TODAY

State of Wisconsin
2001 – 2002 LEGISLATURE

LRB–0585/E2
DAK:wlj

2001 BILL

REGEN

AN ACT *to amend* 146.82 (2) (a) 17. and 450.02 (2); and *to create* 20.435 (4) (j), 49.45 (53), 49.688 and 450.02 (2) (b) of the statutes; **relating to:** requiring pharmacies and pharmacists, as a condition of medical assistance participation, to charge 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 or labelers; expanding prior authorization requirements under medical assistance; requiring the exercise of rule–making authority; making an appropriation; and providing penalties.

2002

Analysis by the Legislative Reference Bureau

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~~ 2002, persons who have applied for and have been found by DHFS to be eligible for prescription drug assistance may use

2002

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, ~~2002~~, 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.

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

SECTION 1. 20.435 (4) (j) of the statutes is created to read:

20.435 **(4)** (j) *Prescription drug assistance; manufacturer and labeler rebates.* All moneys received from rebate payments by manufacturers and labelers under s. 49.688 (6), to be used for payment to pharmacies and pharmacists under s. 49.688 (7) for prescription drug assistance and to be used for administration of the program under s. 49.688.

SECTION 2. 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).

2. "Manufacturer" means a manufacturer of prescription drugs and includes a subsidiary or affiliate of the manufacturer.

3. "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.

(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.

3. Authorization for a physician to prescribe up to one 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.

SECTION 3. 49.688 of the statutes is created to read:

49.688 Prescription drug assistance for low–income persons. (1) In this section:

(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.

(c) "Poverty line" means the nonfarm federal poverty line for the continental United States, as defined by the federal department of labor under 42 USC 9902 (2).

(d) "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.

(e) "Prescription order" has the meaning given in s. 450.01 (21).

(2) A person who is a resident, as defined in s. 27.01 (10) (a), of this state, who is not a recipient of medical assistance, who does not have health care coverage under s. 49.665, whose annual household income, as determined by the department, does not exceed 300% of the poverty line for a family the size of the person's eligible family, and who has not had insurance coverage for prescription drugs for outpatient care for at least 90 days prior to applying under this subsection is eligible to purchase a prescription drug at the amounts specified in sub. (5) (a). The person may apply to the department, on a form provided by the department, for a determination of

eligibility and issuance of a prescription drug card for purchase of prescription drugs under this section.

(3) The department shall devise and distribute a form for applying for the program under sub. (2), shall determine eligibility for each 12–month benefit period of applicants, and shall issue to eligible persons a prescription drug card for use in purchasing prescription drugs, as specified in sub. (4). The department shall promulgate rules that specify the criteria to be used to determine annual household income under sub. (2).

(4) Beginning March 1, ~~2003~~ 2002, as a condition of participation by a pharmacy or pharmacist in the program under ss. 49.45, 49.46, or 49.47, the pharmacy or pharmacist may not charge a person who presents a valid prescription order and a card indicating that he or she meets eligibility requirements under sub. (2) an amount for a prescription drug under the order that exceeds the amounts specified in sub. (5) (a).

(5) (a) The amounts that a pharmacy or pharmacist may charge a person specified in sub. (2) in a 12–month period for a prescription drug are the following:

1. After ~~March 1,~~ February 28, 2002, and before October 1, 2002, the average wholesale price minus 6% or the maximum allowable cost, as determined by the department, whichever is less, plus a dispensing fee that is specified by the department but is not less than the dispensing fee paid under the medical assistance program.

2. After September 30, ~~2003~~ 2002, 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.

(b) The department shall calculate and transmit to pharmacies and pharmacists that are certified providers of medical assistance amounts that may be used in calculating charges under par. (a). The department shall periodically update this information and transmit the updated amounts to pharmacies and pharmacists.

(6) (a) The department or an entity with which the department contracts may enter into a rebate agreement that takes into consideration the rebate agreement specified under 42 USC 1396r–8, the average wholesale price of prescription drugs, and any other available information on prescription drug prices and price discounts, with a manufacturer that sells prescription drugs in this state or with a labeler that repackages prescription drugs for sale in this state. The rebate agreement, if negotiated, shall require that the manufacturer make rebate payments for each prescription drug of the manufacturer that is purchased by persons who are eligible under sub. (2), to the state treasurer to be credited to the appropriation under s. 20.435 (4) (j), each calendar quarter or according to a schedule established by the department.

(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) 1. 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 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 a contested case under ch. 227.

