



General Assembly

Amendment

January Session, 2009

LCO No. 7258

SB0096207258SD0

Offered by:

SEN. LOONEY, 11th Dist.

SEN. CRISCO, 17th Dist.

To: Subst. Senate Bill No. 962

File No. 127

Cal. No. 151

"AN ACT CONCERNING WELLNESS INCENTIVES."

1 Strike everything after the enacting clause and substitute the
2 following in lieu thereof:

3 "Section 1. (NEW) (*Effective January 1, 2010*) (a) For the purposes of
4 this section:

5 (1) "Clinical trial" means an organized, systematic, scientific study of
6 therapies, tests or other clinical interventions for purposes of treatment
7 or palliation or therapeutic intervention for the prevention of a medical
8 condition that is disabling, progressive or life threatening.

9 (2) "Routine patient care costs" means:

10 (A) Medically necessary health care services that are incurred as a
11 result of the treatment being provided to the insured for purposes of
12 such clinical trial that would otherwise be covered if such services
13 were not rendered pursuant to such clinical trial. Such services shall

14 include those rendered by a physician, diagnostic or laboratory tests,
15 hospitalization or other services provided to the insured during the
16 course of treatment in such clinical trial for a condition, or one of its
17 complications, that are consistent with the usual and customary
18 standard of care and would be covered if the insured person were not
19 enrolled in such clinical trial; and

20 (B) Costs incurred for drugs provided to the insured during the
21 course of treatment in such clinical trial, provided such drugs have
22 been approved for sale by the federal Food and Drug Administration.
23 No individual health insurance policy set forth in subsection (b) of this
24 section that provides coverage for prescription drugs shall exclude
25 coverage of such drug provided to the insured during the course of
26 treatment in such clinical trial on the basis that such drug has been
27 provided for the treatment of a condition for which the drug has not
28 been approved by the federal Food and Drug Administration.

29 (b) Each individual health insurance policy providing coverage of
30 the type specified in subdivisions (1), (2), (4), (11) and (12) of section
31 38a-469 of the general statutes delivered, issued for delivery, renewed,
32 amended or continued in this state shall provide coverage for the
33 routine patient care costs associated with clinical trials, other than a
34 cancer clinical trial as set forth in sections 38a-504a to 38a-504g,
35 inclusive, of the general statutes if:

36 (1) The insured suffers from a medical condition that is disabling,
37 progressive or life threatening;

38 (2) The clinical trial is qualified to receive Medicare coverage of its
39 routine costs under the Medicare Clinical Trial Policy established
40 under the September 19, 2000, Medicare National Coverage
41 Determination, as amended from time to time;

42 (3) The insured's treating physician, who is providing health care
43 services to such insured under such policy, (A) determines that the
44 insured's participation in the clinical trial has the potential to provide a
45 therapeutic health benefit to such insured, and (B) recommends that

46 such insured participate in such clinical trial;

47 (4) The insured has signed a statement of consent prior to
48 participating in the clinical trial and has submitted such statement to
49 the entity that issued such policy, acknowledging that the insured has
50 been informed (A) of the therapy, test or other clinical intervention to
51 be undertaken, (B) of alternative methods of treatment that are
52 available, (C) of the general nature and extent of the risks associated
53 with participation in such clinical trial, and (D) that the coverage of
54 routine patient care costs associated with the clinical trial shall be
55 subject to the terms, conditions, restrictions, exclusions and limitations
56 of such policy, including limitations on out-of-network care, except
57 that treatment at an out-of-network hospital as provided in
58 subparagraph (A) of subdivision (2) of subsection (a) of this section
59 shall be made available by the out-of-network hospital and the entity
60 that issued such policy at no greater cost to the insured than if such
61 treatment was available in-network. The insurer or health care center
62 may require that any routine tests or services required under the
63 clinical trial protocol be performed by providers or institutions under
64 contract with the entity that issued such policy.

65 (c) The coverage required pursuant to subsections (a) and (b) of this
66 section shall not include:

67 (1) Any portion of the clinical trial, including any drug or device,
68 that is paid for by a (A) government or any of its agencies,
69 instrumentalities or political subdivisions, or (B) biotechnical,
70 pharmaceutical or medical industry member;

71 (2) Extraneous expenses related to participation in the clinical trial,
72 including, but not limited to, travel and housing expenses that an
73 insured or a person accompanying an insured may incur;

74 (3) Any item or service that is provided to the insured solely to
75 satisfy a need for data collection or analysis that is not directly related
76 to the clinical management of such insured;

77 (4) Costs for the management of research relating to the clinical trial;
78 or

79 (5) Health care services provided as a result of the treatment being
80 provided to the insured for purposes of such clinical trial that are not
81 covered benefits under such insured's policy.

