

2001 SENATE BILL 482

March 5, 2002 – Introduced by Senators PLACHE, BURKE, DECKER and HANSEN, cosponsored by Representatives COGGS, MORRIS-TATUM, KRUSICK, BALOW, BERCEAU, BLACK, BOCK, CARPENTER, HUBER, KREUSER, LASSA, MILLER, PLOUFF, POCAN, RYBA, SHILLING, SINICKI, TURNER and YOUNG. Referred to Committee on Health, Utilities, Veterans and Military Affairs.

1 **AN ACT** *to renumber and amend* 450.02 (2); *to amend* 146.82 (2) (a) 17.; and
2 *to create* 20.435 (4) (jf), 20.435 (4) (jg), 49.45 (53), 49.689 and 450.02 (2) (b) of
3 the statutes; **relating to:** requiring pharmacies and pharmacists, as a
4 condition of medical assistance participation, to charge persons for prescription
5 drugs no more than specific amounts; specifying requirements for rebate
6 agreements between the department of health and family services and drug
7 manufacturers or labelers; expanding prior authorization requirements under
8 medical assistance; requiring the exercise of rule-making authority; making
9 appropriations; 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 May 1, 2003, persons who have applied for and have been found by DHFS to be eligible for prescription drug assistance and who

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have paid an enrollment fee of \$20 for a 12-month benefit period 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 11.25% 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, but a pharmacy or pharmacist may not charge an amount that exceeds the usual and customary charge for the prescription drug. After November 30, 2003, an eligible person may use the prescription drug card to 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 under the program, 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 have not had private health insurance coverage for outpatient prescription drugs for at least 30 consecutive days immediately prior to applying for the program, are not MA recipients, are not enrolled in Badger Care or the prescription drug assistance program for elderly persons (commonly known as Senior Care), and do not have a policy issued under the health insurance risk-sharing plan (HIRSP). The \$20 enrollment fee paid by eligible persons is required to be used for administration of 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. In negotiating a rebate agreement, DHFS may also consider the potential effect of the agreement on MA expenditures. DHFS also may enter into an agreement with another state or with a private organization that represents other states to negotiate rebate agreements with manufacturers and labelers. Under the rebate agreement, the manufacturer or labeler must make payments 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 and the prices at which the most frequently used prescription drugs are available to persons under the program. In addition, DHFS

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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 or pharmacists 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:

- 1 **SECTION 1.** 20.435 (4) (jf) of the statutes is created to read:
- 2 20.435 (4) (jf) *Prescription drug assistance; manufacturer and labeler rebates.*
- 3 All moneys received from rebate payments by manufacturers and labelers under s.
- 4 49.689 (6), to be used for payment to pharmacies and pharmacists under s. 49.689
- 5 (7) for prescription drug assistance.
- 6 **SECTION 2.** 20.435 (4) (jg) of the statutes is created to read:

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1 20.435 (4) (jg) *Prescription drug assistance; enrollment fees.* All moneys
2 received from payment of enrollment fees under s. 49.689 (3), to be used for
3 administration of the program under s. 49.689.

4 **SECTION 3.** 49.45 (53) of the statutes is created to read:

5 49.45 (53) PRIOR AUTHORIZATION FOR LEGEND DRUGS. (a) In this subsection:

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

10 2. “Manufacturer” means a manufacturer of prescription drugs and includes
11 a subsidiary or affiliate of the manufacturer.

12 3. “Prescription drug” means a prescription drug, as defined in s. 450.01 (20),
13 that is included in the drugs specified under s. 49.46 (2) (b) 6. h.

14 (b) The department shall promulgate as rules procedures for use in
15 determining, under s. 49.689 (6) (c), whether to subject prescription drugs produced
16 by a manufacturer or repackaged by a labeler to prior authorization requirements
17 under medical assistance. The rules shall include all of the following:

18 1. Authorization to subject a prescription drug to prior authorization
19 requirements only if considerations relating to safety, efficacy, and disease
20 management are not compromised by denial of the prior authorization or
21 substitution of the drug with an equivalent.

