2001 Jr2 DRAFTING REQUEST

Senate Amendment (SA-SSA1-AB1)

Received: **03/28/2002**

Received By: **kenneda**

Wanted: **As time permits**

Identical to LRB:

For: **Senate Democratic Caucus 266-9220**

By/Representing: **Engel**

This file may be shown to any legislator: **NO**

Drafter: **kenneda**

May Contact:

Addl. Drafters:

Subject: **Public Assistance - medl. assist.**

Extra Copies:

Submit via email: **NO**

Pre Topic:

SCC:.....Engel - CN5525,

Topic:

Preferred prescription drugs for MA and Badger Care

Instructions:

See Attached

Drafting History:

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/P1	kenneda 03/30/2002	jdyer 04/01/2002	pgreensl 04/01/2002	_____ _____	lrb_docadmin 04/01/2002		
/1	kenneda 04/02/2002	jdyer 04/03/2002	rschluet 04/03/2002	_____ _____	lrb_docadmin 04/03/2002		
/2	kenneda 04/03/2002	jdyer 04/04/2002	jfrantze 04/04/2002	_____ _____	lrb_docadmin 04/04/2002		
/3	kenneda 04/04/2002	jdyer 04/04/2002	pgreensl 04/04/2002	_____ _____	lrb_docadmin 04/04/2002		

FE Sent For:

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FE Sent For:

13 4/4 jld 4/4 PS/K PS

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LRBb2865

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May Contact:

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Subject: **Public Assistance - med. assist.**

Extra Copies:

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Extra Copies:

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SCC:.....Engel - CN5525,

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Instructions:

See Attached

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/?	kenneda	/P1 4/ jld	4/	4/			

FE Sent For:

<END>

Health and Family Services

Require the DHFS to develop a list of preferred prescription drugs for MA and BadgerCare, and require pharmaceutical manufacturers to make supplemental rebates to the state. [Rachel Carabell and Charlie Morgan at LFB will have drafting instructions on this provision]

CN 5525 DAK

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

March 28, 2002

DELIVER TO: **Debora Kennedy, LRB**

Addressee Fax #: 4-6948 Addressee Phone #: **6-0137**

# of Pages, Including Cover: **7**

From: **Rachel Carabell, Fiscal Analyst**
(608) 266-3847 phone
(608) 267-6873 fax

For drafting CN 5525--the preferred drug list and supplemental rebates. Call if you have questions.

Increasingly, Medicaid administrators and brand name drug makers are at loggerheads over **rebates**. Led by **Florida** and **Michigan**, a growing number of state **Medicaid** plans are considering **preferred drug formulary programs** as a way to offset rising drug costs and bring their budgets back into line.

Under the plans--which have prevailed against legal challenges from drug manufacturers in Florida and Michigan--manufacturers must agree to pony up additional rebates, or discounts, in order for some of their higher-priced products to gain inclusion on the **preferred drug list**. If they don't, doctors who treat **Medicaid** patients will have to obtain approval before they can prescribe a non-formulary medication, or patients themselves will have to pay extra.

The Pharmaceutical Research and Manufacturers of America has waged a fierce legal campaign against states' efforts to control drug-price inflation.

==========

Fla. Stat. § 409.91195

LexisNexis(TM) Florida Annotated Statutes

*** THIS DOCUMENT IS CURRENT THROUGH THE 2001 LEGISLATIVE SESSION ***

TITLE XXX SOCIAL WELFARE
CHAPTER 409 SOCIAL AND ECONOMIC ASSISTANCE

Fla. Stat. § 409.91195 (2001)

409.91195 Medicaid Pharmaceutical and Therapeutics Committee.

There is created a Medicaid Pharmaceutical and Therapeutics Committee within the Agency for Health Care Administration for the purpose of developing a **preferred drug formulary** pursuant to 42 U.S.C. s. 1396r-8.

(1) The Medicaid Pharmaceutical and Therapeutics Committee shall be comprised as specified in 42 U.S.C. s. 1396r-8 and consist of 11 members appointed by the Governor. Four members shall be physicians, licensed under chapter 458; one member licensed under chapter 459; five members shall be pharmacists licensed under chapter 465; and one member shall be a consumer representative. The members shall be appointed to serve for terms of 2 years from the date of their appointment. Members may be appointed to more than one term. The Agency for Health Care Administration shall serve as staff for the committee and assist them with all ministerial duties. The Governor shall ensure that at least some of the members of the Medicaid Pharmaceutical and Therapeutics Committee represent

Medicaid participating physicians and pharmacies serving all segments and diversity of the Medicaid population, and have experience in either developing or practicing under a **preferred drug formulary.** At least one of the members shall represent the interests of pharmaceutical manufacturers.

(2) Committee members shall select a chairperson and a vice chairperson each year from the committee membership.

(3) The committee shall meet at least quarterly and may meet at other times at the discretion of the chairperson and members. The committee shall comply with rules adopted by the agency, including notice of any meeting of the committee pursuant to the requirements of the Administrative Procedure Act.

(4) Upon ~~recommendation~~ advice of the ~~Medicaid Pharmaceutical and Therapeutics Committee,~~ Committee established in JFC sub the agency shall adopt a preferred drug list. To the extent feasible, the committee shall review all drug classes included in the formulary at least every 12 months, and may recommend additions to and deletions from the formulary, such that the formulary provides for medically appropriate drug therapies for Medicaid patients which achieve cost savings contained in the General Appropriations Act.

(5) Except for mental health-related drugs, antiretroviral drugs, and drugs for nursing home residents and other institutional residents, reimbursement of drugs not included in the formulary is subject to prior authorization.

(6) ~~The Agency for Health Care Administration~~ DHFS shall publish and disseminate the **preferred drug formulary** to all Medicaid providers in the state.

(7) The committee shall ensure that pharmaceutical manufacturers agreeing to provide a supplemental rebate as outlined in this chapter have an opportunity to present evidence supporting inclusion of a product on the preferred drug list. Upon timely notice, the agency shall ensure that any drug that has been approved or had any of its particular uses approved by the United States Food and Drug Administration under a priority review classification will be reviewed by the Medicaid Pharmaceutical and Therapeutics Committee at the next regularly scheduled meeting. To the extent possible, upon notice by a manufacturer the agency shall also schedule a product review for any new product at the next regularly scheduled Medicaid Pharmaceutical and Therapeutics Committee. appropriate

(8) Until the Medicaid Pharmaceutical and Therapeutics Committee is appointed and a preferred drug list adopted by the agency, the agency shall use the existing voluntary preferred drug list adopted pursuant to s. 72, chapter 2000-367, Laws of Florida. Drugs not listed on the voluntary preferred drug list will require prior authorization by the agency or its contractor.

(9) The Medicaid Pharmaceutical and Therapeutics Committee shall develop its preferred drug list recommendations by considering the clinical efficacy, safety, and cost-effectiveness of a product. When the **preferred drug formulary** is adopted by the agency, if a product on the formulary is one of the first four brand-name drugs used by a recipient in a month the drug shall not require prior authorization.

(10) The Medicaid Pharmaceutical and Therapeutics Committee may also make

recommendations to the agency regarding the prior authorization of any prescribed drug covered by Medicaid.

(11) Medicaid recipients may appeal agency **preferred drug formulary** decisions using the Medicaid fair hearing process administered by the Department of Children and Family Services. Require DHFS to inform recipients of this right.

HISTORY: s. 72, ch. 2000-367; s. 8, ch. 2001-104.

Fla. Stat. § 409.91196

TITLE XXX SOCIAL WELFARE
CHAPTER 409 SOCIAL AND ECONOMIC ASSISTANCE

Fla. Stat. § 409.91196 (2001)

§ 409.91196 Supplemental rebate agreements; confidentiality of records and meetings.

(1) Trade secrets, rebate amount, percent of rebate, manufacturer's pricing, and supplemental rebates which are contained in records of the Agency for Health Care Administration and its agents with respect to supplemental rebate negotiations and which are prepared pursuant to a supplemental rebate agreement under n1 s. 409.91195 are confidential and exempt from s. 119.07 and s. 24(a), Art. I of the State Constitution.

