(c)(3)(A) and (l)(3)(B)(iv), is section 264 of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

Section 300gg-21(a) of this title, referred to in subsec. (e), was in the original a reference to section 2735(a) of act July 1, 1944, and was translated as if it referred to section 2722(a) of that act to reflect the probable intent of Congress because of the renumbering of section 2735 as 2722 by Pub. L. 111-148, title I, \$1563(c)(12)(D), formerly \$1562(c)(12)(D), title X, \$10107(b)(1), Mar. 23, 2010, 124 Stat. 269, 911. The act July 1, 1944, does not contain a section 2735.

CODIFICATION

The text of section 300gg–1 of this title, which was amended and transferred to subsecs. (b) to (f) of this section by Pub. L. 111–148, \$1201(3), was based on act July 1, 1944, ch. 373, title XXVII, \$2702, as added Pub. L. 104–191, title I, \$102(a), Aug. 21, 1996, 110 Stat. 1961; amended Pub. L. 110–233, title I, \$102(a)(1)–(3), May 21, 2008, 122 Stat. 888, 890. For text of section 300gg–1 prior to amendment and transfer by Pub. L. 111–148, see Prior Provisions note under section 300gg–1 of this title.

PRIOR PROVISIONS

A prior section 300gg-4, act July 1, 1944, ch. 373, title XXVII, $\S2704$, as added Pub. L. 104-204, title VI, $\S604(a)(3)$, Sept. 26, 1996, 110 Stat. 2939, which related to standards relating to benefits for mothers and newborns, was renumbered section 2725 of act July 1, 1944, by Pub. L. 111-148, title I, $\S1001(2)$, Mar. 23, 2010, 124 Stat. 130, and transferred to section 300gg-25 of this title

A prior section 2705 of act July 1, 1944, was renumbered section 2726 and is classified to section 300gg-26 of this title.

Another prior section 2705 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238d of this title.

AMENDMENTS

2010—Pub. L. 111-148, §1201(3), transferred section 300gg-1 of this title to subsecs. (b) to (f) of this section after amending it by striking out the section catchline "Prohibiting discrimination against individual participants and beneficiaries based on health status", by striking subsec. (a) which prohibited discrimination against individual participants in group health plans based on certain health status-related factors, by amending subsec. (b) by substituting "health insurance issuer offering group or individual health insurance coverage" for "health insurance issuer offering health insurance coverage in connection with a group health plan" in pars. (1) and (3)(B) and by inserting "or individual" after "employer" and "or individual health coverage, as the case may be" before semicolon in par. (2)(A), and by amending subsec. (e) by substituting "(a)(6)" for "(a)(1)(F)" and "300gg-3" for "300gg" and making technical amendment to reference in original act which appears in text as reference to section 300gg-21(a) 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-5. Non-discrimination in health care (a) Providers

A group health plan and a health insurance issuer offering group or individual health insurance coverage shall not discriminate with respect to participation under the plan or coverage against any health care provider who is acting within the scope of that provider's license or certification under applicable State law. This section shall not require that a group

health plan or health insurance issuer contract with any health care provider willing to abide by the terms and conditions for participation established by the plan or issuer. Nothing in this section shall be construed as preventing a group health plan, a health insurance issuer, or the Secretary from establishing varying reimbursement rates based on quality or performance measures.

(b) Individuals

The provisions of section 218c¹ of title 29 (relating to non-discrimination) shall apply with respect to a group health plan or health insurance issuer offering group or individual health insurance coverage.

(July 1, 1944, ch. 373, title XXVII, §2706, as added Pub. L. 111–148, title I, §1201(4), Mar. 23, 2010, 124 Stat. 160.)

ENACTMENT OF SECTION

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

References in Text

Section 218c of title 29, referred to in subsec. (b), was in the original "section 1558 of the Patient Protection and Affordable Care Act", meaning section 1558 of Pub. L. 111–148, and was translated as meaning section 18C of act June 25, 1938, ch. 676, which was added by section 1558 of Pub. L. 111–148, to reflect the probable intent of Congress.

PRIOR PROVISIONS

A prior section 300gg-5, act July 1, 1944, ch. 373, title XXVII, §2705, as added Pub. L. 104-204, title VII, §703(a), Sept. 26, 1996, 110 Stat. 2947, and amended, which related to parity in mental health and substance use disorder benefits, was renumbered section 2726 of act July 1, 1944, and transferred to section 300gg-26 of this title.

A prior section 2706 of act July 1, 1944, was renumbered section 2727 and is classified to section 300gg-27 of this title.

Another prior section 2706 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238e 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-6. Comprehensive health insurance coverage

(a) Coverage for essential health benefits package

A health insurance issuer that offers health insurance coverage in the individual or small group market shall ensure that such coverage includes the essential health benefits package required under section 18022(a) of this title.

(b) Cost-sharing under group health plans

A group health plan shall ensure that any annual cost-sharing imposed under the plan does not exceed the limitations provided for under paragraphs (1) and (2) of section $18022(c)^1$ of this title.

(c) Child-only plans

If a health insurance issuer offers health insurance coverage in any level of coverage speci-

 $^{^{\}mbox{\tiny 1}}\,\mbox{See}$ References in Text note below.

¹ See References in Text note below.

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

Stat. 161.)

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

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, $\S2707$, as added Pub. L. 110–381, $\S2(b)(1)$, 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;
- (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