
- 2. A definition of "equivalent" that includes a specific list of alternate prescription drugs for the purposes of subd. 1. \checkmark
- 3. Authorization for a physician to prescribe up to a month's dosage of a prescription drug that is otherwise subject to prior authorization requirements, if the physician asserts that the equivalent is unacceptable or not immediately available and provides evidence that the prescription drug is medically necessary under medical assistance standards.
- 4. Standards for review by the department of requests by physicians for prescription drugs that are subject to prior authorization requirements.
- 5. Procedures, including hearings, for appeals of denials of requests by physicians for prescription drugs that are subject to prior authorization requirements.
- 6. Coverage under medical assistance, of a prescription drug subject to prior authorization during the pendency of an appeal of a denial of a request by a physician to prescribe the prescription drug.

INSERT 7-10

(a) "Labeler" means a person that receives prescription drugs from a manufacturer or wholesaler, repackages the drugs for later retail sale, and has a labeler code issued by the federal food and drug administration under 21 CFR 207.20 (b). √

(b) "Manufacturer" means a manufacturer of prescription drugs and includes a subsidiary or affiliate of the manufacturer.

INSERT 9-13

2. After September 30, 2003, the rate specified in subd. 1., plus the dispensing fee specified in subd. 1., minus the amount of any rebate payment made by a manufacturer or labeler that is applicable to the prescription drug, as determined by the department. In determining the amount by which a prescription drug shall be discounted under this subdivision, the department shall consider an average of all rebate payments made, as weighted by the sales of prescription drugs subject to the rebates over the most recent 12-month period for which the information is available.

INSERT 10-4

- (b) The department shall collect from pharmacies and pharmacists utilization data necessary to calculate the amounts to be rebated under a rebate agreement under par. (a). Any patient-identifiable data, as defined in s. 153.50 (1) (b) 1., that is collected under this paragraph shall be treated as a patient health care record for purposes of s. 146.82.
- (c) If a manufacturer or labeler elects not to enter into a rebate agreement under par. (a), the department shall determine, under procedures established by rule by the department under s. 49.45 (53), whether to subject the prescription drugs of

the manufacturer or of the labeler to prior authorization requirements under the medical assistance program.

- (d) The department may disseminate to the public information that specifies the names of manufacturers or labelers that elect not to enter into rebate agreements.
- (e) The department shall disseminate to physicians, pharmacies, pharmacists, and, as determined by the department, to other health professionals information about the relative cost of prescription drugs produced by manufacturers or packaged by labelers that enter into rebate agreements in comparison with the cost of prescription drugs produced by manufacturers or packaged by labelers that do not enter into rebate agreements.
- (f) l. If a discrepancy exists in the manufacturer's or labeler's favor between the amount claimed by a pharmacy under sub. (7) and the amount rebated by the manufacturer or labeler under sub. (6), the department may hire an independent auditor who is agreed on by the parties to review the discrepancy. If the discrepancy continues following the audit, the manufacturer or labeler shall justify the reason for the discrepancy or pay to the department any additional amount due.
- 2. If a discrepancy exists that is not in favor of the manufacturer or labeler in the information provided by the department to the manufacturer or labeler regarding the manufacturer's or retailer's rebate, the manufacturer or labeler may hire an independent auditor who is agreed on by the parties to verify the accuracy of the data supplied to the department. If a discrepancy continues following the audit, the department shall justify the reason for the discrepancy or refund to the manufacturer or labeler any excess payment made by the manufacturer or labeler.

3. If a controversy continues after the procedures under subd. 1. or 2. have been 1 2 carried out, the department or the manufacturer or labeler may request a hearing before the division of hearings and appeals of the department of administration as 3 a contested case under ch. 227. 4 **INSERT 10-13** on a weekly or biweekly basis, pay a pharmacy or pharmacist for a prescription 5 drug purchased as specified under sub. (4) an amount that is equal to the pharmacy's 6 or pharmacist's share of the rebate amount, if any, for the prescription drug, as 7 determined by the department under sub. (5) (a) 2. 8 INSERT 11-2 (9) The department shall request from the secretary of the federal department 9 of health and human services a waiver of any federal medicaid laws necessary to 10 implement prior authorization requirements specified in sub. () (c). (11)**INSERT 11-22** (11) The department shall do all of the following: 12 (a) Promote the use of efficacious and reduced-cost prescription drugs, taking 13 into consideration differential dispensing fees, administrative overhead, and 14 incentive payments. 15 16 (b) Undertake outreach efforts to build public awareness of the program under 17 this section and to maximize enrollment by eligible persons. INSERT 12-2 SECTION 2 146.82 (2) (a) 17. of the statutes is amended to read: 18 19 146.82 (2) (a) 17. To the department under s. 49.688 (7) (b) or 50.53 (2). 241, 332, 340; 1987 a. 40, 70, 127, 215, 233, 380, 399; 1989 a. 31, 102, 334, 336; 1991 a. 39; 1993 a. 16, 27, 445, 479; 1995 b.; 1999 a. 32, **7**8, 83, 114, 151; s. 13.93 (1) (b).