82 Sec. 2. (NEW) (*Effective January 1, 2010*) (a) For the purposes of this
83 section:

84 (1) "Clinical trial" means an organized, systematic, scientific study of
85 therapies, tests or other clinical interventions for purposes of treatment
86 or palliation or therapeutic intervention for the prevention of a medical
87 condition that is disabling, progressive or life threatening.

88 (2) "Routine patient care costs" means:

89 (A) Medically necessary health care services that are incurred as a
90 result of the treatment being provided to the insured for purposes of
91 such clinical trial that would otherwise be covered if such services
92 were not rendered pursuant to such clinical trial. Such services shall
93 include those rendered by a physician, diagnostic or laboratory tests,
94 hospitalization or other services provided to the insured during the
95 course of treatment in such clinical trial for a condition, or one of its
96 complications, that are consistent with the usual and customary
97 standard of care and would be covered if the insured person were not
98 enrolled in such clinical trial; and

99 (B) Costs incurred for drugs provided to the insured during the
100 course of treatment in such clinical trial, provided such drugs have
101 been approved for sale by the federal Food and Drug Administration.
102 No group health insurance policy set forth in subsection (b) of this
103 section that provides coverage for prescription drugs shall exclude
104 coverage of such drug provided to the insured during the course of
105 treatment in such clinical trial on the basis that such drug has been
106 provided for the treatment of a condition for which the drug has not
107 been approved by the federal Food and Drug Administration.

108 (b) Each group health insurance policy providing coverage of the
109 type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-
110 469 of the general statutes delivered, issued for delivery, renewed,
111 amended or continued in this state shall provide coverage for the
112 routine patient care costs associated with clinical trials, other than a
113 cancer clinical trial as set forth in sections 38a-504a to 38a-504g,
114 inclusive, of the general statutes if:

115 (1) The insured suffers from a medical condition that is disabling,
116 progressive or life threatening;

117 (2) The clinical trial is qualified to receive Medicare coverage of its
118 routine costs under the Medicare Clinical Trial Policy established
119 under the September 19, 2000, Medicare National Coverage
120 Determination, as amended from time to time;

121 (3) The insured's treating physician, who is providing health care
122 services to such insured under such policy, (A) determines that the
123 insured's participation in the clinical trial has the potential to provide a
124 therapeutic health benefit to such insured, and (B) recommends that
125 such insured participate in such clinical trial;

126 (4) The insured has signed a statement of consent prior to
127 participating in the clinical trial and has submitted such statement to
128 the entity that issued such policy, acknowledging that the insured has
129 been informed (A) of the therapy, test or other clinical intervention to
130 be undertaken, (B) of alternative methods of treatment that are
131 available, (C) of the general nature and extent of the risks associated
132 with participation in such clinical trial, and (D) that the coverage of
133 routine patient care costs associated with the clinical trial shall be
134 subject to the terms, conditions, restrictions, exclusions and limitations
135 of such policy, including limitations on out-of-network care, except
136 that treatment at an out-of-network hospital as provided in
137 subparagraph (A) of subdivision (2) of subsection (a) of this section
138 shall be made available by the out-of-network hospital and the entity
139 that issued such policy at no greater cost to the insured than if such

140 treatment was available in-network. The insurer or health care center
 141 may require that any routine tests or services required under the
 142 clinical trial protocol be performed by providers or institutions under
 143 contract with the entity that issued such policy.

144 (c) The coverage required pursuant to subsections (a) and (b) of this
 145 section shall not include:

146 (1) Any portion of the clinical trial, including any drug or device,
 147 that is paid for by a (A) government or any of its agencies,
 148 instrumentalities or political subdivisions, or (B) biotechnical,
 149 pharmaceutical or medical industry member;

150 (2) Extraneous expenses related to participation in the clinical trial,
 151 including, but not limited to, travel and housing expenses that an
 152 insured or a person accompanying an insured may incur;

153 (3) Any item or service that is provided to the insured solely to
 154 satisfy a need for data collection or analysis that is not directly related
 155 to the clinical management of such insured;

156 (4) Costs for the management of research relating to the clinical trial;
 157 or

158 (5) Health care services provided as a result of the treatment being
 159 provided to the insured for purposes of such clinical trial that are not
 160 covered benefits under such insured's policy."

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>January 1, 2010</i>	New section
Sec. 2	<i>January 1, 2010</i>	New section