(2) Those portions of meetings of the Medicaid Pharmaceutical and Therapeutics Committee at which trade secrets, rebate amount, percent of rebate, manufacturer's pricing, and supplemental rebates are disclosed for discussion or negotiation of a supplemental rebate agreement under n1 s. 409.91195 are exempt from s. 286.011 and s. 24(b), Art. I of the State Constitution.

(3) Subsections (1) and (2) are subject to the Open Government Sunset Review Act of 1995 in accordance with s. 119.15, and shall stand repealed on October 2, 2006, unless reviewed and saved from repeal through reenactment by the Legislature.

HISTORY: ss. 1, 3, ch. 2001-216.

NOTES:
n1 Section 409.91195 relates to establishment of a **preferred drug formulary.** Agency authority to negotiate supplemental rebate agreements is located in s. 409.912(37)(a)7.

Fla. Stat. § 409.912 (2001)

409.912 Cost-effective purchasing of health care.

The agency shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care. The agency shall maximize the use of prepaid per capita and prepaid aggregate fixed-sum basis services when appropriate and other alternative service delivery and reimbursement methodologies, including competitive bidding pursuant to s. 287.057, designed to facilitate the cost-effective purchase of a case-managed continuum of care. The agency shall also require providers to minimize the exposure of recipients to the need for acute inpatient, custodial, and other institutional care and the inappropriate or unnecessary use of high-cost services. The agency may establish prior authorization requirements for certain populations of Medicaid beneficiaries, certain

drug classes, or particular drugs to prevent fraud, abuse, overuse, and possible dangerous drug interactions. The Pharmaceutical and Therapeutics Committee shall make recommendations to the agency on drugs for which prior authorization is required. The agency shall inform the Pharmaceutical and Therapeutics Committee of its decisions regarding drugs subject to prior authorization.

. . . . .

1. The practice pattern identification program shall evaluate practitioner prescribing patterns based on national and regional practice guidelines, comparing practitioners to their peer groups. The agency and its Drug Utilization Review Board shall consult with a panel of practicing health care professionals consisting of the following: the Speaker of the House of Representatives and the President of the Senate shall each appoint three physicians licensed under chapter 458 or chapter 459; and the Governor shall appoint two pharmacists licensed under chapter 465 and one dentist licensed under chapter 466 who is an oral surgeon. Terms of the panel members shall expire at the discretion of the appointing official. The panel shall begin its work by August 1, 1999, regardless of the number of appointments made by that date. The advisory panel shall be responsible for evaluating treatment guidelines and recommending ways to incorporate their use in the practice pattern identification program. Practitioners who are prescribing inappropriately or inefficiently, as determined by the agency, may have their prescribing of certain drugs subject to prior authorization.

2. The agency shall also develop educational interventions designed to promote the proper use of medications by providers and beneficiaries.

3. The agency shall implement a pharmacy fraud, waste, and abuse initiative that may include a surety bond or letter of credit requirement for participating pharmacies, enhanced provider auditing practices, the use of additional fraud and abuse software, recipient management programs for beneficiaries inappropriately using their benefits, and other steps that will eliminate provider and recipient fraud, waste, and abuse. The initiative shall address enforcement efforts to reduce the number and use of counterfeit prescriptions.

. . . . .

(37) (a) The agency shall implement a Medicaid prescribed-drug spending-control program that includes the following components:

1. Medicaid prescribed-drug coverage for brand-name drugs for adult Medicaid recipients is limited to the dispensing of four brand-name drugs per month per recipient. Children are exempt from this restriction. Antiretroviral agents are excluded from this limitation. No requirements for prior authorization or other restrictions on medications used to treat mental illnesses such as schizophrenia, severe depression, or bipolar disorder may be imposed on Medicaid recipients. Medications that will be available without restriction for persons with mental illnesses include atypical antipsychotic medications, conventional antipsychotic medications, selective serotonin reuptake inhibitors, and other medications used for the treatment of serious mental illnesses. The agency shall also limit the amount of a prescribed drug dispensed to no more than a 34-day supply. The agency shall continue to provide unlimited generic drugs, contraceptive drugs and items, and diabetic supplies. Although a drug may be included on the **preferred drug formulary,** it would not be exempt from the four-brand limit. The agency may authorize exceptions to the brand-name-drug restriction based upon the treatment needs of the patients, only when such exceptions are based on prior consultation provided by the agency or an agency contractor, but the agency must establish procedures to ensure that:

a. There will be a response to a request for prior consultation by telephone or other telecommunication device within 24 hours after receipt of a request for prior consultation;

b. A 72-hour supply of the drug prescribed will be provided in an emergency or when the agency does not provide a response within 24 hours as required by sub-subparagraph a.; and

c. Except for the exception for nursing home residents and other institutionalized adults and except for drugs on the restricted formulary for which prior authorization may be sought by an institutional or community pharmacy, prior authorization for an exception to the brand-name-drug restriction is sought by the prescriber and not by the pharmacy. When prior authorization is granted for a patient in an institutional setting beyond the brand-name-drug restriction, such approval is authorized for 12 months and monthly prior authorization is not required for that patient.

2. Reimbursement to pharmacies for Medicaid prescribed drugs shall be set at the average wholesale price less 13.25 percent.

3. The agency shall develop and implement a process for managing the drug therapies of Medicaid recipients who are using significant numbers of prescribed drugs each month. The management process may include, but is not limited to, comprehensive, physician-directed medical-record reviews, claims analyses, and case evaluations to determine the medical necessity and appropriateness of a patient's treatment plan and drug therapies. The agency may contract with a private organization to provide drug-program-management services. The Medicaid drug benefit management program shall include initiatives to manage drug therapies for HIV/AIDS patients, patients using 20 or more unique prescriptions in a 180-day period, and the top 1,000 patients in annual spending.

4. The agency may limit the size of its pharmacy network based on need, competitive bidding, price negotiations, credentialing, or similar criteria. The agency shall give special consideration to rural areas in determining the size and location of pharmacies included in the Medicaid pharmacy network. A pharmacy credentialing process may include criteria such as a pharmacy's full-service status, location, size, patient educational programs, patient consultation, disease-management services, and other characteristics. The agency may impose a moratorium on Medicaid pharmacy enrollment when it is determined that it has a sufficient number of Medicaid-participating providers.

5. The agency shall develop and implement a program that requires Medicaid practitioners who prescribe drugs to use a counterfeit-proof prescription pad for Medicaid prescriptions. The agency shall require the use of standardized counterfeit-proof prescription pads by Medicaid-participating prescribers or prescribers who write prescriptions for Medicaid recipients. The agency may implement the program in targeted geographic areas or statewide.

6. The agency may enter into arrangements that require manufacturers of generic drugs prescribed to Medicaid recipients to provide rebates of at least 15.1 percent of the average manufacturer price for the manufacturer's generic products. These arrangements shall require that if a generic-drug manufacturer pays federal rebates for Medicaid-reimbursed drugs at a level below 15.1 percent, the manufacturer must provide a supplemental rebate to the state in an amount necessary to achieve a 15.1-percent rebate level.

