

Insurance Coverage for Routine Patient Costs during Cancer Clinical Trials

This Act mandates health insurance policies cover routine patient costs incurred for cancer treatment in an approved cancer clinical trial to the same extent that such policy or contract provides coverage for treating any other sickness, injury, disease, or condition covered under the policy or contract, if the insured has been referred for such cancer treatment by two physicians who specialize in oncology and the cancer treatment is given pursuant to an approved cancer clinical trial.

Submitted as:

Iowa:

[HF 2075 \(Enrolled version\)](#)

Status: Enacted into law in 2010.

Suggested State Legislation

(Title, enacting clause, etc.)

1 Section 1. [*Short Title.*] This Act shall be cited as “An Act to Address Insurance
2 Coverage for Routine Patient Costs during Cancer Clinical Trials.”

3
4 Section 2. [*Definitions.*] As used in this Act:

5 (1) “Approved cancer clinical trial” means a scientific study of a new therapy for the
6 treatment of cancer in human beings that meets the requirements set forth in section 4 of this Act
7 and consists of a scientific plan of treatment that includes specified goals, a rationale and
8 background for the plan, criteria for patient selection, specific directions for administering
9 therapy and monitoring patients, a definition of quantitative measures for determining treatment
10 response, and methods for documenting and treating adverse reactions.

11 (2) “Institutional review board” means a board, committee, or other group formally
12 designated by an institution and approved by the National Institutes of Health, Office for
13 Protection from Research Risks, to review, approve the initiation of, and conduct periodic review
14 of biomedical research involving human subjects. “Institutional review board” means the same
15 as “institutional review committee” as used in section 520 (g) of the federal Food, Drug, and
16 Cosmetic Act, as codified in 21 U.S.C. Sec. 301 et seq.

17 (3) (a) “Routine patient care costs” means medically necessary services or treatments
18 that are a benefit under a contract or policy providing for third-party payment or prepayment of
19 health or medical expenses that would be covered if the patient were receiving standard cancer
20 treatment.

21 (b) “Routine patient care costs” does not include any of the following:

22 (I) Costs of any treatments, procedures, drugs, devices, services, or items
23 that are the subject of the approved cancer clinical trial or any other investigational treatments,
24 procedures, drugs, devices, services, or items.

25 (II) Costs of non-health care services that the patient is required to receive
26 as a result of participation in the approved cancer clinical trial.

27 (III) Costs associated with managing the research that is associated with
28 the approved cancer clinical trial.

29 (IV) Costs that would not be covered by the third-party payment provider

30 if non-investigational treatments were provided.

31 (V) Costs of any services, procedures, or tests provided solely to
32 satisfy data collection and analysis needs that are not used in the direct clinical management of
33 the patient participating in an approved cancer clinical trial.

34 (VI) Costs paid for, or not charged for, by the approved cancer
35 clinical trial providers.

36 (VII) Costs for transportation, lodging, food, or other expenses for
37 the patient, a family member, or a companion of the patient that are associated with travel to or
38 from a facility where an approved cancer clinical trial is conducted.

39 (VIII) Costs for services, items, or drugs that are eligible for
40 reimbursement from a source other than a patient's contract or policy providing for third-party
41 payment or prepayment of health or medical expenses, including the sponsor of the approved
42 cancer clinical trial.

43 (IV) Costs associated with approved cancer clinical trials designed
44 exclusively to test toxicity or disease pathophysiology.

45 (X) Costs of extra treatments, services, procedures, tests, or drugs
46 that would not be performed or administered except for participation in the cancer clinical trial.
47 Nothing in this subparagraph subdivision shall limit payment for treatments, services,
48 procedures, tests, or drugs that are otherwise a covered benefit under subparagraph (a).

49 (4) "Therapeutic intent" means that a treatment is aimed at improving a patient's
50 health outcome relative to either survival or quality of life.

51

52 Section 3. [*Coverage Required.*] Notwithstanding the uniformity of treatment
53 requirements of [insert citation], a policy or contract providing for third-party payment or
54 prepayment of health or medical expenses shall provide coverage benefits for routine patient care
55 costs incurred for cancer treatment in an approved cancer clinical trial to the same extent that
56 such policy or contract provides coverage for treating any other sickness, injury, disease, or
57 condition covered under the policy or contract, if the insured has been referred for such cancer
58 treatment by [two] physicians who specialize in oncology and the cancer treatment is given
59 pursuant to an approved cancer clinical trial that meets the criteria set forth in section 4 of this
60 Act. Services that are furnished without charge to a participant in the approved cancer clinical
61 trial are not required to be covered as routine patient care costs pursuant to this section.

62

63 Section 4. [*Criteria.*] Routine patient care costs for cancer treatment given pursuant to an
64 approved cancer clinical trial shall be covered pursuant to this Act if all of the following
65 requirements are met:

66 (1) The treatment is provided with therapeutic intent and is provided pursuant to an
67 approved cancer clinical trial that has been authorized or approved by one of the following:

- 68 (a) The National Institutes of Health.
69 (b) The United States Food and Drug Administration.
70 (c) The United States Department of Defense.
71 (d) The United States Department of Veterans Affairs.

72 (2) The proposed treatment has been reviewed and approved by the applicable qualified
73 institutional review board.

74 (3) The available clinical or preclinical data indicate that the treatment that will be
75 provided pursuant to the approved cancer clinical trial will be at least as effective as the standard
76 therapy and is anticipated to constitute an improvement in therapeutic effectiveness for the
77 treatment of the disease in question.

78

79 Section 5. [*Notice.*] As soon as practical after the insured provides written consent to
80 participate in an approved cancer clinical trial, the physician shall provide notice to the third-
81 party payment provider of the insured’s intent to participate in an approved cancer clinical trial.
82 Failure to provide such notice to the third-party payment provider shall not be the basis for
83 denying the coverage required under Section 3 of this Act.

84
85 Section 6. [*Applicability.*]

86 (A) This Act applies to the following classes of third-party payment provider contracts or
87 policies delivered, issued for delivery, continued, or renewed in this state on or after [July 1,
88 2010]:

89 (1) Individual or group accident and sickness insurance providing coverage on an
90 expense-incurred basis.

91 (2) An individual or group hospital or medical service contract issued pursuant to
92 [insert citation].

93 (3) An individual or group health maintenance organization contract regulated
94 under [insert citation].

95 (4) Any other entity engaged in the business of insurance, risk transfer, or risk
96 retention, which is subject to the jurisdiction of the [commissioner].

97 (5) A plan established pursuant to [insert citation] for public employees.

98 (6) An organized delivery system licensed by the [director of public health].

99 (B) This Act shall not apply to accident-only, specified disease, short-term hospital or
100 medical, hospital confinement indemnity, credit, dental, vision, Medicare supplement, long-term
101 care, basic hospital and medical-surgical expense coverage as defined by the [commissioner],
102 disability income insurance coverage, coverage issued as a supplement to liability insurance,
103 workers’ compensation or similar insurance, or automobile medical payment insurance.

104
105 Section 7. [*Severability.*] [Insert severability clause.]

106
107 Section 8. [*Repealer.*] [Insert repealer clause.]

108
109 Section 9. [*Effective Date.*] [Insert effective date.]