gynecology. Such professional shall agree to otherwise adhere to such plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer.

(B) Obstetrical and gynecological care

A group health plan or health insurance issuer described in paragraph (2) shall treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under subparagraph (A), by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(2) Application of paragraph

A group health plan, or health insurance issuer offering group or individual health insurance coverage, described in this paragraph is a group health plan or coverage that—

- (A) provides coverage for obstetric or gynecologic care; and
- (B) requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(3) Construction

Nothing in paragraph (1) shall be construed to—

- (A) waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care: or
- (B) preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(July 1, 1944, ch. 373, title XXVII, §2719A, as added Pub. L. 111-148, title X, §10101(h), Mar. 23, 2010, 124 Stat. 888.)

REFERENCES IN TEXT

Section 2701 of this Act, referred to in subsec. (b)(1)(D), is a reference to section 2701 of act July 1, 1944. Section 2701, which was classified to section 300gg of this title, was renumbered section 2704, effective for plan years beginning on or after Jan. 1, 2014, with certain exceptions, and amended, by Pub. L. 111–148, title I, §§ 1201(2), 1563(c)(1), formerly §1562(c)(1), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 154, 264, 911, and was transferred to section 300gg–3 of this title. A new section 2701 of act July 1, 1944, related to fair health insurance premiums, was added, effective for plan years beginning on or after Jan. 1, 2014, and amended, by Pub. L. 111–148, title I, §1201(4), title X, §10103(a), Mar. 23, 2010, 124 Stat. 155, 892, and is classified to section 300gg of this title.

CODIFICATION

Pub. L. 111–148, which directed amendment of subpart II of part A of "title XVIII" of act July 1, 1944, by inserting section 2719A after section 2719, was executed by making the insertion in subpart II of part A of title XXVII of the Act, to reflect the probable intent of Congress.

SUBPART 2—EXCLUSION OF PLANS; ENFORCEMENT; PREEMPTION

CODIFICATION

This subpart 2 designation and heading was transferred along with sections 300gg-21 to 300gg-23 of this title to appear before section 300gg-25 of this title to reflect the renumbering of the sections in the original act by Pub. L. 111-148, title I, \$1001(4), 1563(c)(12)(D), (13)(C), (14)(B), formerly \$1562(c)(12)(D), (13)(C), (14)(B), title X, \$10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 269, 911.

AMENDMENTS

2010—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, redesignated subpart 4 as subpart 2.

1996—Pub. L. 104-204, title VI, \$604(a)(2), Sept. 26, 1996, 110 Stat. 2939, redesignated subpart 3 as 4.

§ 300gg-21. Exclusion of certain plans

(a) Limitation on application of provisions relating to group health plans

(1) In general

The requirements of subparts 1 and 2^1 shall apply with respect to group health plans only—

- (A) subject to paragraph (2), in the case of a plan that is a nonfederal governmental plan, and
- (B) with respect to health insurance coverage offered in connection with a group health plan (including such a plan that is a church plan or a governmental plan).

(2) Treatment of non-Federal governmental plans

(A) Election to be excluded

Except as provided in subparagraph (D) or (E), if the plan sponsor of a nonfederal governmental plan which is a group health plan to which the provisions of subparts 1 and 2¹ otherwise apply makes an election under this subparagraph (in such form and manner as the Secretary may by regulations prescribe), then the requirements of such subparts insofar as they apply directly to group health plans (and not merely to group health insurance coverage) shall not apply to such governmental plans for such period except as provided in this paragraph.

(B) Period of election

An election under subparagraph (A) shall apply—

- (i) for a single specified plan year, or
- (ii) in the case of a plan provided pursuant to a collective bargaining agreement, for the term of such agreement.

An election under clause (i) may be extended through subsequent elections under this paragraph.

(C) Notice to enrollees

Under such an election, the plan shall provide for— $\,$

(i) notice to enrollees (on an annual basis and at the time of enrollment under the plan) of the fact and consequences of such election, and

¹ See References in Text note below.

(ii) certification and disclosure of creditable coverage under the plan with respect to enrollees in accordance with section 2701(e).¹

(D) Election not applicable to requirements concerning genetic information

The election described in subparagraph (A) shall not be available with respect to the provisions of subsections (a)(1)(F), (b)(3), (c), and (d) of section $2702^{\,1}$ and the provisions of sections $2701^{\,1}$ and $2702(b)^{\,1}$ to the extent that such provisions apply to genetic information

(E) Election not applicable

The election described in subparagraph (A) shall not be available with respect to the provisions of subparts I and II.