7. The agency may establish a **preferred drug formulary** in accordance with 42 U.S.C. s. 1396r-8, and, pursuant to the establishment of such formulary, it is authorized to negotiate supplemental rebates from manufacturers that are in addition to those required by Title XIX of the Social Security Act and at no less than 10 percent of the average manufacturer price as defined in 42 U.S.C. s. 1936 on the last day of a quarter unless the federal or supplemental rebate, or both, equals or exceeds 25 percent. There is no upper limit on the supplemental rebates the agency may negotiate. The agency

may determine that specific products, brand-name or generic, are competitive at lower rebate percentages. Agreement to pay the minimum supplemental rebate percentage will guarantee a manufacturer that the Medicaid Pharmaceutical and Therapeutics Committee will consider a product for inclusion on the **preferred drug formulary.** However, a pharmaceutical manufacturer is not guaranteed placement on the formulary by simply paying the minimum supplemental rebate. Agency decisions will be made on the clinical efficacy of a drug and recommendations of the Medicaid Pharmaceutical and Therapeutics Committee, as well as the price of competing products minus federal and state rebates. The agency is authorized to contract with an outside agency or contractor to conduct negotiations for supplemental rebates. For the purposes of this section, the term "supplemental rebates" may include, at the agency's discretion, cash rebates and other program benefits that offset a Medicaid expenditure. Such other program benefits may include, but are not limited to, disease management programs, drug product donation programs, drug utilization control programs, prescriber and beneficiary counseling and education, fraud and abuse initiatives, and other services or administrative investments with guaranteed savings to the Medicaid program in the same year the rebate reduction is included in the General Appropriations Act. The agency is authorized to seek any federal waivers to implement this initiative.

8. The agency shall establish an advisory committee for the purposes of studying the feasibility of using a restricted drug formulary for nursing home residents and other institutionalized adults. The committee shall be comprised of seven members appointed by the Secretary of Health Care Administration. The committee members shall include two physicians licensed under chapter 458 or chapter 459; three pharmacists licensed under chapter 465 and appointed from a list of recommendations provided by the Florida Long-Term Care Pharmacy Alliance; and two pharmacists licensed under chapter 465.

(b) The agency shall implement this subsection to the extent that funds are appropriated to administer the Medicaid prescribed-drug spending-control program. The agency may contract all or any part of this program to private organizations.

(c) The agency shall submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 15 of each year. The report must include, but need not be limited to, the progress made in implementing Medicaid cost-containment measures and their effect on Medicaid prescribed-drug expenditures.

Kennedy, Debora

From: Carabell, Rachel
Sent: Thursday, March 28, 2002 11:44 AM
To: Kennedy, Debora
Subject: FW: CN 5525-preferred drug list

I probably should have cc'd you on the first email.

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

-----Original Message-----
From: Burnett, Douglas
Sent: Thursday, March 28, 2002 11:38 AM
To: Carabell, Rachel
Subject: RE: CN 5525-preferred drug list

great. i'll look for it. and i don't think we'll be doing t-rx.

-----Original Message-----
From: Carabell, Rachel
Sent: Thursday, March 28, 2002 11:41 AM
To: Burnett, Douglas
Subject: CN 5525-preferred drug list

HI Doug,
I am sending you a copy of what I am going to send Debora Kennedy for drafting on CN 5525, the preferred drug list. It's based on the Florida statutes. Apparently Michigan created its program administratively and there are no statutory provisions to use. Also, if you don't want to exempt AIDS/HIV and mental health drugs or nursing home and institutional residents, let either me or Debora know.

Also, food for thought...If you decide to include this provision and the T-Rx legislation, the two are going to have to be coordinated. I don't think you can have both adopted individually. Let me know if you have any questions. Thanks.

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

Kennedy, Debora

From: Carabell, Rachel
Sent: Friday, March 29, 2002 9:48 AM
To: Kennedy, Debora
Cc: Morgan, Charlie
Subject: CN 5525 preferred drug list

Debora,
I spoke with Charlie about what to include in the definition of institutionalized persons. We decided that individuals living in ICFs-MR (including the DD Centers) and IMDs (including the state's mental health institutes) should be included in the definition and therefore, excluded from prior authorization.

We included these facilities based on a distinction between people living in facilities that provide both medical and long-term care and those people in facilities that provide long-term residential care, but not necessarily medical care. Nursing homes, ICFs-MR and IMDs seem to fit that definition, but CBRFs and residential care complexes, for example, didn't seem to fit that definition. We did not include hospitals since these facilities provide acute care and not long-term care (plus I don't think they necessarily bill separately for pharmacy-related costs). Let me know if you need anything else. Thanks.

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

Questions for Rachel:

① Does this replace the purpose of the prescrip drug prior auth. committee? No + ensure that committee is advisory

② p. 3 of FAX – how to describe cost savings? Leave out

③ p. 3 of FAX – "other institutional residents"
dd centers?
mh institutes?
c-bhs?
other?

④ p. 3 of FAX – which rebate are they referring to? New one
use lang. in 49.688(6), ex Supt

⑤ p. 4 of FAX – open records? (Yes) + open mtgs. (Yes)

⑥ p. 4 of FAX – sunset date correct? Leave out (D-NOTE)

⑦ p. 6 of FAX – include not stricken language? (No)

⑧ Retroviral – don't use focus on drugs that are used to treat AIDS & HIV (not pts)

Don't use formulary; use preferred drug list

State of Wisconsin
2001 – 2002 LEGISLATURE

LRBb2865/P1
DAK:.....

January 2002 Special Session

SCC:.....Engel – CN5525, Preferred prescription drugs for MA and Badger Care

FOR 2001–03 BUDGET — NOT READY FOR INTRODUCTION

CAUCUS SENATE AMENDMENT ,

TO SENATE SUBSTITUTE AMENDMENT 1,

TO ASSEMBLY BILL 1

At the locations indicated, amend the substitute amendment as follows:

1. Page 12, line 10: after that line insert:

2. Page 16, line 12: after that line insert:

"**SECTION 38r.** 20.435 (4) (jc) of the statutes is created to read:

20.435 **(4)** (jc) *Medical assistance; drug manufacturer rebates.* All moneys received from rebate payments by prescription drug manufacturers under s. 49.45 (49) (h) and (i) 1., to be used for meeting costs of medical assistance under ss. 49.46, 49.465, and 49.47.".

3. Page 38, line 21: delete the material beginning with that line and ending with page 39, line 10 and substitute:

"**SECTION 122k.** 49.45 (49) of the statutes is created to read:

49.45 **(49)** PRESCRIPTION DRUG PRIOR AUTHORIZATION. (a) In this subsection:

1. "Brand name" has the meaning given in s. 450.12 (1) (a).

2. "Chronic mental illness" has the meaning given in s. 51.01 (3g).

3. "Generic name" has the meaning given in s. 450.12 (1) (b).

4. "HIV infection" has the meaning given in s. 252.01 (2).

5. "Institution for mental diseases" has the meaning given in s. 46.~~27~~ (1m) ~~(am)~~.

6. "Intermediate care facility for the mentally retarded" has the meaning given in s. 46.278 (1m) (am).

7. "Nursing home" has the meaning given in s. 50.01 (3).

8. "Pharmacist" has the meaning given in s. 450.01 (15).

9. "Physician" has the meaning given in s. 448.01 (5).

10. "Prescription drug" has the meaning given in s. 450.01 (~~12~~).

(b) Except for all of the following, the department may subject prescription drugs that are prescribed for medical assistance recipients to requirements of prior authorization:

1. Prescription drugs that are used to treat HIV infection or mental illness.

2. Prescription drugs that are prescribed for residents of nursing homes, of institutions for mental diseases, and of intermediate care facilities for the mentally retarded.

3. Prescription drugs that are included in a preferred prescription drug list of the department under par. (f).

(c) The secretary shall exercise his or her authority under s. 15.04 (1) (c) to create a prescription drug prior authorization committee and shall appoint as members at least all of the following:

1. Two physicians who are currently in practice.

2. Two pharmacists.

3. One advocate for recipients of medical assistance who has sufficient medical background, as determined by the department, to evaluate a prescription drug's clinical effectiveness.

(d) The prescription drug prior authorization committee appointed under par. (c) shall do all of the following:

1. Review the department's prior authorization policies and advise the department on issues related to prior authorization decisions made concerning prescription drugs on behalf of medical assistance recipients. In making its review under this subdivision, the committee shall accept information or commentary from representatives of the pharmaceutical manufacturing industry.

