fied under section 18022(d) of this title, the issuer shall also offer such coverage in that level as a plan in which the only enrollees are individuals who, as of the beginning of a plan year, have not attained the age of 21.

(d) Dental only

This section shall not apply to a plan described in section 18031(d)(2)(B)(ii)[1] of this title.

(July 1, 1944, ch. 373, title XXVII, § 2707, as added Pub. L. 111–148, title I, § 1201(4), Mar. 23, 2010, 124 Stat. 161.)

ENACTMENT OF SECTION

For delayed effective date of section, see Effective Date note below.

REFERENCES IN TEXT

Section 18022(c) of this title, referred to in subsec. (b), was in the original ''section 1302(c)'', and was translated as meaning section 1302(c) of Pub. L. 111–148, pars. (1) and (2) of which relate to annual limitations on cost-sharing and deductibles, to reflect the probable intent of Congress.

Section 18031(d)(2)(B)(ii) of this title, referred to in subsec. (d), was in the original ''section 1302(d)(2)(B)(ii)(I)'', and was translated as meaning section 1311(d)(2)(B)(ii) of Pub. L. 111–148, which relates to offering of stand-alone dental benefits, to reflect the probable intent of Congress.

PRIOR PROVISIONS

A prior section 300gg–6, act July 1, 1944, ch. 373, title XXVII, § 2706, as added Pub. L. 105–277, div. A, § 101(f) [title IX, § 903(a)], Oct. 21, 1998, 112 Stat. 2681–337, 2681–438, which related to required coverage for reconstructive surgery following mastectomies, was renumbered section 2727 of act July 1, 1944, and transferred to section 300gg–27 of this title.

A prior section 2707 of act July 1, 1944, was renumbered section 2728 and is classified to section 300gg–28 of this title.

Another prior section 2707 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238f of this title.

EFFECTIVE DATE

Section effective for plan years beginning on or after Jan. 1, 2014, see section 1255 of Pub. L. 111–148, set out as a note under section 300gg of this title.

§ 300gg–7. Prohibition on excessive waiting periods

A group health plan and a health insurance issuer offering group health insurance coverage shall not apply any waiting period (as defined in section 300gg–3(b)(4) of this title) that exceeds 90 days.

(July 1, 1944, ch. 373, title XXVII, § 2708, as added and amended Pub. L. 111–148, title I, § 1201(4), title X, § 10103(b), Mar. 23, 2010, 124 Stat. 161, 892.)

ENACTMENT OF SECTION

For delayed effective date of section, see Effective Date note below.

PRIOR PROVISIONS

A prior section 300gg–7, act July 1, 1944, ch. 373, title XXVII, § 2707, as added Pub. L. 110–381, § 2(b)(1), Oct. 9, 2008, 122 Stat. 4083, which related to coverage of dependent students on medically necessary leave of absence, was renumbered section 2728 of act July 1, 1944, and transferred to section 300gg–28 of this title.

A prior section 2708 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238g of this title.

AMENDMENTS

2010—Pub. L. 111–148, § 10103(b), struck out ''or individual'' after ''offering group''.

EFFECTIVE DATE

Section effective for plan years beginning on or after Jan. 1, 2014, see section 1255 of Pub. L. 111–148, set out as a note under section 300gg of this title.

§ 300gg–8. Coverage for individuals participating in approved clinical trials

(a) Coverage

(1) In general

If a group health plan or a health insurance issuer offering group or individual health insurance coverage provides coverage to a qualified individual, then such plan or issuer—

(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

(B) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

(C) may not discriminate against the individual on the basis of the individual's participation in such trial.

(2) Routine patient costs

(A) Inclusion

For purposes of paragraph (1)(B), subject to subparagraph (B), routine patient costs include all items and services consistent with the coverage provided in the plan (or coverage) that is typically covered for a qualified individual who is not enrolled in a clinical trial.

(B) Exclusion

For purposes of paragraph (1)(B), routine patient costs does not include—

(i) the investigational item, device, or service, itself;

(ii) items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; or

(iii) a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

(3) Use of in-network providers

If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

(4) Use of out-of-network

Notwithstanding paragraph (3), paragraph (1) shall apply to a qualified individual participating in an approved clinical trial that is conducted outside the State in which the qualified individual resides.

(b) Qualified individual defined

For purposes of subsection (a), the term ''qualified individual'' means an individual who

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) cooperative[1] 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 a[2] employer, or individual, as applicable,,[1] provide such information.

[1] So in original. Probably should be preceded by ''A''.

[1] So in original.

[2] So in original. Probably should be ''an''.