(b) Exception for certain benefits

The requirements of subparts 1 and 2¹ shall not apply to any individual coverage or any group health plan (or group health insurance coverage) in relation to its provision of excepted benefits described in section 300gg-91(c)(1) of this title.

(c) Exception for certain benefits if certain conditions met

(1) Limited, excepted benefits

The requirements of subparts 1 and 2¹ shall not apply to any individual coverage or any group health plan (and group health insurance coverage offered in connection with a group health plan) in relation to its provision of excepted benefits described in section 300gg-91(c)(2) of this title if the benefits—

- (A) are provided under a separate policy, certificate, or contract of insurance; or
- (B) are otherwise not an integral part of the plan.

(2) Noncoordinated, excepted benefits

The requirements of subparts 1 and 2¹ shall not apply to any individual coverage or any group health plan (and group health insurance coverage offered in connection with a group health plan) in relation to its provision of excepted benefits described in section 300gg-91(c)(3) of this title if all of the following conditions are met:

- (A) The benefits are provided under a separate policy, certificate, or contract of insurance.
- (B) There is no coordination between the provision of such benefits and any exclusion of benefits under any group health plan maintained by the same plan sponsor.
- (C) Such benefits are paid with respect to an event without regard to whether benefits are provided with respect to such an event under any group health plan maintained by the same plan sponsor or, with respect to individual coverage, under any health insurance coverage maintained by the same health insurance issuer.

(3) Supplemental excepted benefits

The requirements of this part shall not apply to any individual coverage or any group health plan (and group health insurance coverage) in relation to its provision of excepted

benefits described in section $300gg-91(c)(4)^1$ of this title if the benefits are provided under a separate policy, certificate, or contract of insurance.

(d) Treatment of partnerships

For purposes of this part—

(1) Treatment as a group health plan

Any plan, fund, or program which would not be (but for this subsection) an employee welfare benefit plan and which is established or maintained by a partnership, to the extent that such plan, fund, or program provides medical care (including items and services paid for as medical care) to present or former partners in the partnership or to their dependents (as defined under the terms of the plan, fund, or program), directly or through insurance, reimbursement, or otherwise, shall be treated (subject to paragraph (2)) as an employee welfare benefit plan which is a group health plan.

(2) Employer

In the case of a group health plan, the term "employer" also includes the partnership in relation to any partner.

(3) Participants of group health plans

In the case of a group health plan, the term "participant" also includes—

- (A) in connection with a group health plan maintained by a partnership, an individual who is a partner in relation to the partnership or
- (B) in connection with a group health plan maintained by a self-employed individual (under which one or more employees are participants), the self-employed individual,

if such individual is, or may become, eligible to receive a benefit under the plan or such individual's beneficiaries may be eligible to receive any such benefit.

(July 1, 1944, ch. 373, title XXVII, \S 2722, formerly \S 2721, as added Pub. L. 104–191, title I, \S 102(a), Aug. 21, 1996, 110 Stat. 1967; amended Pub. L. 104–204, title VI, \S 604(b)(1), Sept. 26, 1996, 110 Stat. 2940; Pub. L. 110–233, title I, \S 102(c), May 21, 2008, 122 Stat. 895; renumbered \S 2735, renumbered \S 2722, and amended Pub. L. 111–148, title I, \S 1001(4), 1563(a), (c)(12), formerly \S 1562(a), (c)(12), title X, \S 10107(a), (b)(1), Mar. 23, 2010, 124 Stat. 130, 264, 268, 911.)

REFERENCES IN TEXT

Subparts 1 and 2, referred to in subsecs. (a)(1), (2)(A), (b), and (c)(1), (2), may refer to subparts I and II of this part. Pub. L. 111-148, title I, §\$1001(5), 1201(1), 1563(c)(2), (11), formerly §1562(c)(2), (11), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 154, 265, 268, 911, amended this part by substituting "SUBPART I—GENERAL REFORM" for "SUBPART I—PORTABILITY, ACCESS, AND RENEWABILITY REQUIREMENTS" (preceding section 300gg of this title), effective for plan years beginning on or after Jan. 1, 2014, by inserting SUBPART II—IMPROVING COVERAGE" (preceding section 300gg-11 of this title), by striking out "SUBPART 2—OTHER REQUIREMENTS" (preceding section 300gg-4 of this title), and by redesignating subpart 4 as subpart 2 "EXCLUSION OF PLANS; ENFORCEMENT; PRE-EMPTION" (preceding section 300gg-21 of this title).