2. Consider the clinical efficacy, safety, and cost effectiveness of prescription drugs and develop and provide to the department a recommended list of preferred prescription drugs for which prior authorization requirements would be inapplicable. In initially developing and subsequently revising this list, the committee shall do all of the following:

a. Ensure that the manufacturers of prescription drugs that agree to provide a supplemental rebate, as specified in par. (h) or (i), have an opportunity to present evidence supporting inclusion of a product on the list.

b. At least every 12 months, review all prescription drug classes included in the department's list of preferred prescription drugs under par. (f).

c. From the department's list of preferred prescription drugs under par. (f), recommend additions or deletions that permit cost–saving, medically appropriate drug therapies for medical assistance recipients.

(e) The department shall do all of the following on behalf of the prescription drug prior authorization committee:

1. If the department has received timely notice that a drug or any of its uses has received approval by the federal food and drug administration under a priority review classification, ensure that the drug will be reviewed by the committee at the committee's earliest regularly scheduled meeting.

2. If the department has received notice from a drug manufacturer of a new drug product, schedule, to the extent possible, a product review for the product by the committee at the committee's earliest regularly scheduled meeting.

(f) 1. After considering all of the following, the department shall adopt a preferred prescription drug list and shall disseminate the list to all appropriate providers of medical assistance:

a. The recommendation of the prescription drug prior authorization committee under par. (d) 2.

b. The clinical efficacy of a prescription drug.

c. The price of competing products minus payment of any rebate made under 42 USC 1396r–8 and par. (h) or (i).

d. If par. (i) 3. applies.

2. The department shall periodically update the preferred prescription drug list, based on the department's consideration of recommendations of the prescription drug prior authorization committee and shall disseminate the changes to appropriate providers.

(g) A medical assistance recipient may contest the decision of the department to exclude a prescription drug from the preferred prescription drug list under par. (f) by filing, within 45 days after denial of coverage for a prescription drug that is subject to prior authorization, a written request for a hearing under s. 227.44 to the division of hearings and appeals created under s. 15.103 (1). The department shall inform a medical assistance recipient who is denied coverage for a prescription drug because the drug is excluded from the preferred prescription drug list of his or her right to contest the decision.

(h) The department may enter into arrangements with manufacturers of prescription drugs with generic names that are prescribed to recipients of medical assistance that require the manufacturers to provide rebates of at least 15.1 percent of the average manufacturer price for the manufacturer's prescription drug products with generic names. Under these arrangements, if a manufacturer of a prescription drug with a generic name pays a rebate under 42 USC 1396r–8 at a level below 15.1 percent, the manufacturer must provide a supplemental rebate to the department in an amount that, together with the rebate paid under 42 USC 1396r–8, equals at least 15.1 percent. Payments of rebates under this paragraph shall be made to the state treasurer for deposit in the appropriation under s. 20.435 (4) (jc).

(i) 1. After adopting a preferred prescription drug list under par. (f), the department may negotiate rebates from manufacturers of prescription drugs that are in addition to those required under 42 USC 1396r–8. The rate for a supplemental rebate under this subdivision shall be no less than 10 percent of the average manufacturer price, as defined in 42 USC 1396r–8 (k) (1), on the last day of a calendar year quarter, unless the rebate required under 42 USC 1396r–8 plus this supplemental rebate equals 25 percent of the average manufacturer price, except

that the department may determine that a specific prescription drug, whether under a brand name or a generic name, is competitive at a lower rebate percentage. Payments of rebates under this subdivision shall be made to the state treasurer for deposit in the appropriation under s. 20.435 (4) (jc).

2. The supplemental rebate under subd. 1. may include, at the discretion of the department, a program benefit that offsets a medical assistance cost, including a disease management program, a drug product donation program, a drug utilization control program, a program of prescriber and beneficiary counseling and education, or a program to reduce medical assistance fraud and abuse, or may include a cash rebate. The department may request from the federal secretary of health and human services a waiver of federal medicaid laws necessary to permit the department of health and family services to implement this subdivision.

3. If a manufacturer of prescription drugs agrees to pay the minimum supplemental rebate rate under subd. 1., the department shall consider including a prescription drug of the manufacturer in the preferred prescription drug list under par. (f).

(j) Trade secrets, amounts of rebates or supplemental rebates, percentages of rebate rates, and pricing of prescription drugs by prescription drug manufacturers that are contained in records of the department or the department's agent with respect to a supplemental rebate negotiation or supplemental rebate agreement under par. (h) or (i) 1. shall be kept confidential and are not public records under subch. II of ch. 19. Those portions of meetings of the prior authorization prescription drug advisory committee at which trade secrets, amounts of rebates or supplemental rebates, percentages of rebate rates, and pricing of prescription drugs by prescription

drug manufacturers shall be kept confidential and are not subject to subch. V of ch. 19.

(k) The secretary shall exercise his or her authority under s. 15.04 (1) (c) to create an advisory committee to study the feasibility of using a restricted prescription drug formulary for residents of nursing homes, institutions for mental diseases, and intermediate care facilities for the mentally retarded. The secretary shall appoint as members of the advisory committee at least all of the following:

1. Two physicians.

2. Five pharmacists, ~~three~~ 3 of which are recommended by the Pharmacy Society of Wisconsin.

(L) The department may enter into a contract with an entity to perform the duties and exercise the powers of the department under pars. (h) and (i) 1. and 2.

(m) Annually, by January 15, the department shall submit to appropriate standing committees of the legislature under s. 13.172 (3) and to the governor a report on the implementation of the department of the program under this subsection, including any progress made in implementing cost–containment measures under medical assistance and ~~their~~ its effect on expenditures under medical assistance for prescription drugs.»

(END)

D-NOTE

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRBb2865/P1dn
DAK:...:...

To Rachel Carabell:

1. Is the purpose under s. 20.435 (4) (jc) what you want?

2. I wasn't sure if the definition of "chronic mental illness" (see s. 51.01 (3g), stats.) or the definition of "mental illness" (see s. 51.01 (13) (a), stats.) should be used for s. 49.45 (49) (b) 1.; I used the former.

3. I did not refer to AIDS in s. 49.45 (49) (b) 1.; it is a term that is no longer used, since all of the treatments are for HIV (see ch. 252 in 2001 Wisconsin Act 16).

4. Do you know what a "priority review classification" is under s. 49.45 (49) (e) 2.? Am I using the term correctly?

5. I have numerous questions about s. 49.45 (49) (h) to (k) and the proposed material:

a. The US Code citation in #7. (p. 6 of the proposed material) is incorrect—no 42 USC 1936 exists.

b. In the same #7., I do not understand the statement "There is no upper limit on the supplemental rebates the agency may negotiate." and I omitted it. The previous statement limits the rebate amount. Is it, instead, referring to the *number* of rebates the department may negotiate? Has it any use?

c. I'm not quite sure how par. (h) works; according to 42 USC 1396r–8 (c) 1) (B) (i) (V), 15.1 percent is the minimum rebate percentage.

d. I'm confused about similarities (or differences) in pars. (h) and (i): the proposed material defines "average manufacturer price" under 42 USC 1396r–8 (k) (1) for purposes of par. (i) but not for the material included in par. (h); are they the same?

e. I created a whole extra committee under par. (k); is this necessary? Is "formulary" correct in that context? Is the "Pharmacy Society of Wisconsin" appropriate to recommend members?

f. I omitted the sunset date for the open records and open meetings exemptions under par. (j); okay?

Debora A. Kennedy
Managing Attorney
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DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRBb2865/P1dn
DAK:jld:pg

April 1, 2002

To Rachel Carabell:

1. Is the purpose under s. 20.435 (4) (jc) what you want?

2. I wasn't sure if the definition of "chronic mental illness" (see s. 51.01 (3g), stats.) or the definition of "mental illness" (see s. 51.01 (13) (a), stats.) should be used for s. 49.45 (49) (b) 1.; I used the former.

3. I did not refer to AIDS in s. 49.45 (49) (b) 1.; it is a term that is no longer used, since all of the treatments are for HIV (see ch. 252 in 2001 Wisconsin Act 16).