(7) From revenue received under the appropriation account under s. 20.435 (4) (j), department shall, on a weekly or biweekly basis, pay a pharmacy or pharmacist for a prescription drug purchased as specified under sub. (4) an amount that is equal to the pharmacy's or pharmacists share of the rebate amount, if any, for the prescription drug, as determined by the department under sub. (5) (a) 2. The department shall devise and distribute a form for reports by pharmacies and pharmacists under this subsection and may limit payment under this subsection to those prescription drugs for which payment claims are submitted by pharmacies or pharmacists directly to the department. The department may apply to the program under this section the same utilization and cost control procedures that apply under rules promulgated by the department to medical assistance under subch. IV. The department may not impose transaction charges on pharmacies or pharmacists that submit claims or receive payments under this subsection.

(8) The department shall, under methods promulgated by the department by rule, monitor compliance by pharmacies and pharmacists that are certified providers of medical assistance with the requirements of sub. (4) and shall report annually to the legislature under s. 13.172 (2) concerning the compliance. The report shall include information on any pharmacies or pharmacists that discontinue participation as certified providers of medical assistance and the reasons given for the discontinuance.

(9) The department shall request from the secretary of the federal department of health and human services a waiver of any federal medicaid laws necessary to implement prior authorization requirements specified in sub. (6) (c).

(10) (a) The department shall promulgate rules relating to prohibitions on fraud that are substantially similar to applicable provisions under s. 49.49 (1) (a).

(b) A person who is convicted of violating a rule promulgated by the department under par. (a) in connection with that person's furnishing of prescription drugs under this section may be fined not more than $25,000, or imprisoned for not more than 7 years and 6 months, or both.

(c) A person other than a person specified in par. (b) who is convicted of violating a rule promulgated by the department under par. (a) may be fined not more than $10,000, or imprisoned for not more than one year, or both.

(11) The department shall do all of the following:

(a) Promote the use of efficacious and reduced–cost prescription drugs, taking into consideration differential dispensing fees, administrative overhead, and incentive payments.

(b) Undertake outreach efforts to build public awareness of the program under this section and to maximize enrollment by eligible persons.

(12) Except as provided in subs. (6) (c) and (8) to (10), and except for the department's rule–making requirements and authority, the department may enter into a contract with an entity to perform the duties and exercise the powers of the department under this section.

SECTION 4. 146.82 (2) (a) 17. of the statutes is amended to read:

146.82 **(2)** (a) 17. To the department under s. 49.688 (7) (b) or 50.53 (2).

SECTION 5. 450.02 (2) of the statutes is amended to read:

450.02 **(2)** The board shall ~~adopt rules defining~~ promulgate all of the following rules, which apply to all applicants for licensure under s. 450.05:

(a) Defining the active practice of pharmacy. ~~The rules shall apply to all applicants for licensure under s. 450.05.~~

SECTION 6. 450.02 (2) (b) of the statutes is created to read:

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.

SECTION 7. Effective date. This act takes effect on the 2nd day after publication of the 2001–2003 biennial budget act.

(END)

State of Wisconsin

LEGISLATIVE REFERENCE BUREAU

100 NORTH HAMILTON STREET
5TH FLOOR
MADISON, WI 53701-2037

STEPHEN R. MILLER
CHIEF

LEGAL SECTION: (608) 266-3561
LEGAL FAX: (608) 264-6948

March 20, 2001

MEMORANDUM

To: Representative Coggs

From: Debora A. Kennedy, Managing Attorney

Re: LRB-0585 Prescription drugs for elderly--Maine pricing plan

The attached draft was prepared at your request. Please review it carefully to ensure that it is accurate and satisfies your intent. If it does and you would like it jacketed for introduction, please indicate below for which house you would like the draft jacketed and return this memorandum to our office. If you have any questions about jacketing, please call our program assistants at 266-3561. Please allow one day for jacketing.

__✓__ JACKET FOR ASSEMBLY ____ JACKET FOR SENATE

If you have any questions concerning the attached draft, or would like to have it redrafted, please contact me at (608) 266-0137 or at the address indicated at the top of this memorandum.

If the last paragraph of the analysis states that a fiscal estimate will be prepared, the LRB will request that it be prepared after the draft is introduced. You may obtain a fiscal estimate on the attached draft before it is introduced by calling our program assistants at 266-3561. Please note that if you have previously requested that a fiscal estimate be prepared on an earlier version of this draft, you will need to call our program assistants in order to obtain a fiscal estimate on this version before it is introduced.

Please call our program assistants at 266-3561 if you have any questions regarding this memorandum.

