Amendment No. 244

Senate Amendment to Senate Bill No. 29		(BDR 57-265)
Proposed by: Committee on Commerce and	Labor	
Amendment Box:		
Resolves Conflicts with: N/A		
Amends: Summary: No Title: Yes F	Preamble: No Joint Sponso	orship: No Digest: Yes
ASSEMBLY ACTION Initial and Date	SENATE ACTION	Initial and Date
Adopted Lost	· · · · · · · · · · · · · · · · · · ·	
Concurred In Not		
Receded Not	Receded Not [
provided at a facility authorized to conduct a cancer; or	Phase I clinical trials or stud	lies for the treatment of
(2) A Phase II, Phase III or Phase IV study or clinical trial for the treatment of cancer or		
chronic fatigue syndrome, the".		
Amend section 1, page 2, line 12, after "pe	ersonnel" by inserting:	
"for the clinical trial or study".		
Amend section 1, page 2, line 19, by delet	ing "treatment;" and inserting	g:
"treatment [;] and the clinical trial or study	is therapeutic in nature;".	
SH/KP		Date: 4/12/2005

S.B. No. 29—Requires policies of health insurance to provide coverage for certain treatments for cancer.

Amend section 1, page 2, by deleting lines 35 through 39 and inserting:

"(b) The cost of any [reasonably necessary] routine health care services that [are required as a result of the medical treatment provided in the clinical trial or study or as a result of any complication arising out of the medical treatment provided in the clinical trial or study, to the extent that such health care services] would otherwise be covered".

Amend section 1, page 3, line 1, after "services" by inserting "which are".

Amend section 1, page 3, line 3, by deleting "study." and inserting:

"study [.] and which are not directly related to the clinical trial or study.".

Amend section 1, page 4, by deleting lines 14 through 16 and inserting:

"January 1, [2004,] 2006, has the legal effect of including the coverage required by this section, and any provision of the policy that".

Amend section 1, page 4, line 38, after "(b)" by inserting:

- ""Facility authorized to conduct Phase I clinical trials or studies for the treatment of cancer" means a facility that:
- (1) Has in place a Phase I program which permits only selective participation in the program and which uses clear-cut criteria to determine eligibility for participation in the program;
- (2) Operates a protocol review and monitoring system which conforms to the standards set forth in the <u>Policies and Guidelines Relating to the Cancer-Center Support Grant</u> published by the Cancer Centers Branch of the National Cancer Institute;
- (3) Employs at least two researchers and at least one of those researchers receives funding from a federal grant;

- (4) Employs at least three clinical investigators who have experience working in Phase I clinical trials or studies conducted at a facility designated as a comprehensive cancer center by the National Cancer Institute;
- (5) Possesses specialized resources for use in Phase I clinical trials or studies, including, without limitation, equipment that facilitates research and analysis in proteomics, genomics and pharmacokinetics;
 - (6) Is capable of gathering, maintaining and reporting electronic data; and
 - (7) Is capable of responding to audits instituted by federal and state agencies.

(c)".

Amend sec. 2, page 5, line 13, by deleting "The" and inserting:

"[The] In the case of:

- (1) A Phase I clinical trial or study for the treatment of cancer, the medical treatment is provided at a facility authorized to conduct Phase I clinical trials or studies for the treatment of cancer; or
- (2) A Phase II, Phase III or Phase IV study or clinical trial for the treatment of cancer or chronic fatigue syndrome, the".

Amend sec. 2, page 5, line 14, after "personnel" by inserting:

"for the clinical trial or study".

Amend sec. 2, page 5, line 21, by deleting "treatment;" and inserting:

"treatment [;] and the clinical trial or study is therapeutic in nature;".

Amend sec. 2, page 5, by deleting lines 37 through 41 and inserting:

Amend sec. 2, page 6, line 1, after "services" by inserting "which are".

Amend sec. 2, page 6, line 2, by deleting "study." and inserting:

"study [...] and which are not directly related to the clinical trial or study.".

Amend sec. 2, page 7, by deleting lines 13 through 15 and inserting:

"after January 1, [2004,] 2006, has the legal effect of including the coverage required by this section, and any provision of the policy that".