22 2. A definition of “equivalent” that includes a specific list of alternate
23 prescription drugs that could be substituted for a drug that is subject to prior
24 authorization requirements.

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1 3. Authorization for a pharmacy or pharmacist to be reimbursed for up to one
2 month's dosage of a prescription drug that is otherwise subject to prior authorization
3 requirements, if the physician prescribing the drug asserts that the equivalent is
4 unacceptable or not immediately available and provides evidence that the
5 prescription drug is medically necessary under medical assistance standards.

6 4. Standards for review by the department of requests by pharmacies and
7 pharmacists for reimbursement for prescription drugs that are subject to prior
8 authorization requirements.

9 5. Procedures, including hearings, for appeals of denials of requests by
10 pharmacies and pharmacists for reimbursement for prescription drugs that are
11 subject to prior authorization requirements.

12 6. Coverage under medical assistance of a prescription drug that is subject to
13 prior authorization during the pendency of an appeal of a denial of a request for
14 reimbursement for the drug.

15 **SECTION 4.** 49.689 of the statutes is created to read:

16 **49.689 Prescription drug assistance. (1)** In this section:

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

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

23 (c) "Prescription drug" means a prescription drug, as defined in s. 450.01 (20),
24 that is included in the drugs specified under s. 49.46 (2) (b) 6. h.

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

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1 **(2)** (a) A person to whom all of the following applies is eligible to purchase a
2 prescription drug at the amounts specified in sub. (5) (a):

3 1. The person is a resident, as defined in s. 27.01 (10) (a), of this state.

4 2. The person is not a recipient of medical assistance, does not have health care
5 coverage under s. 49.665, does not have a policy issued under ch. 149, and is not
6 enrolled in the program under s. 49.688.

7 3. The person has not had insurance coverage for prescription drugs for
8 outpatient care that is other than that specified in subd. 2. for at least 30 consecutive
9 days immediately before applying under par. (b).

10 (b) A person may apply to the department, on a form provided by the
11 department, for a determination of eligibility and issuance of a prescription drug
12 card for purchase of prescription drugs under this section.

13 **(3)** The department shall devise and distribute a form for applying for the
14 program under sub. (2), shall determine eligibility for each 12-month benefit period
15 of applicants, and, after payment by the applicant of a program enrollment fee of \$20
16 for each 12-month benefit period, shall issue to eligible persons a prescription drug
17 card for use in purchasing prescription drugs, as specified in sub. (4).

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

24 **(5)** (a) The amounts that a pharmacy or pharmacist may charge a person
25 specified in sub. (3) in a 12-month period for a prescription drug are the following:

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1 1. After April 31, 2003, and before December 1, 2003, the lesser of the following:

2 a. The average wholesale price minus 11.25% or the maximum allowable cost,
3 as determined by the department, whichever is less, plus a dispensing fee that is
4 specified by the department but is not less than the dispensing fee paid under the
5 medical assistance program.

6 b. The usual and customary charge of the pharmacy or pharmacist for the
7 proscription drug.

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

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

20 **(6)** (a) The department or an entity with which the department contracts may
21 enter into a rebate agreement that takes into consideration the rebate agreement
22 specified under 42 USC 1396r-8, the average wholesale price of prescription drugs,
23 and any other available information on prescription drug prices and price discounts,
24 with a manufacturer that sells prescription drugs in this state or with a labeler that
25 repackages prescription drugs for sale in this state. The department or the entity

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1 with which the department contracts may also enter into an agreement with another
2 state or with a private organization that represents another state, to negotiate
3 rebate agreements with manufacturers and labelers for prescription drugs produced
4 by the manufacturer or repackaged by the labelers that are purchased by persons
5 who are eligible under sub. (2). In negotiating a rebate agreement, the department
6 or entity with which the department contracts may consider the potential effect of
7 the agreement on expenditures under medical assistance. A rebate agreement, if
8 negotiated under this paragraph, shall require that the manufacturer or labeler
9 make rebate payments for each prescription drug of the manufacturer or labeler that
10 is purchased by persons who are eligible under sub. (2), to the state treasurer to be
11 credited to the appropriation under s. 20.435 (4) (jf), each calendar quarter or
12 according to a schedule established by the department.