DEBRA,
PLEASE
ELIMINATE
THIS ELIGIBILITY
CRITERIA FROM
THE BILL
DAVE

a card, issued by DHFS or outpatient care at a rate that is the averag imum allowable cost, as determined by DHFS ispensing fee that is not less than the dispe ember 30, 2002, an eligible person may o this rate, plus the dispensing fee, minus t ved by DHFS under rebate agreements with the drugs (labelers). In determining the am S must consider an average of all rebate pay f prescription drugs subject to the rebates riod for which the information is available ls the drug at these reduced prices receives a 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~~ AND who have not had insurance coverage for outpatient prescription drugs for at least ~~90~~ 30 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.

SOON - In edit 5/24

State of Wisconsin
2001 – 2002 LEGISLATURE

LRB-0585/2 3
DAK:wlj:pg

2001 BILL

REGEN

AN ACT *to amend* 146.82 (2) (a) 17. and 450.02 (2); and *to create* 20.435 (4) (j), 49.45 (53), 49.688 and 450.02 (2) (b) of the statutes; **relating to:** requiring pharmacies and pharmacists, as a condition of medical assistance participation, to charge ~~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 or labelers; expanding prior authorization requirements under medical assistance; requiring the exercise of rule–making authority; making an appropriation; and providing penalties.

Analysis by the Legislative Reference Bureau

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, 2002, 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, 2002, 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 200% of the federal poverty line for a family the size of the persons' eligible family~~ and who have not had insurance coverage for outpatient prescription drugs for at least ~~90~~ 30 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.

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

SECTION 1. 20.435 (4) (j) of the statutes is created to read:

20.435 **(4)** (j) *Prescription drug assistance; manufacturer and labeler rebates.* All moneys received from rebate payments by manufacturers and labelers under s. 49.688 (6), to be used for payment to pharmacies and pharmacists under s. 49.688 (7) for prescription drug assistance and to be used for administration of the program under s. 49.688.

SECTION 2. 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).

2. "Manufacturer" means a manufacturer of prescription drugs and includes a subsidiary or affiliate of the manufacturer.

3. "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.

(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.

3. Authorization for a physician to prescribe up to one 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.

SECTION 3. 49.688 of the statutes is created to read:

49.688 Prescription drug assistance for low–income persons. (1) In this section:

(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.

(c) "Poverty line" means the nonfarm federal poverty line for the continental United States, as defined by the federal department of labor under 42 USC 9902 (2).

(d) "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.

(e) "Prescription order" has the meaning given in s. 450.01 (21).

(2) A person who is a resident, as defined in s. 27.01 (10) (a), of this state; who is not a recipient of medical assistance; who does not have health care coverage under s. 49.665; whose annual household income, as determined by the department, does not exceed 300% of the poverty line for a family the size of the person's eligible family; and who has not had insurance coverage for prescription drugs for outpatient care for at least 30 days prior to applying under this subsection is eligible to purchase a prescription drug at the amounts specified in sub. (5) (a). The person may apply to the department, on a form provided by the department, for a determination of

eligibility and issuance of a prescription drug card for purchase of prescription drugs under this section.

(3) The department shall devise and distribute a form for applying for the program under sub. (2), shall determine eligibility for each 12–month benefit period of applicants, and shall issue to eligible persons a prescription drug card for use in purchasing prescription drugs, as specified in sub. (4). The department shall promulgate rules that specify the criteria to be used to determine annual household income under sub. (2).

(4) Beginning March 1, 2002, as a condition of participation by a pharmacy or pharmacist in the program under ss. 49.45, 49.46, or 49.47, the pharmacy or pharmacist may not charge a person who presents a valid prescription order and a card indicating that he or she meets eligibility requirements under sub. (2) an amount for a prescription drug under the order that exceeds the amounts specified in sub. (5) (a).

(5) (a) The amounts that a pharmacy or pharmacist may charge a person specified in sub. (2) in a 12–month period for a prescription drug are the following:

1. After February 28, 2002, and before October 1, 2002, the average wholesale price minus 6% or the maximum allowable cost, as determined by the department, whichever is less, plus a dispensing fee that is specified by the department but is not less than the dispensing fee paid under the medical assistance program.

2. After September 30, 2002, 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.

(b) The department shall calculate and transmit to pharmacies and pharmacists that are certified providers of medical assistance amounts that may be used in calculating charges under par. (a). The department shall periodically update this information and transmit the updated amounts to pharmacies and pharmacists.

(6) (a) The department or an entity with which the department contracts may enter into a rebate agreement that takes into consideration the rebate agreement specified under 42 USC 1396r–8, the average wholesale price of prescription drugs, and any other available information on prescription drug prices and price discounts, with a manufacturer that sells prescription drugs in this state or with a labeler that repackages prescription drugs for sale in this state. The rebate agreement, if negotiated, shall require that the manufacturer make rebate payments for each prescription drug of the manufacturer that is purchased by persons who are eligible under sub. (2), to the state treasurer to be credited to the appropriation under s. 20.435 (4) (j), each calendar quarter or according to a schedule established by the department.

