

1 **DIVISION BB—PRIVATE HEALTH**
 2 **INSURANCE AND PUBLIC**
 3 **HEALTH PROVISIONS**

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HEALTH PROVISIONS

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1 **TITLE I—NO SURPRISES ACT**2 **SEC. 101. SHORT TITLE.**

3 This title may be cited as the “No Surprises Act”.

4 **SEC. 102. HEALTH INSURANCE REQUIREMENTS REGARD-**
 5 **ING SURPRISE MEDICAL BILLING.**

6 (a) PUBLIC HEALTH SERVICE ACT AMENDMENTS.—

7 (1) IN GENERAL.—Title XXVII of the Public
 8 Health Service Act (42 U.S.C. 300gg et seq.) is
 9 amended by adding at the end the following new
 10 part:

1 **“PART D—ADDITIONAL COVERAGE PROVISIONS**

2 **“SEC. 2799A-1. PREVENTING SURPRISE MEDICAL BILLS.**

3 “(a) COVERAGE OF EMERGENCY SERVICES.—

4 “(1) IN GENERAL.—If a group health plan, or
5 a health insurance issuer offering group or indi-
6 vidual health insurance coverage, provides or covers
7 any benefits with respect to services in an emergency
8 department of a hospital or with respect to emer-
9 gency services in an independent freestanding emer-
10 gency department (as defined in paragraph (3)(D)),
11 the plan or issuer shall cover emergency services (as
12 defined in paragraph (3)(C))—

13 “(A) without the need for any prior au-
14 thorization determination;

15 “(B) whether the health care provider fur-
16 nishing such services is a participating provider
17 or a participating emergency facility, as appli-
18 cable, with respect to such services;

19 “(C) in a manner so that, if such services
20 are provided to a participant, beneficiary, or en-
21 rollee by a nonparticipating provider or a non-
22 participating emergency facility—

23 “(i) such services will be provided
24 without imposing any requirement under
25 the plan or coverage for prior authoriza-
26 tion of services or any limitation on cov-

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1 erage that is more restrictive than the re-
2 quirements or limitations that apply to
3 emergency services received from partici-
4 pating providers and participating emer-
5 gency facilities with respect to such plan or
6 coverage, respectively;

7 “(ii) the cost-sharing requirement is
8 not greater than the requirement that
9 would apply if such services were provided
10 by a participating provider or a partici-
11 pating emergency facility;

12 “(iii) such cost-sharing requirement is
13 calculated as if the total amount that
14 would have been charged for such services
15 by such participating provider or partici-
16 pating emergency facility were equal to the
17 recognized amount (as defined in para-
18 graph (3)(H)) for such services, plan or
19 coverage, and year;

20 “(iv) the group health plan or health
21 insurance issuer, respectively—

22 “(I) not later than 30 calendar
23 days after the bill for such services is
24 transmitted by such provider or facil-
25 ity, sends to the provider or facility,

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1 as applicable, an initial payment or
2 notice of denial of payment; and

3 “(II) pays a total plan or cov-
4 erage payment directly to such pro-
5 vider or facility, respectively (in ac-
6 cordance, if applicable, with the tim-
7 ing requirement described in sub-
8 section (c)(6)) that is, with applica-
9 tion of any initial payment under sub-
10 clause (I), equal to the amount by
11 which the out-of-network rate (as de-
12 fined in paragraph (3)(K)) for such
13 services exceeds the cost-sharing
14 amount for such services (as deter-
15 mined in accordance with clauses (ii)
16 and (iii)) and year; and

17 “(v) any cost-sharing payments made
18 by the participant, beneficiary, or enrollee
19 with respect to such emergency services so
20 furnished shall be counted toward any in-
21 network deductible or out-of-pocket maxi-
22 mums applied under the plan or coverage,
23 respectively (and such in-network deduct-
24 ible and out-of-pocket maximums shall be
25 applied) in the same manner as if such

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1 cost-sharing payments were made with re-
2 spect to emergency services furnished by a
3 participating provider or a participating
4 emergency facility; and

5 “(D) without regard to any other term or
6 condition of such coverage (other than exclusion
7 or coordination of benefits, or an affiliation or
8 waiting period, permitted under section 2704 of
9 this Act, including as incorporated pursuant to
10 section 715 of the Employee Retirement Income
11 Security Act of 1974 and section 9815 of the
12 Internal Revenue Code of 1986, and other than
13 applicable cost-sharing).

