[probably means this section, amending this section and section 18022 of this title] shall be effective as if included in the enactment of the Patient Protection and Affordable Care Act (Public Law 111–148).''

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.)

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: