



State of Wisconsin
2003 - 2004 LEGISLATURE

P2
LRB-1270/P1

RLR:wj:rs

In 4/28/03
Wanted ~~for~~ TODAY
Please

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

RMK

LPS:
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D - Note

Regem. Cat.

1 AN ACT to renumber and amend 450.02 (2); to amend 149.143 (1) (a); to repeal
2 and recreate 49.45 (49); and to create 20.435 (4) (jg), 20.435 (4) (jt), 20.435
3 (4) (jx), 40.03 (6) (k), 49.69, 49.692, 448.075, 450.02 (2) (b) and 450.075 of the
4 statutes; relating to: prescription drugs, ^{granting rule-making authority,} providing penalties, and making
5 appropriations.

Analysis by the Legislative Reference Bureau

This is a preliminary draft. An analysis will be provided in a later version.

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

6 SECTION 1. 20.435 (4) (jg) of the statutes is created to read:
7 20.435 (4) (jg) Prescription drug assistance; enrollment fees. All moneys
8 received from ^{the} payment of enrollment fees under s. 49.692 (3), to be used for
9 administration of the program under s. 49.692.

IWS
1-9

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

INS 2-2

1

20.435 (4) (jt) Preferred drug list. All moneys received from the payment of fees under s. 49.69 (9), to be used for administration of the preferred drug list under s. 49.69 (4).

lists created

SECTION 3. 20.435 (4) (jx) of the statutes is created to read:

20.435 (4) (jx) Supplemental rebates on prescription drugs, prescription drug

assistance. All moneys received from supplemental rebate payments by manufacturers and labelers under s. 49.69 to provide Medical Assistance and Badger Care benefits specified under s. 49.46 (2) (b) 6. h.; to pay pharmacies and pharmacists under s. 49.688 (7) for prescription drug assistance for elderly persons; to assist victims of disease, as provided in ss. 49.68, 49.683, and 49.685; to reimburse the cost of drugs under s. 49.686; to pay a portion of the operating costs of the health insurance risk-sharing plan under ch. 149; to purchase primary health care services under s. 146.93; and to pay pharmacies and pharmacists under s. 49.692 (6) for prescription drug assistance. The amounts expended under this paragraph shall be allocated as provided under s. 49.69 (7).

INS 2-7

reimburse

INS 2-14

****NOTE: Where possible, this paragraph requires that rebate amounts be used to provide prescription drugs. Should I make the appropriation less restrictive, particularly with respect to Medical Assistance and Badger Care?

INS 2-15

SECTION 4. 40.03 (6) (k) of the statutes is created to read:

40.03 (6) (k) Shall use the preferred drug list created under s. 49.69 (5) for group health insurance plans offered to state employees, except that for state employees covered by a collective bargaining agreement under subch. I or V of ch. 111 the board may use the preferred drug list only if permitted under the collective bargaining agreement.

Upon request of the secretary of the department of health and

Family Services

adopt such policies that encourage use of

SECTION 5. 49.45 (49) of the statutes is repealed and recreated to read:

adopt policies that encourage use of

(4)(a) 20

1 49.45 (49) PRESCRIPTION DRUG PRIOR AUTHORIZATION COMMITTEE. (a) The
2 secretary shall exercise his or her authority under s. 15.04 (1) (c) to create a
3 prescription drug prior authorization committee to do all of the following:

4 1. Advise the department on issues related to prior authorization decisions
5 made concerning prescription drugs on behalf of Medical Assistance recipients.

6 2. Determine the safety and clinical efficacy of prescription drugs for the
7 purpose of creating a preferred drug list^s as required under s. 49.69 (2).[✓]

8 (b) The secretary shall appoint as members of the prescription drug prior
9 authorization committee at least the following:

10 1. Two physicians, as defined in s. 448.01 (5), who are currently in practice.

11 2. Two pharmacists, as defined in s. 450.01 (15).

12 3. One advocate for recipients of Medical Assistance who has sufficient medical
13 background, as determined by the department, to evaluate the clinical efficacy of a
14 prescription drug.

15 4. For the purpose of making determinations under s. 49.69 (2)[✓] regarding the
16 safety and clinical efficacy of prescription drugs within a particular therapeutic
17 class, persons who have medical expertise with respect to the disease or medical
18 condition that the prescription drugs are intended to treat.

19 (c) A member of the prescription drug prior authorization committee may not
20 be employed by or be a party to a contract with (the state,) a manufacturer, as defined
21 in s. 450.01 (12), or a distributor, as defined in s. 450.01 (9),[✓] except that a person
22 whose only contract with the state is as a certified Medical Assistance provider under
23 sub. (2) (a) 11. may be a member. Each committee member shall disclose any
24 potential conflicts^{re} of interest related to an issue on which the committee acts. A
25 member may not vote on an item if the member or the member's employer has a

or a labeler^s as defined in s. 49.69(1)(b)[✓]

safety and

INS
3-24

1 conflict of interest in the outcome of the vote. A member who may not vote on an item
2 due to conflict of interest may participate in discussions related to the item.

****NOTE: This conflict of interest provision is from the Indiana bill. Is it too restrictive, particularly with respect to the ban on state employees, for example doctors who work at a state facility or at the university?

3 (d) Notwithstanding the requirement under s. 15.04 (1) (c) that members of
4 committees serve without compensation, members of the prescription drug prior
5 authorization committee who are not officers or employees of this state shall be paid
6 ~~\$25~~^{#100} for each day on which they are actually and necessarily engaged in performance
7 of their duties, but not to exceed \$1,500 per year.

****NOTE: The request called for honorariums. This provision is modeled on a per diem provision for board members under s. 15.07 (5), stats. Should the per diem amount be different? Do you want to increase a DHFS appropriation to cover the cost of the per diem? The per diem applies to the current activities of the committee as well as the added responsibilities related to the preferred drug list.

8 (e) The prescription drug prior authorization committee shall accept
9 information or commentary from representatives of the pharmaceutical
10 manufacturing industry in the committee's review of prior authorization policies.

INS
4-10-10

INS
4-10B

11 SECTION 6. 49.69 of the statutes is created to read:

INS
4-11

12 **49.69 Preferred drug list; prescription drug cost containment.** (1) In
13 this section:

14 (a) "Committee" means the prescription drug prior authorization committee
15 created under s. 49.45 (49).

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

1 (c) "Local governmental unit" means a political subdivision of this state, a
2 special purpose district in this state, an instrumentality or corporation of the
3 political subdivision or special purpose district or a combination or subunit of any of
4 the foregoing.

5 (d) "Manufacturer" means a person engaged in the production, preparation,
6 propagation, compounding, conversion, or processing of prescription drugs.

7 (e) "Off-list prescription drug" means a prescription drug that is not included
8 on the preferred drug list created under sub. (5) (4)

applicable

9 (f) "Practitioner" has the meaning given in s. 450.01 (17).

10 (g) "Prescription drug" has the meaning given in s. 450.01 (20).

***NOTE: This bill requires DHFS to consider all prescription drugs for the preferred drug list, not just those that are covered under the Medical Assistance Program.

11 (h) "Single-source prescription drug" means a prescription drug that is
12 produced or distributed under an original new drug application approved by the
13 federal food and drug administration under 21 USC 355.

14 (i) "State-supported prescription drug program" means the Medical Assistance
15 Program or the program under s. 49.665, 49.68, 49.683, 49.685, 49.686, 49.688, or
16 146.93 or ch. 149.

health care assistance

17 (j) "Therapeutic class" means a class of prescription drugs that are intended to
18 treat the same disease or medical condition by substantially similar biochemical and
19 physiological mechanisms.

20 (2) (a) By January 1, 2004, the committee shall classify prescription drugs by
21 therapeutic class. The committee may include a prescription drug in a therapeutic
22 class only upon finding that the prescription drug is safe and clinically effective in
23 treating the disease or medical condition that the therapeutic class is intended to

1 treat. The committee shall conduct an evidence-based analysis to determine the
2 safety and clinical efficacy of prescription drugs, including a review of relevant
3 literature. The committee shall periodically review and amend its classification of
4 prescription drugs.

5 (b) Notwithstanding par. (a), the committee may adopt safety and clinical
6 efficacy determinations made by a similar government entity in another state, if the
7 other entity uses standards for determining safety and clinical efficacy that are
8 similar to the standards ^{adopted} used by the committee.

***NOTE: Should the committee be allowed to adopt determinations of clinical efficacy and safety that are made by a private entity, such as a private health insurer?

9 (c) The committee shall make a determination regarding the safety and clinical
10 efficacy of a new single-source prescription drug within 60 days after it is approved
11 by the federal food and drug administration or, if the committee does not receive
12 sufficient information to make a determination within 60 days after approval, within
13 60 days after receiving such information.

INS 6-13

14 (3) (a) The department shall solicit bids or proposals from manufacturers and
15 labelers to provide rebates on prescription drugs that the committee has included in
16 therapeutic classes under sub. (2) and that are purchased under programs or plans
17 specified by the department.

par. (a) 1. ✓

18 (b) Any rebate offered by a manufacturer or labeler in response to a solicitation
19 under ~~this subsection~~ shall be in addition to any rebate that the manufacturer or
20 labeler provides ~~for the prescription drug~~ under 42 USC 1396r-8, if applicable, and
21 to any rebate required under state law or provided under an agreement between the
22 state and a manufacturer or labeler that is in effect on the effective date of this
23 paragraph [revisor inserts date].

INS 6-23

in addition

****NOTE: According to Darcy, some manufacturers currently provide the MA rebate for drugs purchased under Senior Care and some do not. Will the requirement in this paragraph that proposed rebates be supplemental to all current rebates put those manufacturers who currently provide rebates for Senior Care at a disadvantage compared to those who do not? Should this paragraph instead require that rebates be supplemental to the MA rebate, but not require that the rebates be supplemental to rebates under Senior Care and Disease Aids? How will DHFS determine the lowest cost drug in a therapeutic category if the cost of a drug after rebates is different for different programs? This paragraph does not specify that a manufacturer must offer the same supplemental rebate for each program covered in the DHFS solicitation. Should it?

1 (d) (c) The department may join with similar government^{al} entities in other states
2 to solicit rebates under this subsection.

3 (4) (a) The department may solicit bids or proposals under sub (3) for rebates
4 on prescription drugs purchased under any of the following programs or plans:

- 5 1. State-supported prescription drug programs.
- 6 2. The prescription drug assistance program under s. 49.692.
- 7 3. Health care coverage plans offered by the state to state employees.
- 8 4. Health care coverage plans offered by local governmental units to their
- 9 employees, if the local governmental units agree to use the preferred drug list.
- 10 5. Health care coverage plans offered by private entities to their employees, if
- 11 the private entities agree to use the preferred drug list.

12 (b) The department may initially solicit and secure rebates that apply to
13 prescription drugs purchased under one or more of the programs or plans under par.

14 (a) and may subsequently agree, in conjunction with manufacturers and labelers, to
15 apply the rebates to prescription drugs purchased under one or more of the
16 remaining programs or plans.

17 (5) (a) The department shall include the lowest-cost prescription drug in each
18 therapeutic class on a preferred drug list. The department may include one or more
19 additional prescription drugs within a therapeutic class on the preferred drug list,

1 if the cost of the drug is not significantly greater than the cost of the lowest-cost
2 prescription drug within the class.

3 (b) In determining cost under this subsection, the department shall consider
4 dosing practices, any cost reduction realized by the state as a result of rebate
5 agreements under 42 USC 1396r-8 or any other existing rebate agreement, any
6 rebate offered by a manufacturer under this section, and any other relevant cost
7 information.

INS 8-7

8 (d) (c) Notwithstanding pars. (a) and (b), the department shall include on the
9 preferred drug list all prescription drugs that the committee determines are safe and
10 clinically effective for treating acquired immunodeficiency syndrome or the human
11 immunodeficiency virus on both preferred drug lists created under this subsection.

12 (6) By July 1, 2004, the department shall enter into agreements with
13 manufacturers and labelers to pay the proposed rebates, if any, on prescription drugs
14 that are included on the preferred drug list created under sub. (5) and purchased on
15 or after July 1, 2004, under the programs and plans specified by the department
16 under sub. (3) (a). Rebates for prescription drugs purchased under state-supported
17 prescription drug programs or the prescription drug assistance program under s.
18 49.692 shall be paid to the department.

***NOTE: Should the bill specify the length of rebate agreements or how frequently
the department must solicit new proposals?

INS 818

19 (7) All rebates paid to the department under this section shall be credited to
20 the appropriation account under s. 20.435 (4) (jx). The department shall calculate
21 the amount of rebates earned on prescription drugs purchased under each of the
22 state-supported prescription drug programs and the program under s. 49.692, and
23 shall allocate the amount earned under each program for that program or plan

sub (5) and (6)(a), 2, and 3.

under health care coverage plans for state employees, and

health care assistance

lists created under sub. (4)

INS 9-1

****NOTE: The bill appropriates the rebates back into the programs under which they were earned—is this what you intend?

Bold

(9) (8)

1 The department shall implement at least one of the following prescription
2 drug cost containment measures using the preferred drug list by July 1, 2004.

3 (a) The department may require practitioners to obtain prior authorization
4 from the department or its fiscal agent for any off-list prescription drug purchased
5 under a state-supported prescription drug program or the program under s. 49.692
6 and may prohibit reimbursement of pharmacists, pharmacies, or any other provider
7 for any off-list prescription drug purchased under a state-supported prescription
8 drug program for which prior authorization is not obtained. If the department
9 requires prior authorization under this paragraph, and a practitioner requests prior
10 authorization for an off-list prescription drug, the department or its fiscal agent
11 shall respond to the request by telephone or other telecommunication means within
12 24 hours after the request is received. In an emergency situation, the department
13 shall reimburse a pharmacy or pharmacist for at least a 72-hour supply of a
14 prescription without prior authorization.

health care assistance

****NOTE: Please consider how prohibiting reimbursement for off-list drugs will be implemented under the various state-supported prescription drug programs. Implementation seems fairly straightforward for Medical Assistance, Badger Care, and Senior Care, because DHFS pays the pharmacists. For HIRSP, will the state require that private insurers enforce use of the preferred drug list? Does the state pay pharmacists directly under the disease aids programs and Wisconcare? If not, how will this paragraph be enforced?

7-day

15 (b) The department may monitor the purchase of prescription drugs under
16 state-supported prescription drug programs and the program under s. 49.692 to
17 identify practitioners who routinely prescribe off-list prescription drugs without
18 medical justification and request that the medical examining board investigate and,
19 if appropriate, sanction such practitioners under s. 448.075.

INS 7-19

which one is applicable

INS 9-18

****NOTE: You may wish to reconsider requiring the department to implement a cost-containment measure for the proposed prescription drug assistance program since the state does not pay for drugs under that program.

(9) The department shall encourage local governmental units and private entities that provide health insurance coverage to their employees to use the preferred drug list created under sub. (5) in their health insurance plans. The department shall assess a fee against local governmental units and private entities that agree to use the preferred drug list to fund a portion of the administrative costs of maintaining the preferred drug list. All fees paid to the department under this subsection shall be credited to the appropriation account under s. 20.435 (4) (jt).

****NOTE: The provisions in this bill relating to health insurance plans offered by private employers are directed at the employer rather than the insurance company. Is this what you intend?

(a) (10) The department may enter into a contract with an entity to perform the duties and exercise the powers of the department under subs. (3) and (5).

SECTION 7. 49.692 of the statutes is created to read:

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

(a) "Labeler" has the meaning given in s. 49.69 (1) (b).

(b) "Manufacturer" has the meaning given in s. 49.69 (1) (d).

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

****NOTE: The prescription drug assistance program under this section covers only those prescription drugs that are covered as a Medical Assistance Program benefit. The preferred drug list provision applies to all classes of prescription drugs (so that it can serve the needs of government and private entity employees enrolled in health insurance plans that provide broader prescription drug coverage than Medical Assistance). Should the prescription drug assistance program cover all prescription drugs?

(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 prescription drugs for amounts established by the department under sub. (5):

from a participating pharmacy or pharmacist

- 1 1. The person is a resident, as defined in s. 27.01 (10) (a), of this state.
- 2 2. The person is not a recipient of Medical Assistance, does not have health care
- 3 coverage under s. 49.665, does not have a policy issued under ch. 149, and is not
- 4 enrolled in the program under s. 49.688, *and does not have*
- 5 3. The person has not had insurance coverage for prescription drugs for
- 6 outpatient care that is other than that specified in subd. 2. for at least 30 consecutive
- 7 days immediately before applying under par. (b), except that a person who receives
- 8 benefits under 42 USC 1395 to 1395ccc may have supplemental health insurance
- 9 that covers prescription drugs for outpatient care.

*****NOTE: Will the eligibility provisions for this program encourage private insurers to drop coverage for prescription drugs?*

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 for
 16 each 12-month benefit period, shall issue to eligible persons a prescription drug card
 17 for use in purchasing prescription drugs, as specified in sub. (4), *provided under this section*

*JNS
11-17*

~~(4) Beginning, January 1, 2004, as a condition of participation by a pharmacy or pharmacist in the program under s. 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 issued under sub. (3) an amount for a prescription drug under the order that exceeds the maximum amount for the prescription drug established by the department under sub. (5).~~

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23

1 (5) (a) The department shall determine the maximum amount that a pharmacy
2 or pharmacist may, after December 31, 2003, charge a person who presents a card
3 issued under sub. (3) for a prescription drug. The amount may not be less than the
4 amount that the department reimburses a pharmacy or pharmacist for a
5 prescription drug under the Medical Assistance Program plus the dispensing fee a
6 pharmacy or pharmacist may charge under the Medical Assistance Program.

7 (b) Notwithstanding the maximum amount established by the department
8 under par. (a), a pharmacy or pharmacist may not, after December 31, 2003, charge
9 a person who presents a card issued under sub. (3) more than the usual and
10 customary charge of the pharmacy or pharmacist for a prescription drug plus the
11 dispensing fee a pharmacy or pharmacist may charge under the Medical Assistance
12 Program.

13 (c) If the department secures an agreement from a manufacturer or labeler
14 under s. 49.69 to provide a rebate on a prescription drug under this section, the
15 department shall reduce the amount that a pharmacy or pharmacist may charge for
16 the prescription drug by the amount of the rebate.

17 (d) The department shall calculate and transmit to pharmacies and
18 pharmacists that are certified providers of Medical Assistance amounts that may be
19 used in calculating charges under this subsection. The department shall periodically
20 update this information and transmit the updated amounts to pharmacies and
21 pharmacists.

22 (6) (a) If the department secures an agreement from a manufacturer or labeler
23 under s. 49.69 to provide rebates on prescription drugs purchased by persons under
24 this section, the department shall do all of the following:

1 1. Devise and distribute a form for pharmacies and pharmacists to use to report
2 sales of prescription drugs to persons who have cards issued under sub. (3).

3 2. Collect from pharmacies and pharmacists utilization data necessary to
4 calculate the amounts to be reimbursed to the pharmacies and pharmacists under
5 this paragraph.

6 3. From the appropriation account under s. 20.435 (4) (jx), pay pharmacies and
7 pharmacists the appropriate rebate amount for each prescription drug that the
8 pharmacy or pharmacist sells to a person who has a card issued under sub. (3).

9 (b) The department may limit payment under par. (a) to claims that pharmacies
10 or pharmacists submit directly to the department.

11 (c) The department may not impose transaction charges on pharmacies or
12 pharmacists that submit claims or receive payments under par. (a).

13 (b) (d) 1. If a discrepancy exists between a rebate amount claimed by a pharmacy
14 or pharmacist under par. (a) and the amount paid by a manufacturer or labeler, the
15 party claiming a loss as a result of the discrepancy may hire an independent auditor
16 who is agreed on by the parties to review the discrepancy. If the discrepancy is not
17 resolved by the audit, the party advantaged by the discrepancy shall justify the
18 reason for the discrepancy or pay the amount necessary to resolve the discrepancy.

19 2. If the controversy continues after the procedures under subd. 1. have been
20 carried out, the department or the manufacturer or labeler may request a hearing
21 before the division of hearing and appeals of the department of administration as a
22 contested case under ch. 227.

****NOTE: The claims dispute process under par. (d) is taken from 2001 AB-857.
Do you want to include the claims dispute process in this bill? If so, should it be expanded
to apply to rebates paid under Medical Assistance, Badger Care, Senior Care, the Disease
Aids programs, Wisconcare, and HIRSP?

1 (e) Any patient-identifiable data, as defined in s. 153.50 (1) (b) 1. or 2. or as
 2 specified in s. 153.50 (3) (b) 1. to 7., that is collected under par. (a) 2. shall be treated
 3 as a patient health care record for purposes of s. 146.82.

****NOTE: Should the bill require DHFS to negotiate with manufacturers to obtain both the rebate that is provided under Medical Assistance and a supplemental rebate, or should DHFS just negotiate for one rebate for drugs purchased under the proposed prescription drug assistance program?

****NOTE: Should this bill include the following provisions related to the prescription drug assistance program that are in 2001 AB-857: 1) a requirement that DHFS monitor compliance of pharmacies and pharmacists and report to the legislature on compliance; 2) a requirement that DHFS promulgate rules relating to prohibitions on fraud; and 3) penalties for committing fraud that is prohibited by the rules referred to in item number 2?

4 SECTION 8. 149.143 (1) (a) of the statutes is amended to read:

5 149.143 (1) (a) First from the moneys transferred to the fund from the
 6 appropriation account under s. 20.435 (4) (af) and from the moneys appropriated for
 7 the health insurance risk-sharing plan under s. 20.435 (4) (jx).

8 SECTION 9. 448.075 of the statutes is created to read:

9 448.075 Preferred drug list compliance. Upon the request of the
 10 department of health and family services, the board shall investigate a practitioner,
 11 as defined in s. 450.01 (17), to determine whether the practitioner routinely
 12 prescribes prescription drugs that are not on the preferred drug list established
 13 under s. 49.69 to beneficiaries of state-supported prescription drug programs, as
 14 defined in s. 49.69 (1) (i) or to persons enrolled in the prescription drug assistance
 15 program under s. 49.692 without medical justification. If the board determines that
 16 a practitioner routinely prescribes drugs that are not on the preferred drug list
 17 without medical justification, the board may assess a forfeiture of \$250 against the
 18 practitioner.

****NOTE: I set the assessment at \$250 because that is the amount of the lowest fine under s. 448.09. Should it be a different amount or should the bill allow a range? Any forfeitures assessed under this section will go to the school fund.

physician or physician assistant

(jh) and

applicable

(1) sold

no \$ → IWS 14-18 ✓

IWS 14-7

1 **SECTION 10.** 450.02 (2) of the statutes is renumbered 450.02 (2) (intro.) and
2 amended to read:

3 450.02 (2) (intro.) The board shall ~~adopt rules defining~~ promulgate all of the
4 following rules, which apply to all applicants for licensure under s. 450.05:

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

7 **SECTION 11.** 450.02 (2) (b) of the statutes is created to read:

8 450.02 (2) (b) Requiring disclosure by a pharmacist to a prescription drug
9 purchaser who has a card issued under s. 49.692 (3) of the amount of the discount
10 on the retail price of the prescription drug that is provided to the purchaser as a
11 result of the program under s. 49.692.

12 **SECTION 12.** 450.075 of the statutes is created to read:

13 **450.075 Manufacturer gift reporting.** (1) In this section:

14 (a) ~~“Clinical trial” means any experiment in which a drug is administered to~~
15 ~~a human subject in connection with a research study.~~

16 ^(a) (b) “Health benefit plan” has the meaning given in s. 632.745 (11).

17 ^(b) (c) “Hospital” means a facility approved as a hospital under s. 50.35.

18 ^(c) (d) “Nursing home” has the meaning given in s. 50.01 (3).

19 (2) (a) Except as provided in par. (c), each manufacturer shall annually report
20 to the board the value, nature, and purpose of any gift, payment, subsidy, or other
21 economic benefit valued at \$25 or more that the manufacturer directly or indirectly
22 provides to any of the following in connection with the manufacturer’s promotional
23 or marketing activities:

24 1. A practitioner.

25 2. A pharmacist or an owner or operator of a pharmacy.

1 3. A hospital, nursing home, or organization that offers a health benefit plan,
2 or an employee of a hospital, nursing home, or organization that offers a health
3 benefit plan.

4 4. Any other person authorized to purchase prescription drugs for retail or
5 wholesale resale.

****NOTE: The Vermont bill requires manufacturers to report gifts to "any other person in Vermont authorized to prescribe, dispense, or purchase prescription drugs in this state." That provision presumably covers gifts to individual consumers. This bill does not require manufacturers to report gifts to individual consumers. Should it?

6 (b) A manufacturer shall submit the report required under par. (a) by January
7 1 of each year for the 12-month period ending on the previous June 30.

8 (c) A manufacturer is not required to report any of the following under par. (a):

9 1. ^{any} A free sample of ^a prescription drugs ^{as that is} intended to be distributed to ^a patients.

10 2. Payment of reasonable compensation or reimbursement of expenses in
11 connection with a clinical trial.

12 3. A scholarship or other support for a medical student, resident, or fellow to
13 attend an educational or policy-making conference sponsored by a professional
14 association, if the recipient of the scholarship or other support is selected by the
15 association.

****NOTE: If the intent of the reporting requirement is to learn who might be indebted to a pharmaceutical manufacturer, why allow these exceptions?

16 (3) Each manufacturer shall report to the board the name and address of the
17 person responsible for making reports under sub. (2) and shall notify the board of any
18 change in the information required under this subsection.

19 (4) A manufacturer who violates sub. (2) may be required to forfeit not more
20 than \$10,000 for each violation and, notwithstanding s. 814.04, to pay all actual costs

1 incurred by the state in prosecuting the violation, including reasonable attorney
2 fees.

3 (5) The board shall develop a form that manufacturers shall use to submit
4 reports under sub. (2).

5 (6) Any information reported by a manufacturer under this section that
6 constitutes a trade secret, as defined in s. 134.90 (1) (c), shall remain confidential.
7 The board may not release trade secret information obtained under this section,
8 except to the department of justice for the purpose of prosecuting a violation under
9 sub. (4). The form prescribed by the board under sub. (5) shall direct a manufacturer
10 to identify any information that is a trade secret.

11 (7) Annually, by March 1, the board shall submit to the legislature under s.
12 13.172 (2) and to the governor a report ^{describing the} on disclosures made by manufacturers under
13 sub. (2).

****NOTE: What is the board supposed to report—whether manufacturers comply with the reporting requirement, or some summary of the gifts made?

STE ← A.R. (A)

14 SECTION 13. Nonstatutory provisions.

15 (1) ENROLLMENT FEE FOR PRESCRIPTION DRUG ASSISTANCE PROGRAM. The
16 enrollment fee for the prescription drug assistance program under section 49.692 (3) ✓
17 of the statutes, as created by this act, shall be \$20, except that the department of
18 health and family services shall review the costs to administer the prescription drug
19 assistance program after it has been implemented for 12 months and shall reduce
20 the program enrollment fee if the earnings from the fee are greater than the costs
21 incurred by the department in administering the program.

INS
17-21

22 SECTION 14. Effective date. (B) S

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no \$

(1) This act takes effect on the day after publication, on the 2nd day after publication of the 2003-05 biennial budget act, or on July 1, 2003, whichever is later.

(END)

except as follows:

2003-2004 DRAFTING INSERT
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-1270/P2ins
RLR:.....

1 **Ins 1-9:**

2 SECTION ~~4~~^{*} 20.435 (4) (jh)[↓] of the statutes is created to read:

3 20.435 (4) (jh) *Health insurance risk-sharing plan; drug manufacturer rebates.*

4 All moneys received from rebate payments by manufacturers under s. 149.14 (4c) (c),[↓]
5 to pay a portion of the operating costs of the health insurance risk-sharing plan
6 under ch. 149.[↓]

7
8 **Ins 2-2:**

9 (No It)

10 (6) (d) and 448.075 (2), and all moneys received from the payment of
11 prescription drug assessments under ss. 441.16 (7), 447.08, and 448.075 (1)

12 **Ins 2-7:**

13 (No It)

14 program benefits administered under s. 49.45[↓]; to be used for the Badger Care[↓]
15 health care program for low-income families under s. 49.665[↓]

16 **Ins 2-14:**

17 (No It)

18 ; and to be credited to the public employee trust fund.

19 **Ins 2-15:**

20 SECTION ~~4~~^{*} 20.435 (8) (mb) of the statutes, as affected by 2001 Wisconsin Act
21 16, is amended to read:

22 20.435 (8) (mb) *Income augmentation services receipts.* All moneys that are
23 received under 42 USC 670 to 679a, 42 USC 1395 to 1395ddd, and 42 USC 1396 to

STET

1 1396v as the result of income augmentation activities for which the state has
 2 ~~contracted~~^{STET} and all moneys that are received under 42 USC 1396 to 1396v in
 3 reimbursement of the cost of providing targeted case management services to
 4 children whose care is not eligible for reimbursement under 42 USC 670 to 679a, to
 5 be used as provided in s. 46.46 and 2003 Wisconsin Act ... (this act), section ^{A.R.A. (A.R. (A1))}. All
 6 moneys received under this paragraph in excess of the moneys necessary to support
 7 the costs specified in s. 46.46 and 2003 Wisconsin Act ... (this act), section , shall be
 8 deposited in the general fund as a nonappropriated receipt.

History: 1971 c. 125 ss. 138 to 155, 522 (1); 1971 c. 211, 215, 302, 307, 322; 1973 c. 90, 198, 243; 1973 c. 284 s. 32; 1973 c. 308, 321, 322, 333, 336; 1975 c. 39 ss. 153 to 173, 732 (1), (2); 1975 c. 41 s. 52; 1975 c. 82, 224, 292; 1975 c. 413 s. 18; 1975 c. 422, 423; 1975 c. 430 ss. 1, 2, 80; 1977 c. 29 ss. 236 to 273, 1657 (18); 1977 c. 112; 1977 c. 203 s. 106; 1977 c. 213, 233, 327; 1977 c. 354 s. 101; 1977 c. 359; 1977 c. 418 ss. 129 to 137, 924 (18) (d), 929 (55); 1977 c. 428 s. 115; 1977 c. 447; 1979 c. 32 s. 92 (11); 1979 c. 34, 48; 1979 c. 102 s. 237; 1979 c. 111, 175, 177; 1979 c. 221 ss. 118g to 133, 2202 (20); 1979 c. 238, 300, 331, 361; 1981 c. 20 ss. 301 to 356b, 2202 (20) (b), (d), (g); 1981 c. 93 ss. 3 to 8, 186; 1981 c. 298, 314, 317, 359, 390; 1983 a. 27 ss. 318 to 410, 2202 (20); 1983 a. 192, 199, 245; 1983 a. 333 s. 6; 1983 a. 363, 398, 410, 427; 1983 a. 435 ss. 2, 3, 7; 1983 a. 538; 1985 a. 24, 29, 56, 73, 120, 154, 176, 255, 281, 285, 332; 1987 a. 27, 339, 368, 398, 399, 402; 1987 a. 403 ss. 25, 256; 1987 a. 413; 1989 a. 31, 53; 1989 a. 56 ss. 13, 259; 1989 a. 102; 1989 a. 107 ss. 11, 13, 17 to 37; 1989 a. 120, 122, 173, 199, 202, 318, 336, 359; 1991 a. 6, 39, 189, 269, 275, 290, 315, 322; 1993 a. 16, 27, 76, 98, 99, 168, 183, 377, 437, 445, 446, 450, 469, 479, 490, 491; 1995 a. 27 ss. 806 to 961r, 9126 (19); 1995 a. 77, 98; 1995 a. 216 ss. 26, 27; 1995 a. 266, 276, 289, 303, 404, 417, 440, 448, 464, 468; 1997 a. 27 211, 214, 216, 217, 527 to 609; 1997 a. 35, 105, 231, 237, 280, 293; 1999 a. 5, 9, 32, 52, 84, 103, 109, 113, 133, 185, 186; 2001 a. 16, 69, 103, 105.

9 **SECTION 20.435 (8) (mb) of the statutes, as affected by 2001 Wisconsin Act**

10 16 and 2003 Wisconsin Act ... (this act), is amended to read:

11 20.435 (8) (mb) *Income augmentation services receipts.* All moneys that are
 12 received under 42 USC 670 to 679a, 42 USC 1395 to 1395ddd, and 42 USC 1396 to
 13 1396v as the result of income augmentation activities for which the state has
 14 contracted and all moneys that are received under 42 USC 1396 to 1396v in
 15 reimbursement of the cost of providing targeted case management services to
 16 children whose care is not eligible for reimbursement under 42 USC 670 to 679a, to
 17 be used as provided in s. 46.46 and 2003 Wisconsin Act ... (this act), section ^{A.R.A. (A.R. (A1))}. All
 18 moneys received under this paragraph in excess of the moneys necessary to support
 19 the costs specified in s. 46.46 and 2003 Wisconsin Act ... (this act), section , shall
 20 be deposited in the general fund as a nonappropriated receipt.

History: 1971 c. 125 ss. 138 to 155, 522 (1); 1971 c. 211, 215, 302, 307, 322; 1973 c. 90, 198, 243; 1973 c. 284 s. 32; 1973 c. 308, 321, 322, 333, 336; 1975 c. 39 ss. 153 to 173, 732 (1), (2); 1975 c. 41 s. 52; 1975 c. 82, 224, 292; 1975 c. 413 s. 18; 1975 c. 422, 423; 1975 c. 430 ss. 1, 2, 80; 1977 c. 29 ss. 236 to 273, 1657 (18); 1977 c. 112; 1977 c. 203 s. 106; 1977 c. 213, 233, 327; 1977 c. 354 s. 101; 1977 c. 359; 1977 c. 418 ss. 129 to 137, 924 (18) (d), 929 (55); 1977 c. 428 s. 115; 1977 c. 447; 1979 c. 32 s. 92 (11); 1979 c. 34, 48; 1979 c. 102 s. 237; 1979 c. 111, 175, 177; 1979 c. 221 ss. 118g to 133, 2202 (20); 1979 c. 238, 300, 331, 361; 1981 c. 20 ss. 301 to 356b, 2202 (20) (b), (d), (g); 1981 c. 93 ss. 3 to 8, 186; 1981 c. 298, 314, 317, 359, 390; 1983 a. 27 ss. 318 to 410, 2202 (20); 1983 a. 192, 199, 245; 1983 a. 333 s. 6; 1983 a. 363, 398, 410, 427; 1983 a. 435 ss. 2, 3, 7; 1983 a. 538; 1985 a. 24, 29, 56, 73, 120, 154, 176, 255, 281, 285, 332; 1987 a. 27, 339, 368, 398, 399, 402; 1987 a. 403 ss. 25, 256; 1987 a. 413; 1989 a. 31, 53;

1989 a. 56 ss. 13, 259; 1989 a. 102; 1989 a. 107 ss. 11, 13, 17 to 37; 1989 a. 120, 122, 173, 199, 202, 318, 336, 359; 1991 a. 6, 39, 189, 269, 275, 290, 315, 322; 1993 a. 16, 27, 76, 98, 99, 168, 183, 377, 437, 445, 446, 450, 469, 479, 490, 491; 1995 a. 27 ss. 806 to 961r, 9126 (19); 1995 a. 77, 98; 1995 a. 216 ss. 26, 27; 1995 a. 266, 276, 289, 303, 404, 417, 440, 448, 464, 468; 1997 a. 27 ss. 211, 214, 216, 217, 527 to 609; 1997 a. 35, 105, 231, 237, 280, 293; 1999 a. 5, 9, 32, 52, 84, 103, 109, 113, 133, 185, 186; 2001 a. 16, 69, 103, 105.

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No ff

Ins 3-24:

and shall disclose the receipt of grant funding from a manufacturer, distributor, or labeler ^{within} ~~in~~ the previous 36 months or ownership of stock in a manufacturer, distributor, or labeler.

No ff

Ins 4-10:

and from consumer advocates

No ff

Ins 4-10B:

and in its determinations regarding the safety and clinical efficacy of prescription drugs

Ins 4-11:

SECTION ~~4.~~ [#] 49.68 (3) (b) of the statutes is amended to read:

49.68 (3) (b) From the appropriation accounts under ss. 20.435 (4) (e) and, (je), and (jx) the state shall pay the cost of medical treatment required as a direct result of chronic renal disease of certified patients from the date of certification, including the cost of administering recombinant human erythropoietin to appropriate patients, whether the treatment is rendered in an approved facility in the state or in a dialysis or transplantation center which is approved as such by a contiguous state, subject to the conditions specified under par. (d). Approved facilities may include a hospital in-center dialysis unit or a nonhospital dialysis center which is closely affiliated with a home dialysis program supervised by an approved facility.

1 Aid shall also be provided for all reasonable expenses incurred by a potential
 2 living-related donor, including evaluation, hospitalization, surgical costs and
 3 postoperative follow-up to the extent that these costs are not reimbursable under the
 4 federal medicare program or other insurance. In addition, all expenses incurred in
 5 the procurement, transportation and preservation of cadaveric donor kidneys shall
 6 be covered to the extent that these costs are not otherwise reimbursable. All
 7 donor-related costs are chargeable to the recipient and reimbursable under this
 8 subsection.

History: 1973 c. 308; 1975 c. 39; 1977 c. 29; 1981 c. 314; 1983 a. 27; 1985 a. 332 s. 251 (1); 1989 a. 311; 1991 a. 316; 1993 a. 16, 449, 491; 1995 a. 27 ss. 3035 to 3044; Stats. 1995 s. 49.68; 2001 a. 16.

9 SECTION 49.683 (2) of the statutes is amended to read:

10 49.683 (2) Approved costs for medical care under sub. (1) shall be paid from the
 11 appropriation accounts under s. 20.435 (4) (e) and, (je), and (jx).

History: 1973 c. 300; Stats. 1973 s. 49.635; 1973 c. 336 s. 55; Stats. 1973 s. 146.36; 1975 c. 39; 1979 c. 34 s. 2102 (43) (a); 1983 a. 27 s. 1562; Stats. 1983 s. 49.483; 1993 a. 16, 449; 1995 a. 27 ss. 3045, 3046, 3047; Stats. 1995 s. 49.683; 1997 a. 27; 1999 a. 9; 2001 a. 16.

12 SECTION 49.685 (2) of the statutes is amended to read:

13 49.685 (2) ASSISTANCE PROGRAM. From the appropriation accounts under s.
 14 20.435 (4) (e) and, (je), and (jx) the department shall establish a program of financial
 15 assistance to persons suffering from hemophilia and other related congenital
 16 bleeding disorders. The program shall assist such persons to purchase the blood
 17 derivatives and supplies necessary for home care. The program shall be
 18 administered through the comprehensive hemophilia treatment centers.

History: 1977 c. 213; 1979 c. 32; 1981 a. 27; 1983 a. 189 s. 329 (10); 1983 a. 544 s. 47 (1); 1985 a. 29 s. 3202 (23), (46); 1987 a. 27; 1987 a. 312 s. 17; 1993 a. 16, 449; 1995 a. 27 ss. 3048 to 3060; Stats. 1995 s. 49.685; 2001 a. 16.

19 SECTION 49.688 (7) (a) of the statutes is amended to read:

20 49.688 (7) (a) Except as provided in par. (b), from the appropriation accounts
 21 under s. 20.435 (4) (bv) and, (j), ~~beginning on September 1, 2002,~~ and (jx) the
 22 department shall, under a schedule that is identical to that used by the department
 23 for payment of pharmacy provider claims under medical assistance, provide to

1 pharmacies and pharmacists payments for prescription drugs sold by the
 2 pharmacies or pharmacists to persons eligible under sub. (2) who have paid the
 3 deductible specified under sub. (3) (b) 1. or 2. or who, under sub. (3) (b) 1., are not
 4 required to pay a deductible. The payment for each prescription drug under this
 5 paragraph shall be at the program payment rate, minus any copayment paid by the
 6 person under sub. (5) (a) 2. or 4., and plus, if applicable, incentive payments that are
 7 similar to those provided under s. 49.45 (8v). The department shall devise and
 8 distribute a claim form for use by pharmacies and pharmacists under this paragraph
 9 and may limit payment under this paragraph to those prescription drugs for which
 10 payment claims are submitted by pharmacists or pharmacies directly to the
 11 department. The department may apply to the program under this section the same
 12 utilization and cost control procedures that apply under rules promulgated by the
 13 department to medical assistance under subch. IV of ch. 49.

History: 2001 a. 16, 109.