4. Do you know what a "priority review classification" is under s. 49.45 (49) (e) 1.? Am I using the term correctly?

5. I have numerous questions about s. 49.45 (49) (h) to (k) and the proposed material:

a. The US Code citation in #7. (p. 6 of the proposed material) is incorrect—no 42 USC 1936 exists.

b. In the same #7., I do not understand the statement "There is no upper limit on the supplemental rebates the agency may negotiate." and I omitted it. The previous statement limits the rebate amount. Is it, instead, referring to the *number* of rebates the department may negotiate? Has it any use?

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d. I'm confused about similarities (or differences) in pars. (h) and (i): the proposed material defines "average manufacturer price" under 42 USC 1396r–8 (k) (1) for purposes of par. (i) but not for the material included in par. (h); are they the same?

e. I created a whole extra committee under par. (k); is this necessary? Is "formulary" correct in that context? Is the "Pharmacy Society of Wisconsin" appropriate to recommend members?

f. I omitted the sunset date for the open records and open meetings exemptions under par. (j); okay?

Debora A. Kennedy
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4/2/01 Drafting instructions from Rachel Carabell : Redraft b 2865/P1

✓ ① Delete approp - add lang. to par. (h) : Payment shall be used to offset expenditures under ss. 20.435 (4)(b), (bc), (bv), (o), + (t)

✓ ② Instead of "priority review classification" use "priority new drug application"

✓ ③ Add to "mental illness" in 49.45-(49)(b)1. – "including anxiety, depression, + psychosis".

✓ ④ Define "average manuf price" – 42 USC 1396r-8(k)(1).

✓ ⑤ Define "preferred prescrip. drug list" – list of prescrip drugs to which prior auth. does not apply

✓ ⑥ For pars. (h) + (i) :

For generic drugs, a min. of 15.1% in comb w/ fed rebate unless agency thinks is competitive at lower rebate percentage

For brand name, min. of 25.1% " "

✓ ⑦ Require DHFS to notify all ma recips of right to contest DHFS' decision to exclude from preferred prescrip drug list.

✓ ⑧ Make ppdl publicly available.

✓ ⑨ Keep confidentiality in accord w/ 42 USC 1396r-8 (b)(3)(D).

✓ ⑩ Require DHFS study + report to standing comms + gov. re using ~~reduced~~ preferred pd list for residents of nhs, imds + icfmrs – July 1, 2003

SOON - 2nd edit 4/2

State of Wisconsin

2001 – 2002 LEGISLATURE

LRBb2865/P1
DAK:jld:pg

January 2002 Special Session

D-NOTE

SCC:.....Engel – CN5525, Preferred prescription drugs for MA and Badger Care

FOR 2001–03 BUDGET — NOT READY FOR INTRODUCTION

CAUCUS SENATE AMENDMENT ,

TO SENATE SUBSTITUTE AMENDMENT 1,

TO ASSEMBLY BILL 1

At the locations indicated, amend the substitute amendment as follows:

1. Page 16, line 12: after that line insert:

"**SECTION 38r.** 20.435 (4) (jc) of the statutes is created to read:

20.435 **(4)** (jc) *Medical assistance; drug manufacturer rebates.* All moneys received from rebate payments by prescription drug manufacturers under s. 49.45 (49) (h) and (i) 1., to be used for meeting costs of medical assistance under ss. 49.46, 49.465, 49.468, and 49.47.".

2. Page 38, line 21: delete the material beginning with that line and ending with page 39, line 10, and substitute:

"**SECTION 122b.** 49.45 (49) of the statutes is created to read:

49.45 **(49)** PRESCRIPTION DRUG PRIOR AUTHORIZATION. (a) In this subsection:

1. "Average manufacturer price" has the meaning given in 42 USC 1396r-8 (k)(1).

~~1. "Brand name" has the meaning given in s. 450.12 (1) (a).~~

~~2. "Chronic mental illness" has the meaning given in s. 51.01 (3g).~~

~~3. "Generic name" has the meaning given in s. 450.12 (1) (b).~~

2. "HIV infection" has the meaning given in s. 252.01 (2).

3. "Institution for mental diseases" has the meaning given in s. 46.011 (1m).

4. "Intermediate care facility for the mentally retarded" has the meaning given in s. 46.278 (1m) (am).

5. "Nursing home" has the meaning given in s. 50.01 (3).

6. "Pharmacist" has the meaning given in s. 450.01 (15).

7. "Physician" has the meaning given in s. 448.01 (5).

INSERT 2-11

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

(b) Except for all of the following, the department may subject prescription drugs that are prescribed for medical assistance recipients to requirements of prior authorization:

1. Prescription drugs that are used to treat ~~HIV infection or chronic~~ mental illness, including anxiety, depression, or psychosis, or to treat HIV infection.

2. Prescription drugs that are prescribed for residents of nursing homes, of institutions for mental diseases, and of intermediate care facilities for the mentally retarded.

3. Prescription drugs that are included in a preferred prescription drug list of the department under par. (f).

(c) The secretary shall exercise his or her authority under s. 15.04 (1) (c) to create a prescription drug prior authorization committee and shall appoint as members at least all of the following:

1. Two physicians who are currently in practice.

2. Two pharmacists.

3. One advocate for recipients of medical assistance who has sufficient medical background, as determined by the department, to evaluate a prescription drug's clinical effectiveness.

(d) The prescription drug prior authorization committee appointed under par. (c) shall do all of the following:

1. Review the department's prior authorization policies and advise the department on issues related to prior authorization decisions made concerning prescription drugs on behalf of medical assistance recipients. In making its review under this subdivision, the committee shall accept information or commentary from representatives of the pharmaceutical manufacturing industry.

2. Consider the clinical efficacy, safety, and cost effectiveness of prescription drugs and develop and provide to the department a recommended ~~list of~~ preferred prescription drugs ~~for which prior authorization requirements would be inapplicable~~. In initially developing and subsequently revising ~~this~~ list, the committee shall do all of the ~~following~~:

a. Ensure that the manufacturers of prescription drugs that agree to provide a supplemental rebate, as specified in par. (h) ~~of this~~, have an opportunity to present evidence supporting inclusion of a product on the list.

b. At least every 12 months, review all prescription drug classes included in the department's list of preferred prescription drugs under par. (f).

c. From the department's list of preferred prescription drugs under par. (f), recommend additions or deletions that permit cost–saving, medically appropriate drug therapies for medical assistance recipients.

(e) The department shall do all of the following on behalf of the prescription drug prior authorization committee:

1. If the department has received timely notice that a drug or any of its uses has received approval by the federal food and drug administration under a priority review classification, ensure that the drug will be reviewed by the committee at the committee's earliest regularly scheduled meeting.

2. If the department has received notice from a drug manufacturer of a new drug product, schedule, to the extent possible, a product review for the product by the committee at the committee's earliest regularly scheduled meeting.

(f) 1. After considering all of the following, the department shall adopt a preferred prescription drug list and shall disseminate the list to all appropriate providers of medical assistance:

a. The recommendation of the prescription drug prior authorization committee under par. (d) 2.

b. The clinical efficacy of a prescription drug.

c. The price of competing products minus payment of any rebate made under 42 USC 1396r–8 and par. (h).

d. If par. (h) 4. applies.

2. The department shall periodically update the preferred prescription drug list, based on the department's consideration of recommendations of the prescription drug prior authorization committee and shall disseminate the changes to appropriate providers.

(g) A medical assistance recipient may contest the decision of the department to exclude a prescription drug from the preferred prescription drug list under par. (f) by filing, within 45 days after denial of coverage for a prescription drug that is subject

to prior authorization, a written request for a hearing under s. 227.44 to the division of hearings and appeals created under s. 15.103 (1). The department shall inform a medical assistance recipient who is denied coverage for a prescription drug because the drug is excluded from the preferred prescription drug list of his or her right to contest the decision.

(h) ~~The department may enter into arrangements with manufacturers of prescription drugs with generic names that are prescribed to recipients of medical assistance that require the manufacturers to provide rebates of at least 15.1% of the average manufacturer price for the manufacturer's prescription drug products with generic names. Under these arrangements, if a manufacturer of a prescription drug with a generic name pays a rebate under 42 USC 1396r–8 at a level below 15.1%, the~~ manufacturer must provide a supplemental rebate to the department in an amount that, together with the rebate paid under 42 USC 1396r–8, equals at least 15.1%. Payments of rebates under this paragraph shall be ~~made to the state treasurer for deposit in the appropriation under s. 20.435 (4)~~ (jc).

(i) 1. After adopting a preferred prescription drug list under par. (f), the department may negotiate rebates from manufacturers of prescription drugs that are in addition to those required under 42 USC 1396r–8. The rate for a supplemental rebate under this subdivision shall be no less than 10% of the average manufacturer price, ~~as defined in 42 USC 1396r–8 (k) (1),~~ on the last day of a calendar year quarter, unless the rebate required under 42 USC 1396r–8 plus this supplemental rebate equals 25% of the average manufacturer price, except that the department may determine that a specific prescription drug, ~~whether under a brand name or a generic name,~~ is competitive at a lower rebate percentage. Payments of rebates under this

~~subdivision~~ shall be made to ~~the~~ state treasurer for deposit in the appropriation under s. 20.~~435~~ (4) (jc).

INSERT 6-2

3. The supplemental rebate under subd. 1. may include, at the discretion of the department, a program benefit that offsets a medical assistance cost, including a disease management program, a drug product donation program, a drug utilization control program, a program of prescriber and beneficiary counseling and education, or a program to reduce medical assistance fraud and abuse, or may include a cash rebate. The department may request from the federal secretary of health and human services a waiver of federal medicaid laws necessary to permit the department of health and family services to implement this subdivision.

4. If a manufacturer of prescription drugs agrees to pay the minimum supplemental rebate rate under subd. 1., the department shall consider including a prescription drug of the manufacturer in the preferred prescription drug list under par. (f).

(i) Trade secrets, amounts of rebates or supplemental rebates, percentages of rebate rates, and pricing of prescription drugs by prescription drug manufacturers that are contained in records of the department or the department's agent with respect to a supplemental rebate negotiation or supplemental rebate agreement under par. (h) ~~or~~ 1. ~~shall be kept confidential and~~ are not public records under subch. II of ch. 19. Those portions of meetings of the prior authorization prescription drug advisory committee at which trade secrets, amounts of rebates or supplemental rebates, percentages of rebate rates, and pricing of prescription drugs by prescription drug manufacturers ~~shall be kept confidential and~~ are not subject to subch. V of ch. 19.

and shall be kept confidential in accordance with 42 USC 1396r-8 (b)(3)(D)

(k) The secretary shall exercise his or her authority under s. 15.04 (1) (c) to create an advisory committee to study the feasibility of using a restricted prescription drug formulary for residents of nursing homes, institutions for mental diseases, and intermediate care facilities for the mentally retarded. The secretary shall appoint as members of the advisory committee at least all of the following:

1. Two physicians.

2. Five pharmacists, 3 of which are recommended by the Pharmacy Society of Wisconsin.

(j) The department may enter into a contract with an entity to perform the duties and exercise the powers of the department under pars. (h) ~~and (i)~~ and (k).

INSERT 7-10

(L) Annually, by January 15, the department shall submit to appropriate standing committees of the legislature under s. 13.172 (3) and to the governor a report on the implementation of the department of the program under this subsection, including any progress made in implementing cost–containment measures under medical assistance and its effect on expenditures under medical assistance for prescription drugs.

(END)

INSERT 7-16

1. a. and b.

D-NOTE

INSERT 2–11

8. "Preferred prescription drug list" means a list of prescription drugs to which prior authorization does not apply.

INSERT 6–2

(h) 1. If a manufacturer of a prescription drug pays a rebate under 42 USC 1396r–8, one of the following applies:

a. If the rebate is less than 15.1%, the department may enter into an arrangement with the manufacturer that requires the manufacturer to provide a supplemental rebate to the department in an amount that, together with the rebate paid under 42 USC 1396r–8, equals at least 15.1% of the average manufacturer price for the manufacturer's prescription drug products that are provided to medical assistance recipients, except that the department may determine that a specific prescription drug is competitive at a lower rebate percentage.

b. If the rebate is at least 15.1%, the department may enter into an arrangement with the manufacturer that requires the manufacturer to provide a supplemental rebate to the department in an amount that, together with the rebate paid under 42 USC 1396r–8, equals at least 25.1% of the average manufacturer price for the manufacturer's prescription drug products that are provided to medical assistance recipients, except that the department may determine that a specific prescription drug is competitive at a lower rebate percentage.

2. Payment of rebates under subd. 1. shall be used to offset expenditures under s. 20.435 (4) (b), (bc), and (v).

INSERT 7–10

INS 7-10

(k) The department shall make the preferred prescription drug list under par. (f) publicly available.

, under sub. (49)(g),

NO CS

INSERT 7–16

SECTION 122c. 49.45 (50) of the statutes is created to read:

49.45 **(50)** RIGHT TO APPEAL PRESCRIPTION DRUG COVERAGE DECISION. The department shall inform each medical assistance recipient of his or her right to contest a decision by the department to exclude a prescription drug from the preferred prescription drug list under sub. (49) (f), if the decision results in denial of coverage to the recipient for the prescription drug.".

1. Page 358, line 15: after that line insert:

SC

"(8) STUDY ON USE OF MEDICAL ASSISTANCE PREFERRED PRESCRIPTION DRUG LIST IN CERTAIN FACILITIES. By July 1, 2003, the department of health and family services shall study the feasibility of using a preferred prescription drug list for the prescription drugs provided to medical assistance recipients who are residents of nursing homes, institutions for mental diseases, and intermediate care facilities for the mentally retarded and shall report findings of the study to the legislature in the manner provided under section 13.172 (3) of the statutes, and to the governor.".

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRBb2865/1dn
DAK:jld:pg

To Rachel Carabell:

Please review the appropriation accounts specified in s. 49.45 (49) (h) 2.

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

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRBb2865/1dn
DAK:jld:rs

April 3, 2002

To Rachel Carabell:

Please review the appropriation accounts specified in s. 49.45 (49) (h) 2.

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

TELEPHONE DRAFTING INSTRUCTIONS

Drafting instructions received by Debora Kennedy.

DATE: 4/3

CONVERSATION WITH: Rachel Carabell

OF: LFB

TELEPHONE NO:

REGARDING LRB # OR DRAFT TOPIC:

INSTRUCTIONS:

✓ (1) Include 20.435 (4) (b), (o) and (p) in approps. to which rebate $ goes — state only retains 40% of a rebate; rest goes back to Feds

✓ (2) Change study date to 1/1/03, bec. DHFS can use info from Fla's study

(3) ~~Authorize~~ Require

Beginning July 1, 2003 — [redacted] prior auth list

~~Require~~ Beg July 1, 2003 ~~have~~ authorize

✓ (4) put (K) under (f)

SOON - Jr edit 4/3

State of Wisconsin
2001 - 2002 LEGISLATURE

January 2002 Special Session

LRBb2865/~~B~~2
DAK:jld:~~rs~~

SCC:.....Engel – CN5525, Preferred prescription drugs for MA and Badger Care

FOR 2001–03 BUDGET — NOT READY FOR INTRODUCTION

CAUCUS SENATE AMENDMENT ,

TO SENATE SUBSTITUTE AMENDMENT 1,

TO ASSEMBLY BILL 1

At the locations indicated, amend the substitute amendment as follows:

1. Page 38, line 21: delete the material beginning with that line and ending with page 39, line 10, and substitute:

"**SECTION 122b.** 49.45 (49) of the statutes is created to read:

49.45 **(49)** PRESCRIPTION DRUG PRIOR AUTHORIZATION. (a) In this subsection:

1. "Average manufacturer price" has the meaning given in 42 USC 1396r–8 (k) (1).