(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) 1. 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 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 a contested case under ch. 227.

(7) From revenue received under the appropriation account under s. 20.435 (4) (j), department shall, on a weekly or biweekly basis, pay a pharmacy or pharmacist for a prescription drug purchased as specified under sub. (4) an amount that is equal to the pharmacy's or pharmacists share of the rebate amount, if any, for the prescription drug, as determined by the department under sub. (5) (a) 2. The department shall devise and distribute a form for reports by pharmacies and pharmacists under this subsection and may limit payment under this subsection to those prescription drugs for which payment claims are submitted by pharmacies or pharmacists directly to the department. The department may apply to the program under this section the same utilization and cost control procedures that apply under rules promulgated by the department to medical assistance under subch. IV. The department may not impose transaction charges on pharmacies or pharmacists that submit claims or receive payments under this subsection.

(8) The department shall, under methods promulgated by the department by rule, monitor compliance by pharmacies and pharmacists that are certified providers of medical assistance with the requirements of sub. (4) and shall report annually to the legislature under s. 13.172 (2) concerning the compliance. The report shall include information on any pharmacies or pharmacists that discontinue participation as certified providers of medical assistance and the reasons given for the discontinuance.

(9) The department shall request from the secretary of the federal department of health and human services a waiver of any federal medicaid laws necessary to implement prior authorization requirements specified in sub. (6) (c).

(10) (a) The department shall promulgate rules relating to prohibitions on fraud that are substantially similar to applicable provisions under s. 49.49 (1) (a).

(b) A person who is convicted of violating a rule promulgated by the department under par. (a) in connection with that person's furnishing of prescription drugs under this section may be fined not more than $25,000, or imprisoned for not more than 7 years and 6 months, or both.

(c) A person other than a person specified in par. (b) who is convicted of violating a rule promulgated by the department under par. (a) may be fined not more than $10,000, or imprisoned for not more than one year, or both.

(11) The department shall do all of the following:

(a) Promote the use of efficacious and reduced–cost prescription drugs, taking into consideration differential dispensing fees, administrative overhead, and incentive payments.

(b) Undertake outreach efforts to build public awareness of the program under this section and to maximize enrollment by eligible persons.

(12) Except as provided in subs. (6) (c) and (8) to (10), and except for the department's rule–making requirements and authority, the department may enter into a contract with an entity to perform the duties and exercise the powers of the department under this section.

SECTION 4. 146.82 (2) (a) 17. of the statutes is amended to read:

146.82 **(2)** (a) 17. To the department under s. 49.688 (7) (b) or 50.53 (2).

SECTION 5. 450.02 (2) of the statutes is amended to read:

450.02 **(2)** The board shall ~~adopt rules defining~~ promulgate all of the following rules, which apply to all applicants for licensure under s. 450.05:

(a) Defining the active practice of pharmacy. ~~The rules shall apply to all applicants for licensure under s. 450.05.~~

SECTION 6. 450.02 (2) (b) of the statutes is created to read:

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.

SECTION 7. Effective date. This act takes effect on the 2nd day after publication of the 2001–2003 biennial budget act.

(END)

State of Wisconsin
2001 – 2002 LEGISLATURE

LRB–0585/3
DAK:wlj:pg

2001 ASSEMBLY BILL

DEBORA.
AS WE DISCUSSED,
PLEASE CHANGE
TO AWP MINUS
11.25%.
THANKS,
DAVE.

AN ACT ... 2 (2); and ***to create*** 20.435 (4) (j), 49.45 ... statutes; **relating to:** requiring pharm... ndition of medical assistance partic... tion drugs no more than specific amou... requirements for rebate agreements between the department of health and family services and drug manufacturers or labelers; expanding prior authorization requirements under medical assistance; requiring the exercise of rule–making authority; making an appropriation; and providing penalties.

Analysis by the Legislative Reference Bureau

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, 2002, persons who have applied for and have been found by DHFS to be eligible for prescription drug assistance may use

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.

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

SECTION 1. 20.435 (4) (j) of the statutes is created to read:

20.435 **(4)** (j) *Prescription drug assistance; manufacturer and labeler rebates.* All moneys received from rebate payments by manufacturers and labelers under s. 49.688 (6), to be used for payment to pharmacies and pharmacists under s. 49.688 (7) for prescription drug assistance and to be used for administration of the program under s. 49.688.

SECTION 2. 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).

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.

SECTION 3. 49.688 of the statutes is created to read:

49.688 Prescription drug assistance. (1) In this section:

(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.

(c) "Poverty line" means the nonfarm federal poverty line for the continental United States, as defined by the federal department of labor under 42 USC 9902 (2).

(d) "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.

(e) "Prescription order" has the meaning given in s. 450.01 (21).

(2) A person who is a resident, as defined in s. 27.01 (10) (a), of this state; who is not a recipient of medical assistance; who does not have health care coverage under s. 49.665; and who has not had insurance coverage for prescription drugs for outpatient care for at least 30 days prior to applying under this subsection is eligible to purchase a prescription drug at the amounts specified in sub. (5) (a). The person may apply to the department, on a form provided by the department, for a determination of eligibility and issuance of a prescription drug card for purchase of prescription drugs under this section.

used in calculating charges under par. (a). The department shall periodically update this information and transmit the updated amounts to pharmacies and pharmacists.

(6) (a) The department or an entity with which the department contracts may enter into a rebate agreement that takes into consideration the rebate agreement specified under 42 USC 1396r–8, the average wholesale price of prescription drugs, and any other available information on prescription drug prices and price discounts, with a manufacturer that sells prescription drugs in this state or with a labeler that repackages prescription drugs for sale in this state. The rebate agreement, if negotiated, shall require that the manufacturer make rebate payments for each prescription drug of the manufacturer that is purchased by persons who are eligible under sub. (2), to the state treasurer to be credited to the appropriation under s. 20.435 (4) (j), each calendar quarter or according to a schedule established by the department.

(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.

before the division of hearings and appeals of the department of administration as a contested case under ch. 227.

(7) From revenue received under the appropriation account under s. 20.435 (4) (j), department shall, on a weekly or biweekly basis, pay a pharmacy or pharmacist for a prescription drug purchased as specified under sub. (4) an amount that is equal to the pharmacy's or pharmacists share of the rebate amount, if any, for the prescription drug, as determined by the department under sub. (5) (a) 2. The department shall devise and distribute a form for reports by pharmacies and pharmacists under this subsection and may limit payment under this subsection to those prescription drugs for which payment claims are submitted by pharmacies or pharmacists directly to the department. The department may apply to the program under this section the same utilization and cost control procedures that apply under rules promulgated by the department to medical assistance under subch. IV. The department may not impose transaction charges on pharmacies or pharmacists that submit claims or receive payments under this subsection.

(8) The department shall, under methods promulgated by the department by rule, monitor compliance by pharmacies and pharmacists that are certified providers of medical assistance with the requirements of sub. (4) and shall report annually to the legislature under s. 13.172 (2) concerning the compliance. The report shall include information on any pharmacies or pharmacists that discontinue participation as certified providers of medical assistance and the reasons given for the discontinuance.

(9) The department shall request from the secretary of the federal department of health and human services a waiver of any federal medicaid laws necessary to implement prior authorization requirements specified in sub. (6) (c).

(a) Defining the active practice of pharmacy. ~~The rules shall apply to all applicants for licensure under s. 450.05.~~

SECTION 6. 450.02 (2) (b) of the statutes is created to read:

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.

SECTION 7. Effective date. This act takes effect on the 2nd day after publication of the 2001–2003 biennial budget act.

(END)

Kennedy, Debora

From: de Felice, David Patrick
Sent: Tuesday, August 14, 2001 2:51 PM
To: Kennedy, Debora
Subject: Prescription Drug Bill

Importance: High

Debora,

Please hold off revising the AWP reimbursement rate in the bill as we had discussed.

There is some new information I have to bring to Rep. Coggs' attention, and he's at NCSL in San Antonio. Rather than have you do a re-draft, please wait until I talk to him.

I'll call you Friday or next week.

Thanks,

Dave

Dave de Felice
Office of Rep. G. Spencer Coggs
David.deFelice@legis.state.wi.us
608-266-5580 phone
608-282-3617 fax

Kennedy, Debora

From: Carabell, Rachel
Sent: Friday, September 28, 2001 5:10 PM
To: Kennedy, Debora
Subject: LRB 0585/3

Debora,

I have a quick question, that I wanted to get to you before you started a /4 of this draft. On page 4, line 6, should the cross reference be to s. 49.688 (6)(c), rather than (7)(c)? Thanks!

Rachel Carabell
Legislative Fiscal Bureau
rachel.carabell@legis.state.wi.us
Phone: 608-266-3847

Kennedy, Debora

From: Carabell, Rachel
Sent: Friday, September 28, 2001 5:56 PM
To: Kennedy, Debora
Subject: LRB 0585/3

Sorry...but here's another one...on page 10, line 21, should the reference be to (6)(b), rather than (7)(b)? Thanks.