14

Ins 6-13:

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(3) (a) The department shall solicit bids or proposals from manufacturers and
 17 labelers to provide rebates on prescription drugs that the committee has included in
 18 therapeutic classes under sub. (2) and that are purchased under the following
 19 programs or plans:

20

1. One solicitation shall be for rebates on drugs purchased under
 21 state-supported health care assistance programs.

21

22

2. Subject to sub. (8), a ^{2nd} ~~second~~ solicitation shall be for rebates on prescription
 23 drugs that are purchased under the prescription drug assistance program under s.

1 49.692[✓] or under a health care coverage plan offered by the state, a local governmental
2 unit, or a private employer^g to its employees.

3
4 **Ins 6-23:**

5 (c) Any rebate offered by a manufacturer or labeler in response to a solicitation
6 under par. (a) 2. shall be equal to the amount of the rebate that the manufacturer or
7 labeler provides under 42 USC 1396r-8, if any.

at least
that is required

8
9 **Ins 8-7:**

10 (4) (a) Using the method prescribed under pars. (b) and (c), the department
11 shall create preferred drug lists for the following programs or plans:

- 12 1. One preferred drug list for state-supported health care assistance programs.
13 2. A ^{2nd} ~~second~~ preferred drug list for the prescription drug assistance program

14 under s. 49.692 and for health care coverage plans offered by the state, a local
15 governmental unit, or a private employer to its employees.

16 (b) The department shall identify the lowest-cost drug in each therapeutic
17 class and place it on ^a the preferred drug list. The department may include one or more
18 additional prescription drugs within a therapeutic class on ^{that} the preferred drug list if
19 the cost of the additional prescription drug is not significantly greater than the cost
20 of the lowest-cost prescription drug within the class.

21 (c) In determining cost under this subsection, the department shall consider
22 any rebate offered under sub. (3) (a) 1. or 2.[✓], whichever is applicable, any existing
23 rebate agreement or requirement, dosing practices, and any other relevant cost
24 information.

1 **Ins 8-18:**

2 (5) (a) By July 1, 2004, the department shall enter into agreements with the
3 manufacturers or labelers of the prescription drugs on the preferred drug list under
4 sub. (4) (a) 1. to pay the state the rebates proposed under sub. (3) (a) 1. on prescription
5 drugs that are purchased under state-supported health care assistance programs on
6 or after July 1, 2004.

7 (6) (a) Subject to sub. (8), the department shall enter into agreements with the
8 manufacturers or labelers of prescription drugs on the preferred drug list under sub.
9 (4) (a) 2. to pay the rebates proposed under sub. (3) (a) 2. on prescription drugs that
10 are purchased under the following programs or plans:

11 1. The prescription drug assistance program under s. 49.692.

12 2. Health care coverage plans offered by the state to state employees who are
13 not subject to collective bargaining.

14 3. Health care coverage plans offered by the state to state employees who are
15 subject to collective bargaining, if the employees agree through collective bargaining
16 to subject their health care coverage to policies that encourage use of the preferred
17 drug list.

18 4. Health care coverage plans offered by a local governmental unit or private
19 employer to its employees, if the department approves the plan, or the employment
20 contract that provides for the plan under par. (b).

21 (b) An entity that provides, purchases, or negotiates health insurance coverage
22 for employees of a local governmental unit or private employer may apply to the
23 department to approve a health care coverage plan, or an employment contract that
24 provides for health care coverage. The department shall approve the plan or contract
25 if it includes policies to encourage use of the preferred drug list under sub. (4) (a) 2.

*under sub.
(4) (a) 2
Δ Δ*

1 (c) For purposes of this section, all of the following constitute policies to
2 encourage use of the preferred drug list:

3 1. Prior authorization for off-list prescription drugs.

4 2. Higher copayments for off-list prescription drugs than for drugs that are on
5 the preferred drug list.

6 3. Discipline or penalties for practitioners who prescribe off-list prescription
7 drugs without medical justification.

8 (d) The department shall charge entities that receive rebates under par. (a) 4.
9 a fee to support the administrative costs of creating and maintaining the preferred
10 drug lists under sub. (4). The department shall promulgate rules establishing the
11 method for determining the amount of the fee. All fees collected under this
12 paragraph shall be credited to the appropriation account under s. 20.435 (4) (jt).

13 (e) Manufacturers and labelers shall pay rebates under par. (a) 1., 2., and 3.,
14 to the state, and shall pay rebates under par. (a) 4. to the entity designated by the
15 department.

16
17 **Ins 9-1:**

18 (8) The department shall determine when to cover each of the programs or
19 plans under sub. (6) (a) 1., 2., 3., and 4. in solicitations under sub. (3) (a) 2. and in
20 agreements under sub. (6) (a).
STEP period

21
22 **Ins 9-18:**

23 , board of nursing, or dentistry examining board, whichever is applicable,
24

25 **Ins 9-19:**

Woff

Not

1 441.16 (7), 447.08, or

2

3 **Ins 10-9:**

4 (b) The department may not contract under this subsection with an entity if the
5 entity, its parent company, or its subsidiary has any direct or indirect financial
6 interest in sales of a particular prescription drug. The department shall require an
7 entity to disclose all such financial interests before the department contracts with
8 the entity under this subsection.

9 (c) An entity that enters into a contract with the department under this
10 subsection, or a parent company or subsidiary of that entity, may not incur a financial
11 interest in sales of a particular prescription drug during the term of the contract.

12 (d) The department shall periodically audit any entity with which it contracts
13 under this subsection to determine whether the entity, its parent company, or a
14 subsidiary has any financial interests that are prohibited under this subsection.

15

16 **Ins 10-13:**

17 (c) "Participating pharmacy or pharmacist" means a pharmacy or pharmacist
18 that agrees to sell prescription drugs to a person who has a prescription drug card
19 issued under sub. (3) for the amount provided under sub. (5).

20

21 **Ins 11-17:**

22 (4) The department shall set maximum prices and a maximum dispensing fee
23 for prescription drugs purchased under this section.

24 (5) Beginning January 1, 2004, a participating pharmacy or pharmacist may
25 not charge a person who presents a valid prescription order and a prescription drug

1 card issued under sub. (3) more than the maximum price established by the
2 department under sub. (4) for a prescription drug, less any rebate amount agreed to
3 under s. 49.69 (6) (a) 1., plus the maximum dispensing fee established by the
4 department under sub. (4).

5 (6) (a) From the appropriation account under ^{s.} 20.435 (4) (jx) and 20.435 ^g (8) ^{and}
6 (mb), the department shall reimburse participating pharmacies and pharmacists the
7 applicable rebate amounts specified in agreements under ^{s.} 49.69 (6) (a) 1., if any, for
8 each prescription drug that the pharmacy sells to a person who has a prescription
9 drug card issued under sub. (3).

11 **Ins 13-22:**

12 (7) The department shall promulgate rules establishing the following:

13 (a) The method for determining the maximum retail price for a prescription
14 drug.

15 (b) The method for determining the maximum dispensing fee.

16 (c) The method for informing participating pharmacies and pharmacists of the
17 maximum prices, dispensing fees, and rebate amounts for prescription drugs.

18 (d) The process by which a participating pharmacy or pharmacist may claim
19 reimbursement for rebates.

A.R.
Y

20 SECTION ~~§~~ 49.692 (6) (a) of the statutes, as created by 2003 Wisconsin Act ...

21 (this act), is amended to read:

22 49.692 (6) (a) From the appropriation account under ^{s.} 20.435 (4) (jx) and ~~20.435~~
23 (8) ~~(mb)~~, the department shall reimburse participating pharmacies and pharmacists
24 the applicable rebate amounts specified in agreements under ^{s.} 49.69 (6) (a) 1., if any,

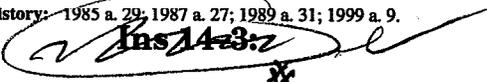
1 for each prescription drug that the pharmacy sells to a person who has a prescription
2 drug card issued under sub. (3).

3 

4 SECTION ~~9~~ 146.93 (1) (a) of the statutes is amended to read:

5 146.93 (1) (a) From the ~~appropriation~~ appropriation accounts under s. 20.435
6 (4) (gp) and (jx), the department shall maintain a program for the provision of
7 primary health care services based on the primary health care program in existence
8 on June 30, 1987. The department may promulgate rules necessary to implement
9 the program.

