

## AMENDMENTS

2020—Subsec. (e), Pub. L. 116–260 added subsec. (e).

## Statutory Notes and Related Subsidiaries

## EFFECTIVE DATE OF 2020 AMENDMENT

Amendment by Pub. L. 116–260 applicable with respect to plan years beginning on or after Jan. 1, 2022, see section 102(e) of div. BB of Pub. L. 116–260, set out as a note under section 8902 of Title 5, Government Organization and Employees.

## § 300gg–19b. Information on prescription drugs

## (a) In general

A group health plan or a health insurance issuer offering group or individual health insurance coverage shall—

(1) not restrict, directly or indirectly, any pharmacy that dispenses a prescription drug to an enrollee in the plan or coverage from informing (or penalize such pharmacy for informing) an enrollee of any differential between the enrollee's out-of-pocket cost under the plan or coverage with respect to acquisition of the drug and the amount an individual would pay for acquisition of the drug without using any health plan or health insurance coverage; and

(2) ensure that any entity that provides pharmacy benefits management services under a contract with any such health plan or health insurance coverage does not, with respect to such plan or coverage, restrict, directly or indirectly, a pharmacy that dispenses a prescription drug from informing (or penalize such pharmacy for informing) an enrollee of any differential between the enrollee's out-of-pocket cost under the plan or coverage with respect to acquisition of the drug and the amount an individual would pay for acquisition of the drug without using any health plan or health insurance coverage.

## (b) Definition

For purposes of this section, the term “out-of-pocket cost”, with respect to acquisition of a drug, means the amount to be paid by the enrollee under the plan or coverage, including any cost-sharing (including any deductible, copayment, or coinsurance) and, as determined by the Secretary, any other expenditure.

(July 1, 1944, ch. 373, title XXVII, § 2729, as added Pub. L. 115–263, § 2, Oct. 10, 2018, 132 Stat. 3672.)

SUBPART 2—EXCLUSION OF PLANS;  
ENFORCEMENT; PREEMPTION

## Editorial Notes

## 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.

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.

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<sup>1</sup> and part D 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 2<sup>1</sup> 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

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

## (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<sup>1</sup> and the provisions of sections 2701<sup>1</sup> and 2702(b)<sup>1</sup> 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.

<sup>1</sup> See References in Text note below.

**(F) Sunset of election option****(i) In general**

Notwithstanding the preceding provisions of this paragraph—

(I) no election described in subparagraph (A) with respect to section 300gg-26 of this title may be made on or after December 29, 2022; and

(II) except as provided in clause (ii), no such election with respect to section 300gg-26 of this title expiring on or after the date that is 180 days after December 29, 2022, may be renewed.

**(ii) Exception for certain collectively bargained plans**

Notwithstanding clause (i)(II), a plan described in subparagraph (B)(ii) that is subject to multiple agreements described in such subparagraph of varying lengths and that has an election described in subparagraph (A) with respect to section 300gg-26 of this title in effect as of December 29, 2022, that expires on or after the date that is 180 days after December 29, 2022, may extend such election until the date on which the term of the last such agreement expires.

**(b) Exception for certain benefits**

The requirements of subparts 1 and 2<sup>1</sup> and part D 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 2<sup>1</sup> and part D 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 2<sup>1</sup> and part D 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 and part D 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)<sup>1</sup> 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 and part D—

**(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, § 2722, formerly § 2721, as added Pub. L. 104-191, title I, § 102(a), Aug. 21, 1996, 110 Stat. 1967; amended Pub. L. 104-204, title VI, § 604(b)(1), Sept. 26, 1996, 110 Stat. 2940; Pub. L. 110-233, title I, § 102(c), May 21, 2008, 122 Stat. 895; renumbered § 2735, renumbered § 2722, and amended Pub. L. 111-148, title I, §§ 1001(4), 1563(a), (c)(12), formerly § 1562(a), (c)(12), title X, § 10107(a), (b)(1), Mar. 23, 2010, 124 Stat. 130, 264, 268, 911; Pub. L. 116-260, div. BB, title I, § 102(a)(3)(B), Dec. 27, 2020, 134 Stat. 2772; Pub. L. 117-328, div. FF, title I, § 1321, Dec. 29, 2022, 136 Stat. 5697.)

**Editorial Notes****REFERENCES IN TEXT**

Subparts 1 and 2, referred to in subsecs. (a)(1), (2)(A), (b), and (c)(1), (2), were amended by 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. The subpart 1 designation and heading “PORTABILITY, ACCESS, AND RENEWABILITY REQUIREMENTS” were struck out and a new subpart I designation and heading “GENERAL REFORM” were enacted preceding section 300gg of this title, effective for plan years beginning on or after Jan. 1, 2014. A new subpart II designation and heading “IMPROVING COVERAGE” were enacted preceding section 300gg-11 of this title. The subpart 2 designation and heading “OTHER REQUIREMENTS” were struck out preceding section 300gg-4 of this title, and subpart 4 was redesignated as subpart 2 “EXCLUSION OF PLANS; ENFORCEMENT; PREEMPTION” 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, §1201(4), title X, §10103(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 this title.

#### AMENDMENTS

2022—Subsec. (a)(2)(F). Pub. L. 117-328 added subpar. (F).

2020—Subsecs. (a)(1), (b), (c)(1), (2). Pub. L. 116-260, §102(a)(3)(B)(i)–(iv), inserted “and part D” after “subparts 1 and 2” in introductory provisions of subsecs. (a)(1) and (c)(1), (2) and in subsec. (b).

Subsecs. (c)(3), (d). Pub. L. 116-260, §102(a)(3)(B)(v), (vi), inserted “and part D” after “this part”.

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, §§1563(a)(1) and 1563(c)(12)(A), formerly §§1562(a)(1) and 1562(c)(12)(A), as renumbered by Pub. L. 111-148, §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 insur-

ance 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.

Pub. 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”.

Pub. L. 111-148, §1563(a)(2)(B)(i), formerly §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”.

Pub. L. 111-148, §1563(a)(2)(B)(iii), 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 provisions.

Pub. L. 111-148, §1563(a)(4)(B)(i), formerly §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 subpar. (D).

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.

#### Statutory Notes and Related Subsidiaries

##### EFFECTIVE DATE OF 2020 AMENDMENT

Amendment by Pub. L. 116-260 applicable with respect to plan years beginning on or after Jan. 1, 2022,

see section 102(e) of div. BB of Pub. L. 116-260, set out as a note under section 8902 of Title 5, Government Organization and Employees.

#### 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-23<sup>1</sup> 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 and part D 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 or part D with respect to health insurance issuers in the State, the Secretary shall enforce such provision (or provisions) under subsection (b) 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 or part D only—

(A) as provided under subsection (a)(2); 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 or part D 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

(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 part D 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 fail-

<sup>1</sup> See References in Text note below.