Rachel Carabell
Legislative Fiscal Bureau
rachel.carabell@legis.state.wi.us
Phone: 608-266-3847

Kennedy, Debora

From: Carabell, Rachel
Sent: Friday, September 28, 2001 5:18 PM
To: Kennedy, Debora
Subject: LRB 0585/3

Sorry, but I've got another one for you....on page 7, lines 8-13. There is no reference there to labelers...it only references that "the rebate agreement...shall require that the manufacturer make rebate payments....to the state treasurer to be credited to...."

Shouldn't there be a similar reference to labelers?

Sorry for bringing up these comments at such a late date...but, I tend not to notice these things until I am forced to summarize the language. :)

Rachel Carabell
Legislative Fiscal Bureau
rachel.carabell@legis.state.wi.us
Phone: 608-266-3847

Kennedy, Debora

From: Carabell, Rachel
Sent: Friday, September 28, 2001 6:11 PM
To: Kennedy, Debora
Subject: LRB 0585/3

to the manual. or label

Terribly sorry about this one...but on page 8, line 21, to whom is DHFS supposed to justify the reason for the discrepancy? Does this need to be identified or am I just missing it?

Also, on page 9, line 4, is it necessary to specify on a weekly or biweekly basis? The reason I ask is, what if DHFS or an entity with whom DHFS contracts pays twice per week? Maybe this is a question for Dave..

Also, any thoughts on having a different effective date?

Sorry for the numerous emails...but of course, it's easier for me to spit these off to you as I think of them...but frustrating for you, I'm sure, to receive so many emails...on the other hand, if I had known I'd have so many, I could have combined them into one. Sorry! :(

Rachel Carabell
Legislative Fiscal Bureau
rachel.carabell@legis.state.wi.us
Phone: 608-266-3847

8/28/01

From Dave de Felice

Redraft 0585/3

Rate is AWP minus 11.25%

Exclude from eligibility those who are enrolled ~~receive benefits~~ under 49.688 (budget);
Exclude 49.688 from this program
Remember this program

DAK indicated must wait until budget bill is signed.

Rachel: Can expand eligibility of Sr. Care
(as alternative to 2 separate program)

Kennedy, Debora

From: Sybell, Debra
Sent: Thursday, January 17, 2002 9:15 AM
To: Kennedy, Debora
Cc: de Felice, David Patrick
Subject: FW: A paper copy is on the way

Debora:

Here are the drafting instructions for the Rx Drug Assistance proposal. If you have any questions, please feel free to contact me or Rachel with LFB. I believe Rep. Coggs would like his draft to be identical.

Thanks!

Deb Sybell
Senator Plache's Office
6-1832

-----Original Message-----
From: Swain, Sandy
Sent: Tuesday, January 15, 2002 4:16 PM
To: Sybell, Debra; de Felice, David Patrick
Subject: A paper copy is on the way

Plache&Coggs.pdf

Plache&Coggs

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

January 15, 2002

TO: Senator Kimberly Plache
Room 415 South, State Capitol

Representative Spencer Coggs
Room 214 North, State Capitol

FROM: Rachel Carabell, Fiscal Analyst

SUBJECT: Prescription Drug Assistance Proposal

This memorandum describes a proposal that would enable some Wisconsin residents to receive a discounted price for prescription drugs dispensed by participating pharmacies. Individuals who do not have health insurance coverage for outpatient prescription drugs could enroll in this program. Consequently, persons enrolled in medical assistance (MA), BadgerCare, the health insurance risk-sharing plan (HIRSP) or SeniorCare (the prescription drug assistance program created in 2001 Wisconsin Act 16) or private health care plans that offer outpatient prescription drug coverage would not be eligible for this program. It is estimated that approximately 1.1 million persons in Wisconsin could be eligible to enroll in this program.

This memorandum does not provide an estimate of the fiscal effect of the proposal, including the effect of the program on MA, nor does it provide an estimate of value of the discounts that would be available to program enrollees.

The program would be administered by the Department of Health and Family Services (DHFS). Initially, assistance would be available to enrollees in the form of discounted prices provided by pharmacies and pharmacists participating in the program. Eventually, assistance would also be available through additional discounts that would be funded from revenue received from pharmaceutical manufacturers and labelers that make rebate payments for drugs purchased under the program. Drugs produced or distributed by manufacturers and labelers not entering into rebate agreements with DHFS could be subject to prior authorization requirements under the state's MA program.

Eligibility and Enrollment. Any Wisconsin resident who is not enrolled in MA, BadgerCare or SeniorCare or who has not had health insurance coverage for outpatient prescription drugs for at least 30 days before applying for the program would eligible to participate. DHFS would be required to devise and distribute a form for applying for the program and must determine eligibility for each 12-month benefit period. Enrollees would receive a prescription drug card for use in purchasing prescription drugs under the program. Program participants would be required to pay a $20 fee for each 12-month benefit period as a condition of enrollment. DHFS would use the revenue from this fee to support the administrative costs of the program.