10 History: 1985 a. 29; 1987 a. 27; 1989 a. 31; 1999 a. 9.



11 SECTION ~~10~~ 149.14 (4c) (c) of the statutes is created to read:

12 149.14 (4c) (c) The department or an entity with which the department
13 contracts shall provide to a drug manufacturer that sells drugs for prescribed use in
14 this state documents designed for use by the manufacturer in entering into a rebate
15 agreement with the department or entity that is modeled on the rebate agreement
16 specified under 42 USC 1396r-8. The department or entity may enter into a rebate
17 agreement under this paragraph that shall include all of the following as
18 requirements:

- 19 1. That, as a condition of coverage for prescription drugs of a manufacturer
20 under this section other than prescription drugs that are prescribed for the
21 treatment of acquired immunodeficiency syndrome or human immunodeficiency
22 virus, the manufacturer shall make rebate payments for each prescription drug of
23 the manufacturer, that is prescribed for and purchased by an eligible person, to the

1 state treasurer to be credited to the appropriation account under s. 20.435 (4) (jh),
2 each calendar quarter or according to a schedule established by the department.

3 2. That the amount of the rebate payment shall be determined by a method
4 specified in 42 USC 1396r-8 (c).

END INSERT 13-22

History: 1983 a. 27; 1989 a. 56; 1991 a. 39; 1993 a. 16, 449; 1995 a. 27 ss. 3063 to 3065; Stats. 1995 s. 49.687; 1997 a. 27; 1999 a. 9; 2001 a. 16.

5
6 **Ins 14-7**

7 **SECTION 14. 441.16 (7) of the statutes is created to read:**

8 441.16 (7) Upon the request of the department of health and family services,
9 the board shall investigate an advanced practice nurse to determine whether the
10 advanced practice nurse routinely prescribes prescription drugs that are not on the
11 applicable preferred drug list established under s. 49.69[✓] to beneficiaries of
12 state-supported health care assistance programs, as defined in s. 49.69 (1) (i)[✓], or to
13 persons enrolled in the prescription drug assistance program under s. 49.692[✓],
14 without medical justification. If the board determines that an advanced practice
15 nurse routinely prescribes drugs that are not on the applicable preferred drug list
16 without medical justification, the board shall require the advanced practice nurse to
17 complete a preferred drug list class under s. 448.075 (2)[✓] at the earliest possible
18 opportunity, shall reprimand the advanced practice nurse, and may require the
19 advanced practice nurse to pay a forfeiture not to exceed \$50. If the board imposes
20 a forfeiture under this subsection, it shall also impose a prescription drug
21 assessment of \$200. All prescription drug assessments paid under this ^{sub}section shall
22 be credited to the appropriation account under s. 20.435 (4) (jt)[✓].

23 **SECTION 14. 447.08 of the statutes is created to read:**

1 **447.08 Preferred drug list compliance.** Upon the request of the
2 department of health and family services, the board shall investigate a dentist to
3 determine whether the dentist routinely prescribes prescription drugs that are not
4 on the applicable preferred drug list established under s. 49.69[✓] to beneficiaries of
5 state-supported health care assistance programs, as defined in s. 49.69 (1) (i)[✓], or to
6 persons enrolled in the prescription drug assistance program under s. 49.692,[✓]
7 without medical justification. If the board determines that a dentist routinely
8 prescribes drugs that are not on the applicable preferred drug list without medical
9 justification, the board shall require the dentist to complete a preferred drug list
10 class under s. 448.075 (2)[✓] at the earliest possible opportunity, shall reprimand the
11 dentist, and may require the dentist to pay a forfeiture not to exceed \$50. If the board
12 imposes a forfeiture under this section, it shall also impose a prescription drug
13 assessment of \$200. All prescription drug assessments paid under this section shall
14 be credited to ~~in~~^o the appropriation account under s. 20.435 (4) (jt).[✓]

15
16 **Ins 14-18:**

17 ~~No ff~~ health care assistance programs, as defined in s. 49.69 (1) (i)[✓], or to persons
18 enrolled in the prescription drug assistance program under s. 49.692,[✓] without
19 medical justification. If the board determines that a physician or physician assistant
20 routinely prescribes drugs that are not on the applicable preferred drug list without
21 medical justification, the board shall require the physician or physician assistant to
22 complete a preferred drug list class under sub. (2)[✓] at the earliest possible opportunity,
23 shall reprimand the physician or physician assistant, and may require the physician
24 or physician assistant to pay a forfeiture not to exceed \$50. If the board imposes a
25 forfeiture under this subsection, it shall also impose a prescription drug assessment

1 of \$200. All prescription drug assessments paid under this ^{sub} section shall be credited
2 to the appropriation account under s. 20.435 (4) (jt). ✓

3 (2) The department ^{of regulation and licensing} shall offer a class on preferred drug lists at least once every
4 ³ ~~three~~ months. The department ^{of regulation and licensing} shall consult with the department of health and

5 family services in developing the curriculum for the class and the curriculum shall
6 shall include instruction on the contents of the preferred drug lists created under s.

7 49.69 (4). ✓ The department ^{of regulation and licensing} shall charge practitioners who are required under sub.
8 (1) or s. 441.16 (7) ✓ or 447.08 ✓ to attend the class to pay a fee for the class. All fees

9 collected under this subsection shall be credited to the appropriation account under
10 s. 20.435 (4) (jt). ✓

11
12

Ins 17-21:

13 (2) REPORT TO LEGISLATURE. By July 1, 2006, the department of health and
14 family services shall report to the appropriate standing committees of the
15 legislature, in the manner provided under section 13.172 (3) ✓ of the statutes, on the
16 creation of preferred drug lists, the status of supplemental prescription drug rebate
17 agreements, and the implementation of prescription drug cost controls under section
18 49.69 ✓ of the statutes, as created by this act.

NonSTATS

19 A.R. (A1) (3) USE OF INCOME AUGMENTATION RECEIPTS FOR INITIAL REIMBURSEMENT TO
20 PHARMACISTS AND PHARMACIES. If after supporting the costs specified in section 46.46 ✓

21 of the statutes, there remain any moneys in the appropriation account under section
22 20.435 (8) (mb) of the statutes, as affected by this act, those remaining moneys are

23 allocated to the department of health and family services to reimburse pharmacies
24 and pharmacists under section 49.692 (6) of the statutes, as created by this act, until

25 such time as there is enough money in the account under s. 20.435 (4) (jx) to make

of section of the statutes,
as created
by
this
act,

1 timely reimbursement payments to pharmacies and pharmacists under section
2 49.692 (6) (a) of the statutes, as created by this act. The department of health and
3 family services may not expend or encumber any moneys allocated under this
4 subsection unless the department submits a plan for the proposed use of those
5 moneys to the secretary of administration. If the secretary of administration
6 approves the plan, he or she shall submit the plan to the joint committee on finance.
7 If the cochairpersons of the committee do not notify the secretary of administration
8 within 14 working days after the date of the secretary's submittal of the plan that the
9 committee has scheduled a meeting for the purpose of reviewing the plan, the
10 department of health and family services may implement the plan as proposed by the
11 department of health and family services and approved by the secretary of
12 administration. If, within 14 working days after the date of the secretary's
13 submittal, the cochairpersons of the committee notify the secretary that the
14 committee has scheduled a meeting for the purpose of reviewing the plan, the
15 department of health and family services may implement the plan only upon the
16 approval of the committee.

17

18

Ins 18-2:

19

(1) The treatment of sections 20.435 (8) (mb) (by SECTION) and 49.692 (6)

20

(a) (by SECTION) of the statutes takes effect on July 1, 2005.

A.R. (X)

A.R. (Y)

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-1270/P2dn

RLR:/:....