Amend sec. 2, page 7, line 38, after "(b)" by inserting:

- (1) Has in place a Phase I program which permits only selective participation in the program and which uses clear-cut criteria to determine eligibility for participation in the program;
- (2) Operates a protocol review and monitoring system which conforms to the standards set forth in the <u>Policies and Guidelines Relating to the Cancer-Center Support Grant published by</u> the Cancer Centers Branch of the National Cancer Institute;
- (3) Employs at least two researchers and at least one of those researchers receives funding from a federal grant;

- (4) Employs at least three clinical investigators who have experience working in Phase I clinical trials or studies conducted at a facility designated as a comprehensive cancer center by the National Cancer Institute;
- (5) Possesses specialized resources for use in Phase I clinical trials or studies, including, without limitation, equipment that facilitates research and analysis in proteomics, genomics and pharmacokinetics;
 - (6) Is capable of gathering, maintaining and reporting electronic data; and
 - (7) Is capable of responding to audits instituted by federal and state agencies.

(c)".

Amend sec. 3, page 8, line 15, by deleting "The" and inserting:

"[The] In the case of:

- (1) A Phase I clinical trial or study for the treatment of cancer, the medical treatment is provided at a facility authorized to conduct Phase I clinical trials or studies for the treatment of cancer; or
- (2) A Phase II, Phase III or Phase IV study or clinical trial for the treatment of cancer or chronic fatigue syndrome, the".

Amend sec. 3, page 8, line 16, after "personnel" by inserting:

"for the clinical trial or study".

Amend sec. 3, page 8, line 23, by deleting "treatment;" and inserting:

"treatment [;] and the clinical trial or study is therapeutic in nature;".

Amend sec. 3, page 8, by deleting lines 39 through 43 and inserting:

Amend sec. 3, page 9, line 3, after "services" by inserting "which are".

Amend sec. 3, page 9, line 4, by deleting "study." and inserting:

"study [...] and which are not directly related to the clinical trial or study.".

Amend sec. 3, page 10, by deleting lines 18 through 20 and inserting:

"January 1, [2004,] 2006, has the legal effect of including the coverage required by this section, and any provision of the policy that".

Amend sec. 3, page 10, line 43, after "(b)" by inserting:

- (1) Has in place a Phase I program which permits only selective participation in the program and which uses clear-cut criteria to determine eligibility for participation in the program;
- (2) Operates a protocol review and monitoring system which conforms to the standards set forth in the <u>Policies and Guidelines Relating to the Cancer-Center Support Grant published by</u> the Cancer Centers Branch of the National Cancer Institute;
- (3) Employs at least two researchers and at least one of those researchers receives funding from a federal grant;

- (4) Employs at least three clinical investigators who have experience working in Phase I clinical trials or studies conducted at a facility designated as a comprehensive cancer center by the National Cancer Institute;
- (5) Possesses specialized resources for use in Phase I clinical trials or studies, including, without limitation, equipment that facilitates research and analysis in proteomics, genomics and pharmacokinetics;
 - (6) Is capable of gathering, maintaining and reporting electronic data; and
 - (7) Is capable of responding to audits instituted by federal and state agencies.(c)".

Amend sec. 4, page 11, line 20, by deleting "The" and inserting:

"[The] In the case of:

- (1) A Phase I clinical trial or study for the treatment of cancer, the medical treatment is provided at a facility authorized to conduct Phase I clinical trials or studies for the treatment of cancer; or
- (2) A Phase II, Phase III or Phase IV study or clinical trial for the treatment of cancer or chronic fatigue syndrome, the".

Amend sec. 4, page 11, line 21, after "personnel" by inserting:

"for the clinical trial or study".

Amend sec. 4, page 11, line 28, by deleting "treatment;" and inserting:

"treatment [;] and the clinical trial or study is therapeutic in nature;".

Amend sec. 4, pages 11 and 12, by deleting lines 44 and 45 on page 11 and lines 1 through 3 on page 12, and inserting:

Amend sec. 4, page 12, line 7, after "services" by inserting "which are".

Amend sec. 4, page 12, line 8, by deleting "study." and inserting:

"study [.] and which are not directly related to the clinical trial or study.".

Amend sec. 4, page 13, by deleting lines 20 through 22 and inserting:

"January 1, [2004,] 2006, has the legal effect of including the coverage required by this section, and any provision of the policy that conflicts".