Amount of Assistance. Initially, program participants would receive a pharmacy discount when purchasing prescription drugs under the program. Eventually, program participants would also receive a rebate discount under the program. DHFS would reimburse pharmacies and pharmacists only for the equivalent of the rebate discount.

Pharmacy Discount. Beginning May 1, 2003, as a condition of participation in MA, pharmacies and pharmacists would be prohibited from charging individuals participating in the program an amount that exceeds a specified pharmacy price. This specified pharmacy price would equal the average wholesale price (AWP) minus a 6% discount or the maximum allowable cost, as determined by DHFS, whichever is less, plus a dispensing fee specified by DHFS. The dispensing fee could not be less than the dispensing fee paid under MA. In no case would the amount charged be more than the pharmacies' or pharmacists' usual and customary charge for a prescription.

Rebate Discount. Beginning December 1, 2003, enrollees would receive an additional discount equal to the amount of any rebate payment made by a pharmaceutical manufacturer or labeler applicable to the drug. DHFS would determine the amount of any rebate payment applicable to the drug after considering an average of all the rebate payments made under the program, as weighted by the sales of prescription drugs subject to the rebate over the most recent 12-month period for which such information is available. Effective December 1, 2003, pharmacies and pharmacists would be prohibited from charging program participants an amount that exceeds the amounts identified under the pharmacy discount, less the amount of the rebate discount.

Pharmacist Disclosure of Discounts. The Pharmacy Examining Board would be required to promulgate rules that would require a pharmacist to disclose to program participants the amount of the discount from the retail price of the prescription drug provided to participants.

Rebates Agreements with Pharmaceutical Manufacturers and Labelers. DHFS would be authorized to enter into rebate agreements with pharmaceutical manufacturers that sell prescription drugs in this state and pharmaceutical labelers that repackage prescription drugs for sale in this state. The rebate agreements would be required to take into consideration the rebate agreements under MA, the average wholesale price of prescription drugs and any other available information on prescription drug prices and price discounts. In addition, DHFS would be able to

consider the potential effect of an agreement on MA expenditures when negotiating with manufacturers and labelers. The rebate agreements, if negotiated, would require that manufacturers and labelers make rebate payments for each prescription drug of the manufacturer or labeler that is purchased under the program each calendar quarter or according to a schedule established by DHFS. Revenue from those payments would be deposited in a DHFS program revenue appropriation.

DHFS would be required to collect from pharmacies and pharmacists utilization data necessary to calculate the amounts to be rebated under an agreement. If a manufacturer or labeler elects not to enter into a rebate agreement under the program, DHFS would be required to determine whether to subject the prescription drugs produced by the manufacturer or repackaged by the labeler, to prior authorization requirements under MA.

The proposal includes procedures for resolving discrepancies between the amounts DHFS determines would be paid by the manufacturer or labeler under a rebate agreement and the amount of rebate paid by the manufacturer or labeler that include the hiring of an independent auditor to review the discrepancy. If a controversy continues after an independent auditor's review, DHFS or the manufacturer or labeler could request a hearing before the Division of Hearings and Appeals in the Department of Administration.

Multi-State Compacts. DHFS could enter into agreements with other states or a private organization representing other states, to negotiate with manufacturers and labelers for agreements on rebate payments for prescription drugs purchased under the new program. New

Prior Authorization under MA. DHFS would be required to promulgate rules for procedures to determine whether to subject all prescription drugs produced by a manufacturer or repackaged by a labeler, to prior authorization requirements under MA. These rules would have to include: 49.45 (53) (b)

- 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;

- A definition of "equivalent" that includes a specific list of alternative drugs that could be substituted for another drug subject to prior authorization requirements;

- Authorization for a pharmacy or pharmacist to be reimbursed for up to one month's dosage of a prescription drug that is otherwise subject to prior authorization requirements, if the prescriber asserts that the equivalent is unacceptable or not immediately available and provides evidence that the prescription drug is medically necessary under MA standards;

- Standards for DHFS review of pharmacies' and pharmacists' requests for reimbursement of prescription drugs that are subject to prior authorization requirements;

- Procedures, including hearings, for appeals of denials of pharmacies' or pharmacists' requests for reimbursement of prescription drugs that are subject to prior authorization requirements; and
- MA coverage of a prescription drug subject to prior authorization pending appeal of a denial of a prior authorization request.