13 (b) The department shall collect from pharmacies and pharmacists utilization
14 data necessary to calculate the amounts to be rebated under a rebate agreement
15 under par. (a). Any patient-identifiable data, as defined in s. 153.50 (1) (b) 1. or 2.
16 or as specified in s. 153.50 (3) (b) 1. to 7., that is collected under this paragraph shall
17 be treated as a patient health care record for purposes of s. 146.82.

18 (c) If a manufacturer or labeler elects not to enter into a rebate agreement
19 under par. (a), the department shall determine, under procedures established by rule
20 by the department under s. 49.45 (53), whether to subject the prescription drugs
21 produced by the manufacturer or repackaged by the labeler to prior authorization
22 requirements under the medical assistance program.

23 (d) The department may disseminate to the public, by use of the Internet or
24 other means, information that specifies the names of manufacturers or labelers that
25 elect not to enter into rebate agreements and the prices at which the most frequently

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1 used prescription drugs are available to persons issued a prescription drug card
2 under sub. (3).

3 (e) The department shall disseminate to physicians, pharmacies, pharmacists,
4 and, as determined by the department, other health professionals information about
5 the relative cost of prescription drugs produced by manufacturers or repackaged by
6 labelers that enter into rebate agreements in comparison with the cost of
7 prescription drugs produced by manufacturers or repackaged by labelers that do not
8 enter into rebate agreements.

9 (f) 1. If a discrepancy exists in the manufacturer's or labeler's favor between the
10 amount claimed by a pharmacy or pharmacist under sub. (7) and the amount rebated
11 by the manufacturer or labeler under this subsection, the department may hire an
12 independent auditor who is agreed on by the parties to review the discrepancy. If the
13 discrepancy continues following the audit, the manufacturer or labeler shall justify
14 the reason for the discrepancy or pay to the department any additional amount due.

15 2. If a discrepancy exists that is not in favor of the manufacturer or labeler in
16 the information provided by the department to the manufacturer or labeler
17 regarding the manufacturer's or labeler's rebate, the manufacturer or labeler may
18 hire an independent auditor who is agreed on by the parties to verify the accuracy
19 of the data supplied by the department. If a discrepancy continues following the
20 audit, the department shall justify the reason for the discrepancy to the
21 manufacturer or labeler or refund to the manufacturer or labeler any excess payment
22 made by the manufacturer or labeler.

23 3. If a controversy continues after the procedures under subd. 1. or 2. have been
24 carried out, the department or the manufacturer or labeler may request a hearing

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

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

16 (8) The department shall do all of the following:

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

23 (b) Request from the secretary of the federal department of health and human
24 services a waiver of any federal medicaid laws necessary to implement prior
25 authorization requirements specified in sub. (6) (c).

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1 (c) Promote the use of efficacious and reduced-cost prescription drugs, taking
2 into consideration differential dispensing fees, administrative overhead, and
3 incentive payments.

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

6 (e) Promulgate rules relating to prohibitions on fraud that are substantially
7 similar to applicable provisions under s. 49.49 (1) (a).

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

12 **(10)** (a) A person who is convicted of violating a rule promulgated by the
13 department under sub. (8) (e) in connection with that person's furnishing of
14 prescription drugs under this section may be fined not more than \$25,000, or
15 imprisoned for not more than 7 years and 6 months, or both.

16 (b) A person other than a person specified in par. (a) who is convicted of
17 violating a rule promulgated by the department under sub. (8) (e) may be fined not
18 more than \$10,000, or imprisoned for not more than one year, or both.

19 **SECTION 5.** 146.82 (2) (a) 17. of the statutes is amended to read:

20 146.82 **(2)** (a) 17. To the department under s. 49.689 (6) (b) or 50.53 (2).

21 **SECTION 6.** 450.02 (2) of the statutes is renumbered 450.02 (2) (intro.) and
22 amended to read:

23 450.02 **(2)** (intro.) The board shall adopt rules defining promulgate all of the
24 following rules, which apply to all applicants for licensure under s. 450.05:

