FRIDAY 2/1

State of Wisconsin
2001 – 2002 LEGISLATURE

LRB-0585/~~6~~4
DAK:~~wlj:rpg~~

D-NOTE

wlj & gs

RAS
SAV
X-refs
CRS

2001 ASSEMBLY BILL

regenerate

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 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~~ 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 ~~March 1, 2002~~ May 1, 2003, persons who have applied for and have been found by DHFS to be eligible for prescription drug assistance may use

and who have paid an enrollment fee of $20 for a 12-month benefit period

ASSEMBLY BILL

use the prescription drug card to

11.25%

November 30, 2003

INSERT A1

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, do not have coverage under Badger Care, and~~ have not had insurance coverage for outpatient prescription drugs for at least 30 days prior to applying for the program.

under the program

private health

immediately

INSERT A2

consecutive

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

INSERT A3

INSERT A4

or pharmacists

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) (jf) of the statutes is created to read:

20.435 **(4)** (jf) *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~~.

INSERT 3-6

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)~~ 49.689 (6) (c), whether to subject ~~all~~ any 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.~~ that could be substituted for a drug that is subject to prior authorization requirements

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 prescribing the drug 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~~ pharmacies and pharmacists for reimbursement for prescription drugs that are subject to prior authorization requirements.

5. Procedures, including hearings, for appeals of denials of requests by ~~physicians~~ pharmacies and pharmacists for reimbursement 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.** **(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) 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 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).

(4) Beginning ~~March 1, 2002~~ May 1, 2003, 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)~~ (3) in a 12–month period for a prescription drug are the following:

1. After ~~February 28, 2002~~, and before ~~October 1, 2002~~ December 1, 2003, the average wholesale price minus ~~5%~~ 11.25% 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.

INSERT 6-16

2. After ~~September 30, 2002~~ November 30, 2003, the rate specified in subd. 1., plus the dispensing fee specified in subd. 1., minus the amount of any rebate payment made by a manufacturer or labeler that is applicable to the prescription drug, as determined by the department. In determining the amount by which a prescription drug shall be discounted under this subdivision, the department shall consider an average of all rebate payments made 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.

(b) The department shall calculate and transmit to pharmacies and pharmacists that are certified providers of medical assistance amounts that may be

INSERT 7-8

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) ~~(b)~~, 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.

In negotiating a rebate agreement, the department or entity with which the department contracts may consider the potential effect of the agreement on expenditures under medical assistance.

(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. and the prices at which the most frequently used prescription drugs are available to persons issued a prescription drug card under sub. (3)

(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~~ repackaged by labelers that enter into rebate agreements in comparison with the cost of prescription drugs produced by manufacturers or ~~packaged~~ repackaged 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 or pharmacist 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~~ this subsection. 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~~ by 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

to the manufacturer or labeler

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

~~(11)~~ (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.

~~(12)~~ (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:~~

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

(e) 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~~ 49.689 <use twice> 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)

D-NOTE

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; but pharmacy or pharmacist may not charge an amount that exceeds the usual and customary charge for the prescription drug

INSERT A-2

, are not MA recipients, are not enrolled in BadgerCare 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

p. 102

INSERT A 3

nonstat In negotiating a rebate agreement, DHFS may also consider the potential effect of the agreement on MA expenditures.

p. 2 D 2

INSERT A3

no # 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. represents rebate agreements with manufacturers and labelers.

End D INSERT A3

INSERT A 4

and the prices at which the most frequently prices frequently used prescription drugs are available to persons under the program persons program

[INSERT 3-6]

(H) SECTION #. CR; 20.435(4)(jg)

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

INSERT 5.21

colon

no ¶ :

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

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

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

INSERT 6-16

b. The usual and customary charge of the pharmacy or pharmacist for the prescription drug.

✓

INSERT 7-8

not The department or the entity with which the department contracts may also enter into an agreement with another state or with a private organization that represents another state, to negotiate rebate agreements with labelers prescription manufacturers and labelers for prescription drugs produced by the manufacturer or labelers repackaged by the labeler that are purchased by persons who are eligible under sub. (2).

