



State of Wisconsin

LEGISLATIVE REFERENCE BUREAU

RESEARCH APPENDIX -

PLEASE DO NOT REMOVE FROM DRAFTING FILE

Date Added To File: 11/15/02 (Per PJK)



The drafting file for 2001 LRB-4232 has been

transferred to the drafting file for 2003 LRB-0680

This cover sheet, the final request sheet, and the final version of the 2001 draft were copied on yellow paper, and returned to the original 2001 drafting file.

For research purposes, because the attached 2001 draft was incorporated into a new 2003 draft, this cover sheet and the complete drafting file was transferred, as a separate appendix, to the 2003 drafting file. If introduced this section will be scanned and added, as a separate appendix, to the electronic drafting file folder.



The drafting file for 2003 LRB _____ has been

copied/added to the drafting file for 2003 LRB _____

For research purposes, because the attached 2003 draft was incorporated into another 2003 draft, the attached drafting file was copied on yellow paper (darkened/auto centered/reduced to 90%), and added, as a appendix, to the new 2003 drafting file. If introduced this section will be scanned and added, as a separate appendix, to the electronic drafting file folder.

This cover sheet was copied on yellow paper and added to rear of the original 2003 drafting file. The drafting file was then returned, intact, to its folder and filed.

2001 DRAFTING REQUEST

Bill

Received: **11/09/2001**

Received By: **kahlepj**

Wanted: **As time permits**

Identical to LRB:

For: **Daniel Vrakas (608) 266-3007**

By/Representing: **Bonnie Deering**

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

Drafter: **kahlepj**

May Contact:

Addl. Drafters:

Subject: **Insurance - health**

Extra Copies:

Submit via email: **YES**

Requester's email: **Rep.Vrakas@legis.state.wi.us**

Carbon copy (CC:) to:

Pre Topic:

No specific pre topic given

Topic:

Require health insurance coverage of off-label drugs for treatment of cancer

Instructions:

See Attached

Drafting History:

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Typed</u>	<u>Proofed</u>	<u>Submitted</u>	<u>Jacketed</u>	<u>Required</u>
/?	kahlepj 11/12/2001	rschluet 11/16/2001		_____			S&L
/1			jfrantze 11/20/2001	_____	lrb_docadmin 11/20/2001		S&L
/2	kahlepj	rschluet	pgreensl	_____	lrb_docadmin		S&L

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Typed</u>	<u>Proofed</u>	<u>Submitted</u>	<u>Jacketed</u>	<u>Required</u>
	01/18/2002	01/30/2002	01/30/2002	_____	01/30/2002		
/3	kahlepj 03/08/2002	rschluet 04/01/2002	pgreensl 04/02/2002	_____	lrb_docadmin 04/02/2002		S&L
/4	kahlepj 05/16/2002	rschluet 05/22/2002	pgreensl 05/22/2002	_____	lrb_docadmin 05/22/2002		

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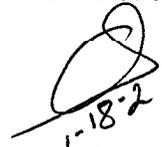
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FE Sent For:

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Daniel P. Vrakas

Wisconsin State Representative

Majority Caucus Chair

Assembly Chair: Joint Survey Committee on Retirement Systems
Vice-Chair: Assembly Committee on Labor and Workforce Development
Member: State Building Commission

TO: Debora Kennedy, LRB
FROM: Bonnie Deering, ~~Office of Rep. Dan Vrakas~~
RE: Off-label use of prescription drugs
DATE: November 9, 2001

Debora: I am sending this request to you, but please forward it to the correct person if you are not the correct drafter.

Rep. Vrakas would like to have a bill drafted that would allow for the use of off-label drugs ***for cancer treatment only***. This proposal would give doctors the authority to prescribe medication for cancer treatment that has been FDA approved, but not necessarily approved for the patient's specific type of cancer. For example, if a patient had liver cancer and the doctor thought that a treatment for lung cancer would work better/faster, but the lung cancer treatment has not been FDA approved for liver cancer, this bill would allow the doctor to still prescribe the lung cancer treatment for the liver cancer patient. The treatment/medicine must be FDA approved and must be noted in a standard reference compendia or at least two peer reviewed professional medical journals. The bill should list somewhere that it in no way includes experimental drugs.

I have included a memo from the Association of Community Cancer Centers Uniform Legislation and a copy of the Illinois law. Again, please note that we wish to have this law pertain only to cancer treatment. The Uniform Legislation covers life-threatening illnesses, such as cancer, AIDS and coronary heart disease. We want to cover only cancer treatment.

Thank you. Please call 6-3007 if you have any questions.

ASSOCIATION OF COMMUNITY CANCER CENTERS
UNIFORM LEGISLATION

An ACT to amend the insurance law, in relation to insurance coverage for drugs including life-threatening illnesses, such as cancer, AIDS, and coronary heart disease.

SECTION 1. The legislature finds and declares the following:

1. The citizens of this state rely upon health insurance to cover the cost of obtaining health care.
2. It is essential that the citizens' expectation that their health care costs will be paid by their insurance policies is not disappointed and that they obtain the coverage necessary and appropriate for their care within the terms of their insurance policies.
3. Some insurers deny payment for drugs that have been approved by the Federal Food and Drug Administration (FDA) when the drugs are used for indications other than those stated in the labeling approved by the FDA (off-label use) while other insurers with similar coverage terms do pay for off-label use.
4. Denial of payment for off-label use can interrupt or effectively deny access to necessary and appropriate treatment for a person being treated for a life-threatening illness.
5. Equity among employers who obtain insurance coverage for their employees and fair competition among insurance companies require that insurance companies assure citizens reimbursement for drugs in the same way and in the way citizens expect.
6. Off-label use of an FDA-approved drug is legal when prescribed in a medically appropriate way and is often necessary to provide needed care. Approximately 50% of cancer drug treatment is for off-label indications. The FDA and the Federal Department of Health and Human Services recognize the wide variety of effective uses of FDA-approved drugs for off-label indications. Information on the appropriate off-label use of FDA-approved drugs is obtained from

compendia published by the United States Pharmacopeial Convention, and the American Society of Hospital Pharmacists. In addition, scientific studies of off-label use of drugs published in recognized peer-reviewed professional journals provide information on appropriate use of drugs for off-label indications. The Omnibus Budget Reconciliation Act of 1990 recognizes these compendia and peer-reviewed literature as appropriate sources for reimbursement and requires Medicaid agencies to pay for off-label use of drugs prescribed for Medicaid patients if the use is stated in any of such sources. The Omnibus Budget Reconciliation Act of 1993 applies the same criteria and coverage to Medicare patients. Thirty-one states have also passed similar legislation or administrative rules, most based on the attached uniform legislation. The National Association of Insurance Commissioners and the Council of State Governments have also adopted model acts based on the ACCC model legislation.

7. Use of FDA-approved drugs for off-label indications provides efficacious drugs at a lower cost. To require that all appropriate uses of a drug undergo approval by the FDA would substantially increase the cost of drugs, delay or even deny patients' ability to obtain medically effective treatment. FDA approval for each use would require substantial expenditure and time to undergo the clinical trials necessary to obtain FDA approval. This is particularly the case when a drug is off patent and in generic production, and consequently is available at a lower price. Once a drug is in generic production by multiple manufacturers, it is not economically feasible for a manufacturer to incur the cost of FDA approval.
8. Reimbursement for off-label indications of FDA-approved drugs is necessary to conform to the way in which appropriate medical treatment is provided, to make needed drugs available to patients, and to contain health care costs.

SECTION 2. For the purposes of this Act the following definitions apply:

1. "Insurance policy" means any individual, group, or blanket policy written by a medical expense indemnity corporation, a hospital service corporation, a health care service plan contract, or a private insurance plan issued, amended, delivered or renewed in this state, or which provides such insurance for residents of this state.
2. "Standard reference compendia" means (a) the United States Pharmacopoeia Drug Information, or (b) the American Hospital Formulary Service Drug Information.
3. "Medical literature" means published scientific studies published in any peer-reviewed national professional journal.

SECTION 3. Section ___ of the insurance code (or appropriate health and safety code, disability insurance policy code) is amended to read as follows:

- (1) No insurance policy which provides coverage for drugs shall exclude coverage of any such drug for a particular indication on the ground that the drug has not been approved by the Federal Food and Drug Administration for that indication, if such drug is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature, or by the Commissioner.
- (2) Any coverage of a drug required by this section shall also include medically necessary services associated with the administration of the drug.
- (3) This section shall not be construed to alter existing law with regard to provisions limiting the coverage of drugs that have not been approved by the Federal Food and Drug Administration.
- (4) This section shall not be construed to require coverage for any drug when the Federal Food and Drug Administration has determined its use to be contraindicated.
- (5) This section shall not be construed to require coverage for experimental drugs not otherwise approved for any indication by the Federal Food and Drug Administration.
- (6) The Commissioner shall create a panel of seven medical experts to review off-label uses not included in either of the two standard references or in the medical literature and to advise him in such instances whether a particular off-label use is medically appropriate. The panel shall make such recommendation from time to time and whenever a particular dispute about payment for such off-label use is brought to the Commissioner. This seven-member panel shall include: (a) three medical oncologists selected by the state medical oncology association, (b) two specialists in the management of AIDS patients selected by the state AIDS medical provider organization, (c) one specialist in heart disease appointed by _____, and (d) one physician selected by the state medical association.
- (7) The Commissioner shall have the authority to direct any person which issues an insurance policy to make payments required by this section.

For information contact:
Mr. Christian Downs
Director, Provider Economics and Public Policy
Association of Community Cancer Centers
11600 Nebel Street, Suite 201
Rockville, MD 20852-2557
Phone: 301/984-9496
Fax: 301/770-1949

5/370j. Requirements not applicable to insurers

§ 370j. Requirements not applicable to insurers. Except as otherwise provided, no insurer authorized to do business in this State shall be subject to any of the requirements of applicable to administrators.

It is applicable to self-insured employers, trust funds, other ERISA exempt organizations of Illinois. Such organizations are not subject to this Article even though they are administrators for administration of health care services under contractual arrangements of the preferred provider program.

Added by P.A. 84-618, § 1, eff. Sept. 19, 1985. Amended by P.A. 84-1431, Art. 22, § 2, eff.

1991, ch. 73, ¶ 982j.

m

1. All administrators of a preferred provider organization subject to this Article shall register with the State, which shall by rule establish the registration including minimum solvency and annual registration fee for each administrator.

The administrator shall compile and maintain a list of administrators and insurers annually of administrators and insurers.

Operating agreements authorized under this Article.

Laws 1987, p. 696, § 370k, added by P.A. 84-618, § 1, eff. Sept. 19, 1985.

Formerly Ill.Rev.Stat.1991, ch. 73, ¶ 982k.

5/370l. Fiduciary and bonding requirements

§ 370l. Fiduciary and bonding requirements. Each administrator who handles money for purposes of payment for health care services subject to this Article shall (1) establish and maintain a fiduciary account, separate and apart from any and all other accounts, for the receipt and disbursement of funds for reimbursement for programs covered under this Article, or (2) post or cause to be posted, a bond of indemnity in an amount equal to not less than 10% of the total estimated annual reimbursements under such programs.

If a bond of indemnity is posted, it shall be held by the Director of Insurance for the benefit and indemnification of the beneficiaries and payors of services under the programs subject to this Article.

An administrator who operates more than one such program may establish and maintain a separate fiduciary account or bond of indemnity for each such program, or may operate and maintain a consolidated fiduciary account or bond of indemnity for all such programs.

Laws 1987, p. 696, § 370l, added by P.A. 84-618, § 1, eff. Sept. 19, 1985.

Formerly Ill.Rev.Stat.1991, ch. 73, ¶ 982l.

5/370m. Program requirements

§ 370m. Program Requirements. Each administrator shall provide to each beneficiary of any program subject to this Article a document which (1) sets forth those providers with which agreements or arrangements have been made to provide health care services to such beneficiary, a source for the beneficiary to contact regarding changes in such providers and a clear description of any incentives for the beneficiary to utilize such providers, (2) discloses the extent of coverage as well as any limitations or exclusions of health

care services under the program, (3) clearly sets out the circumstances under which reimbursement will be made to a beneficiary unable to utilize the services of a provider with which an arrangement or agreement has been made, (4) a description of the process for addressing a beneficiary complaint under the program, and (5) discloses deductible and coinsurance amounts charged to any person receiving health care services from such a provider.

Laws 1987, p. 696, § 370m, added by P.A. 84-618, § 1, eff. Sept. 19, 1985.

Formerly Ill.Rev.Stat.1991, ch. 73, ¶ 982m.

5/370n. Utilization review requirements

§ 370n. Utilization Review Requirements: Any preferred provider organization providing hospital, medical or dental services must include a program of utilization review.

This Section applies to insurers and administrators.

Laws 1987, p. 696, § 370n, added by P.A. 84-618, § 1, eff. Sept. 19, 1985. Amended by P.A. 84-1431, Art. 22, § 2, eff. Nov. 25, 1986.

Formerly Ill.Rev.Stat.1991, ch. 73, ¶ 982n.

5/370o. Emergency care

§ 370o. Emergency Care. Any preferred provider contract, subject to this Article shall provide the beneficiary or insured emergency care coverage such that payment for this coverage is not dependent upon whether such services are performed by a preferred or nonpreferred provider and such coverage shall be at the same benefit level as if the service or treatment had been rendered by a plan provider.

Laws 1987, p. 696, § 370o, added by P.A. 84-618, § 1, eff. Sept. 19, 1985. Amended by P.A. 85-476, § 1, eff. Jan. 1, 1988.

Formerly Ill.Rev.Stat.1991, ch. 73, ¶ 982o.

5/370p. Failure to register

§ 370p. Failure to register. Any administrator subject to this Article who fails to register or pay the fee required by this Article shall be construed to be an unauthorized insurer as defined in Article VII of the "Illinois Insurance Code", as now or hereafter amended, and shall be subject to the penalties contained therein.

Laws 1987, p. 696, § 370p, added by P.A. 84-618, § 1, eff. Sept. 19, 1985.

Formerly Ill.Rev.Stat.1991, ch. 73, ¶ 982p.

1215 ILCS 5/121 et seq.

5/370q. Conflicting provisions

§ 370q. To the extent of any conflict between this Article and any other statutory provision, this Article prevails over the conflicting provision. Agreements may be entered into under this Article notwithstanding any policy provision to the contrary.

Laws 1987, p. 696, § 370q, added by P.A. 84-618, § 1, eff. Sept. 19, 1985.

Formerly Ill.Rev.Stat.1991, ch. 73, ¶ 982q.

***5/370r. Prescription drugs; cancer treatment**

§ 370r. Prescription drugs; cancer treatment. No group-term life insurance policy of accident or health insurance that provides coverage for prescribed drugs approved by the federal Food and Drug Administration for the treatment of certain types of cancer shall exclude coverage of any drug on the basis that the drug

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law

has been prescribed for the treatment of a type of cancer for which the drug has not been approved by the federal Food and Drug Administration. The drug, however, must be approved by the federal Food and Drug Administration and must be recognized for the treatment of the specific type of cancer for which the drug has been prescribed in any one of the following established reference compendia:

- (a) the American Medical Association Drug Evaluations;
- (b) the American Hospital Formulary Service Drug Information; or
- (c) the United States Pharmacopeia Drug Information; or if not in the compendia, recommended for that particular type of cancer in formal clinical studies, the results of which have been published in at least two peer reviewed professional medical journals published in the United States or Great Britain.

Any coverage required by this Section shall also include those medically necessary services associated with the administration of a drug.

Despite the provisions of this Section, coverage shall not be required for any experimental or investigational drugs or any drug that the federal Food and Drug Administration has determined to be contraindicated for treatment of the specific type of cancer for which the drug has been prescribed. This Section shall apply only to cancer drugs. Nothing in this Section shall be construed, expressly or by implication, to create, impair, alter, limit, notify, enlarge, abrogate or prohibit reimbursement for drugs used in the treatment of any other disease or condition.

Laws 1937, p. 696, § 370r, added by P.A. 87-980, § 1, eff. Jan. 1, 1993.

Formerly Ill.Rev.Stat., ch. 73, ¶ 982r.

ARTICLE XXI. ASSESSMENT ACCIDENT AND ASSESSMENT ACCIDENT AND HEALTH COMPANIES

5/371 to 5/377. §§ 371 to 377. Repealed by P.A. 86-753, § 2, eff. Jan. 1, 1990

ARTICLE XXII. CASUALTY INSURANCE, FIDELITY BONDS AND SURETY CONTRACTS

Section

- 5/378. Scope of article.
- 5/379. Repealed.
- 5/379.1. Unearned premium reserve.
- 5/380. Repealed.
- 5/381 to 5/387. Repealed.
- 5/388. Standard provision for liability policies—Provisions forbidden.
- 5/388-1. Physical examination as condition of renewal.
- 5/388a. Group vehicle insurance defined.
- 5/388b. Group vehicle insurance authorized.
- 5/388c. "Entire contract" specified.
- 5/388d. Certificates required.
- 5/388e. New members of group.
- 5/388f. Conversion rights.
- 5/388g. Cancellation restricted.
- 5/389. Definition.
- 5/390. Corporate bonds satisfy legal requirement.
- 5/391. Trustee may have corporate surety.
- 5/392. Estoppel.

Section

5/392.1. Casualty and surety companies exempted from filing appeal bonds upon proof of liability—Taxable costs.

5/378. Scope of article

§ 378. Scope of Article. This article shall apply to all companies authorized in this State to transact the kind or kinds of business enumerated in Class 2 of Section 4.

Every such company shall, at all times, maintain reserves in an amount estimated in the aggregate to provide for the payment of all losses and claims incurred, whether reported or unreported, which are unpaid and for which such company may be liable, and to provide for the expenses of adjustment or settlement of such losses and claims. Such reserves shall be computed in accordance with regulations made from time to time by the Director after notice and hearing, upon reasonable consideration of the ascertained experience and the character of such kinds of business for the purpose of adequately protecting the insured and securing the solvency of such company.

Whenever the loss and loss expense experience of such company shows the reserves, calculated in accordance with such regulations, to be inadequate, the Director may require such company to maintain additional reserves.

Each company that writes liability or compensation policies shall include in the annual statement required by law, a schedule of its experience thereunder in such form as the Director may prescribe.

Laws 1937, p. 696, § 378. Amended by Laws 1967, p. 1812, § 1, eff. July 20, 1967.

Formerly Ill.Rev.Stat.1991, ch. 73, ¶ 990.

5/379. § 379. Repealed by Laws 1967, p. 1812, § 2, eff. July 20, 1967

5/379.1. Unearned premium reserve

§ 379.1. Unearned Premium Reserve. Every insurance company authorized to transact in this State any of the kind or kinds of business enumerated in Class 2 of Section 4 except accident and health insurance shall maintain an unearned premium reserve on all policies and bonds in force which shall be calculated in the manner described in Section 393.1 of this Code.

Laws 1937, p. 696, § 379.1, added by Laws 1967, p. 1745, § 1, eff. July 18, 1967.

Formerly Ill.Rev.Stat.1991, ch. 73, ¶ 991.1.

5/380. § 380. Repealed by Laws 1967, p. 1745, § 2, eff. July 18, 1967

5/381 to 5/387. §§ 381 to 387. Repealed by Laws 1967, p. 1812, § 2, eff. July 20, 1967

5/388. Standard provision for liability policies—Provisions forbidden

§ 388. Standard provision for liability policies—Provisions forbidden. No policy of insurance against liability or indemnity for loss or damage to any person other than the insured, or to the property of any person other than the insured, for which any insured is liable, shall be issued or delivered in this State after July 1, 1937, by any company subject to this Article unless it contains in substance a provision that the insolvency or bankruptcy of the insured

For further information see the *state and local* fiscal estimate, which will be printed as an appendix to this bill.

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

¶ SEC. 40.51 (8) of the statutes is amended to read:

1 40.51 (8) Every health care coverage plan offered by the state under sub. (6)
2 shall comply with ss. 631.89, 631.90, 631.93 (2), 631.95, 632.72 (2), 632.746 (1) to (8)
3 and (10), 632.747, 632.748, 632.83, 632.835, 632.85, 632.853, 632.855, 632.87 (3) to
4 (5), 632.895 (5m) and (8) to ~~(14)~~ (15)✓, and 632.896.

5 SECTION 1. 40.51 (8m)✓ of the statutes is amended to read:

6 40.51 (8m) Every health care coverage plan offered by the group insurance
7 board under sub. (7) shall comply with ss. 631.95, 632.746 (1) to (8) and (10), 632.747,
8 632.748, 632.83, 632.835, 632.85, 632.853, 632.855, and 632.895 (11) to ~~(14)~~ (15)✓.

9 SECTION 2. 66.0137 (4)✓ of the statutes is amended to read:

10 66.0137 (4) SELF-INSURED HEALTH PLANS. If a city, including a 1st class city, or
11 a village provides health care benefits under its home rule power, or if a town
12 provides health care benefits, to its officers and employees on a self-insured basis,
13 the self-insured plan shall comply with ss. 49.493 (3) (d), 631.89, 631.90, 631.93 (2),
14 632.746 (10) (a) 2. and (b) 2., 632.747 (3), 632.85, 632.853, 632.855, 632.87 (4) and (5),
15 632.895 (9) to ~~(14)~~ (15)✓, 632.896, and 767.25 (4m) (d).

16 SECTION 3. 111.91 (2) (n)✓ of the statutes is amended to read:

17 111.91 (2) (n) The provision to employees of the health insurance coverage
18 required under s. ^{plain} ~~ss.~~ 632.895 (11) to (14) (15)✓.

19 SECTION 4. 120.13 (2) (g)✓ of the statutes is amended to read:

20 120.13 (2) (g) Every self-insured plan under par. (b) shall comply with ss.
21 49.493 (3) (d), 631.89, 631.90, 631.93 (2), 632.746 (10) (a) 2. and (b) 2., 632.747 (3),

1 632.85, 632.853, 632.855, 632.87 (4) and (5), 632.895 (9) to (14) (15), 632.896, and
2 767.25 (4m) (d).

3 SECTION 5. 185.981 (4t) of the statutes is amended to read:

4 185.981 (4t) A sickness care plan operated by a cooperative association is
5 subject to ss. 252.14, 631.17, 631.89, 631.95, 632.72 (2), 632.745 to 632.749, 632.85,
6 632.853, 632.855, 632.87 (2m), (3), (4), and (5), 632.895 (10) to (14) (15), and 632.897
7 (10) and chs. 149 and 155.

8 SECTION 6. 185.983 (1) (intro.) of the statutes is amended to read:

9 185.983 (1) (intro.) Every such voluntary nonprofit sickness care plan shall be
10 exempt from chs. 600 to 646, with the exception of ss. 601.04, 601.13, 601.31, 601.41,
11 601.42, 601.43, 601.44, 601.45, 611.67, 619.04, 628.34 (10), 631.17, 631.89, 631.93,
12 631.95, 632.72 (2), 632.745 to 632.749, 632.775, 632.79, 632.795, 632.85, 632.853,
13 632.855, 632.87 (2m), (3), (4), and (5), 632.895 (5) and (9) to (14) (15), 632.896, and
14 632.897 (10) and chs. 609, 630, 635, 645, and 646, but the sponsoring association
15 shall:

16 SECTION 7. 609.87 of the statutes is created to read:

17 609.87 Coverage of certain drugs for cancer treatment. Defined network
18 plans are subject to s. 632.895 (15).

19 SECTION 8. 632.895 (15) of the statutes is created to read:

20 632.895 (15) COVERAGE OF CERTAIN DRUGS FOR CANCER TREATMENT. (a) Except as
21 provided in pars. (d) and ~~(e)~~, every disability insurance policy, and every self-insured
22 health plan of the state or a county, city, village, town, or school district, that provides
23 coverage of prescription medication shall provide coverage of a drug that is
24 prescribed by a licensed physician for ~~the treatment of~~ cancer if all of the following
25 apply:

treatng

treating

1 1. The federal food and drug administration has approved the drug for use in
2 ~~the drug~~ at least one type of cancer, regardless of whether that is the type of
3 cancer for which it is prescribed.

4 2. The drug is recognized as effective for treating the type of cancer for which
5 it is prescribed in any of the following:

6 a. The American Medical Association Drug Evaluations. ✓

7 b. The American Hospital Formulary Service Drug Information. ✓

8 c. The United States Pharmacopeia Drug Information. ✓

9 d. ~~Research~~ ^{clinical} studies published in ~~one or more~~ peer-reviewed national
10 professional medical journals. ✓

the results of which have been

at least 2

11 (b) A disability insurance policy or a self-insured health plan that is required
12 to provide the coverage under par. (a) shall also provide coverage for medically
13 necessary services related to administering a drug for which coverage is required
14 under par. (a).

15 (c) The coverage required under pars. (a) and (b) may be subject to any
16 limitations, exclusions, or cost-sharing provisions that apply generally to
17 prescription medication or services under the disability insurance policy or the
18 self-insured health plan.

19 (d) The coverage requirement under par. (a) does not apply to experimental
20 drugs or to any of the following types of health care plans:

21 1. A disability insurance policy that covers only certain specified diseases other
22 than cancer.

23 2. A health care plan offered by a limited service health organization, as defined
24 in s. 609.01 (3), or by a preferred provider plan, as defined in s. 609.01 (4), that is not
25 a defined network plan, as defined in s. 609.01 (1b).

SECTION 9. Initial applicability.

(1) This act first applies to all of the following:

(a) Except as provided in paragraphs (b) and (c), disability insurance policies that are issued or renewed, and self-insured health plans that are established, extended, modified or renewed, on the effective date of this paragraph.

(b) Disability insurance policies covering employees who are affected by a collective bargaining agreement containing provisions inconsistent with this act that are issued or renewed on the earlier of the following:

1. The day on which the collective bargaining agreement expires.

2. The day on which the collective bargaining agreement is extended, modified or renewed.

(c) Self-insured health plans covering employees who are affected by a collective bargaining agreement containing provisions inconsistent with this act that are established, extended, modified or renewed on the earlier of the following:

1. The day on which the collective bargaining agreement expires.

2. The day on which the collective bargaining agreement is extended, modified or renewed.

SECTION 10. Effective date.

(1) This act takes effect on the first day of the 7th month beginning after publication.

(END)

- therapeutic i.**, the ratio of LD₅₀ to ED₅₀, used in quantitative comparison of drugs.
- thoracic i.**, anteroposterior diameter of the thorax times 100 divided by the transverse diameter of the thorax. SYN chest i.
- tibiofemoral i.**, the ratio obtained by multiplying the length of the tibia by 100 and dividing by the length of the femur.
- transversovertical i.**, SYN vertical i.
- tuberculoopsonic i.**, the opsonic i. calculated in relation to tuberculous infection, with an actively growing culture of *Mycobacterium tuberculosis* or the strain of tubercle bacillus from the patient being used in the test.
- ultraviolet i.**, a daily i. issued by the U.S. National Weather Service for many cities, forecasting the amount of dangerous ultraviolet light that will arrive at the earth's surface about noon the following day.
- uricolytic i.**, the percentage of uric acid oxidized to allantoin before being secreted.
- vertical i.**, the relation of the height to the length of the skull: (height × 100)/length. SYN height-length i., length-height i., transversovertical i.
- vital i.**, the ratio of births to deaths within a population during a given time.
- Volpe-Manhold i. (V-MI)**, an index for comparing the amount of dental calculus in individuals.
- volume i.**, an indication of the relative size (e.g., volume) of erythrocytes, calculated as follows: hematocrit value, expressed as per cent of normal ÷ red blood cell count, expressed as per cent of normal = volume i.
- zygomatocauricular i.**, the ratio between the zygomatic and the auricular diameters of the skull or head
-
- in-di-can** (in'di-kan). 1. Indoxyl β-D-glucoside from *Indigofera* species and *Polygonum tinctorium*; a source of indigo. SYN plant i. 2. 3-Indoxylsulfuric acid, a substance found (as its salts) in sweat and in variable amounts in urine; indicative, when in quantity, of protein putrefaction in the intestine (indicanturia). SYN metabolic i., urooxanthin.
- metabolic i.**, SYN indican (2).
- plant i.**, SYN indican (1).
- in-di-can-i-dro-sis** (in'di-kan-i-drō'sis). Excretion of indican in the sweat. [indicant + G. *hidrōs*, sweat]
- in-di-cant** (in'di-kant). 1. Pointing out; indicating. 2. An indication; especially a symptom indicating the proper line of treatment. [L. *in-dico*, pres. p. *-ans* (*-ant*), to point out]
- in-di-can-u-ria** (in'di-kan-ū'rē-ā). An increased urinary excretion of indican, a derivative of indol formed chiefly in the intestine when protein is putrefied; indol is also formed during the putrefaction of protein in other sites.
- in-di-ca-tion** (in-di-kā'shūn). The basis for initiation of a treatment for a disease or of a diagnostic test; may be furnished by a knowledge of the cause (**causal i.**), by the symptoms present (**symptomatic i.**), or by the nature of the disease (**specific i.**). [L. fr. *in-dico*, pp. *-atus*, to point out, fr. *dico*, to proclaim]
- off label i.**, use of a medication for a purpose other than that approved by the FDA.
- in-di-ca-tor** (in'di-kā-ter, -tor). 1. In chemical analysis, a substance that changes color within a certain definite range of pH or oxidation potential, or in any way renders visible the completion of a chemical reaction; e.g., litmus, phenolsulfonphthalein. 2. An isotope that is used as a tracer. 3. The labeled substance whose distribution between reactants of a system is used to determine the amount of analyte present. [L. one that points out]
- alizarin i.**, a solution consisting of 1 g sodium alizarin sulfonate dissolved in 100 mL distilled water; used as an i. for free acidity in gastric contents.
- clinical i.**, a measure, process, or outcome used to judge a particular clinical situation and indicate whether the care delivered was appropriate.
- health i.**, variable, susceptible to direct measurement, that reflects the state of health of persons in a community.
- oxidation-reduction i.**, a substance that undergoes oxidation or change at a specific oxidation potential. SYN redox i., SYN oxidation-reduction i.
- in-di-ces** (in'di-sēz). Alternative plural of *Indica*.
- In-di-el-la** (in-dē-el'ā). Old name for *Madurella*.
- in-dig-e-nous** (in-dij'ē-nūs). Native; natural to a region where found. [L. *indigonus*, born in the form of *in*], + G. *-gen*, producing]
- in-di-ges-tion** (in-di-jes'chūn). Nonspecific term for symptoms resulting from a failure of proper digestion of food in the alimentary tract.
- acid i.**, i. resulting from hyperchlorhydria; often used as a synonym for pyrosis.
- fat i.**, SYN steatorrhea.
- gastric i.**, SYN dyspepsia.
- nervous i.**, i. caused by emotional upsets or stress.
- in-di-go** (in'di-gō) [C.I. 73000]. A blue dye used in *Indigofera tinctoria*, and other species of *Indigofera* (Leguminosae); also made synthetically. SYN indigo. [L. *indicum*; fr. G. *indikon*, indigo, ntr. of *indikos*]
- in-di-go blue.** SYN indigo.
- in-di-go car-mine** [C.I. 73015]. A blue dye used in the treatment of kidney function and as a special stain for SYN sodium indigotin disulfonate.
- in-dig-o-tin** (in-dig'ō-tin, in-di-gō'tin). SYN indigo.
- in-di-go-u-ria, in-di-gu-ria** (in'di-gō-ū'rē-ā, in-di-gō-ū'rē-ā). Excretion of indigo in the urine.
- in-dis-po-si-tion** (in-dis-pō-zish'ūn). Illness, usually of a chronic nature. [L. *in* neg. + *dispositio*, an arrangement, fr. *pono*, to place apart]
- in-di-um (In)** (in'dē-ūm). A metallic element, atomic wt. 114.82. [*indigo*, because of its blue color]
- in-di-um-111** (¹¹¹In). A cyclotron-produced radioisotope with a half-life of 2.8049 days and with gamma ray emission of 245.3 kiloelectron volts. In a chloride form, used as a bone marrow and tumor-localizing tracer; in a chloride form, used as a cerebrospinal fluid tracer. It is also used as a white labeling agent and as an antibody label.
- i. chloride, i. trichloride, Cl₃In**; used in electron spin resonance spectroscopy in thin tissue sections.
- in-di-um-113m** (^{113m}In). A radioactive isomer of indium with a half-life of 1.658 hours; it has been used in cisternography as a diagnostic aid in cardiac output.
- in-di-vid-u-a-tion** (in'di-vid-ū-ā'shūn). 1. Development of an individual from the specific. 2. In Jungian psychology, the process by which one's personality is differentiated, developed, and integrated. 3. Regional activity in an embryo as a result of an organizer.
- in-do-cy-a-nine green** (in-dō-sī-ā-nēn). A tricarbochrome that binds to serum albumin and is used in blood volume determinations and in liver function tests.
- in-do-cy-bin** (in-dō-sī-bin). SYN psilocybin.
- in-dol-ac-e-tu-ria** (in'dōl-as-ē-too'rē-ā). Excretion of an excessive amount of indoleacetic acid in the urine; a manifestation of Hartnup disease, also seen in patients with carcinoid tumor.
- in-dol-a-mine** (in-dōl'ā-mēn). General term for an indole derivative containing a primary, secondary, or tertiary amino group (e.g., serotonin).
- in-dole** (in'dōl). 1. 2,3-Benzopyrrole; basis of many biologically active substances (e.g., serotonin, tryptophan); formed by the decarboxylation of tryptophan. SYN ketole. 2. Any of many alkaloids containing the indole structure.
- in-do-lent** (in'dō-lent). Inactive; sluggish; painless or insidious; said of a morbid process. [L. *in* neg. + *doleo*, pr. p. *dolens*, to feel pain]
- in-dol-ic acids** (in-dōl'ik). Metabolites of L-tryptophan that are found within the body or by intestinal microorganisms; the principal ones encountered in urine are indoleacetic acid, indoleacetyl acid, 5-hydroxyindoleacetic acid, and indolelactic acid.

Kahler, Pam

From: Deering, Bonnie
Sent: Thursday, January 17, 2002 9:55 AM
To: Kahler, Pam
Subject: LRB 4232/1 off label drug use

Pam: I just got back some information on changes that we would like made to LRB 4232/1 relating to required coverage of off-label drugs for the treatment of cancer. Mind you that I am aware that you guys are and will be swamped with the budget repair bill so I will wait patiently. Thanks.

Somewhere in the legislation we need to add the definition of "peer reviewed medical literature or I believe the draft has it as "peer-reviewed national professional medical journals" on page 4, line 12. Please add the definition as something like this:

Medical literature means articles from major peer reviewed medical journals that have recognized the drug or combination of drugs' safety and effectiveness for treatment of the indication for which it has been prescribed. Each article shall meet the uniform requirements for manuscripts submitted to biomedical journals established by the international committee of medical journal editors or be published in a journal specified by the United States Code, title 42, section 1394x, paragraph (t), clause (2), item (B), as amended, as acceptable peer review medical literature. Each article much use generally acceptable scientific standards and must not use case reports to satisfy this criterion.

substantive

*2 articles
?
2 journals
- that the following standard
?
? what criterion?*

Then on page 4, lines 3-5 please delete present language and replace with:

The federal food and drug administration has approved the drug for use in treating at least one indication.

Then on page 4, line 18 please add language to say:

limitations, exclusions, or cost-sharing provisions **greater than those** that apply generally to

add "not" ?

Bonnie Deering

that the individual needs such shoes under a comprehensive plan of care related to the individual's diabetic condition;

(B) the particular type of shoes are prescribed by a podiatrist or other qualified physician (as established by the Secretary); and

(C) the shoes are fitted and furnished by a podiatrist or other qualified individual (such as a pedorthist or orthotist, as established by the Secretary) who is not the physician described in subparagraph (A) (unless the Secretary finds that the physician is the only such qualified individual in the area);

(13) screening mammography (as defined in subsection (jj) of this section);

(14) screening pap smear and screening pelvic exam; and

(15) bone mass measurement (as defined in subsection (rr) of this section).

No diagnostic tests performed in any laboratory, including a laboratory that is part of a rural health clinic, or a hospital (which, for purposes of this sentence, means an institution considered a hospital for purposes of section 1395f(d) of this title) shall be included within paragraph (3) unless such laboratory—

(16) if situated in any State in which State or applicable local law provides for licensing of establishments of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing establishments of this nature, as meeting the standards established for such licensing; and

(17)(A) meets the certification requirements under section 263a of this title; and

(B) meets such other conditions relating to the health and safety of individuals with respect to whom such tests are performed as the Secretary may find necessary.

There shall be excluded from the diagnostic services specified in paragraph (2)(C) any item or service (except services referred to in paragraph (1)) which would not be included under subsection (b) of this section if it were furnished to an inpatient of a hospital. None of the items and services referred to in the preceding paragraphs (other than paragraphs (1) and (2)(A)) of this subsection which are furnished to a patient of an institution which meets the definition of a hospital for purposes of section 1395f(d) of this title shall be included unless such other conditions are met as the Secretary may find necessary relating to health and safety of individuals with respect to whom such items and services are furnished.

(t) Drugs and biologicals

(1) The term "drugs" and the term "biologicals", except for purposes of subsection (m)(5) of this section and paragraph (2) include only such drugs and biologicals, respectively, as are included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary, or the United States Homeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein), or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital.

(2)(A) For purposes of paragraph (1), the term "drugs" also includes any drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication (as described in subparagraph (B)).

(B) In subparagraph (A), the term "medically accepted indication", with respect to the use of a drug, includes any use which has been approved by the Food and Drug Administration for the drug, and includes another use of the drug if—

(i) the drug has been approved by the Food and Drug Administration; and

(ii)(I) such use is supported by one or more citations which are included (or approved for inclusion) in one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, the United States Pharmacopoeia-Drug Information, and other authoritative compendia as identified by the Secretary, unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia, or

(II) the carrier involved determines, based upon guidance provided by the Secretary to carriers for determining accepted uses of drugs, that such use is medically accepted based on supportive clinical evidence in peer reviewed medical

literature approved by the Secretary under this subclause by the Secretary may identify medical

(u) Provider of se

The term "prov nursing facility, ec hospice program, o fund.

(v) Reasonable co

(1)(A) The reas excluding therefrom delivery of needed tions establishing t determining such c except that in any c determined under considered the reas to in the precedin principles generally zations (which have be made by persor account of services may provide for de capita, or other be stances, may provi may provide for th costs or incurred cc recognized as reas delivery of needed established under percentage of char tions shall (i) take (excluding therefrom accordance with re covered by the insu under the methods covered services to subchapter will not individuals not so cc for the making of s services for any fisc determining costs p

(B) In the case shall not include p

(C) Where a hos faculty of such scho reasonable cost of e the reasonable cost

(i) for which if—

(I) paym be made ur furnished b

(II) such such servic

(ii) for which such hospital pa to the medical sc

nder a comprehensive plan of care
prescribed by a podiatrist or other
secretary); and

by a podiatrist or other qualified
st, as established by the Secretary
paragraph (A) (unless the Secretary
qualified individual in the area);
subsection (j) of this section);
exam; and
subsection (rr) of this section).

cluding a laboratory that is part of a
poses of this sentence, means an
ction 1395f(d) of this title) shall be

or applicable local law provides for
s licensed pursuant to such law, or
r locality responsible for licensing
e standards established for such

under section 263a of this title; and
the health and safety of individuals
med as the Secretary may find

specified in paragraph (2)(C) any
paragraph (1) which would not be
re furnished to an inpatient of a
n the preceding paragraphs (other
ch are furnished to a patient of an
purposes of section 1395f(d) of this
re met as the Secretary may find
with respect to whom such items

except for purposes of subsection
only such drugs and biologicals,
y) in the United States Pharmacopoeia,
omeopathic Pharmacopoeia, or in
for any drugs and biologicals
the pharmacy and drug therapeutic
staff of the hospital furnishing

ugs" also includes any drugs or
egimen for a medically accepted

pted indication", with respect to
approved by the Food and Drug
f the drug if—

Drug Administration; and
itations which are included (or
owing compendia: the American
e American Medical Association
ia-Drug Information, and other
etary, unless the Secretary has
te or the use is identified as not

pon guidance provided by the
ses of drugs, that such use is
dence in peer reviewed medical

literature appearing in publications which have been identified for purposes of this
subclause by the Secretary.

The Secretary may revise the list of compendia in clause (ii)(1) as is appropriate for
identifying medically accepted indications for drugs.

(u) Provider of services

The term "provider of services" means a hospital, critical access hospital, skilled
nursing facility, comprehensive outpatient rehabilitation facility, home health agency,
hospice program, or, for purposes of section 1395f(g) and section 1395(e) of this title, a
fund.

(v) Reasonable costs

(1)(A) The reasonable cost of any services shall be the cost actually incurred,
excluding therefrom any part of incurred cost found to be unnecessary in the efficient
delivery of needed health services, and shall be determined in accordance with regula-
tions establishing the method or methods to be used, and the items to be included, in
determining such costs for various types or classes of institutions, agencies, and services;
except that in any case to which paragraph (2) or (3) applies, the amount of the payment
determined under such paragraph with respect to the services involved shall be
considered the reasonable cost of such services. In prescribing the regulations referred
to in the preceding sentence, the Secretary shall consider, among other things, the
principles generally applied by national organizations or established prepayment organi-
zations (which have developed such principles) in computing the amount of payment, to
be made by persons other than the recipients of services, to providers of services on
account of services furnished to such recipients by such providers. Such regulations
may provide for determination of the costs of services on a per diem, per unit, per
capita, or other basis, may provide for using different methods in different circum-
stances, may provide for the use of estimates of costs of particular items or services,
may provide for the establishment of limits on the direct or indirect overall incurred
costs or incurred costs of specific items or services or groups of items or services to be
recognized as reasonable based on estimates of the costs necessary in the efficient
delivery of needed health services to individuals covered by the insurance programs
established under this subchapter, and may provide for the use of charges or a
percentage of charges where this method reasonably reflects the costs. Such regula-
tions shall (i) take into account both direct and indirect costs of providers of services
(excluding therefrom any such costs, including standby costs, which are determined in
accordance with regulations to be unnecessary in the efficient delivery of services
covered by the insurance programs established under this subchapter) in order that,
under the methods of determining costs, the necessary costs of efficiently delivering
covered services to individuals covered by the insurance programs established by this
subchapter will not be borne by individuals not so covered, and the costs with respect to
individuals not so covered will not be borne by such insurance programs, and (ii) provide
for the making of suitable retroactive corrective adjustments where, for a provider of
services for any fiscal period, the aggregate reimbursement produced by the methods of
determining costs proves to be either inadequate or excessive.

(B) In the case of extended care services, the regulations under subparagraph (A)
shall not include provision for specific recognition of a return on equity capital.

(C) Where a hospital has an arrangement with a medical school under which the
faculty of such school provides services at such hospital, an amount not in excess of the
reasonable cost of such services to the medical school shall be included in determining
the reasonable cost to the hospital of furnishing services—

(i) for which payment may be made under part A of this subchapter, but only
if—

- (I) payment for such services as furnished under such arrangement would
be made under part A of this subchapter to the hospital had such services been
furnished by the hospital, and
- (II) such hospital pays to the medical school at least the reasonable cost of
such services to the medical school, or

(ii) for which payment may be made under part B of this subchapter, but only if
such hospital pays to the medical school at least the reasonable cost of such services
to the medical school.

Kahler, Pam

From: Deering, Bonnie
Sent: Thursday, January 17, 2002 2:01 PM
To: Kahler, Pam
Subject: off label

Okay, how about this definition for peer-reviewed medical literature:
"peer-reviewed medical literature" means a published scientific study in a journal or other publication in which original manuscripts have been published only after having been critically reviewed for scientific accuracy, validity and reliability by unbiased independent experts, and that has been determined by the International Committee of Medical Journal Editors to have met the Uniform Requirements for Manuscripts submitted to biomedical journals. Peer-reviewed medical literature does not include publications or supplements to publications that are sponsored to a significant extent by a pharmaceutical manufacturing company or health carrier.

What has been?

My contact on this said that the other definition was taken out of Minnesota law, but is happy with this if it will work out. This definition comes from the National Association of Insurance Commissioners model language.

Again, let me know if you have any problems. Most of this is way over my head anyway so I just pass the concerns along to our groups working on this. Thanks!

Bonnie Deering
Office of State Representative Dan Vrakas
119 West, State Capitol

*Change to ... ?
get rid of ... ?*



State of Wisconsin
2001 - 2002 LEGISLATURE

LRB-4232/2

PJK:rs&jld:jf

T
N mis run
Rep

2001 BILL

D-note

Gen

1 AN ACT to amend 40.51 (8), 40.51 (8m), 66.0137 (4), 111.91 (2) (n), 120.13 (2) (g),
2 185.981 (4t) and 185.983 (1) (intro.); and to create 609.87 and 632.895 (15) of
3 the statutes; relating to: required coverage of off-label drugs for the treatment
4 of cancer:

Analysis by the Legislative Reference Bureau

This bill requires health care plans that provide coverage of prescription medication to provide coverage of a drug, and services related to administering the drug, that is prescribed for use in the treatment of cancer by a licensed physician, if the federal food and drug administration has approved the drug for use in treating at least one ~~type of cancer~~ ~~for which it is prescribed~~ ~~for the treatment of cancer~~. In order for the requirement to apply, however, the drug must be recognized as effective for treating the type of cancer for which it is prescribed in the American Medical Association Drug Evaluations, the American Hospital Formulary Service Drug Information, the United States Pharmacopeia Drug Information, or ~~other~~ ~~sources~~ ~~of~~ ~~information~~ ~~that~~ ~~have~~ ~~been~~ ~~published~~ ~~in~~ ~~at~~ ~~least~~ ~~two~~ ~~peer-reviewed~~ ~~medical~~ ~~journals~~.

The coverage requirement applies to both individual and group health insurance policies and plans, including health care plans offered by the state or a municipality or school district. The coverage may be subject to any limitations, exclusions, or cost-sharing provisions that apply generally under the policy or plan. The requirement does not apply to limited benefit plans, such as vision or dental

at least two articles

Smart A-1

that are greater than those

not

BILL

plans, or to policies that cover only certain specified diseases other than cancer. The required coverage does not apply to experimental drugs.

For further information see the *state and local* fiscal estimate, which will be printed as an appendix to this bill.

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

1 **SECTION 1.** 40.51 (8) of the statutes is amended to read:

2 40.51 (8) Every health care coverage plan offered by the state under sub. (6)
3 shall comply with ss. 631.89, 631.90, 631.93 (2), 631.95, 632.72 (2), 632.746 (1) to (8)
4 and (10), 632.747, 632.748, 632.83, 632.835, 632.85, 632.853, 632.855, 632.87 (3) to
5 (5), 632.895 (5m) and (8) to ~~(14)~~ (15), and 632.896.

6 **SECTION 2.** 40.51 (8m) of the statutes is amended to read:

7 40.51 (8m) Every health care coverage plan offered by the group insurance
8 board under sub. (7) shall comply with ss. 631.95, 632.746 (1) to (8) and (10), 632.747,
9 632.748, 632.83, 632.835, 632.85, 632.853, 632.855, and 632.895 (11) to ~~(14)~~ (15).

10 **SECTION 3.** 66.0137 (4) of the statutes is amended to read:

11 66.0137 (4) SELF-INSURED HEALTH PLANS. If a city, including a 1st class city, or
12 a village provides health care benefits under its home rule power, or if a town
13 provides health care benefits, to its officers and employees on a self-insured basis,
14 the self-insured plan shall comply with ss. 49.493 (3) (d), 631.89, 631.90, 631.93 (2),
15 632.746 (10) (a) 2. and (b) 2., 632.747 (3), 632.85, 632.853, 632.855, 632.87 (4) and (5),
16 632.895 (9) to ~~(14)~~ (15), 632.896, and 767.25 (4m) (d).

17 **SECTION 4.** 111.91 (2) (n) of the statutes is amended to read:

18 111.91 (2) (n) The provision to employees of the health insurance coverage
19 required under s. 632.895 (11) to ~~(14)~~ (15).

20 **SECTION 5.** 120.13 (2) (g) of the statutes is amended to read:

BILL

1 120.13 (2) (g) Every self-insured plan under par. (b) shall comply with ss.
2 49.493 (3) (d), 631.89, 631.90, 631.93 (2), 632.746 (10) (a) 2. and (b) 2., 632.747 (3),
3 632.85, 632.853, 632.855, 632.87 (4) and (5), 632.895 (9) to ~~(14)~~ (15), 632.896, and
4 767.25 (4m) (d).

5 **SECTION 6.** 185.981 (4t) of the statutes is amended to read:

6 185.981 (4t) A sickness care plan operated by a cooperative association is
7 subject to ss. 252.14, 631.17, 631.89, 631.95, 632.72 (2), 632.745 to 632.749, 632.85,
8 632.853, 632.855, 632.87 (2m), (3), (4), and (5), 632.895 (10) to ~~(14)~~ (15), and 632.897
9 (10) and chs. 149 and 155.

10 **SECTION 7.** 185.983 (1) (intro.) of the statutes is amended to read:

11 185.983 (1) (intro.) Every such voluntary nonprofit sickness care plan shall be
12 exempt from chs. 600 to 646, with the exception of ss. 601.04, 601.13, 601.31, 601.41,
13 601.42, 601.43, 601.44, 601.45, 611.67, 619.04, 628.34 (10), 631.17, 631.89, 631.93,
14 631.95, 632.72 (2), 632.745 to 632.749, 632.775, 632.79, 632.795, 632.85, 632.853,
15 632.855, 632.87 (2m), (3), (4), and (5), 632.895 (5) and (9) to ~~(14)~~ (15), 632.896, and
16 632.897 (10) and chs. 609, 630, 635, 645, and 646, but the sponsoring association
17 shall:

18 **SECTION 8.** 609.87 of the statutes is created to read:

19 **609.87 Coverage of certain drugs for cancer treatment.** Defined network
20 plans are subject to s. 632.895 (15).

21 **SECTION 9.** 632.895 (15) of the statutes is created to read:

22 632.895 (15) **COVERAGE OF CERTAIN DRUGS FOR CANCER TREATMENT.** (a) Except as
23 provided in par. (a), every disability insurance policy, and every self-insured health
24 plan of the state or a county, city, village, town, or school district, that provides

Insert
3-22

22

23

24

BILL

1 coverage of prescription medication shall provide coverage of a drug that is
2 prescribed by a licensed physician for treating cancer if all of the following apply:

3 1. The federal food and drug administration has approved the drug for use in
4 treating at least one ~~type of cancer or a subset of members of a type of cancer~~

5 ~~for which it is prescribed.~~ indication

6 2. The drug is recognized as effective for treating the type of cancer for which
7 it is prescribed in any of the following:

- 8 a. The American Medical Association Drug Evaluations.
- 9 b. The American Hospital Formulary Service Drug Information.
- 10 c. The United States Pharmacopeia Drug Information.

11 d. ~~experimental~~ studies, the results of which have been published in at least 2
12 peer-reviewed ~~scientific~~ medical journals.

Insert 4-12

13 ~~(a)~~ A disability insurance policy or a self-insured health plan that is required
14 to provide the coverage under par. ~~(a)~~^b shall also provide coverage for medically
15 necessary services related to administering a drug for which coverage is required
16 under par. ~~(a)~~^b.

17 ~~(b)~~ The coverage required under pars. ~~(a)~~^b and ~~(b)~~^c may be subject to any
18 limitations, exclusions, or cost-sharing provisions ~~(a)~~^b that apply generally to
19 prescription medication or services under the disability insurance policy or the
20 self-insured health plan.

21 ~~(c)~~ The coverage requirement under par. ~~(a)~~^b does not apply to experimental
22 drugs or to any of the following types of health care plans:

23 1. A disability insurance policy that covers only certain specified diseases other
24 than cancer.

that are greater than those

Inset A-1

with indication, which is defined as the basis
for initiating a diagnostic test or a
treatment for a disease.

(end of ins A-1)

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INSERT 3-22

1 ^{not} In this subsection:

2 ¶ 1. "Indication" means the basis for initiation of a treatment for a disease ~~or~~
3 ~~diagnosis~~, which basis may be derived from a knowledge of the cause, from
4 symptoms present, or from the nature of the disease.

a diagnostic test or
↑

5 ¶ 2. "Peer-reviewed medical journal" means a journal or other publication in
6 which original manuscripts are published only after they have been critically
7 reviewed for scientific accuracy, validity, and reliability by unbiased independent
8 experts and determined by the International Committee of Medical Journal Editors
9 to meet the ~~Uniform Requirements for Manuscripts~~ submitted to biomedical
10 journals. "Peer-reviewed medical journal" does not include a publication or
11 supplement to a publication that is sponsored to a significant extent by a
12 pharmaceutical manufacturing company or health insurer.

13 ¶ (b)

(END OF INSERT 3-22)

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INSERT 4-12

- 1 ~~C~~ d. At least 2[✓] articles published in one or more peer-reviewed medical journals.

(END OF INSERT 4-12)

DRAFTER'S NOTE
FROM THE
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LRB-4232/2dn

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Reid

Date

may still be ✓

1. The definition for "peer-reviewed medical journal" ~~is still~~ a problem because it requires many subjective determinations. Will everyone agree on whether an expert is unbiased and independent? How much is a "significant extent"? In the language I was given, I wasn't sure exactly what "that has been determined...to have met the Uniform Requirements for Manuscripts..." was meant to modify. It could modify "a published scientific study," "a journal or other publication," or the singular of "original manuscripts." For the definition in the draft, I used the language to modify "original manuscripts," by providing that original manuscripts are published in the journal in question only after having been critically reviewed and determined to meet the specified requirements. Let me know if this does not work.

2. I included a definition for "indication" because standard dictionaries do not provide a definition for the term in the context in which it is used in the draft. The definition in the draft came from a medical dictionary.

3. Do you want to be more specific than "scientific studies"? The implication is that more than one study must show the effectiveness of a drug in the treatment of cancer, but it is vague, especially since, in the statutes, the singular includes the plural and the plural includes the singular (see s. 990.001 (1)). You could specify "more than one" study or "at least one" study so that there is no question and more consistency among insurers.

Pamela J. Kahler
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Phone: (608) 266-2682
E-mail: pam.kahler@legis.state.wi.us

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-4232/2dn
FJK:rs&jld:jf

January 30, 2002

1. The definition for "peer-reviewed medical journal" may still be a problem because it requires many subjective determinations. Will everyone agree on whether an expert is unbiased and independent? How much is a "significant extent"? In the language I was given, I wasn't sure exactly what "that has been determined...to have met the Uniform Requirements for Manuscripts..." was meant to modify. It could modify "a published scientific study," "a journal or other publication," or the singular of "original manuscripts." For the definition in the draft, I used the language to modify "original manuscripts," by providing that original manuscripts are published in the journal in question only after having been critically reviewed and determined to meet the specified requirements. Let me know if this does not work.
2. I included a definition for "indication" because standard dictionaries do not provide a definition for the term in the context in which it is used in the draft. The definition in the draft came from a medical dictionary.

Pamela J. Kahler
Senior Legislative Attorney
Phone: (608) 266-2682
E-mail: pam.kahler@legis.state.wi.us

Kahler, Pam

From: Deering, Bonnie
Sent: Tuesday, March 05, 2002 2:47 PM
To: Kahler, Pam
Subject: off label drug use LRB 4232/2

I realize that you are extremely busy with the budget reform bill, but any word regarding the changes below to the off label drug bill? We have no intentions of introducing this bill this session (obviously) but the Cancer Society is having their day at the Capitol on March 19th. They would like to have the draft to ask other legislators for support for next session. I can obviously put something general together but they have asked if the draft would be ready.

Obviously, I can wait until after session ends on the 14th to work on this, but I just thought I would ask. Thanks!!!

Bonnie Deering
Office of State Representative Dan Vrakas
119 West, State Capitol

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

From: Deering, Bonnie
Sent: Wednesday, February 27, 2002 2:39 PM
To: Kahler, Pam
Subject: off label drug use LRB 4232/2

Pam: listed below please find a follow up change that will hopefully answer your questions about the off label drug proposal. Please give me a call, 6-3007, if you have any questions. Thanks!

On page 4 replace "peer-reviewed medical journal" with the following definition:

2. "Medical literature" means the official United States Pharmacopoeia Drug Information, the American Hospital Formulary Service Drug Information, or published scientific studies published in any peer-reviewed national professional journal provided that each of the following applies:

- a. One article from a major peer-reviewed professional medical journal has recognized, based on scientific or medical criteria, the drug's safety and effectiveness for treatment of the indication for which it has been prescribed; and
- b. No article for a major peer-reviewed professional medical journal has concluded, based on scientific or medical criteria, that the drug is unsafe or ineffective or that the drug's safety and effectiveness cannot be determined for the treatment of the indication for which it has been prescribed; and
- c. Each article meets the uniform requirements for manuscripts submitted to biomedical journals established by the International Committee of Medical Journal Editors or is published in a journal specified by the United States Department of Health and Human Services pursuant to Section 1861(t)(2)(b) of the Social Security Act, 107 Stat. 591 (1993), 42 U.S.C. sec. 1395(x)(t)(2)(B), as amended, as accepted peer-reviewed medical literature.

Replace lines 19-24 on page 4 with the following:

2. The drug is recognized in medical literature as effective for treating the type of cancer for which it is prescribed.

4 0 1

Bonnie Deering
Office of State Representative Dan Vrakas
119 West, State Capitol



State of Wisconsin
2001 - 2002 LEGISLATURE

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2001 BILL

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1 AN ACT to amend 40.51 (8), 40.51 (8m), 66.0137 (4), 111.91 (2) (n), 120.13 (2) (g),
2 185.981 (4t) and 185.983 (1) (intro.); and to create 609.87 and 632.895 (15) of
3 the statutes; relating to: required coverage of off-label drugs for the treatment
4 of cancer.

Insert A

Analysis by the Legislative Reference Bureau

This bill requires health care plans that provide coverage of prescription medication to provide coverage of a drug, and services related to administering the drug, that is prescribed for use in the treatment of cancer by a licensed physician, if the federal food and drug administration has approved the drug for use in treating at least one indication, which is defined as the basis for initiating a diagnostic test or treatment for a disease. In order for the requirement to apply, however, the drug must be recognized as effective for treating the type of cancer for which it is prescribed in the American Medical Association Drug Evaluations, the American Hospital Formulary Service Drug Information, the United States Pharmacopeia Drug Information, or at least two articles published in one or more peer-reviewed medical journals.

The coverage requirement applies to both individual and group health insurance policies and plans, including health care plans offered by the state or a municipality or school district. The coverage may not be subject to any limitations, exclusions, or cost-sharing provisions that are greater than those that apply generally under the policy or plan. The requirement does not apply to limited benefit plans, such as vision or dental plans, or to policies that cover only certain specified

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diseases other than cancer. The required coverage does not apply to experimental drugs.

For further information see the *state and local* fiscal estimate, which will be printed as an appendix to this bill.

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

1 **SECTION 1.** 40.51 (8) [✓] of the statutes is amended to read:

2 40.51 (8) Every health care coverage plan offered by the state under sub. (6)
3 shall comply with ss. 631.89, 631.90, 631.93 (2), 631.95, 632.72 (2), 632.746 (1) to (8)
4 and (10), 632.747, 632.748, 632.83, 632.835, 632.85, 632.853, 632.855, 632.87 (3) to
5 (5), 632.895 (5m) and (8) to ~~(14)~~ (15), and 632.896.

6 **SECTION 2.** 40.51 (8m) [✓] of the statutes is amended to read:

7 40.51 (8m) Every health care coverage plan offered by the group insurance
8 board under sub. (7) shall comply with ss. 631.95, 632.746 (1) to (8) and (10), 632.747,
9 632.748, 632.83, 632.835, 632.85, 632.853, 632.855, and 632.895 (11) to ~~(14)~~ (15).

10 **SECTION 3.** 66.0137 (4) [✓] of the statutes is amended to read:

11 66.0137 (4) SELF-INSURED HEALTH PLANS. If a city, including a 1st class city, or
12 a village provides health care benefits under its home rule power, or if a town
13 provides health care benefits, to its officers and employees on a self-insured basis,
14 the self-insured plan shall comply with ss. 49.493 (3) (d), 631.89, 631.90, 631.93 (2),
15 632.746 (10) (a) 2. and (b) 2., 632.747 (3), 632.85, 632.853, 632.855, 632.87 (4) and (5),
16 632.895 (9) to ~~(14)~~ (15), 632.896, and 767.25 (4m) (d).

17 **SECTION 4.** 111.91 (2) (n) [✓] of the statutes is amended to read:

18 111.91 (2) (n) The provision to employees of the health insurance coverage
19 required under s. 632.895 (11) to ~~(14)~~ (15).

20 **SECTION 5.** 120.13 (2) (g) [✓] of the statutes is amended to read:

BILL

1 120.13 (2) (g) Every self-insured plan under par. (b) shall comply with ss.
2 49.493 (3) (d), 631.89, 631.90, 631.93 (2), 632.746 (10) (a) 2. and (b) 2., 632.747 (3),
3 632.85, 632.853, 632.855, 632.87 (4) and (5), 632.895 (9) to ~~(14)~~ (15), 632.896, and
4 767.25 (4m) (d).

5 **SECTION 6.** 185.981 (4t) [✓] of the statutes is amended to read:

6 185.981 (4t) A sickness care plan operated by a cooperative association is
7 subject to ss. 252.14, 631.17, 631.89, 631.95, 632.72 (2), 632.745 to 632.749, 632.85,
8 632.853, 632.855, 632.87 (2m), (3), (4), and (5), 632.895 (10) to ~~(14)~~ (15), and 632.897
9 (10) and chs. 149 and 155.

10 **SECTION 7.** 185.983 (1) (intro.) [✓] of the statutes is amended to read:

11 185.983 (1) (intro.) Every such voluntary nonprofit sickness care plan shall be
12 exempt from chs. 600 to 646, with the exception of ss. 601.04, 601.13, 601.31, 601.41,
13 601.42, 601.43, 601.44, 601.45, 611.67, 619.04, 628.34 (10), 631.17, 631.89, 631.93,
14 631.95, 632.72 (2), 632.745 to 632.749, 632.775, 632.79, 632.795, 632.85, 632.853,
15 632.855, 632.87 (2m), (3), (4), and (5), 632.895 (5) and (9) to ~~(14)~~ (15), 632.896, and
16 632.897 (10) and chs. 609, 630, 635, 645, and 646, but the sponsoring association
17 shall:

18 **SECTION 8.** 609.87 [✓] of the statutes is created to read:

19 **609.87 Coverage of certain drugs for cancer treatment.** Defined network
20 plans are subject to s. 632.895 (15) [✓].

21 **SECTION 9.** 632.895 (15) [✓] of the statutes is created to read:

22 **632.895 (15) COVERAGE OF CERTAIN DRUGS FOR CANCER TREATMENT.** (a) In this
23 subsection:

BILL ✓

Insert 4-1 →

① 2. ~~4~~ "Indication" means the basis for initiation of a diagnostic test or a treatment
2 for a disease, which basis may be derived from a knowledge of the cause, from
3 symptoms present, or from the nature of the disease.

4 2. "Peer-reviewed medical journal" means a journal or other publication in
5 which original manuscripts are published only after they have been critically
6 reviewed for scientific accuracy, validity, and reliability by unbiased independent
7 experts and determined by the International Committee of Medical Journal Editors
8 to meet the uniform requirements for manuscripts submitted to biomedical journals.
9 "Peer-reviewed medical journal" does not include a publication or supplement to a
10 publication that is sponsored to a significant extent by a pharmaceutical
11 manufacturing company or health insurer.

12 (b) Except as provided in par. (e), every disability insurance policy, and every
13 self-insured health plan of the state or a county, city, village, town, or school district,
14 that provides coverage of prescription medication shall provide coverage of a drug
15 that is prescribed by a licensed physician for treating cancer if all of the following
16 apply:

17 1. The federal food and drug administration has approved the drug for use in
18 treating at least one indication.

19 2. The drug is recognized as effective for treating the type of cancer for which
20 it is prescribed in any of the following:

21 ~~a. The American Medical Association Drug Evaluations.~~

22 a. ~~4~~ The American Hospital Formulary Service Drug Information.

23 b. ~~5~~ The United States Pharmacopeia Drug Information.

24 c. ~~4~~ At least ~~2~~ articles published in one or more peer-reviewed medical journals.

official →

✓ one article ←

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Insert 5-1 →

1 (c) A disability insurance policy or a self-insured health plan that is required
2 to provide the coverage under par. (b) shall also provide coverage for medically
3 necessary services related to administering a drug for which coverage is required
4 under par. (b).

5 (d) The coverage required under pars. (b) and (c) may not be subject to any
6 limitations, exclusions, or cost-sharing provisions that are greater than those that
7 apply generally to prescription medication or services under the disability insurance
8 policy or the self-insured health plan.

9 (e) The coverage requirement under par. (b) does not apply to experimental
10 drugs or to any of the following types of health care plans:

11 1. A disability insurance policy that covers only certain specified diseases other
12 than cancer.

13 2. A health care plan offered by a limited service health organization, as defined
14 in s. 609.01 (3), or by a preferred provider plan, as defined in s. 609.01 (4), that is not
15 a defined network plan, as defined in s. 609.01 (1b).

16 **SECTION 10. Initial applicability.**

17 (1) This act first applies to all of the following:

18 (a) Except as provided in paragraphs (b) and (c), disability insurance policies
19 that are issued or renewed, and self-insured health plans that are established,
20 extended, modified, or renewed, on the effective date of this paragraph.

21 (b) Disability insurance policies covering employees who are affected by a
22 collective bargaining agreement containing provisions inconsistent with this act
23 that are issued or renewed on the earlier of the following:

24 1. The day on which the collective bargaining agreement expires.

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INSERT A

This analysis has not been updated from the version in the /2. I will update the analysis after the language in the draft is approved as final.

(END OF INSERT A)

INSERT 4-1

1 1. "Article" means an article that is published in a peer-reviewed national
2 medical journal and that satisfies all of the following:

3 a. The article meets the uniform requirements established by the International
4 Committee of Medical Journal Editors for manuscripts submitted to biomedical
5 journals on the journal in which ^{the article} it is published is specified as accepted peer-reviewed
6 medical literature by the ^{federal} secretary of ~~the federal department~~ of health and human
7 services under 42 USC 1395x (t) (2) ^(B) (ii) (II).

8 b. The article is based on one or more scientific studies that used scientific or
9 medical criteria.

(END OF INSERT 4-1)

INSERT 5-1

10 3. No article has concluded that the drug is unsafe or ineffective ^{or that the}
11 drug's safety or ineffectiveness cannot be determined ^{for treatment of the indication}
12 for which it is prescribed.

(END OF INSERT 5-1)

6-4-12

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-4232/2dn
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Date

Keep

The language that was submitted to me for a definition of "medical literature" does not accurately reflect the relationships among the concepts. In this redraft, I have tried to establish the relationships more clearly. I need a bit of help in that regard, however, because I can't tell from the proposed language exactly what the relationships are supposed to be.

Is how I have structured s. 632.895 (15) (b) [✓] correct? In other words, if the American Hospital Formulary Service Drug Information, for example, recognizes a drug as effective, does it matter whether an article in a medical journal has found the drug unsafe or ineffective, or does that matter *only* if the only source recognizing the drug as effective is another article? If the latter, par. (b) must be structured differently.

If at least one article recognizing the effectiveness of a drug is all that is needed to require insurance coverage of the drug (with no articles finding the drug unsafe or ineffective), there is no reason to use the phrase "medical literature" and then define medical literature to mean at least one article. And you definitely want to use "at least" one article, because if you say "one article" that means insurance coverage is not required if two or more articles recognize the drug as effective.

If this redraft still does not accomplish what you want, or close to it, I may need to speak directly with the person submitting the language so that I can better explain the problem and so that the person can explain what he or she wants instead of trying to draft it without explanation.

Pamela J. Kahler
Senior Legislative Attorney
Phone: (608) 266-2682
E-mail: pam.kahler@legis.state.wi.us

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-4232/3dn
PJK:rs&jld:pg

April 1, 2002

The language that was submitted to me for a definition of "medical literature" does not accurately reflect the relationships among the concepts. In this redraft, I have tried to establish the relationships more clearly. I need a bit of help in that regard, however, because I can't tell from the proposed language exactly what the relationships are supposed to be.

Is how I have structured s. 632.895 (15) (b) correct? In other words, if the American Hospital Formulary Service Drug Information, for example, recognizes a drug as effective, does it matter whether an article in a medical journal has found the drug unsafe or ineffective, or does that matter *only* if the only source recognizing the drug as effective is another article? If the latter, par. (b) must be structured differently.

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If this redraft still does not accomplish what you want, or close to it, I may need to speak directly with the person submitting the language so that I can better explain the problem and so that the person can explain what he or she wants instead of trying to draft it without explanation.

Pamela J. Kahler
Senior Legislative Attorney
Phone: (608) 266-2682
E-mail: pam.kahler@legis.state.wi.us

Meeting on 5-14 1:00 pm

p 5, lines 2-4 remove (redundant of 2.)

p. 4, lines 10+11 remove (redundant of requirements in a.)

p 4, line 3 remove "peer-reviewed national medical journal"

p. 5, lines 13+14 remove part about experimental drugs (would not be approved by FDA if were experimental)

BILL

exclusions, or cost-sharing provisions that are greater than those that apply generally under the policy or plan. The requirement does not apply to limited benefit plans, such as vision or dental plans, or to policies that cover only certain specified diseases other than cancer. ~~The required coverage does not apply to experimental drugs.~~

For further information see the *state and local* fiscal estimate, which will be printed as an appendix to this bill.

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

1 **SECTION 1.** 40.51 (8)[✓] of the statutes is amended to read:
2 40.51 (8) Every health care coverage plan offered by the state under sub. (6)
3 shall comply with ss. 631.89, 631.90, 631.93 (2), 631.95, 632.72 (2), 632.746 (1) to (8)
4 and (10), 632.747, 632.748, 632.83, 632.835, 632.85, 632.853, 632.855, 632.87 (3) to
5 (5), 632.895 (5m) and (8) to ~~(14)~~ (15)[✓] and 632.896.

6 **SECTION 2.** 40.51 (8m) of the statutes is amended to read:
7 40.51 (8m) Every health care coverage plan offered by the group insurance
8 board under sub. (7) shall comply with ss. 631.95, 632.746 (1) to (8) and (10), 632.747,
9 632.748, 632.83, 632.835, 632.85, 632.853, 632.855, and 632.895 (11) to ~~(14)~~ (15)[✓].

10 **SECTION 3.** 66.0137 (4)[✓] of the statutes is amended to read:
11 66.0137 (4) **SELF-INSURED HEALTH PLANS.** If a city, including a 1st class city, or
12 a village provides health care benefits under its home rule power, or if a town
13 provides health care benefits, to its officers and employees on a self-insured basis,
14 the self-insured plan shall comply with ss. 49.493 (3) (d), 631.89, 631.90, 631.93 (2),
15 632.746 (10) (a) 2. and (b) 2., 632.747 (3), 632.85, 632.853, 632.855, 632.87 (4) and (5),
16 632.895 (9) to ~~(14)~~ (15)[✓], 632.896, and 767.25 (4m) (d).

17 **SECTION 4.** 111.91 (2) (n)[✓] of the statutes is amended to read:

BILL

1 111.91 (2) (n) The provision to employees of the health insurance coverage
2 required under s. 632.895 (11) to ~~(14)~~ (15).

3 **SECTION 5.** 120.13 (2) (g) [✓] of the statutes is amended to read:

4 120.13 (2) (g) Every self-insured plan under par. (b) shall comply with ss.
5 49.493 (3) (d), 631.89, 631.90, 631.93 (2), 632.746 (10) (a) 2. and (b) 2., 632.747 (3),
6 632.85, 632.853, 632.855, 632.87 (4) and (5), 632.895 (9) to ~~(14)~~ (15), 632.896, and
7 767.25 (4m) (d).

8 **SECTION 6.** 185.981 (4t) [✓] of the statutes is amended to read:

9 185.981 (4t) A sickness care plan operated by a cooperative association is
10 subject to ss. 252.14, 631.17, 631.89, 631.95, 632.72 (2), 632.745 to 632.749, 632.85,
11 632.853, 632.855, 632.87 (2m), (3), (4), and (5), 632.895 (10) to ~~(14)~~ (15), and 632.897
12 (10) and chs. 149 and 155.

13 **SECTION 7.** 185.983 (1) (intro.) [✓] of the statutes is amended to read:

14 185.983 (1) (intro.) Every such voluntary nonprofit sickness care plan shall be
15 exempt from chs. 600 to 646, with the exception of ss. 601.04, 601.13, 601.31, 601.41,
16 601.42, 601.43, 601.44, 601.45, 611.67, 619.04, 628.34 (10), 631.17, 631.89, 631.93,
17 631.95, 632.72 (2), 632.745 to 632.749, 632.775, 632.79, 632.795, 632.85, 632.853,
18 632.855, 632.87 (2m), (3), (4), and (5), 632.895 (5) and (9) to ~~(14)~~ (15), 632.896, and
19 632.897 (10) and chs. 609, 630, 635, 645, and 646, but the sponsoring association
20 shall:

21 **SECTION 8.** 609.87 [✓] of the statutes is created to read:

22 **609.87 Coverage of certain drugs for cancer treatment.** Defined network
23 plans are subject to s. 632.895 (15) [✓].

24 **SECTION 9.** 632.895 (15) [✓] of the statutes is created to read:

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632.895 (15) COVERAGE OF CERTAIN DRUGS FOR CANCER TREATMENT. (a) In this

subsection, "indication"

NO
4

1. "Article" means an article that is published in a peer-reviewed national medical journal and that satisfies all of the following:

a. The article meets the uniform requirements established by the International Committee of Medical Journal Editors for manuscripts submitted to biomedical journals or, if not, the journal in which the article is published is specified as accepted peer-reviewed medical literature by the federal secretary of health and human services under 42 USC 1395x (t) (2) (B) (ii) (II).

b. The article is based on one or more scientific studies that used scientific or medical criteria.

2. "Indication" means the basis for initiation of a diagnostic test or a treatment for a disease, which basis may be derived from a knowledge of the cause, from symptoms present, or from the nature of the disease.

(b) Except as provided in par. (e), every disability insurance policy, and every self-insured health plan of the state or a county, city, village, town, or school district, that provides coverage of prescription medication shall provide coverage of a drug that is prescribed by a licensed physician for treating cancer if all of the following apply:

1. The federal food and drug administration has approved the drug for use in treating at least one indication.

2. The drug is recognized as effective for treating the type of cancer for which it is prescribed in any of the following:

a. The American Hospital Formulary Service Drug Information.

b. The official United States Pharmacopeia Drug Information.

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Insert 5-4

1 e. At least one article.
 2 3. No article has concluded that the drug is unsafe or ineffective, or that the
 3 drug's safety or ineffectiveness cannot be determined, for treatment of the indication
 4 for which it is prescribed.

5 (c) A disability insurance policy or a self-insured health plan that is required
 6 to provide the coverage under par. (b) shall also provide coverage for medically
 7 necessary services related to administering a drug for which coverage is required
 8 under par. (b).

9 (d) The coverage required under pars. (b) and (c) may not be subject to any
 10 limitations, exclusions, or cost-sharing provisions that are greater than those that
 11 apply generally to prescription medication or services under the disability insurance
 12 policy or the self-insured health plan.

13 (e) The coverage requirement under par. (b) does not apply ~~to any of the following~~
 14 ~~types~~ to any of the following types of health care plans:

- 15 1. A disability insurance policy that covers only certain specified diseases other
- 16 than cancer.
- 17 2. A health care plan offered by a limited service health organization, as defined
- 18 in s. 609.01 (3), or by a preferred provider plan, as defined in s. 609.01 (4), that is not
- 19 a defined network plan, as defined in s. 609.01 (1b).

SECTION 10. Initial applicability.

(1) This act first applies to all of the following:

22 (a) Except as provided in paragraphs (b) and (c), disability insurance policies
 23 that are issued or renewed, and self-insured health plans that are established,
 24 extended, modified, or renewed, on the effective date of this paragraph.

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1 (b) Disability insurance policies covering employees who are affected by a
2 collective bargaining agreement containing provisions inconsistent with this act
3 that are issued or renewed on the earlier of the following:

4 1. The day on which the collective bargaining agreement expires.

5 2. The day on which the collective bargaining agreement is extended, modified,
6 or renewed.

7 (c) Self-insured health plans covering employees who are affected by a
8 collective bargaining agreement containing provisions inconsistent with this act
9 that are established, extended, modified, or renewed on the earlier of the following:

10 1. The day on which the collective bargaining agreement expires.

11 2. The day on which the collective bargaining agreement is extended, modified,
12 or renewed.

13 **SECTION 11. Effective date.**

14 (1) This act takes effect on the first day of the 7th month beginning after
15 publication.

16 (END)

D. J. J.

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FROM THE
LEGISLATIVE REFERENCE BUREAU

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not approved by the federal food and drug administration for use in treating at least one indication, which is defined in the bill as the basis for initiating a diagnostic test or treatment for a disease; and ~~insert~~ *plain*
(END OF INSERT A)

Semicolon

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not one published article that meets uniform requirements for manuscripts submitted to biomedical journals or that is published in a journal that is specified as accepted peer-reviewed medical literature by the federal secretary of health and human services under ~~a~~ federal law requirement

(END OF INSERT B)

an existing

INSERT 5-4

- 1 *At* c. At least one article that is published in a journal and that meets the uniform
- 2 requirements established by the International Committee of Medical Journal
- 3 Editors for manuscripts submitted to biomedical journals or, if not, the journal in
- 4 which the article is published is specified as accepted peer-reviewed medical
- 5 literature by the federal secretary of health and human services under 42 USC 1395x
- 6 (t) (2) (B) (ii) (II).

(END OF INSERT 5-4)

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-4232/4dn

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Date

in A. 632.895 (15)
(b) 2-C. ✓

That is

1. As I explained at our meeting on May 14, we normally do not use a definition in a statutory unit for a word or phrase used in the statutory unit only once. That is the reason in this version of the draft I replaced the word "article" with what was its definition. Unfortunately, even though "indication" is used only once also, its definition cannot easily be used in place of the word. So ~~the~~ definition remains. → that

2. One issue that might arise concerning this draft is a possible delegation of legislative authority in violation of art. IV, sec. 1, of the Wisconsin Constitution. Under the draft, not the legislature but the federal secretary of health and human services determines what journals are accepted peer-reviewed journals, the International Committee of Medical Journal Editors determines requirements for manuscripts, and the American Hospital Formulary Service Drug Information and United States Pharmacopoeia Drug Information recognize the effectiveness of a drug, all for purposes of insurance coverage under the statute created in the draft. In my opinion, none of these determinations, however, violates the constitution because they are all fact-finding rather than law-making, which the Wisconsin supreme court found acceptable and not unconstitutional in *State v. Wakeen*, 263 Wis. 401 (1953).

In that case, the definition of "drug" in a Wisconsin criminal statute was based on what the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary recognized as intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals. The court stated that it was well recognized that the legislature may not delegate its power to *make a law* but may "make a law to delegate a power to determine some fact or state of things upon which the law makes, or intends to make, its own action depend." Thus, the operation of a statute may depend on a determination of some fact by a private party. The court also found it important that the party or entity making the determination was eminently qualified to make the determination and that the determination was not made in response to a delegation of power, but was made independently of the statute for another purpose.

→ All of the characteristics of the determinations that the court found perfectly acceptable apply to the outside determinations upon which this draft relies. Thus, under this draft, while there may be delegation of fact-finding authority, there is no delegation of legislative or law-making authority.

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DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-4232/4dn
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May 22, 2002

1. As I explained at our meeting on May 14, we normally do not use a definition in a statutory unit for a word or phrase that is used in the statutory unit only once. That is the reason in this version of the draft I replaced the word "article" in s. 632.895 (15) (b) 2. c. with what was its definition. Unfortunately, even though "indication" is used only once also, its definition cannot easily be used in place of the word. So that definition remains.

2. One issue that might arise concerning this draft is a possible delegation of legislative authority in violation of art. IV, sec. 1, of the Wisconsin Constitution. Under the draft, not the legislature but the federal secretary of health and human services determines what journals are accepted peer-reviewed journals, the International Committee of Medical Journal Editors determines requirements for manuscripts, and the American Hospital Formulary Service Drug Information and United States Pharmacopoeia Drug Information recognize the effectiveness of a drug, all for purposes of insurance coverage under the statute created in the draft. In my opinion, none of these determinations, however, violates the constitution because they are all fact-finding rather than law-making, which the Wisconsin supreme court found acceptable and not unconstitutional in *State v. Wakeen*, 263 Wis. 401 (1953).

In that case, the definition of "drug" in a Wisconsin criminal statute was based on what the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary recognized as intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals. The court stated that it was well recognized that the legislature may not delegate its power to *make a law* but may "make a law to delegate a power to determine some fact or state of things upon which the law makes, or intends to make, its own action depend." Thus, the operation of a statute may depend on a determination of some fact by a private party. The court also found it important that the party or entity making the determination was eminently qualified to make the determination and that the determination was not made in response to a delegation of power, but was made independently of the statute for another purpose.

All of the characteristics of determinations that the court found perfectly acceptable apply to the outside determinations upon which this draft relies. Thus, under this

draft, while there may be delegation of fact-finding authority, there is no delegation of legislative or law-making authority.

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State of Wisconsin
2001 - 2002 LEGISLATURE

LRB-4232/4
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2001 BILL

1 AN ACT *to amend* 40.51 (8), 40.51 (8m), 66.0137 (4), 111.91 (2) (n), 120.13 (2) (g),
2 185.981 (4t) and 185.983 (1) (intro.); and *to create* 609.87 and 632.895 (15) of
3 the statutes; **relating to:** required coverage of off-label drugs for the treatment
4 of cancer.

Analysis by the Legislative Reference Bureau

This bill requires health care plans that provide coverage of prescription medication to provide coverage of a drug, and services related to administering the drug, that is prescribed by a licensed physician for treating cancer. In order for the requirement to apply, however, the drug must be approved by the federal food and drug administration for use in treating at least one indication, which is defined in the bill as the basis for initiating a diagnostic test or treatment for a disease; and must be recognized as effective for treating the type of cancer for which it is prescribed in the American Hospital Formulary Service Drug Information, the official United States Pharmacopeia Drug Information, or at least one published article that meets uniform requirements for manuscripts submitted to biomedical journals or that is published in a journal that is specified as accepted peer-reviewed medical literature by the federal secretary of health and human services under an existing federal law requirement.

The coverage requirement applies to both individual and group health insurance policies and plans, including health care plans offered by the state or a municipality or school district. The coverage may not be subject to any limitations, exclusions, or cost-sharing provisions that are greater than those that apply

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generally under the policy or plan. The requirement does not apply to limited benefit plans, such as vision or dental plans, or to policies that cover only certain specified diseases other than cancer.

For further information see the *state and local* fiscal estimate, which will be printed as an appendix to this bill.

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

1 **SECTION 1.** 40.51 (8) of the statutes is amended to read:

2 40.51 (8) Every health care coverage plan offered by the state under sub. (6)
3 shall comply with ss. 631.89, 631.90, 631.93 (2), 631.95, 632.72 (2), 632.746 (1) to (8)
4 and (10), 632.747, 632.748, 632.83, 632.835, 632.85, 632.853, 632.855, 632.87 (3) to
5 (5), 632.895 (5m) and (8) to ~~(14)~~ (15), and 632.896.

6 **SECTION 2.** 40.51 (8m) of the statutes is amended to read:

7 40.51 (8m) Every health care coverage plan offered by the group insurance
8 board under sub. (7) shall comply with ss. 631.95, 632.746 (1) to (8) and (10), 632.747,
9 632.748, 632.83, 632.835, 632.85, 632.853, 632.855, and 632.895 (11) to ~~(14)~~ (15).

10 **SECTION 3.** 66.0137 (4) of the statutes is amended to read:

11 66.0137 (4) SELF-INSURED HEALTH PLANS. If a city, including a 1st class city, or
12 a village provides health care benefits under its home rule power, or if a town
13 provides health care benefits, to its officers and employees on a self-insured basis,
14 the self-insured plan shall comply with ss. 49.493 (3) (d), 631.89, 631.90, 631.93 (2),
15 632.746 (10) (a) 2. and (b) 2., 632.747 (3), 632.85, 632.853, 632.855, 632.87 (4) and (5),
16 632.895 (9) to (14) (15), 632.896, and 767.25 (4m) (d).

17 **SECTION 4.** 111.91 (2) (n) of the statutes is amended to read:

18 111.91 (2) (n) The provision to employees of the health insurance coverage
19 required under s. 632.895 (11) to ~~(14)~~ (15).

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1 **SECTION 5.** 120.13 (2) (g) of the statutes is amended to read:

2 120.13 (2) (g) Every self-insured plan under par. (b) shall comply with ss.
3 49.493 (3) (d), 631.89, 631.90, 631.93 (2), 632.746 (10) (a) 2. and (b) 2., 632.747 (3),
4 632.85, 632.853, 632.855, 632.87 (4) and (5), 632.895 (9) to ~~(14)~~ (15), 632.896, and
5 767.25 (4m) (d).

6 **SECTION 6.** 185.981 (4t) of the statutes is amended to read:

7 185.981 (4t) A sickness care plan operated by a cooperative association is
8 subject to ss. 252.14, 631.17, 631.89, 631.95, 632.72 (2), 632.745 to 632.749, 632.85,
9 632.853, 632.855, 632.87 (2m), (3), (4), and (5), 632.895 (10) to ~~(14)~~ (15), and 632.897
10 (10) and chs. 149 and 155.

11 **SECTION 7.** 185.983 (1) (intro.) of the statutes is amended to read:

12 185.983 (1) (intro.) Every such voluntary nonprofit sickness care plan shall be
13 exempt from chs. 600 to 646, with the exception of ss. 601.04, 601.13, 601.31, 601.41,
14 601.42, 601.43, 601.44, 601.45, 611.67, 619.04, 628.34 (10), 631.17, 631.89, 631.93,
15 631.95, 632.72 (2), 632.745 to 632.749, 632.775, 632.79, 632.795, 632.85, 632.853,
16 632.855, 632.87 (2m), (3), (4), and (5), 632.895 (5) and (9) to ~~(14)~~ (15), 632.896, and
17 632.897 (10) and chs. 609, 630, 635, 645, and 646, but the sponsoring association
18 shall:

19 **SECTION 8.** 609.87 of the statutes is created to read:

20 **609.87 Coverage of certain drugs for cancer treatment.** Defined network
21 plans are subject to s. 632.895 (15).

22 **SECTION 9.** 632.895 (15) of the statutes is created to read:

23 632.895 (15) **COVERAGE OF CERTAIN DRUGS FOR CANCER TREATMENT.** (a) In this
24 subsection, "indication" means the basis for initiation of a diagnostic test or a

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1 treatment for a disease, which basis may be derived from a knowledge of the cause,
2 from symptoms present, or from the nature of the disease.

3 (b) Except as provided in par. (e), every disability insurance policy, and every
4 self-insured health plan of the state or a county, city, village, town, or school district,
5 that provides coverage of prescription medication shall provide coverage of a drug
6 that is prescribed by a licensed physician for treating cancer if all of the following
7 apply:

8 1. The federal food and drug administration has approved the drug for use in
9 treating at least one indication.

10 2. The drug is recognized as effective for treating the type of cancer for which
11 it is prescribed in any of the following:

12 a. The American Hospital Formulary Service Drug Information.

13 b. The official United States Pharmacopeia Drug Information.

14 c. At least one article that is published in a journal and that meets the uniform
15 requirements established by the International Committee of Medical Journal
16 Editors for manuscripts submitted to biomedical journals or, if not, the journal in
17 which the article is published is specified as accepted peer-reviewed medical
18 literature by the federal secretary of health and human services under 42 USC 1395x
19 (t) (2) (B) (ii) (II).

20 (c) A disability insurance policy or a self-insured health plan that is required
21 to provide the coverage under par. (b) shall also provide coverage for medically
22 necessary services related to administering a drug for which coverage is required
23 under par. (b).

24 (d) The coverage required under pars. (b) and (c) may not be subject to any
25 limitations, exclusions, or cost-sharing provisions that are greater than those that

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1 apply generally to prescription medication or services under the disability insurance
2 policy or the self-insured health plan.

3 (e) The coverage requirement under par. (b) does not apply to any of the
4 following types of health care plans:

5 1. A disability insurance policy that covers only certain specified diseases other
6 than cancer.

7 2. A health care plan offered by a limited service health organization, as defined
8 in s. 609.01 (3), or by a preferred provider plan, as defined in s. 609.01 (4), that is not
9 a defined network plan, as defined in s. 609.01 (1b).

10 **SECTION 10. Initial applicability.**

11 (1) This act first applies to all of the following:

12 (a) Except as provided in paragraphs (b) and (c), disability insurance policies
13 that are issued or renewed, and self-insured health plans that are established,
14 extended, modified, or renewed, on the effective date of this paragraph.

15 (b) Disability insurance policies covering employees who are affected by a
16 collective bargaining agreement containing provisions inconsistent with this act
17 that are issued or renewed on the earlier of the following:

18 1. The day on which the collective bargaining agreement expires.

19 2. The day on which the collective bargaining agreement is extended, modified,
20 or renewed.

21 (c) Self-insured health plans covering employees who are affected by a
22 collective bargaining agreement containing provisions inconsistent with this act
23 that are established, extended, modified, or renewed on the earlier of the following:

24 1. The day on which the collective bargaining agreement expires.