Wlj

Representatives Underheim and Coggs

1. At the April 10, 2003, meeting we discussed using child welfare income augmentation money to make the initial rebate reimbursement payments to pharmacies and pharmacists under the prescription drug assistance program. Under the bill, the appropriation of income augmentation money is not a loan, because there will never be enough money in the rebate receipts account to both make timely payments to pharmacies and pharmacists and to repay the income augmentation money that is used for start-up payments. The bill repeals DHFS authority to use income augmentation money for payments to pharmacies and pharmacists effective July 1, 2005. Also, the bill requires DHFS to obtain approval from the joint finance committee for using income augmentation money to pay pharmacies and pharmacies, because use of income augmentation money for any purpose other than the three purposes provided under s. 46.46, stats., is subject to joint finance approval under current law.
2. Proposed s. 49.69 (10) (b) and (c), stats., prohibit DHFS from contracting with an entity that has a financial interest in sales of a particular prescription drug. At the April 10 meeting we discussed barring DHFS from contracting with an entity that has a "conflict of interest." I think that "conflict of interest" is too vague. With whom is the conflict — the department, the private employer, the beneficiary of the health insurance coverage plan? These groups might have conflicts amongst themselves. Please let me know if the language in the bill does not satisfy your intent.
3. The bill does not allow persons who independently purchase their own health care coverage to use the preferred drug list and receive rebates. Should it? For example, a self-employed person might purchase a health care coverage plan that is negotiated by a trade association. Should the trade association be able to apply to DHFS for approval of the plan so that the self-employed person may benefit from the rebates?
4. The process for resolving discrepancies in the rebate amount that pharmacists claim and the amount manufacturers pay under the preferred drug assistance program seems to assume that DHFS is a passive party in the rebate reimbursement process, simply paying the amount that a pharmacist claims without checking the claims for accuracy. If this is not the case, you may wish to have DHFS promulgate rules establishing a claims dispute process, rather than using the process under proposed s. 49.692 (6), stats., that is taken from 2001 AB-857.

5. The bill requires that DHFS promulgate rules establishing several important components of the prescription drug assistance program. The implementation date for the program is January 1, 2004. You may wish to amend this bill to provide DHFS emergency rule^omaking authority to promulgate the required rules for this program.

Robin Ryan
Legislative Attorney
Phone: (608) 261-6927
E-mail: robin.ryan@legis.state.wi.us

Underheim, name, Dave de Felice, Rachel Carabel
Dick Sweet, Cit. Action, AARP, CWRG

LRB - 1270 § 2253
4/2/03

Rebate on state e'ye plans should go
to ETF

ETF participates, not the HMOs

p. 3 conflict of interest:

include disclosure of past grants - within
previous 3 years

& include ownership of specific stocks
(not mutual fund shares)

- just require disclosure - not exemption
a bar to participating in decisions

p. 4, & 8 - add requirement to hear
from consumer advocates - not
just manufacturers

do allow state employees & univ. employees
on PAC

(- Budgetary Care providers excepted, in
same way as MA providers, in
for bar)

pay PAC members \$100/day - no cap
don't increase any app'rs. for now

p 5, line 10 - put all pres. drugs on list

MA best price req - have to have a
2-tiered system?

- require rebate for all gyps to be at least
the MA rebate

in current - maybe separate lists

Ryan, Robin

From: Sweet, Richard
Sent: April 02, 2003 11:46 AM
To: Ryan, Robin
Cc: de Felice, David Patrick; Wischnewski, Marne; Carabell, Rachel
Subject: Changes in PDL draft

Robin:

Gregg Underheim had to leave a little before 11, so we only got through about page 7 of the draft. He wanted me to forward the changes that the group made after you left, even though there will be more changes coming before a subsequent draft is prepared:

- 1. The supplemental rebate would be the same for all of the programs and groups covered, except the expansion group. For that group, the supplemental rebate would have to be at least the current MA rebate amount. The draft should allow for the possibility of 2 PDLs--one for the expansion group and one for everyone else, although they may end up being the same.**
- 2. The answer to your question on page 6, after line 8, would be no. The group decided to stick with just public efficacy determinations.**
- 3. The group discussed borrowing start-up money from somewhere else (possibly the MA trust fund), but didn't make a decision on that before Gregg had to leave.**

Thanks for your help.

Dick

4/10/03

LRB 1270 & 2253

Underheim, Maine Dave DeFelice
Dick Sweet, Rachel Canabel
~~Canabel~~, Cit Action, AARP

Require periodic review of costs
(answer to question on length of agreement)

Require DHTS to rpt. on implementation
of PDLs - to Leg. Std. Coms.

p. 8, line 18 - no

p. 9 - prove 7-day supply of drugs
in emergency

p. 9, line 14 - no problems

p. 9 - need to involve examining bds.
for nurses & dentists

p. 10 - don't have state do PA for
note PA prog - but do give Dept.
authority to review prescribing
practices

p. 10 - for Loc. gov & priv. eyes -
DHTS to approve coverage plan / contract
before these grps can use PDL / get
rebates

have DHS promulgate rule on how
fee assessed to loc gov. / private

Bar DHS from contracting w/ entity
that has conflict of int.

Require DHS to get disclosure

- prohibit entity from incurring conflict
- require DHS to periodically audit
for conflicts

p. 11 req. for PDA

get rid of 30 bar - just analyze
if have current drug coverage (except
Medigap)

p. 11 subs 21-6 - all by rule
(except p. 13, line 13)

20.435(8)(mb) use income aug. funds
for startup to pay pharmacies -
treat as a loan!

Discipline - for docs, nurses, dentists

#258

PDL class (Reg. & licensing)
disciplinary record
Sealed app.

\$50 fee

\$1200 assess - practitioner must pay
& can't count towards
Cont. Ed.

p. 16 - delete lines 10-15

p. 17 - a summary - for the rpt

Ryan, Robin

From: Sweet, Richard
Sent: April 22, 2003 3:38 PM
To: Ryan, Robin
Cc: Wischnewski, Marne; de Felice, David Patrick
Subject: PDL draft

Robin:

I had a meeting with Rep. Underheim and DHFS on some HIRSP-related topics. DHFS suggested that Gregg's and Spencer's PDL draft should include specific language authorizing DHFS to collect rebates under HIRSP, similar to what is done with SeniorCare and the disease aids programs. For example, see s. 49.687(3), Stats. Gregg agreed that this change should be made. (Dave, I'm cc'ing you to make sure that Spencer is okay with this.)

Am I getting this to you in time to include it in the next PDL draft?

Thanks for your help.

Dick Sweet
Senior Staff Attorney
Wisconsin Legislative Council
(608)266-2982
richard.sweet@legis.state.wi.us

1270/P1 already allows DHFS to collect rebates under HIRSP

Instructions for §2 require that HIRSP rebate be same as what will get for MA - new piece will be that DHFS can buy purchase of drugs for which the MA rebate is not provided.

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-1270/P2dn
RI.R:wlj:pg

May 2, 2003

Representatives Underheim and Coggs:

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Robin Ryan
Legislative Attorney
Phone: (608) 261-6927
E-mail: robin.ryan@legis.state.wi.us

CAB 1270

mtg. 5/7/03

with Rep Underheim Dave DeFelice (Cogg's office)
Dick Sweet, Main W., Citizen Action, CWA6,
MARP

- (1) Take out doctor penalties - remove fine and assessment, keep class requirement. Allow class to be a visit to doctor's office. Doctor still pays cost of class.
- (2) Allow negotiation on rebate amount for non-public assistance PDL. - i.e. it doesn't have to be the MA rebate amount.
- (3) Have PTC determine relative efficacy when class.
- (4) Don't need PTC to classify into therapeutic classes since FDA already does this per DHFS.
- (5) DHFS will choose drugs for PDLs based on cost & efficacy.
- (6) Require that loc. gov. get approval thru collective bargaining for represented employees before require use of PDL.
- (7) D-Note # 3 - do include people who purchase individually.
- (8) D-Note # 4 - address payment.

discrepancy resolution by rule

(9) D-note #5. - grant exception to emergency rule making ~~for~~ requirements

(10) Change Card program start date
July ~~to~~ Sept ??

(11) allow mail-order pharmacists to participate in card program.

Ryan, Robin

From: Wischnewski, Marne
Sent: May 07, 2003 5:07 PM
To: Ryan, Robin; de Felice, David Patrick; Sweet, Richard
Subject: RE: start-date for card program

Gregg suggested Sept 1, 04. How does that sound??

Marne Wischnewski
Committee Clerk/Assembly Committee on Health
Office of Rep. Gregg Underheim
(608) 266-2254

-----Original Message-----

From: Ryan, Robin
Sent: Wednesday, May 07, 2003 1:54 PM
To: Wischnewski, Marne; de Felice, David Patrick; Sweet, Richard
Subject: start-date for card program

Did we change the start-date for the card program at the meeting today? Right now it is January 1, 2004 in the bill. We were talking about July 1, 2004 when we went off on a tangent and I didn't catch how this was resolved.
thanks