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB–0585/4dn
DAK:wlf:pg

To Representative Coggs:

The following are issues that arose in drafting this bill or are items for your information:

1. In s. 49.45 (53) (b) I changed "all" to "any," since it is possible that DHFS will not subject all drugs of a manufacturer or labeler to prior authorization requirements.

2. With respect to s. 49.689 (2) (a):

a. Note that I did not include payment of the program fee as a condition of eligibility; instead, I included it as a requirement under s. 49.689 (3) prior to issuance of a prescription drug card; therefore, it will be unnecessary for an applicant for eligibility to send in the $20 before he or she is determined eligible. Is this what you want?

b. In s. 49.689 (2) (a) 3., not that I have required that the person not have insurance coverage for 30 *consecutive* days *immediately prior* to applying for the program. Okay?

~~3.~~ a. As ~~this paragraph~~ is drafted, each person who is eligible will have to pay the $20 enrollment fee; there is no provision for a couple, for instance, to pay a single $20 fee. Is the provision drafted as you wish?

~~a.~~ b. I have included participation in medical assistance, Badger Care, HIRSP, Senior Care, and private health insurance coverage as factors that would render a person ineligible. Are there any other state programs that you would want to include in this group?

~~b.~~ c. With respect to DHFS' agreements with other states to negotiate rebate agreements (s. 49.689 (9) (b)), should requirements be put on those rebate agreements, e.g., that they take into account the factors specified in s. 49.689 (6) (a)? If DHFS or its agent enters into such an agreement with another state

~~4.~~ d. I have written the provision concerning DHFS' agreements with other states to negotiate rebate agreements into s. 49.689 (6) (a), so that the requirements for rebate agreements under that paragraph would apply to any rebate agreements that would result from an intrastate agreement. Is that what you want?

~~5.~~ e. I have specified in s. 49.689 (6) (f) that DHFS must justify *to the manufacturer or labeler* the reason for a discrepancy that is not in favor of the manufacturer or labeler

in the information provided to the manufacturer or labeler concerning the rebate; this previously was unspecified. Okay?

I made the bill effective on publication. Is that what you want?

Please let me know if you have questions about the bill or if I can provide you with any additional assistance.

Debora A. Kennedy
Managing Attorney
Phone: (608) 266–0137
E–mail: debora.kennedy@legis.state.wi.us

I would appreciate your providing Rachel Carabell of the Legislative Fiscal Bureau with a copy of this bill.

In s. 48.684 (6)(b), I have expanded the types of patient-identifiable data that must be treated as a patient health care record to include data ~~under~~ as defined in s. 153.50 (1)(b) 1. or 2. and data specified in s. 153.50 (3)(b) 1. to 7. Please review.

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB–0585/4dn
DAK:cjs:ch

February 1, 2002

To Representative Coggs:

The following are issues that arose in drafting this bill or are items for your information:

1. In s. 49.45 (53) (b) I changed "all" to "any," since it is possible that DHFS will not subject all drugs of a manufacturer or labeler to prior authorization requirements.

2. With respect to s. 49.689 (2) (a):

a. Note that I did not include payment of the program fee as a condition of eligibility; instead, I included it as a requirement under s. 49.689 (3) prior to issuance of a prescription drug card; therefore, it will be unnecessary for an applicant for eligibility to send in the $20 before he or she is determined eligible. Is this what you want?

b. In s. 49.689 (2) (a) 3., not that I have required that the person not have insurance coverage for 30 *consecutive* days *immediately prior* to applying for the program. Okay?

c. I have included participation in medical assistance, Badger Care, HIRSP, Senior Care, and private health insurance coverage as factors that would render a person ineligible. Are there any other state programs that you would want to include in this group?

3. As s. 49.689 (3) is drafted, each person who is eligible will have to pay the $20 enrollment fee; there is no provision for a couple, for instance, to pay a single $20 fee. Is the provision drafted as you wish?

4. I have written the provision concerning DHFS' agreements with other states to negotiate rebate agreements into s. 49.689 (6) (a), so that the requirements for rebate agreements under that paragraph would apply to any rebate agreements that would result from an intrastate agreement. Is that what you want?

5. I have specified in s. 49.689 (6) (f) that DHFS must justify *to the manufacturer or labeler* the reason for a discrepancy that is not in favor of the manufacturer or labeler in the information provided to the manufacturer or labeler concerning the rebate; this previously was unspecified. Okay?

6. I made the bill effective on publication. Is that what you want?

7. In s. 49.689 (6) (b), I have expanded the types of patient–identifiable data that must be treated as a patient health care record to include data as defined in s. 153.50 (1) (b) 1. or 2. and data specified in s. 153.50 (3) (b) 1. to 7. Please review.

I would appreciate your providing Rachel Carabell of the Legislative Fiscal Bureau with a copy of this bill for her review.

Please let me know if you have questions about the bill or if I can provide you with any additional assistance.

Debora A. Kennedy
Managing Attorney
Phone: (608) 266–0137
E–mail: debora.kennedy@legis.state.wi.us

Kennedy, Debora

From: de Felice, David Patrick
Sent: Monday, February 18, 2002 4:19 PM
To: Kennedy, Debora
Subject: FW: T-Rx - drafter's note

-----Original Message-----
From: Sybell, Debra
Sent: Tuesday, February 12, 2002 11:13 AM
To: de Felice, David Patrick
Cc: Carabell, Rachel; Kennedy, Debora
Subject: T-Rx - drafter's note

We received a drafter's note back with our draft. Rachel Carabell suggested the following changes.

1. Eliminate reference to "any" in s. 49.45 (53)(b).
2. Delete the definition for "poverty line" from s. 49.689(1)(c) since this term is not used in the draft.
3. Specify that such information could be distributed over the Internet or by another means under s. 49.689(6)(d).
4. Delete "retailer's" rebate and change to "labeler's" rebate for consistency under s. 49.689(6)(f) 2.
5. Check with DHFS whether the expansion of types of patient identifiable data that must be treated as a patient health care record in s. 49.689(6)(b) would interfere with the Department's ability to execute rebate agreements. I have submitted this question to Russ Pederson with DHFS. I have not heard back from him yet.

Please feel free to contact Rachel with LFB or Debora with LRB to discuss.

Deb Sybell
Senator Kim Plache's Office
6-1832

Kennedy, Debora

From: Carabell, Rachel
Sent: Friday, February 15, 2002 11:53 AM
To: Kennedy, Debora
Subject: FW: T-Rx

Forwarded to Dave de Felice 2/18/02

I spoke with Deb about DHFS' response to our question. She said to go ahead and redraft their proposal with the changes we discussed earlier. Also, when you send a copy of the draft to Deb and/or Dave de Felice could you suggest that they share a copy with me as well? thanks!

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

-----Original Message-----
From: Pederson, Russell
Sent: Friday, February 15, 2002 10:50 AM
To: Sybell, Debra
Cc: Carabell, Rachel
Subject: Re: T-Rx

Deb,

In response to your question, the provision would not bar the Department from providing necessary information to drug manufacturers with which we maintain rebate agreements.

In general, manufacturers are invoiced according to the specific drug utilization. If a manufacturer disputes the invoice, Medicaid may provide additional claim detail but the detail does not include person or patient identifiable information.

Hope this helps.

Russ

>>> Sybell, Debra 02/07/02 11:09AM >>>

The draft specifies:

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

The drafter's note reads:

In the above section, "I have expanded the types of patient-identifiable data
that must be treated as a patient health care record to include data as defined in s. 153.50(1)(b)1. or 2. and data specified in s. 153.50(3)(b)1. to
7. Please review."

Question: Would this provision bar the Department from providing information
to drug manufacturers which would be essential to executing the rebate agreements?

Please feel free to consult with Rachel Carabell with LFB at 6-3847.

Thanks for your assistance.