Payments to Pharmacies and Pharmacists. DHFS would use revenue from the rebates paid by manufacturers or labelers to pay pharmacists or pharmacies for prescription drugs purchased under the program. DHFS would be required to pay pharmacies or pharmacies, on a weekly or biweekly basis, an amount that would equal the pharmacy or pharmacists' share of the rebate discount, as determined by DHFS. DHFS would be required to devise and distribute a form for reports by pharmacies and pharmacists and could limit payments to pharmacies and pharmacists for only those prescription drugs for which payment claims are submitted directly to DHFS.

DHFS would be authorized to apply the same utilization and cost control procedures that apply to MA, under rules promulgated by DHFS, to the program created under this proposal. DHFS would be prohibited from imposing transaction charges on pharmacies or pharmacists that submit claims or receive payments under the program.

DHFS Responsibilities. Under the proposal, DHFS would be required to:

- Calculate and transmit to MA-certified pharmacies and pharmacists amounts that may be used in calculating what a pharmacy or pharmacist could charge program participants. DHFS would be required to periodically update this information and transmit the updated information to the pharmacies and pharmacists.

- Disseminate information to the public, via the internet and other appropriate sources, that specifies the names of pharmaceutical manufacturers and labelers that elect not to enter into rebate agreements under the program and the price at which the most utilized prescription drugs would be available to program participants.

- Disseminate to physicians, pharmacies, pharmacists and other health professionals information about the relative cost of prescription drugs produced by manufacturers or repackaged by labelers that enter into rebate agreements in comparison with the cost of prescription drugs produced by pharmaceutical manufacturers or packaged by pharmaceutical labelers that do not enter into rebate agreements.

- Under rules promulgated by DHFS, monitor compliance by pharmacies and pharmacists with the requirement that they not charge program participants an amount more than the amount specified under the program. Further, DHFS would be required to report annually to the Legislature concerning pharmacies' and pharmacists' compliance with the requirement. The

report would have to include information on any pharmacies or pharmacists that discontinue participation in MA and the reasons given for the discontinuance.

- Request from the Secretary of the U.S. Department of Health and Human Services any waivers of federal law necessary to implement the prior authorization requirements under the proposal.

- Promote the use of efficacious and reduced-cost prescription drugs, taking into consideration differential dispensing fees, administrative overhead, and incentive payments.

- Undertake outreach efforts to build public awareness of the program created under this proposal and maximize enrollment by eligible persons.

Under the proposal, DHFS would be authorized to enter into a contract with an entity to perform the duties and exercise its powers under the program created in the proposal. This authority would not include DHFS' responsibility to develop prior authorization requirements under MA for drugs produced or repackaged by entities that do not enter into rebate agreements under the program. Additionally, this authority would not apply to DHFS' responsibilities to monitor compliance by pharmacies and pharmacists participating in the program and report to the Legislature on that compliance, to request the necessary waivers of federal law or to promulgate rules related to the proposal.

Additional Provisions. The proposal includes other provisions relating to confidentiality of patient records, prohibitions on fraud under the program, and would create two new DHFS program revenue appropriations.

Confidentiality of Patient Records. Under the proposal, any patient-identifiable data collected by DHFS would be treated as a patient health care record for purposes of confidentiality. Additionally, it would modify current law provisions regarding confidentiality of patient health care records to specify that patient health care records must be released to DHFS upon request, without the informed consent of the patient for purposes of calculating rebate amounts under the program.

Fraud Provisions. DHFS would be required to promulgate rules relating to prohibitions on fraud that are substantially similar to applicable provisions under MA. Persons convicted of violating rules promulgated by DHFS in connection with that person's furnishing of prescription drugs could not be fined more than $25,000, or imprisoned for not more than seven years and six months, or both. Other persons convicted of violating the rules promulgated by DHFS could not be fined more than $10,000, or imprisoned for not more than one year, or both.

Program Revenue Appropriations. The proposal would create two program revenue appropriations in DHFS. One appropriation would authorize DHFS to use all rebate revenue DHFS receives from manufacturers to reimburse pharmacies and pharmacists for the portion of the

discount provided to program participants that represents the rebate discount. The second appropriation would authorize DHFS to expend all revenue it collects from enrollment fees to fund program administration costs.

Let me know if I can be of further assistance.

RC/lah

Kennedy, Debora

From: Sybell, Debra
Sent: Wednesday, January 30, 2002 9:13 AM
To: Kennedy, Debora
Subject: Prescription Drug Cost Relief Draft

Please revise the pharmacist reimbursement rate. It should be equal to the Medicaid rate of AWP-11.25% rather than the SeniorCare rate of AWP-6%.

Deb Sybell
Senator Kim Plache's Office
6-1832