2. "HIV infection" has the meaning given in s. 252.01 (2).

3. "Institution for mental diseases" has the meaning given in s. 46.011 (1m).

4. "Intermediate care facility for the mentally retarded" has the meaning given in s. 46.278 (1m) (am).

5. "Nursing home" has the meaning given in s. 50.01 (3).

6. "Pharmacist" has the meaning given in s. 450.01 (15).

7. "Physician" has the meaning given in s. 448.01 (5).

8. "Preferred prescription drug list" means a list of prescription drugs to which prior authorization does not apply.

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

(b) Except for all of the following, the department ~~may~~ shall subject all prescription drugs that are prescribed for medical assistance recipients to requirements of prior authorization:

1. Prescription drugs that are used to treat mental illness, including anxiety, depression, or psychosis, or to treat HIV infection.

2. Prescription drugs that are prescribed for residents of nursing homes, of institutions for mental diseases, and of intermediate care facilities for the mentally retarded.

3. Prescription drugs that are included in a preferred prescription drug list of the department under par. (f).

(c) The secretary shall exercise his or her authority under s. 15.04 (1) (c) to create a prescription drug prior authorization committee and shall appoint as members at least all of the following:

1. Two physicians who are currently in practice.

2. Two pharmacists.

3. One advocate for recipients of medical assistance who has sufficient medical background, as determined by the department, to evaluate a prescription drug's clinical effectiveness.

(d) The prescription drug prior authorization committee appointed under par. (c) shall do all of the following:

1. Review the department's prior authorization policies and advise the department on issues related to prior authorization decisions made concerning prescription drugs on behalf of medical assistance recipients. In making its review under this subdivision, the committee shall accept information or commentary from representatives of the pharmaceutical manufacturing industry.

2. Consider the clinical efficacy, safety, and cost effectiveness of prescription drugs and develop and provide to the department a recommended preferred prescription drug list. In initially developing and subsequently revising the preferred prescription drug list, the committee shall do all of the following:

a. Ensure that the manufacturers of prescription drugs that agree to provide a supplemental rebate, as specified in par. (h), have an opportunity to present evidence supporting inclusion of a product on the list.

b. At least every 12 months, review all prescription drug classes included in the department's list of preferred prescription drugs under par. (f).

c. From the department's list of preferred prescription drugs under par. (f), recommend additions or deletions that permit cost–saving, medically appropriate drug therapies for medical assistance recipients.

(e) The department shall do all of the following on behalf of the prescription drug prior authorization committee:

1. If the department has received timely notice that a drug or any of its uses has received approval by the federal food and drug administration under a priority new drug application, ensure that the drug will be reviewed by the committee at the committee's earliest regularly scheduled meeting.

2. If the department has received notice from a drug manufacturer of a new drug product, schedule, to the extent possible, a product review for the product by the committee at the committee's earliest regularly scheduled meeting.

(f) 1. After considering all of the following, the department ~~shall~~ adopt a preferred prescription drug list and shall disseminate the list to all appropriate providers of medical assistance:

a. The recommendation of the prescription drug prior authorization committee under par. (d) 2.

b. The clinical efficacy of a prescription drug.

c. The price of competing products minus payment of any rebate made under 42 USC 1396r–8 and par. (h).

d. If par. (h) 4. applies.

2. The department shall periodically update the preferred prescription drug list, based on the department's consideration of recommendations of the prescription drug prior authorization committee and shall disseminate the changes to appropriate providers.

(g) A medical assistance recipient may contest the decision of the department to exclude a prescription drug from the preferred prescription drug list under par. (f) by filing, within 45 days after denial of coverage for a prescription drug that is subject to prior authorization, a written request for a hearing under s. 227.44 to the division of hearings and appeals created under s. 15.103 (1).

(h) 1. If a manufacturer of a prescription drug pays a rebate under 42 USC 1396r–8, one of the following applies:

a. If the rebate is less than 15.1%, the department may enter into an arrangement with the manufacturer that requires the manufacturer to provide a supplemental rebate to the department in an amount that, together with the rebate paid under 42 USC 1396r–8, equals at least 15.1% of the average manufacturer price for the manufacturer's prescription drug products that are provided to medical assistance recipients, except that the department may determine that a specific prescription drug is competitive at a lower rebate percentage.

b. If the rebate is at least 15.1%, the department may enter into an arrangement with the manufacturer that requires the manufacturer to provide a supplemental rebate to the department in an amount that, together with the rebate paid under 42 USC 1396r–8, equals at least 25.1% of the average manufacturer price for the manufacturer's prescription drug products that are provided to medical assistance recipients, except that the department may determine that a specific prescription drug is competitive at a lower rebate percentage.

2. Payment of rebates under subd. 1. shall be used to offset expenditures under s. 20.435 (4) (b), (bc), ~~and (bv)~~. (bv), (o), and (p) ✓

3. The supplemental rebate under subd. 1. a. or b. may include, at the discretion of the department, a program benefit that offsets a medical assistance cost, including a disease management program, a drug product donation program, a drug utilization control program, a program of prescriber and beneficiary counseling and education, or a program to reduce medical assistance fraud and abuse, or may include a cash rebate. The department may request from the federal secretary of health and human

services a waiver of federal medicaid laws necessary to permit the department of health and family services to implement this subdivision.

4. If a manufacturer of prescription drugs agrees to pay the minimum supplemental rebate rate under subd. 1. a. or b., the department shall consider including a prescription drug of the manufacturer in the preferred prescription drug list under par. (f).

(i) Trade secrets, amounts of rebates or supplemental rebates, percentages of rebate rates, and pricing of prescription drugs by prescription drug manufacturers that are contained in records of the department or the department's agent with respect to a supplemental rebate negotiation or supplemental rebate agreement under par. (h) 1. are not public records under subch. II of ch. 19 and shall be kept confidential in accordance with 42 USC 1396r–8 (b) (3) (D). Those portions of meetings of the prior authorization prescription drug advisory committee at which trade secrets, amounts of rebates or supplemental rebates, percentages of rebate rates, and pricing of prescription drugs by prescription drug manufacturers are not subject to subch. V of ch. 19 and shall be kept confidential in accordance with 42 USC 1396r–8 (b) (3) (D).

(j) The department may enter into a contract with an entity to perform the duties and exercise the powers of the department under pars. (h) 1. a. and b.

MOVE THIS TO p. 4, l. 20

~~(k)~~ The department shall make the preferred prescription drug list under ~~par.~~ subd. 1. and the updates under subd. 2. ~~(f)~~ publicly available.

(k) Annually, by January 15, the department shall submit to appropriate standing committees of the legislature under s. 13.172 (3) and to the governor a report on the implementation of the department of the program under this subsection, including any progress made in implementing cost–containment

measures under medical assistance and its effect on expenditures under medical assistance for prescription drugs.

SECTION 122c. 49.45 (50) of the statutes is created to read:

49.45 **(50)** RIGHT TO APPEAL PRESCRIPTION DRUG COVERAGE DECISION. The department shall inform each medical assistance recipient of his or her right, under sub. (49) (g), to contest a decision by the department to exclude a prescription drug from the preferred prescription drug list under sub. (49) (f), if the decision results in denial of coverage to the recipient for the prescription drug.".

2. Page 358, line 15: after that line insert:

"(5c) STUDY ON USE OF MEDICAL ASSISTANCE PREFERRED PRESCRIPTION DRUG LIST IN CERTAIN FACILITIES. By ~~July~~ January 1, 2003, the department of health and family services shall study the feasibility of using a preferred prescription drug list for the prescription drugs provided to medical assistance recipients who are residents of nursing homes, institutions for mental diseases, and intermediate care facilities for the mentally retarded and shall report findings of the study to the legislature in the manner provided under section 13.172 (3) of the statutes, and to the governor.".

(END)

TELEPHONE DRAFTING INSTRUCTIONS

Drafting instructions received by Debora Kennedy.

DATE: 4/4/02

CONVERSATION WITH: Rachel Carabell

OF: LFB

TELEPHONE NO:

REGARDING LRB # OR DRAFT TOPIC:

INSTRUCTIONS:

Decis. of dept. to exclude a drug from
should be drug prior authoriz for
~~must be~~ a drug excluded
from the list

w/in 45 days
after denial

49.45(50) as well

TODAY 4/4

State of Wisconsin
2001 - 2002 LEGISLATURE

LRBb2865/P3
DAK:jld:

January 2002 Special Session

NOW

SCC:.....Engel – CN5525, Preferred prescription drugs for MA and Badger Care

FOR 2001–03 BUDGET — NOT READY FOR INTRODUCTION

CAUCUS SENATE AMENDMENT ,

TO SENATE SUBSTITUTE AMENDMENT 1,

TO ASSEMBLY BILL 1

At the locations indicated, amend the substitute amendment as follows:

1. Page 38, line 21: delete the material beginning with that line and ending with page 39, line 10, and substitute:

"**SECTION 122b.** 49.45 (49) of the statutes is created to read:

49.45 **(49)** PRESCRIPTION DRUG PRIOR AUTHORIZATION. (a) In this subsection:

1. "Average manufacturer price" has the meaning given in 42 USC 1396r–8 (k) (1).

2. "HIV infection" has the meaning given in s. 252.01 (2).

3. "Institution for mental diseases" has the meaning given in s. 46.011 (1m).

4. "Intermediate care facility for the mentally retarded" has the meaning given in s. 46.278 (1m) (am).

5. "Nursing home" has the meaning given in s. 50.01 (3).

6. "Pharmacist" has the meaning given in s. 450.01 (15).

7. "Physician" has the meaning given in s. 448.01 (5).

8. "Preferred prescription drug list" means a list of prescription drugs to which prior authorization does not apply.

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

(b) Except for all of the following, beginning July 1, 2003, the department shall subject all prescription drugs that are prescribed for medical assistance recipients to requirements of prior authorization:

1. Prescription drugs that are used to treat mental illness, including anxiety, depression, or psychosis, or to treat HIV infection.

2. Prescription drugs that are prescribed for residents of nursing homes, of institutions for mental diseases, and of intermediate care facilities for the mentally retarded.

3. Prescription drugs that are included in a preferred prescription drug list of the department under par. (f).

(c) The secretary shall exercise his or her authority under s. 15.04 (1) (c) to create a prescription drug prior authorization committee and shall appoint as members at least all of the following:

1. Two physicians who are currently in practice.

2. Two pharmacists.

3. One advocate for recipients of medical assistance who has sufficient medical background, as determined by the department, to evaluate a prescription drug's clinical effectiveness.

(d) The prescription drug prior authorization committee appointed under par. (c) shall do all of the following:

1. Review the department's prior authorization policies and advise the department on issues related to prior authorization decisions made concerning prescription drugs on behalf of medical assistance recipients. In making its review under this subdivision, the committee shall accept information or commentary from representatives of the pharmaceutical manufacturing industry.

2. Consider the clinical efficacy, safety, and cost effectiveness of prescription drugs and develop and provide to the department a recommended preferred prescription drug list. In initially developing and subsequently revising the preferred prescription drug list, the committee shall do all of the following:

a. Ensure that the manufacturers of prescription drugs that agree to provide a supplemental rebate, as specified in par. (h), have an opportunity to present evidence supporting inclusion of a product on the list.

b. At least every 12 months, review all prescription drug classes included in the department's list of preferred prescription drugs under par. (f).

c. From the department's list of preferred prescription drugs under par. (f), recommend additions or deletions that permit cost–saving, medically appropriate drug therapies for medical assistance recipients.

(e) The department shall do all of the following on behalf of the prescription drug prior authorization committee:

1. If the department has received timely notice that a drug or any of its uses has received approval by the federal food and drug administration under a priority new drug application, ensure that the drug will be reviewed by the committee at the committee's earliest regularly scheduled meeting.

2. If the department has received notice from a drug manufacturer of a new drug product, schedule, to the extent possible, a product review for the product by the committee at the committee's earliest regularly scheduled meeting.

(f) 1. After considering all of the following, the department may, beginning July 1, 2002, adopt a preferred prescription drug list and shall disseminate the list to all appropriate providers of medical assistance:

a. The recommendation of the prescription drug prior authorization committee under par. (d) 2.

b. The clinical efficacy of a prescription drug.

c. The price of competing products minus payment of any rebate made under 42 USC 1396r–8 and par. (h).

d. If par. (h) 4. applies.

2. The department shall periodically update the preferred prescription drug list, based on the department's consideration of recommendations of the prescription drug prior authorization committee and shall disseminate the changes to appropriate providers.

3. The department shall make the preferred prescription drug list under subd. 1. and the updates under subd. 2. publicly available. that is excluded

(g) A medical assistance recipient may contest the decision of the department to exclude a prescription drug from the preferred prescription drug list under par. (f) by filing, within 45 days after denial of coverage for a prescription drug that is subject

deny prior authorization for

to prior authorization, a written request for a hearing under s. 227.44 to the division of hearings and appeals created under s. 15.103 (1).

(h) 1. If a manufacturer of a prescription drug pays a rebate under 42 USC 1396r–8, one of the following applies:

a. If the rebate is less than 15.1%, the department may enter into an arrangement with the manufacturer that requires the manufacturer to provide a supplemental rebate to the department in an amount that, together with the rebate paid under 42 USC 1396r–8, equals at least 15.1% of the average manufacturer price for the manufacturer's prescription drug products that are provided to medical assistance recipients, except that the department may determine that a specific prescription drug is competitive at a lower rebate percentage.

b. If the rebate is at least 15.1%, the department may enter into an arrangement with the manufacturer that requires the manufacturer to provide a supplemental rebate to the department in an amount that, together with the rebate paid under 42 USC 1396r–8, equals at least 25.1% of the average manufacturer price for the manufacturer's prescription drug products that are provided to medical assistance recipients, except that the department may determine that a specific prescription drug is competitive at a lower rebate percentage.

2. Payment of rebates under subd. 1. shall be used to offset expenditures under s. 20.435 (4) (b), (bc), (bv), (o), and (p).

3. The supplemental rebate under subd. 1. a. or b. may include, at the discretion of the department, a program benefit that offsets a medical assistance cost, including a disease management program, a drug product donation program, a drug utilization control program, a program of prescriber and beneficiary counseling and education, or a program to reduce medical assistance fraud and abuse, or may include a cash

rebate. The department may request from the federal secretary of health and human services a waiver of federal medicaid laws necessary to permit the department of health and family services to implement this subdivision.

4. If a manufacturer of prescription drugs agrees to pay the minimum supplemental rebate rate under subd. 1. a. or b., the department shall consider including a prescription drug of the manufacturer in the preferred prescription drug list under par. (f).

(i) Trade secrets, amounts of rebates or supplemental rebates, percentages of rebate rates, and pricing of prescription drugs by prescription drug manufacturers that are contained in records of the department or the department's agent with respect to a supplemental rebate negotiation or supplemental rebate agreement under par. (h) 1. are not public records under subch. II of ch. 19 and shall be kept confidential in accordance with 42 USC 1396r–8 (b) (3) (D). Those portions of meetings of the prior authorization prescription drug advisory committee at which trade secrets, amounts of rebates or supplemental rebates, percentages of rebate rates, and pricing of prescription drugs by prescription drug manufacturers are not subject to subch. V of ch. 19 and shall be kept confidential in accordance with 42 USC 1396r–8 (b) (3) (D).

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(END)

State of Wisconsin
2001 – 2002 LEGISLATURE
January 2002 Special Session

LRBb2865/3
DAK:jld:pg

SCC:.....Engel – CN5525, Preferred prescription drugs for MA and Badger Care

FOR 2001–03 BUDGET — NOT READY FOR INTRODUCTION

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