Deb Sybell
Senator Plache's Office
6-1832

TUESDAY

State of Wisconsin
2001 – 2002 LEGISLATURE

D-NOTE

LRB–0585/4 5
DAK:wlj&cjs:

stays

SAV

2001 ASSEMBLY BILL

Rep Cat

AN ACT *to renumber and amend* 450.02 (2); *to amend* 146.82 (2) (a) 17.; and *to create* 20.435 (4) (jf), 20.435 (4) (jg), 49.45 (53), 49.689 and 450.02 (2) (b) of the statutes; **relating to:** requiring pharmacies and pharmacists, as a condition of medical assistance participation, to charge 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 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

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

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:

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

20.435 **(4)** (jf) *Prescription drug assistance; manufacturer and labeler rebates.* All moneys received from rebate payments by manufacturers and labelers under s. 49.689 (6), to be used for payment to pharmacies and pharmacists under s. 49.689 (7) for prescription drug assistance.

SECTION 2. 20.435 (4) (jg) of the statutes is created to read:

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

SECTION 3. 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 use in determining, under s. 49.689 (6) (c), whether to subject ~~any~~ 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 that could be substituted for a drug that is subject to prior authorization requirements.

3. 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 physician prescribing the drug 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 pharmacies and pharmacists for reimbursement for prescription drugs that are subject to prior authorization requirements.

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

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

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

49.689 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).

(c) "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.

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

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

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

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

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

(b) A 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, after payment by the applicant of a program enrollment fee of $20 for each 12–month benefit period, shall issue to eligible persons a prescription drug card for use in purchasing prescription drugs, as specified in sub. (4).

(4) Beginning May 1, 2003, 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. (3) in a 12–month period for a prescription drug are the following:

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

a. The average wholesale price minus 11.25% 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.

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

2. After November 30, 2003, the rate specified in subd. 1., plus the dispensing fee specified in subd. 1., minus the amount of any rebate payment made by a manufacturer or labeler that is applicable to the prescription drug, as determined by the department. In determining the amount by which a prescription drug shall be discounted under this subdivision, the department shall consider an average of all rebate payments made 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.

(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 department or the entity with which the department contracts may also enter into an agreement with another state or with a private organization that represents another state, to negotiate rebate agreements with manufacturers and labelers for prescription drugs produced by the manufacturer or repackaged by the labelers that are purchased by persons who are eligible under sub. (2). In negotiating a rebate agreement, the department or entity with which the department contracts may consider the potential effect of the agreement on expenditures under medical assistance. A rebate agreement, if negotiated under this paragraph, shall require that the manufacturer or labeler make rebate payments for each prescription drug of the manufacturer or labeler 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) (jf), 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. or 2. or as specified in s. 153.50 (3) (b) 1. to 7., 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

produced by the manufacturer or repackaged by the labeler to prior authorization requirements under the medical assistance program, by use of the Internet or other means.

(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 and the prices at which the most frequently used prescription drugs are available to persons issued a prescription drug card under sub. (3).

(e) The department shall disseminate to physicians, pharmacies, pharmacists, and, as determined by the department, 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 manufacturers or repackaged 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 or pharmacist under sub. (7) and the amount rebated by the manufacturer or labeler under this subsection, 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~~ labeler'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 by the department. If a discrepancy continues following the audit, the department shall justify the reason for the discrepancy to the

manufacturer or labeler 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) (jf), the 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 do all of the following:

(a) 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 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.

(b) 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).

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

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

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

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

(10) (a) A person who is convicted of violating a rule promulgated by the department under sub. (8) (e) 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.

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

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

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

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

450.02 **(2)** (intro.) 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 7. 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. 49.689 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. 49.689.

(END)

D-NOTE

D-NOTE

To Dave de Felice:

¶ This redraft incorporates the first four changes, as Rachel Carabell's of Rachel Carabell's suggested changes, as specified in your e-mail of February 12, but does not incorporate the fifth suggested change, in light of Russ Pederson's response from DHFS.

¶ I would appreciate it if you would ask Rachel to review this redraft.

¶ Thank you.

DAK

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB–0585/5dn
DAK:cjs:pg

February 19, 2002

To Dave deFelice:

This redraft incorporates the first four of Rachel Carabell's suggested changes, as specified in your e–mail of February 12, but does not incorporate the fifth suggested change, in light of Russ Pederson's response from DHFS.

I would appreciate it if you would ask Rachel to review this redraft.

Thank you.

Debora A. Kennedy
Managing Attorney
Phone: (608) 266–0137
E–mail: debora.kennedy@legis.state.wi.us