14 “(2) AUDIT PROCESS AND REGULATIONS FOR
15 QUALIFYING PAYMENT AMOUNTS.—

16 “(A) AUDIT PROCESS.—

17 “(i) IN GENERAL.—Not later than Oc-
18 tober 1, 2021, the Secretary, in consulta-
19 tion with the Secretary of Labor and the
20 Secretary of the Treasury, shall establish
21 through rulemaking a process, in accord-
22 ance with clause (ii), under which group
23 health plans and health insurance issuers
24 offering group or individual health insur-
25 ance coverage are audited by the Secretary

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1 or applicable State authority to ensure
2 that—

3 “(I) such plans and coverage are
4 in compliance with the requirement of
5 applying a qualifying payment amount
6 under this section; and

7 “(II) such qualifying payment
8 amount so applied satisfies the defini-
9 tion under paragraph (3)(E) with re-
10 spect to the year involved, including
11 with respect to a group health plan or
12 health insurance issuer described in
13 clause (ii) of such paragraph (3)(E).

14 “(ii) AUDIT SAMPLES.—Under the
15 process established pursuant to clause (i),
16 the Secretary—

17 “(I) shall conduct audits de-
18 scribed in such clause, with respect to
19 a year (beginning with 2022), of a
20 sample with respect to such year of
21 claims data from not more than 25
22 group health plans and health insur-
23 ance issuers offering group or indi-
24 vidual health insurance coverage; and

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1 “(II) may audit any group health
2 plan or health insurance issuer offer-
3 ing group or individual health insur-
4 ance coverage if the Secretary has re-
5 ceived any complaint or other infor-
6 mation about such plan or coverage,
7 respectively, that involves the compli-
8 ance of the plan or coverage, respec-
9 tively, with either of the requirements
10 described in subclauses (I) and (II) of
11 such clause.

12 “(iii) REPORTS.—Beginning for 2022,
13 the Secretary shall annually submit to
14 Congress a report on the number of plans
15 and issuers with respect to which audits
16 were conducted during such year pursuant
17 to this subparagraph.

18 “(B) RULEMAKING.—Not later than July
19 1, 2021, the Secretary, in consultation with the
20 Secretary of Labor and the Secretary of the
21 Treasury, shall establish through rulemaking—

22 “(i) the methodology the group health
23 plan or health insurance issuer offering
24 group or individual health insurance cov-
25 erage shall use to determine the qualifying

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1 payment amount, differentiating by indi-
2 vidual market, large group market, and
3 small group market;

4 “(ii) the information such plan or
5 issuer, respectively, shall share with the
6 nonparticipating provider or nonpartici-
7 pating facility, as applicable, when making
8 such a determination;

9 “(iii) the geographic regions applied
10 for purposes of this subparagraph, taking
11 into account access to items and services in
12 rural and underserved areas, including
13 health professional shortage areas, as de-
14 fined in section 332; and

15 “(iv) a process to receive complaints
16 of violations of the requirements described
17 in subclauses (I) and (II) of subparagraph
18 (A)(i) by group health plans and health in-
19 surance issuers offering group or indi-
20 vidual health insurance coverage.

21 Such rulemaking shall take into account pay-
22 ments that are made by such plan or issuer, re-
23 spectively, that are not on a fee-for-service
24 basis. Such methodology may account for rel-
25 evant payment adjustments that take into ac-

1 count quality or facility type (including higher
2 acuity settings and the case-mix of various fa-
3 cility types) that are otherwise taken into ac-
4 count for purposes of determining payment
5 amounts with respect to participating facilities.
6 In carrying out clause (iii), the Secretary shall
7 consult with the National Association of Insur-
8 ance Commissioners to establish the geographic
9 regions under such clause and shall periodically
10 update such regions, as appropriate, taking into
11 account the findings of the report submitted
12 under section 109(a) of the No Surprises Act.

