

is a participant or beneficiary in a health plan or with coverage described in subsection (a)(1) and who meets the following conditions:

(1) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or other life-threatening disease or condition.

(2) Either—

(A) the referring health care professional is a participating health care provider and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

(B) the participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

(c) Limitations on coverage

This section shall not be construed to require a group health plan, or a health insurance issuer offering group or individual health insurance coverage, to provide benefits for routine patient care services provided outside of the plan's (or coverage's) health care provider network unless out-of-network benefits are otherwise provided under the plan (or coverage).

(d) Approved clinical trial defined

(1) In general

In this section, the term "approved clinical trial" means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition and is described in any of the following subparagraphs:

(A) **FEDERALLY FUNDED TRIALS.**—The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:

- (i) The National Institutes of Health.
- (ii) The Centers for Disease Control and Prevention.
- (iii) The Agency for Health Care Research and Quality.
- (iv) The Centers for Medicare & Medicaid Services.
- (v) cooperative¹ group or center of any of the entities described in clauses (i) through (iv) or the Department of Defense or the Department of Veterans Affairs.
- (vi) A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.
- (vii) Any of the following if the conditions described in paragraph (2) are met:
 - (I) The Department of Veterans Affairs.
 - (II) The Department of Defense.
 - (III) The Department of Energy.

(B) The study or investigation is conducted under an investigational new drug

application reviewed by the Food and Drug Administration.

(C) The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

(2) Conditions for departments

The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines—

(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

(e) Life-threatening condition defined

In this section, the term "life-threatening condition" means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

(f) Construction

Nothing in this section shall be construed to limit a plan's or issuer's coverage with respect to clinical trials.

(g) Application to FEHBP

Notwithstanding any provision of chapter 89 of title 5, this section shall apply to health plans offered under the program under such chapter.

(h) Preemption

Notwithstanding any other provision of this chapter, nothing in this section shall preempt State laws that require a clinical trials policy for State regulated health insurance plans that is in addition to the policy required under this section.

(July 1, 1944, ch. 373, title XXVII, §2709, as added Pub. L. 111-148, title X, §10103(c), Mar. 23, 2010, 124 Stat. 892.)

CODIFICATION

Another section 2709 of act July 1, 1944, is classified to section 300gg-9 of this title.

PRIOR PROVISIONS

A prior section 2709 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238h of this title.

§ 300gg-9. Disclosure of information

(a) Disclosure of information by health plan issuers

In connection with the offering of any health insurance coverage to a small employer or an individual, a health insurance issuer—

(1) shall make a reasonable disclosure to such employer, or individual, as applicable,¹ as part of its solicitation and sales materials, of the availability of information described in subsection (b) of this section, and

(2) upon request of such a² employer, or individual, as applicable,¹ provide such information.

¹ So in original.

² So in original. Probably should be "an".

¹ So in original. Probably should be preceded by "A".

(b) Information described**(1) In general**

Subject to paragraph (3), with respect to a health insurance issuer offering health insurance coverage to a² employer, or individual, as applicable,¹ information described in this subsection is information concerning—

(A) the provisions of such coverage concerning issuer's right to change premium rates and the factors that may affect changes in premium rates; and

(B) the benefits and premiums available under all health insurance coverage for which the employer, or individual, as applicable, is qualified.

(2) Form of information

Information under this subsection shall be provided to employers, or individuals, as applicable, in a manner determined to be understandable by the average employer, or individual, as applicable,¹ and shall be sufficient to reasonably inform employers, or individuals, as applicable, of their rights and obligations under the health insurance coverage.

(3) Exception

An issuer is not required under this section to disclose any information that is proprietary and trade secret information under applicable law.

(July 1, 1944, ch. 373, title XXVII, § 2709, formerly § 2713, as added Pub. L. 104-191, title I, § 102(a), Aug. 21, 1996, 110 Stat. 1966; renumbered § 2733, renumbered § 2709, and amended Pub. L. 111-148, title I, §§ 1001(3), 1563(c)(10), formerly § 1562(c)(10), title X, § 10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 268, 911.)

CODIFICATION

Section was formerly classified to section 300gg-13 of this title prior to renumbering by Pub. L. 111-148.

Another section 2709 of act July 1, 1944, is classified to section 300gg-8 of this title.

PRIOR PROVISIONS

A prior section 2709 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238h of this title.

AMENDMENTS

2010—Subsec. (a). Pub. L. 111-148, § 1563(c)(10)(A), formerly § 1562(c)(10)(A), as renumbered by Pub. L. 111-148, § 10107(b)(1), in introductory provisions substituted “small employer or an individual” for “small employer”, in par. (1) inserted “, or individual, as applicable,” after “employer”, and in par. (2) substituted “employer, or individual, as applicable,” for “small employer”.

Subsec. (b)(1). Pub. L. 111-148, § 1563(c)(10)(B)(i), formerly § 1562(c)(10)(B)(i), as renumbered by Pub. L. 111-148, § 10107(b)(1), in introductory provisions substituted “employer, or individual, as applicable,” for “small employer”, in subpar. (A), inserted “and” at end, struck out subpars. (B) and (C) which related to provisions of coverage relating to renewability of coverage and preexisting condition exclusions, respectively, in subpar. (D), inserted “, or individual, as applicable,” after “employer”, and redesignated subpar. (D) as (B).

Subsec. (b)(2). Pub. L. 111-148, § 1563(c)(10)(B)(ii), formerly § 1562(c)(10)(B)(ii), as renumbered by Pub. L. 111-148, § 10107(b)(1), substituted “employer, or individual, as applicable,” for “small employer” and “employ-

ers, or individuals, as applicable,” for “small employers” in two places.

EFFECTIVE DATE

Section applicable with respect to group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning after June 30, 1997, except as otherwise provided, see section 102(c) of Pub. L. 104-191, set out as a note under section 300gg of this title.

SUBPART II—IMPROVING COVERAGE

A prior subpart 2, consisting of sections 300gg-4 to 300gg-7, related to other requirements, prior to repeal of the subpart designation and heading and transfer of sections 300gg-4 to 300gg-7 to 300gg-25 to 300gg-28, respectively, of this title by Pub. L. 111-148, title I, §§ 1001(2), 1563(c)(2), formerly § 1562(c)(2), title X, § 10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 265, 911.

Another prior subpart 2, consisting of sections 300gg-11 to 300gg-13, related to provisions applicable only to health insurance issuers, was redesignated subpart 3 of this part by Pub. L. 104-204, title VI, § 604(a)(2), Sept. 26, 1996, 110 Stat. 2939.

A prior subpart 3, consisting of sections 300gg-11 to 300gg-13, related to provisions applicable only to health insurance issuers, prior to repeal of the subpart designation and heading by Pub. L. 111-148, title I, § 1563(c)(7), formerly § 1562(c)(7), title X, § 10107(b)(1), Mar. 23, 2010, 124 Stat. 266, 911.

A prior subpart 4, consisting of sections 300gg-21 to 300gg-23, which related to exclusion of plans, enforcement, and preemption, was redesignated subpart 2 of this part by Pub. L. 111-148, title I, § 1563(c)(11), formerly § 1562(c)(11), title X, § 10107(b)(1), Mar. 23, 2010, 124 Stat. 268, 911.

§ 300gg-11. No lifetime or annual limits**(a) Prohibition****(1) In general**

A group health plan and a health insurance issuer offering group or individual health insurance coverage may not establish—

(A) lifetime limits on the dollar value of benefits for any participant or beneficiary;

or

(B) except as provided in paragraph (2), annual limits on the dollar value of benefits for any participant or beneficiary.

(2) Annual limits prior to 2014

With respect to plan years beginning prior to January 1, 2014, a group health plan and a health insurance issuer offering group or individual health insurance coverage may only establish a restricted annual limit on the dollar value of benefits for any participant or beneficiary with respect to the scope of benefits that are essential health benefits under section 18022(b) of this title, as determined by the Secretary. In defining the term “restricted annual limit” for purposes of the preceding sentence, the Secretary shall ensure that access to needed services is made available with a minimal impact on premiums.

(b) Per beneficiary limits

Subsection (a) shall not be construed to prevent a group health plan or health insurance coverage from placing annual or lifetime per beneficiary limits on specific covered benefits that are not essential health benefits under section 18022(b) of this title, to the extent that such limits are otherwise permitted under Federal or State law.