

2005 DRAFTING REQUEST

Bill

Received: 05/12/2005

Received By: **chanaman**

Wanted: **As time permits**

Identical to LRB:

For: **Scott Gunderson (608) 266-3363**

By/Representing: **Mike**

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

Drafter: **chanaman**

May Contact:

Addl. Drafters: **pkahler**

Subject: **Insurance - health**

Extra Copies: **PJK**

Submit via email: **YES**

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

Carbon copy (CC:) to:

Pre Topic:

No specific pre topic given

Topic:

Requiring insurers to cover routine costs in clinical trials if costs are generally covered

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>
/?	chanaman 05/27/2005	csicilia 05/31/2005		_____			S&L
/1			rschluet 05/31/2005	_____	lnorthro 05/31/2005	mbarman 06/08/2005	

FE Sent For:

↳ At Intro,

<END>

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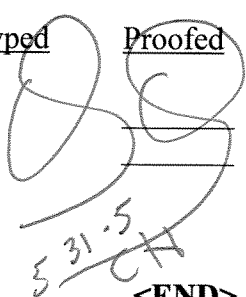
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Requiring insurers to cover routine costs in clinical trials if costs are generally covered

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/?	chanaman	1 cjs 5/29 05					S&L

FE Sent For:

5-31-05
CH
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632-87-

Beginning with Page 1, Line 1

AN ACT to amend 40.51 (8), 40.51 (8m), 66.0137 (4), 111.91 (2) (n), 120.13 (2) (g),

185.981 (4t) and 185.983 (1) (intro.); and to create 609.87, 632.855 (4) and 632.895 (15) of the statutes; relating to: insurance coverage of routine patient care costs in cancer clinical trials.

Beginning with Page 3, Line 18

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

609.87 Coverage of routine patient care costs in cancer clinical trials. Defined network plans are subject to s. 632.895 (15).

SECTION 9. 632.855 (4) of the statutes is created to read:

Beginning with Page 3, line 22

632.855 (4) ROUTINE PATIENT CARE COSTS IN CANCER CLINICAL TRIALS. Notwithstanding subs. (2) and (3), a health care plan or self-insured health plan may not limit or deny the coverage required under s. 632.895 (15).

SECTION 10. 632.895 (15) of the statutes is created to read:

Beginning with Page 4, line 1

632.895 (15) ROUTINE PATIENT CARE COSTS IN CANCER CLINICAL TRIALS. (a) In this subsection:

1. "Clinical trial" means a test of a medical intervention for treatment of cancer.

Beginning with Page 4, line 3

2. a. "~~Routine Clinical trial~~ patient care cost" means the cost of ~~routine~~ medically necessary health care services that are provided to an insured during treatment for cancer. "~~Clinical trial~~ Routine patient care cost" includes the cost of health care services that are typically required for the provision and appropriate monitoring of the medical intervention, ~~and for the prevention,~~ diagnosis, and treatment of complications arising from the medical intervention.

out b/c
it broadens
scope

2008-9

Beginning with Page 4, line 8

b. "Clinical trial Routine patient care cost" does not include cost of the investigational drug or device, costs associated with the medical intervention, costs associated with managing the research of the clinical trial, or costs that would not be covered by the insured's policy or plan for an established treatment.

3. "Medical intervention" is a drug, item, or service.

(b) Except as provided in par. (d), every disability insurance policy, and every self-insured health plan of the state or a county, city, village, town, or school district, shall cover any clinical trial patient cost incurred by an insured under the policy or plan if all of the following apply:

1. The clinical trial does one of the following:

- a. Tests how to administer an investigational medical intervention.
- b. Tests responses to an investigational medical intervention.

Beginning with Page 4, line 20

c. Compares the effectiveness of ~~2~~-investigational and/or established medical interventions.

d. Studies new uses of established medical interventions.

Parity
If its covered under your plan - It should be covered for a clinical trial



State of Wisconsin
2005 - 2006 LEGISLATURE

LRB-3030/2

CMH:.....

TUES.

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PDR

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

SA ✓
K-ref ✓

1 AN ACT ^{significant} relating to: coverage of certain ^{health care} costs in cancer clinical trials.

Analysis by the Legislative Reference Bureau

This bill prohibits a health care plan from denying coverage for a health care service, item, or drug in a cancer clinical trial if the service, item, or drug would have been covered if ^{had it not been} it were not administered in a clinical trial and if the clinical trial meets certain requirements. First, the cancer clinical trial must test how to administer a health care service, item, or drug, test responses to a service, item, or drug, or compare the effectiveness of services, items, or drugs, or study new uses of services, items, or drugs. Also, the cancer clinical trial must be approved by one of the following: 1) a National Institute of Health; 2) the Federal Food and Drug Administration; 3) the U.S. Department of Defense; 4) the U.S. Department of Veterans Affairs; or 5) an institution that is approved by the Office for Human Research Protections of the U.S. Department of Health and Human Services.

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:

- 2 SECTION 1. 40.51 (8) of the statutes is amended to read:
- 3 40.51 (8) Every health care coverage plan offered by the state under sub. (6)
- 4 shall comply with ss. 631.89, 631.90, 631.93 (2), 631.95, 632.72 (2), 632.746 (1) to (8)

1 and (10), 632.747, 632.748, 632.83, 632.835, 632.85, 632.853, 632.855, 632.87 (3) to
 2 ~~(5)~~ (6), 632.895 (5m) and (8) to (14) and 632.896.

History: 1981 c. 96; 1983 a. 27; 1985 a. 29; 1987 a. 27, 107, 356; 1987 a. 403 s. 256; 1989 a. 31, 93, 121, 129, 182, 201, 336, 359; 1991 a. 39, 70, 113, 152, 269, 315, 1993 a. 450, 481; 1995 a. 289; 1997 a. 27, 155, 202, 237, 252; 1999 a. 32, 95, 115, 155; 2001 a. 16, 38, 104; 2003 a. 33.

3 **SECTION 2. 66.0137 (4) of the statutes is amended to read:**

4 **66.0137 (4) SELF-INSURED HEALTH PLANS.** If a city, including a 1st class city, or
 5 a village provides health care benefits under its home rule power, or if a town
 6 provides health care benefits, to its officers and employees on a self-insured basis,
 7 the self-insured plan shall comply with ss. 49.493 (3) (d), 631.89, 631.90, 631.93 (2),
 8 632.746 (10) (a) 2. and (b) 2., 632.747 (3), 632.85, 632.853, 632.855, 632.87 (4) ~~and,~~
 9 (5), and (6), 632.895 (9) to (14), 632.896 and 767.25 (4m) (d).

History: 1999 a. 9, 115; 1999 a. 150 ss. 34, 303 to 306; Stats. 1999 s. 66.0137; 1999 a. 186 s. 63; 2001 a. 16, 30.

10 **SECTION 3. 120.13 (2) (g) of the statutes is amended to read:**

11 **120.13 (2) (g)** Every self-insured plan under par. (b) shall comply with ss.
 12 49.493 (3) (d), 631.89, 631.90, 631.93 (2), 632.746 (10) (a) 2. and (b) 2., 632.747 (3),
 13 632.85, 632.853, 632.855, 632.87 (4) ~~and,~~ (5), and (6), 632.895 (9) to (14), 632.896 and
 14 767.25 (4m) (d).

History: 1973 c. 94, 290; 1975 c. 115, 321; 1977 c. 206, 211, 418, 429; 1979 c. 20, 202, 221, 301, 355; 1981 c. 96, 314, 335; 1983 a. 27, 193, 207, 339, 370, 518, 538; 1985 a. 29 ss. 1725e to 1726m, 1731; 1985 a. 101, 135, 211; 1985 a. 218 ss. 12, 13, 22; 1985 a. 332; 1987 a. 88, 187; 1989 a. 31, 201, 336, 359; 1991 a. 39, 226, 269; 1993 a. 16, 27, 284, 334, 399, 450, 481, 491; 1995 a. 27 ss. 4024, 9126 (19), 9145 (1); 1995 a. 29, 32, 33, 65, 75, 225, 235, 289, 439; 1997 a. 27, 155, 164, 191, 237, 335; 1999 a. 9, 19, 73, 83, 115, 128; 1999 a. 150 s. 672; 1999 a. 186; 2001 a. 38, 98, 103, 105; 2003 a. 254.

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

16 **185.981 (4t)** A sickness care plan operated by a cooperative association is
 17 subject to ss. 252.14, 631.17, 631.89, 631.95, 632.72 (2), 632.745 to 632.749, 632.85,
 18 632.853, 632.855, 632.87 (2m), (3), (4) ~~and,~~ (5), and (6), 632.895 (10) to (14) and
 19 632.897 (10) and chs. 149 and 155.

History: 1971 c. 40 s. 93; 1971 c. 307 s. 118; 1975 c. 98; 1975 c. 223 s. 28; 1975 c. 224 s. 146; 1975 c. 421; 1981 c. 39 s. 22; 1981 c. 205; 1981 c. 391 s. 210; 1985 a. 29; 1985 a. 30 s. 42; 1987 a. 27 ss. 1917e, 3202 (47) (a); 1987 a. 312 s. 17; 1989 a. 121, 129, 200, 201, 336; 1991 a. 39, 123, 269; 1993 a. 27, 450, 481; 1995 a. 27, 118, 289; 1997 a. 27, 155, 237; 1999 a. 95, 115; 2003 a. 321.