13 “(3) DEFINITIONS.—In this part and part E:

14 “(A) EMERGENCY DEPARTMENT OF A HOS-
15 PITAL.—The term ‘emergency department of a
16 hospital’ includes a hospital outpatient depart-
17 ment that provides emergency services (as de-
18 fined in subparagraph (C)(i)).

19 “(B) EMERGENCY MEDICAL CONDITION.—
20 The term ‘emergency medical condition’ means
21 a medical condition manifesting itself by acute
22 symptoms of sufficient severity (including se-
23 vere pain) such that a prudent layperson, who
24 possesses an average knowledge of health and
25 medicine, could reasonably expect the absence

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1 of immediate medical attention to result in a
2 condition described in clause (i), (ii), or (iii) of
3 section 1867(e)(1)(A) of the Social Security
4 Act.

5 “(C) EMERGENCY SERVICES.—

6 “(i) IN GENERAL.—The term ‘emer-
7 gency services’, with respect to an emer-
8 gency medical condition, means—

9 “(I) a medical screening exam-
10 ination (as required under section
11 1867 of the Social Security Act, or as
12 would be required under such section
13 if such section applied to an inde-
14 pendent freestanding emergency de-
15 partment) that is within the capability
16 of the emergency department of a hos-
17 pital or of an independent free-
18 standing emergency department, as
19 applicable, including ancillary services
20 routinely available to the emergency
21 department to evaluate such emer-
22 gency medical condition; and

23 “(II) within the capabilities of
24 the staff and facilities available at the
25 hospital or the independent free-

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1 standing emergency department, as
2 applicable, such further medical exam-
3 ination and treatment as are required
4 under section 1867 of such Act, or as
5 would be required under such section
6 if such section applied to an inde-
7 pendent freestanding emergency de-
8 partment, to stabilize the patient (re-
9 gardless of the department of the hos-
10 pital in which such further examina-
11 tion or treatment is furnished).

12 “(ii) INCLUSION OF ADDITIONAL
13 SERVICES.—

14 “(I) IN GENERAL.—For purposes
15 of this subsection and section 2799B-
16 1, in the case of a participant, bene-
17 ficiary, or enrollee who is enrolled in
18 a group health plan or group or indi-
19 vidual health insurance coverage of-
20 fered by a health insurance issuer and
21 who is furnished services described in
22 clause (i) with respect to an emer-
23 gency medical condition, the term
24 ‘emergency services’ shall include, un-
25 less each of the conditions described

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1 in subclause (II) are met, in addition
2 to the items and services described in
3 clause (i), items and services—

4 “(aa) for which benefits are
5 provided or covered under the
6 plan or coverage, respectively;
7 and

8 “(bb) that are furnished by
9 a nonparticipating provider or
10 nonparticipating emergency facil-
11 ity (regardless of the department
12 of the hospital in which such
13 items or services are furnished)
14 after the participant, beneficiary,
15 or enrollee is stabilized and as
16 part of outpatient observation or
17 an inpatient or outpatient stay
18 with respect to the visit in which
19 the services described in clause
20 (i) are furnished.

21 “(II) CONDITIONS.—For pur-
22 poses of subclause (I), the conditions
23 described in this subclause, with re-
24 spect to a participant, beneficiary, or
25 enrollee who is stabilized and fur-

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1 nished additional items and services
2 described in subclause (I) after such
3 stabilization by a provider or facility
4 described in subclause (I), are the fol-
5 lowing;

6 “(aa) Such provider or facil-
7 ity determines such individual is
8 able to travel using nonmedical
9 transportation or nonemergency
10 medical transportation.

11 “(bb) Such provider fur-
12 nishing such additional items and
13 services satisfies the notice and
14 consent criteria of section
15 2799B–2(d) with respect to such
16 items and services.

