2005 DRAFTING REQUEST

Assembly Substitute Amendment (ASA-AB617)

Received: **11/03/2005**

Received By: **pkahler**

Wanted: **Today**

Identical to LRB:

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

By/Representing: **Laura Rose**

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

Drafter: **pkahler**

May Contact:

Addl. Drafters:

Subject: **Insurance - health**

Extra Copies:

Submit via email: **YES**

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

Carbon copy (CC:) to: **laura.rose@legis.state.wi.us**

Pre Topic:

No specific pre topic given

Topic:

Coverage of cancer clinical trials

Instructions:

See Attached

Drafting History:

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/?	pkahler 11/08/2005	jdyer 11/10/2005		_____ _____			
/1			chaugen 11/10/2005	_____ _____	mbarman 11/10/2005	mbarman 11/10/2005	

FE Sent For:

<END>

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/?	pkahler	11/10 jld	ch 11/10	ch pk 11/10			

FE Sent For:

<END>

Sub to AB 617 Rep for Gundrum

s0287

keep SA 1
add new submitted language

copy to Laura Rose

LRBa1165/1
PJK:wlj:rs

SENATE AMENDMENT ,

TO 2005 SENATE BILL 288

At the locations indicated, amend the bill as follows:

1. Page 4, line 19: delete lines 19 to 21.

(END)

Laura - Here is the definition Pat, Michael & Paul Crafted. The changes are those the UW & Cancer Society agree to. They will accept this definition with those changes. Still waiting on Pat, Michael & Paul as to whether they support the def. with the changes.

Proposed language regarding the definition of "Routine patient care costs".
(Proposed language would replace LRBa1125/1)

Section 10. 632.87 (6) of the statutes is created to read:

632.87 (6) (a) For purposes of this [ ] "routine patient care costs" means all of the following:

1. coverage for any health care service, item, or drug for the treatment of cancer that is administered in a clinical trial if an insured person's policy, plan, or contract would have covered the health care service, item, or drug had it not been administered in a clinical trial.

2. health care services, items, and drugs that are typically provided in health care; including all health care services, items and drugs that are provided to the patient during the course of treatment in the cancer clinical trial for a condition, or one of its complications, that is consistent with the usual and customary standard of care and would be covered if the insured person were not enrolled in a cancer clinical trial.

Paul ① Add lang re: Diagnostic modality

(b) Notwithstanding the provisions of par. (a), routine patient care costs shall not include the health care service, item, or investigational drug that is the subject of the trial; any service, item, or drug provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient; ~~complications of the patient's condition arising from the patient's participation in the trial;~~ the cost of an investigational drug or device that has not been approved for market by the federal Food and Drug Administration; transportation, lodging, food or any other expenses associated with travel to or from a facility providing the cancer clinical trial, for the insured person or any family member or companion; any services, items, or drugs provided by the trial sponsors free of charge for any patient; or any services, items, or drugs that are eligible for reimbursement by a person other than the insurer, including the sponsor of the trial.

② Cancer Society et. al want removed

(c) No policy, plan, or contract may exclude coverage for any "routine patient care costs" for the treatment of cancer that are administered in a clinical trial if the clinical trial satisfies all of the following.

Change - "The principal purpose to" "A principal purpose" 2.

1. ~~The principal~~ A purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes. — Should read, "participant's" ③

3. The trial has therapeutic intent and is not designed exclusively to test toxicity or disease pathophysiology.

NOTE: Insert (a) and (b) from page 4 of the bill here as 3. and 4..

The treatment provided as part of the trial is given w/ the intention of improving the participant's health outcome ④

Add a statement to ensure all phases of a clinical trials are covered (I-4).

Nothing in this section limits coverage of clinical trials in phases I-4.

Greetings,

As we discussed at this afternoon's meeting, here is the language we would like to include relating to diagnostic modality:

On the first page of the WALHI proposal, in paragraph 2 after "... ~~that is consistent~~ with the usual and customary standard of care" add: ", including the type and frequency of any diagnostic modality,"

The concerns prompting this addition of the language are as follows:

1. Diagnostic modalities--x-rays, MRI, CT scans, blood tests, etc.--are often part of standard treatment; however, a course of therapy will typically involve one or two scans, for example. Inclusion of the language clarifies that coverage for any diagnostic modalities called for in the trial is limited to the modalities typically found in standard cancer treatment. Further, the language protects the insured purchasers from being responsible for the cost of multiple scans, for example, that are not consistent with standard care but are instead part of the experimental protocol.

2. Explicit language leaves no question with respect to the intent of the legislation. And since diagnostic modalities are a big part of experimental treatment, it is likely there would be disputes without such language.

Additionally, we are in the process of checking with our members to get reaction on the outcome of today's discussion.

Regards,

Paul

From Pat Osborne 10.25.05

Proposed Modification to Senate Amendment 3 (LRBa1126/1) Relating to Out-of-Network Coverage.

Replace the language starting on page 2, line 2 of SA 3 to SB 288 with the following:

(b) The coverage that may not be excluded under this subsection is subject to all terms, conditions, restrictions, exclusions, and limitations that apply to any other coverage under the policy, plan or contract, including the treatment of services performed by participating and non-participating providers.

(c) Nothing in this (section) shall require a plan, policy, or contract to offer, nor prohibit a plan, policy, or contract from offering, clinical trial services by a participating provider.

(d) Nothing in this section shall require the clinical trial services performed by a non-participating provider to be reimbursed at a participating provider rate.

Emellow: cd. be more clear. is "crafter"

2005 Date (time) needed SOON (≈ 11-8)

LRBs 0287/1

PJK + CMH : jld:lmk/cjs

"Kay"

SUBSTITUTE AMENDMENT [TO A BILL]

Use the appropriate components and routines developed for substitute amendments.

D-note

LPS - please check auto refs

~~S,~~ A SUBSTITUTE AMENDMENT

TO 2005 ~~SB~~ AB 617 LRB- /

AN ACT . . . [generate catalog] ***to repeal*** . . . ; ***to renumber*** . . . ; ***to consolidate and renumber*** . . . ; ***to renumber and amend*** . . . ; ***to consolidate, renumber and amend*** . . . ; ***to amend*** . . . ; ***to repeal and recreate*** . . . ; and ***to create*** . . . of the statutes; **relating to:** . . . . . .

. . . . . .

. . . . . .

. . . . . .

. . . . . .

[NOTE: See section 4.02 (2) (br), Drafting Manual, for specific order of standard phrases.]

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

SECTION #.

State of Wisconsin
2005 – 2006 LEGISLATURE

LRBs0286/3
PJK&CMH:lmk/cjs/jld:ch

SENATE SUBSTITUTE AMENDMENT ,

TO 2005 SENATE BILL 288

AN ACT ***to renumber*** 632.855 (3); ***to amend*** 40.51 (8), 66.0137 (4), 120.13 (2) (g), 185.981 (4t), 185.983 (1) (intro.), 632.855 (2) (intro.) and 632.87 (1); and ***to create*** 632.855 (3) (bm) and 632.87 (6) of the statutes; **relating to:** coverage of certain health care costs in cancer clinical trials.

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

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

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

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

66.0137 **(4)** SELF-INSURED HEALTH PLANS. If a city, including a 1st class city, or a village provides health care benefits under its home rule power, or if a town

provides health care benefits, to its officers and employees on a self–insured basis, the self–insured plan shall comply with ss. 49.493 (3) (d), 631.89, 631.90, 631.93 (2), 632.746 (10) (a) 2. and (b) 2., 632.747 (3), 632.85, 632.853, 632.855, 632.87 (4) ~~and,~~ (5), and (6), 632.895 (9) to (14), 632.896 and 767.25 (4m) (d).

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

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

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

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

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

185.983 **(1)** Every such voluntary nonprofit sickness care plan shall be exempt from chs. 600 to 646, with the exception of ss. 601.04, 601.13, 601.31, 601.41, 601.42, 601.43, 601.44, 601.45, 611.67, 619.04, 628.34 (10), 631.17, 631.89, 631.93, 631.95, 632.72 (2), 632.745 to 632.749, 632.775, 632.79, 632.795, 632.85, 632.853, 632.855, 632.87 (2m), (3), (4) ~~and,~~ (5), and (6), 632.895 (5) and (9) to (14), 632.896 and 632.897 (10) and chs. 609, 630, 635, 645 and 646, but the sponsoring association shall:

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

632.855 **(2)** DISCLOSURE OF LIMITATIONS. (intro.) ~~A~~ Subject to s. 632.87 (6), a health care plan or a self–insured health plan that limits coverage of experimental

treatment shall define the limitation and disclose the limits in any agreement, policy or certificate of coverage. This disclosure shall include the following information:

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

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

632.855 **(3)** (bm) A health care plan or a self–insured health plan may not deny coverage under par. (am) of an experimental treatment, procedure, drug, or device for an insured if the denial violates s. 632.87 (6).

SECTION 9. 632.87 (1) of the statutes is amended to read:

632.87 **(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), or (6).

SECTION 10. 632.87 (6) of the statutes is created to read:

632.87 **(6)** (a) 1. Except as provided in subd. 2., in this subsection, "routine patient care" means all of the following:

a. All health care services, items, and drugs for the treatment of cancer.

b. All health care services, items, and drugs that are typically provided in health care; including health care services, items, and drugs provided to a patient during the course of treatment in a cancer clinical trial for a condition or any of its complications; and that are consistent with the usual and customary standard of care, including the type and frequency of any diagnostic modality.

2. "Routine patient care" does not include the health care service, item, or investigational drug that is the subject of the cancer clinical trial; any health care service, item, or drug provided solely to satisfy data collection and analysis needs

that are not used in the direct clinical management of the patient; an investigational drug or device that has not been approved for market by the federal food and drug administration; transportation, lodging, food, or other expenses for the patient or a family member or companion of the patient that are associated with travel to or from a facility providing the cancer clinical trial; any services, items, or drugs provided by the cancer clinical trial sponsors free of charge for any patient; or any services, items, or drugs that are eligible for reimbursement by a person other than the insurer, including the sponsor of the cancer clinical trial.

(b) No policy, plan, or contract may exclude coverage for the cost of any routine patient care that is administered to an insured in a cancer clinical trial satisfying the criteria under par. (c) and that would be covered under the policy, plan, or contract if the insured were not enrolled in a cancer clinical trial.

(c) A cancer clinical trial under par. (b) must satisfy all of the following criteria:

1. A purpose of the trial is to test whether the intervention potentially improves the trial participant's health outcomes.

2. The treatment provided as part of the trial is given with the intention of improving the trial participant's health outcomes.

3. The trial has therapeutic intent and is not designed exclusively to test toxicity or disease pathophysiology.

4. The trial does one of the following:

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

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

c. Compares the effectiveness of health care services, items, or drugs for the treatment of cancer with that of other health care services, items, or drugs for the treatment of cancer.

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

5. The trial is approved by one of the following:

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

b. The federal food and drug administration.

c. The federal department of defense.

d. The federal department of veterans affairs.

(d) 1. The coverage that may not be excluded under this subsection shall apply to all phases of a cancer clinical trial.

2. The coverage that may not be excluded under this subsection is subject to all terms, conditions, restrictions, exclusions, and limitations that apply to any other coverage under the policy, plan, or contract, including the treatment under the policy, plan, or contract of services performed by participating and nonparticipating providers.

(e) 1. Nothing in the subsection requires a policy, plan, or contract to offer; or prohibits a policy, plan, or contract from offering; cancer clinical trial services by a participating provider.

2. Nothing in this subsection requires services that are performed in a cancer clinical trial by a nonparticipating provider of a policy, plan, or contract to be reimbursed at the same rate as a participating provider of the policy, plan, or contract.

SECTION 11. 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 12. Effective date.

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

(END)

D-note

This substitute amendment is the same as Senate Substitute Amendment 1 to Senate Bill 288.

PJK ← "Kay"

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRBs0287/1dn
PJK:jld:ch

November 10, 2005

This substitute amendment is the same as Senate Substitute Amendment 1 to Senate Bill 288.

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