Amend sec. 4, page 13, line 45, after "(b)" by inserting:

- (1) Has in place a Phase I program which permits only selective participation in the program and which uses clear-cut criteria to determine eligibility for participation in the program;
- (2) Operates a protocol review and monitoring system which conforms to the standards set forth in the <u>Policies and Guidelines Relating to the Cancer-Center Support Grant published by</u> the Cancer Centers Branch of the National Cancer Institute;
- (3) Employs at least two researchers and at least one of those researchers receives funding from a federal grant;

- (4) Employs at least three clinical investigators who have experience working in Phase I clinical trials or studies conducted at a facility designated as a comprehensive cancer center by the National Cancer Institute;
- (5) Possesses specialized resources for use in Phase I clinical trials or studies, including, without limitation, equipment that facilitates research and analysis in proteomics, genomics and pharmacokinetics;
 - (6) Is capable of gathering, maintaining and reporting electronic data; and
 - (7) Is capable of responding to audits instituted by federal and state agencies.(c)".

Amend sec. 5, page 14, line 21, by deleting "The" and inserting:

"[The] In the case of:

- (1) A Phase I clinical trial or study for the treatment of cancer, the medical treatment is provided at a facility authorized to conduct Phase I clinical trials or studies for the treatment of cancer; or
- (2) A Phase II, Phase III or Phase IV study or clinical trial for the treatment of cancer or chronic fatigue syndrome, the".

Amend sec. 5, page 14, line 22, after "personnel" by inserting:

"for the clinical trial or study".

Amend sec. 5, page 14, line 29, by deleting "treatment;" and inserting:

"treatment [;] and the clinical trial or study is therapeutic in nature;".

Amend sec. 5, page 15, by deleting lines 1 through 5 and inserting:

Amend sec. 5, page 15, line 9, after "services" by inserting "which are".

Amend sec. 5, page 15, line 10, by deleting "study." and inserting:

"study [...] and which are not directly related to the clinical trial or study.".

Amend sec. 5, page 16, by deleting lines 23 through 25 and inserting:

"January 1, [2004,] 2006, has the legal effect of including the coverage required by this section, and any provision of the policy that conflicts".

Amend sec. 5, page 17, line 3, after "(b)" by inserting:

- (1) Has in place a Phase I program which permits only selective participation in the program and which uses clear-cut criteria to determine eligibility for participation in the program;
- (2) Operates a protocol review and monitoring system which conforms to the standards set forth in the <u>Policies and Guidelines Relating to the Cancer-Center Support Grant published by</u> the Cancer Centers Branch of the National Cancer Institute;
- (3) Employs at least two researchers and at least one of those researchers receives funding from a federal grant;

- (4) Employs at least three clinical investigators who have experience working in Phase I clinical trials or studies conducted at a facility designated as a comprehensive cancer center by the National Cancer Institute;
- (5) Possesses specialized resources for use in Phase I clinical trials or studies, including, without limitation, equipment that facilitates research and analysis in proteomics, genomics and pharmacokinetics;
 - (6) Is capable of gathering, maintaining and reporting electronic data; and
 - (7) Is capable of responding to audits instituted by federal and state agencies.

(c)".

Amend the bill as a whole by adding a new section designated sec. 6, following sec. 5, to read as follows:

"Sec. 6. This act becomes effective on January 1, 2006.".

Amend the title of the bill to read as follows:

"AN ACT relating to health insurance; requiring policies of health insurance to provide coverage for certain medical treatment provided to an insured who participates in certain Phase I studies or clinical trials for the treatment of cancer; revising the types of medical treatment that must be covered when an insured participates in certain studies or clinical trials for the treatment of cancer or chronic fatigue syndrome; and providing other matters properly relating thereto.".

If this amendment is adopted, the Legislative

Counsel's Digest will be changed to read as follows:

Legislative Counsel's Digest:

Existing law requires health insurance policies to provide coverage for certain medical treatment provided to an insured who participates in certain Phase II, Phase III or Phase IV studies or clinical trials for the treatment of cancer or chronic fatigue syndrome. (NRS 689A.04033, 689B.0306, 695B.1903, 695C.1693, 695G.173)

This bill requires health insurance policies also to provide such coverage for an insured who participates in certain Phase I studies or clinical trials for the treatment of cancer. To qualify for the coverage required by this bill, the Phase I study or clinical trial must be conducted at a facility that meets certain standards and requirements for conducting a Phase I study or clinical trial.

This bill also revises the types of medical treatment that must be covered when an insured participates in a study or clinical trial for the treatment of cancer or chronic fatigue syndrome.