Section 2701, referred to in subsec. (a)(2)(C)(ii), (D), is a reference to section 2701 of act July 1, 1944. Section 2701, which was classified to section 300gg of this title,

was renumbered section 2704, effective for plan years beginning on or after Jan. 1, 2014, with certain exceptions, and amended, by Pub. L. 111-148, title I, §§ 1201(2), 1563(c)(1), formerly §1562(c)(1), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 154, 264, 911, and was transferred to section 300gg-3 of this title. A new section 2701 of act July 1, 1944, related to fair health insurance premiums, was added, effective for plan years beginning on or after Jan. 1, 2014, and amended, by Pub. L. 111–148, title I, $\S1201(4)$, title X, $\S10103(a)$, Mar. 23, 2010, 124 Stat. 155, 892, and is classified to section 300gg of this title.

Section 2702, referred to in subsec. (a)(2)(D), is a reference to section 2702 of act July 1, 1944. Section 2702, which was classified to section 300gg-1 of this title, was amended by Pub. L. 111-148, title I, §1201(3), Mar. 23, 2010, 124 Stat. 154, and was transferred to subsecs. (b) to (f) of section 300gg-4 of this title, effective for plan years beginning on or after Jan. 1, 2014. A new section 2702 of act July 1, 1944, related to guaranteed availability of coverage, was added by Pub. L. 111-148, title I, §1201(4), Mar. 23, 2010, 124 Stat. 156, effective for plan years beginning on or after Jan. 1, 2014, and is classified to section 300gg-1 of this title.

Section 300gg-91(c)(4) of this title, referred to in subsec. (c)(3), was in the original "section 27971(c)(4)" and was translated as reading "section 2791(c)(4)", meaning section 2791(c)(4) of act July 1, 1944, as added by Pub. L. 104-191, §102(a), to reflect the probable intent of Congress. Act July 1, 1944, does not contain a section 27971.

PRIOR PROVISIONS

A prior section 2722 of act July 1, 1944, was renumbered section 2723 and is classified to section 300gg-22 of

AMENDMENTS

2010—Pub. L. 111–148, §1563(c)(12)(B), formerly §1562(c)(12)(B), as renumbered by Pub. L. 111-148, §10107(b)(1), which directed amendment of section by substituting "subpart 1" for "subparts 1 through 3" wherever appearing, could not be executed because the words "subparts 1 through 3" did not appear subsequent to amendments by section 1563(a)(2)(A), (B)(ii), (3), (4)(A), (B)(i) of Pub. L. 111-148. See below.

Subsec. (a). Pub. L. 111-148, §1563(c)(12)(C), formerly §1562(c)(12)(C), as renumbered by Pub. L. 111-148, 10107(b)(1), redesignated subsec. (b) as (a).

Pub. L. 111–148, $\S 1563(a)(1)$ and 1563(c)(12)(A), formerly §§ 1562(a)(1) and 1562(c)(12)(A), as renumbered by Pub. L. 111-148, $\S 10107(b)(1)$, made identical amendment, striking out subsec. (a). Prior to amendment, text read as follows: "The requirements of subparts 1 and 3 shall not apply to any group health plan (and health insurance coverage offered in connection with a group health plan) for any plan year if, on the first day of such plan year, such plan has less than 2 participants who are current employees."

Subsec. (b). Pub. L. 111-148, §1563(c)(12)(C), formerly 1562(c)(12)(C), as renumbered by Pub. L. 111–148, §10107(b)(1), redesignated subsec. (c) as (b). Former subsec. (b) redesignated (a).

Pub. L. 111-148, §1563(a)(2)(A), formerly §1562(a)(2)(A), as renumbered by Pub. L. 111-148, §10107(b)(1), substituted "subparts 1 and 2" for "subparts 1 through 3" in introductory provisions.

L. 111-148, §1563(a)(2)(B)(ii), formerly 1562(a)(2)(B)(ii), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "subparts 1 and 2" for "subparts 1 through 3".