20 **SECTION 5. 185.983 (1) (intro.) of the statutes is amended to read:**

21 **185.983 (1)** Every such voluntary nonprofit sickness care plan shall be exempt
 22 from chs. 600 to 646, with the exception of ss. 601.04, 601.13, 601.31, 601.41, 601.42,

1 601.43, 601.44, 601.45, 611.67, 619.04, 628.34 (10), 631.17, 631.89, 631.93, 631.95,
2 632.72 (2), 632.745 to 632.749, 632.775, 632.79, 632.795, 632.85, 632.853, 632.855,
3 632.87 (2m), (3), (4) and, (5), and (6), 632.895 (5) and (9) to (14), 632.896 and 632.897
4 (10) and chs. 609, 630, 635, 645 and 646, but the sponsoring association shall:

History: 1975 c. 98; 1975 c. 224 s. 146; 1975 c. 352; 1975 c. 422 s. 163; 1977 c. 339; 1979 c. 89; 1981 c. 20; 1981 c. 39 s. 22; 1981 c. 82; 1981 c. 391 s. 210; 1983 a. 189 s. 329 (25); 1983 a. 396; 1985 a. 29 ss. 2060d to 2060r, 3202 (30); 1987 a. 27, 325; 1989 a. 23, 31, 129, 200, 201, 336, 359; 1991 a. 39, 189, 250, 269, 315; 1993 a. 450, 481, 482; 1995 a. 289; 1997 a. 27, 155, 237; 1999 a. 95, 115; 2003 a. 321

5 SECTION 6. 632.855 (2) (intro.) of the statutes is amended to read:

6 632.855 (2) DISCLOSURE OF LIMITATIONS. (intro.) ~~A~~ Subject to s. 632.87 (6), a
7 health care plan or a self-insured health plan that limits coverage of experimental
8 treatment shall define the limitation and disclose the limits in any agreement, policy
9 or certificate of coverage. This disclosure shall include the following information:

History: 1997 a. 237.

10 SECTION 7. 632.855 (3) of the statutes is renumbered 632.855 (3) (a).

11 SECTION 8. 632.855 (3) (b) of the statutes is created to read:

12 632.855 (3) (b) A health care plan or a self-insured plan may not deny coverage
13 under par. (a) of an experimental treatment, procedure, drug, or device for an insured
14 if the denial violates s. 632.87 (6).

15 SECTION 9. 632.87 (6) of the statutes is created to read:

16 632.87 (6) No policy, plan, or contract may exclude coverage for any health care
17 service, item, or drug for the treatment of cancer that is administered in a clinical
18 trial if the policy, plan, or contract would have covered the health care service, item,
19 or drug had it not been administered in a clinical trial and if the clinical trial satisfies
20 all of the following:

21 (a) The clinical trial does one of the following:

22 1. Tests how to administer a health care service, item, or drug for the treatment
23 of cancer.

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1 2. Tests responses to a health care service, item, or drug for the treatment of
2 cancer.

3 3. Compares the effectiveness of health care services, items, or drugs for the
4 treatment of cancer with other *health care* services, items, or drugs for the treatment of cancer.

5 4. Studies new uses of health care services, items, or drugs for the treatment
6 of cancer.

7 (b) The clinical trial is approved by one of the following:

8 1. A National Institute of Health, or one of its cooperative groups or centers,
9 under the federal department of health and human services.

10 2. The federal food and drug administration.

11 3. The federal department of defense.

12 4. The federal department of veterans affairs.

13 5. An institutional review board of an institution that is approved by the office
14 for human research protections of the federal department of health and human
15 services.

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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Section # 0 →
Amj 632.87(1)

INS 3-15

(1) No insurer may refuse to provide or pay for benefits for health care services provided by a licensed health care professional on the ground that the services were not rendered by a physician as defined in s. 990.01 (28), unless the contract clearly excludes services by such practitioners, but no contract or plan may exclude services in violation of sub. (2), (2m), (3), (4) or (5).

#632.87

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Barman, Mike

From: Bruhn, Mike
Sent: Tuesday, June 07, 2005 3:38 PM
To: LRB.Legal
Subject: Draft review: LRB 05-3030/1 Topic: Requiring insurers to cover routine costs in clinical trials if costs are generally covered

It has been requested by <Bruhn, Mike> that the following draft be jacketed for the ASSEMBLY:

Draft review: LRB 05-3030/1 Topic: Requiring insurers to cover routine costs in clinical trials if costs are generally covered