450.02 (2) of the statutes is amended to read:

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History: 1979
a. 98, 169, 417; 19

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April 1979
April

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1	450.02 (2) The board shall adopt rules defining promulgate all of the following
2	rules, which apply to all applicants for licensure under s. 450.05: (a) Defining the
3	active practice of pharmacy. The rules shall apply to all applicants for licensure

History: 1985 a. 146; 1987 a. 65; 1987 a. 448; 1997 a. 68; 1997 a. 237 s. 727m.

SECTION 45, 450.02 (2) (b) of the statutes is created to read:

under s. 450.05.

450.02 (2) (b) Requiring disclosure by a pharmacist to a prescription drug purchaser who is a program participant under s. 49.688 of the amount of the discount on the retail price of the prescription drug that is provided to the participant as the result of the program under s. 49.688.

DRAFTER'S NOTE FROM THE LEGISLATIVE REFERENCE BUREAU

LRB-0585/kdn DAK: WL

To Representative Coggs:

Please review this draft very carefully; some of its features are included in either 2001 Senate Bill 1 or 2001 Assembly Bill 120, or both. The following are issues that arose in drafting:

- 1. In the bills mentioned above, "prescription drug" is defined to be, among other things, a drug manufactured by a manufacturer that enters into a rebate agreement. As that definition operates under those bills, therefore, if a manufacturer elects not to enter into a rebate agreement, the manufacturer's drugs would not be purchased by program participants. I did not draft the term "prescription drug" in the same fashion for this bill, because the program participants will be receiving a discounted price for purchase of drugs, regardless of whether the manufacturer or labeler enters into a rebate agreement. If this is not your intent, please let me know.
- 2. Section 49.688 (3) requires that DHFS determine eligibility for each 12-month benefit period of applicants. Originally when we spoke of this issue, you had eliminated the benefit period, which made little sense if all state residents were eligible. However, if only those residents at or below 300% of the federal poverty line are eligible, it would seem to be important for DHFS to review their income annually; otherwise fraud might occur. Does this meet your intent?
- 3. Section 49.688 (4) requires a pharmacy or pharmacist to charge no more than the discounted prices as a condition of participation by the pharmacy or pharmacist in the medical assistance program. Okay?
- 4. An alternative to requiring that a person have had no insurance coverage for outpatient prescription drugs for 90 days prior to applying for the program (see s. 49.688 (2)) would be to state that if an eligible person has other available coverage for payment of prescription drugs, the program applies only to costs of prescription drugs for the person that are not covered under the other available coverage.
- 5. Please review the language concerning the discounted amount for a drug under s. 49.688 (5) (a) 2.; the language occurs in the Model Act, but I'm not entirely sure of its meaning, or how it would work.
- 6. Please review s. 49.688 (6) (b). I lack knowledge concerning any federal statute or regulation that would require confidentiality protection for the utilization data

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collected under that paragraph. Is my treatment concerning the data as a patient health care record what you want?

- 7. Section 49.688 (7) permits DHFS to apply to the prescription drug program the same utilization and cost control procedures that apply under medical assistance. Okay?
- 8. Please note that, although the "Explanation of Legal Issues in the Prescription Drug Fair Pricing Act" that accompanies the Model Act indicates that the prescription drug program in general, and the prior authorization provisions in particular will lower some drug prices that the Medicaid program pays, there appears to be no direct way that is specified in the Model Act's language, or in this draft, that accomplishes that assertion.

I would suggest that Charlie Morgan or Rachel Carabell, or both, review this draft.

Please let me know if I may provide you with further assistance with regard to the draft.

Debora A. Kennedy Managing Attorney Phone: (608) 266–0137

E-mail: debora.kennedy@legis.state.wi.us

publication of the budget bies and have set

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the start date for the program to be march 1, 2003.

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(a) Awp mines 6% (as in the Model Act) or the

maximum allowable cost (MAC), as determined by

DHFS, whichever is less, because it is my

understanding that occasionally the MAC is

lower Oray?

LRB–0585/1dn DAK:wlj:jf

DRAFTER'S NOTE FROM THE LEGISLATIVE REFERENCE BUREAU

March 15, 2001

To Representative Coggs:

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- 6. Please review s. 49.688 (6) (b). I lack knowledge concerning any federal statute or regulation that would require confidentiality protection for the utilization data

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- 8. Please note that, although the "Explanation of Legal Issues in the Prescription Drug Fair Pricing Act" that accompanies the Model Act indicates that the prescription drug program in general, and the prior authorization provisions in particular, will lower some drug prices that the Medicaid program pays, there appears to be no direct way that is specified in the Model Act's language, or in this draft, that accomplishes that assertion.
- 9. I have made the bill effective after publication of the budget bill and have set the start day for the program to be March 1, 2003. Okay?
- 10. I have made the rate, under s. 49.688 (5) (a), AWP minus 6% (as in the Model Act) or the maximum allowable cost (MAC), as determined by DHFS, whichever is less, because it is my understanding that occasionally the MAC is lower. Okay?

I would suggest that Charlie Morgan or Rachel Carabell, or both, review this draft.

Please let me know if I may provide you with further assistance with regard to the draft.

Debora A. Kennedy Managing Attorney Phone: (608) 266–0137

E-mail: debora.kennedy@legis.state.wi.us

STATE OF WISCONSIN – LEGISLATIVE REFERENCE BUREAU – LEGAL SECTION (608–266–3561)

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Change Start date of	o much 1, 2002.
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