111–148, §1563(a)(2)(B)(i), §1562(a)(2)(B)(i), as renumbered by Pub. L. 111-148, §10107(b)(1), substituted "subparagraph (D) or (E)" for

"subparagraph (D)".
Subsec. (b)(2)(E). Pub. L. 111–148, §10107(a), substituted "subparts I and II" for "subpart 1".

111–148, §1563(a)(2)(B)(iii), L. formerly \$1562(a)(2)(B)(iii), as renumbered by Pub. L. 111-148, §10107(b)(1), added subpar. (E).

Subsec. (c). Pub. L. 111-148, 1563(c)(12)(C), formerly $1562(c)(12)(C), \ as \ renumbered \ by Pub. L. 111–148,$ §10107(b)(1), redesignated subsec. (d) as (c). Former subsec. (c) redesignated (b).

Pub. L. 111-148, §1563(a)(3), formerly §1562(a)(3), as renumbered by Pub. L. 111-148, \$10107(b)(1), substituted "subparts 1 and 2 shall not apply to any individual coverage or any group" for "subparts 1 through 3 shall not apply to any group"

Subsec. (d). Pub. L. 111-148, §1563(c)(12)(C), formerly §1562(c)(12)(C), as renumbered by Pub. L. 111-148, §10107(b)(1), redesignated subsec. (e) as (d). Former subsec. (d) redesignated (c).

Pub. L. 111-148, §1563(a)(4)(A), formerly §1562(a)(4)(A), as renumbered by Pub. L. 111-148, §10107(b)(1), substituted "subparts 1 and 2 shall not apply to any individual coverage or any group" for "subparts 1 through 3 shall not apply to any group" in introductory provi-

111–148, $\S1563(a)(4)(B)(i)$, Pub. §1562(a)(4)(B)(i), as renumbered by Pub. L. 111-148, §10107(b)(1), substituted "subparts 1 and 2 shall not apply to any individual coverage or any group" for 'subparts 1 through 3 shall not apply to any group" in introductory provisions.

Subsec. (d)(2)(C). Pub. L. 111-148, §1563(a)(4)(B)(ii), formerly §1562(a)(4)(B)(ii), as renumbered by Pub. L. 111-148, §10107(b)(1), which directed amendment of subpar. (C) by inserting "or, with respect to individual coverage, under any health insurance coverage maintained by the same health insurance issuer" without language specifying placement, was executed by making the insertion before period at end to reflect the probable intent of Congress.

Subsec. (d)(3). Pub. L. 111-148, §1563(a)(4)(C), formerly §1562(a)(4)(C), as renumbered by Pub. L. 111-148, §10107(b)(1), substituted "any individual coverage or any group" for "any group"

Subsec. (e). Pub. L. 111-148, §1563(c)(12)(C), formerly §1562(c)(12)(C), as renumbered by Pub. L. 111-148, §10107(b)(1), redesignated subsec. (e) as (d).

2008—Subsec. (b)(2)(A). Pub. L. 110-233, §102(c)(1), substituted "Except as provided in subparagraph (D), if the plan sponsor' for "If the plan sponsor".

Subsec. (b)(2)(D). Pub. L. 110–233, §102(c)(2), added sub-

1996—Subsec. (a). Pub. L. 104-204, §604(b)(1)(A), substituted "subparts 1 and 3" for "subparts 1 and 2"

Subsec. (b) to (d). Pub. L. 104-204, §604(b)(1)(B), substituted "subparts 1 through 3" for "subparts 1 and 2" wherever appearing.

EFFECTIVE DATE OF 2008 AMENDMENT

Pub. L. 110-233, title I, §102(d)(2), May 21, 2008, 122 Stat. 895, provided that: "The amendments made by this section [enacting section 300gg-53 of this title and amending this section and sections 300gg-1, 300gg-22, 300gg-61, and 300gg-91 of this title] shall apply-

(A) with respect to group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning after the date that is 1 year after the date of enactment of this Act [May 21, 2008]; and

"(B) with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after the date that is 1 year after the date of enactment of this Act.'

Effective Date of 1996 Amendment

Amendment by Pub. L. 104-204 applicable with respect to group health plans for plan years beginning on or after Jan. 1, 1998, see section 604(c) of Pub. L. 104-204 set out as an Effective Date note under section 300gg-25 of this title.

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.

REGULATIONS

Pub. L. 110–233, title I, \$102(d)(1), May 21, 2008, 122 Stat. 895, provided that: "Not later than 12 months after the date of enactment of this Act [May 21, 2008], the Secretary of Health and Human Services shall issue final regulations to carry out the amendments made by this section [see Effective Date of 2008 Amendment note above]."

ASSURING COORDINATION

Pub. L. 110–233, title I, §106, May 21, 2008, 122 Stat. 905, provided that: "Except as provided in section 105(b)(1) [42 U.S.C. 1320d–9 note], the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury shall ensure, through the execution of an interagency memorandum of understanding among such Secretaries, that—

"(1) regulations, rulings, and interpretations issued by such Secretaries relating to the same matter over which two or more such Secretaries have responsibility under this title [enacting sections 300gg–53 and 1320d–9 of this title and section 9834 of Title 26, Internal Revenue Code, amending this section, sections 300gg–1, 300gg–22, 300gg–61, 300gg–91, and 1395ss of this title, sections 9802 and 9832 of Title 26, and sections 1132, 1182, and 1191b of Title 29, Labor, and enacting provisions set out as notes under this section, sections 1320d–9 and 1395ss of this title, section 9802 of Title 26, and section 1132 of Title 29] (and the amendments made by this title) are administered so as to have the same effect at all times; and

"(2) coordination of policies relating to enforcing the same requirements through such Secretaries in order to have a coordinated enforcement strategy that avoids duplication of enforcement efforts and assigns priorities in enforcement."

§ 300gg-22. Enforcement

(a) State enforcement

(1) State authority

Subject to section 300gg-23¹ of this title, each State may require that health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State in the individual or group market meet the requirements of this part with respect to such issuers.

(2) Failure to implement provisions

In the case of a determination by the Secretary that a State has failed to substantially enforce a provision (or provisions) in this part with respect to health insurance issuers in the State, the Secretary shall enforce such provision (or provisions) under subsection (b) of this section insofar as they relate to the issuance, sale, renewal, and offering of health insurance coverage in connection with group health plans or individual health insurance coverage in such State.

(b) Secretarial enforcement authority

(1) Limitation

The provisions of this subsection shall apply to enforcement of a provision (or provisions) of this part only—

- (A) as provided under subsection (a)(2) of this section; and
- (B) with respect to individual health insurance coverage or group health plans that are non-Federal governmental plans.

(2) Imposition of penalties

In the cases described in paragraph (1)—

(A) In general

Subject to the succeeding provisions of this subsection, any non-Federal governmental plan that is a group health plan and any health insurance issuer that fails to meet a provision of this part applicable to such plan or issuer is subject to a civil money penalty under this subsection.

(B) Liability for penalty

In the case of a failure by—

- (i) a health insurance issuer, the issuer is liable for such penalty, or
- (ii) a group health plan that is a non-Federal governmental plan which is—
 - (I) sponsored by 2 or more employers, the plan is liable for such penalty, or
 - $(\widehat{\mbox{II}})$ not so sponsored, the employer is liable for such penalty.

(C) Amount of penalty

(i) In general

The maximum amount of penalty imposed under this paragraph is \$100 for each day for each individual with respect to which such a failure occurs.

(ii) Considerations in imposition

In determining the amount of any penalty to be assessed under this paragraph, the Secretary shall take into account the previous record of compliance of the entity being assessed with the applicable provisions of this part and the gravity of the violation.

(iii) Limitations

(I) Penalty not to apply where failure not discovered exercising reasonable diligence

No civil money penalty shall be imposed under this paragraph on any failure during any period for which it is established to the satisfaction of the Secretary that none of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that such failure existed.

(II) Penalty not to apply to failures corrected within 30 days

No civil money penalty shall be imposed under this paragraph on any failure if such failure was due to reasonable cause and not to willful neglect, and such failure is corrected during the 30-day period beginning on the first day any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that such failure existed.

(D) Administrative review

(i) Opportunity for hearing

The entity assessed shall be afforded an opportunity for hearing by the Secretary upon request made within 30 days after the date of the issuance of a notice of assessment. In such hearing the decision shall be made on the record pursuant to section 554 of title 5. If no hearing is requested, the as-

¹ See References in Text note below.