17 “(cc) Such individual is in a
18 condition to receive (as deter-
19 mined in accordance with guide-
20 lines issued by the Secretary pur-
21 suant to rulemaking) the infor-
22 mation described in section
23 2799B–2 and to provide in-
24 formed consent under such sec-

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1 tion, in accordance with applica-
2 ble State law.

3 “(dd) Such other conditions,
4 as specified by the Secretary,
5 such as conditions relating to co-
6 ordinating care transitions to
7 participating providers and facili-
8 ties.

9 “(D) INDEPENDENT FREESTANDING
10 EMERGENCY DEPARTMENT.—The term ‘inde-
11 pendent freestanding emergency department’
12 means a health care facility that—

13 “(i) is geographically separate and
14 distinct and licensed separately from a hos-
15 pital under applicable State law; and

16 “(ii) provides any of the emergency
17 services (as defined in subparagraph
18 (C)(i)).

19 “(E) QUALIFYING PAYMENT AMOUNT.—

20 “(i) IN GENERAL.—The term ‘quali-
21 fying payment amount’ means, subject to
22 clauses (ii) and (iii), with respect to a
23 sponsor of a group health plan and health
24 insurance issuer offering group or indi-
25 vidual health insurance coverage—

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1 “(I) for an item or service fur-
2 nished during 2022, the median of the
3 contracted rates recognized by the
4 plan or issuer, respectively (deter-
5 mined with respect to all such plans
6 of such sponsor or all such coverage
7 offered by such issuer that are offered
8 within the same insurance market
9 (specified in subclause (I), (II), (III),
10 or (IV) of clause (iv)) as the plan or
11 coverage) as the total maximum pay-
12 ment (including the cost-sharing
13 amount imposed for such item or
14 service and the amount to be paid by
15 the plan or issuer, respectively) under
16 such plans or coverage, respectively,
17 on January 31, 2019, for the same or
18 a similar item or service that is pro-
19 vided by a provider in the same or
20 similar specialty and provided in the
21 geographic region in which the item or
22 service is furnished, consistent with
23 the methodology established by the
24 Secretary under paragraph (2)(B), in-
25 creased by the percentage increase in

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1 the consumer price index for all urban
2 consumers (United States city aver-
3 age) over 2019, such percentage in-
4 crease over 2020, and such percentage
5 increase over 2021; and

6 “(II) for an item or service fur-
7 nished during 2023 or a subsequent
8 year, the qualifying payment amount
9 determined under this clause for such
10 an item or service furnished in the
11 previous year, increased by the per-
12 centage increase in the consumer price
13 index for all urban consumers (United
14 States city average) over such pre-
15 vious year.

16 “(ii) NEW PLANS AND COVERAGE.—
17 The term ‘qualifying payment amount’
18 means, with respect to a sponsor of a
19 group health plan or health insurance
20 issuer offering group or individual health
21 insurance coverage in a geographic region
22 in which such sponsor or issuer, respec-
23 tively, did not offer any group health plan
24 or health insurance coverage during
25 2019—

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1 “(I) for the first year in which
2 such group health plan, group health
3 insurance coverage, or individual
4 health insurance coverage, respec-
5 tively, is offered in such region, a rate
6 (determined in accordance with a
7 methodology established by the Sec-
8 retary) for items and services that are
9 covered by such plan or coverage and
10 furnished during such first year; and

11 “(II) for each subsequent year
12 such group health plan, group health
13 insurance coverage, or individual
14 health insurance coverage, respec-
15 tively, is offered in such region, the
16 qualifying payment amount deter-
17 mined under this clause for such
18 items and services furnished in the
19 previous year, increased by the per-
20 centage increase in the consumer price
21 index for all urban consumers (United
22 States city average) over such pre-
23 vious year.

24 “(iii) INSUFFICIENT INFORMATION;
25 NEWLY COVERED ITEMS AND SERVICES.—

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1 In the case of a sponsor of a group health
2 plan or health insurance issuer offering
3 group or individual health insurance cov-
4 erage that does not have sufficient infor-
5 mation to calculate the median of the con-
6 tracted rates described in clause (i)(I) in
7 2019 (or, in the case of a newly covered
8 item or service (as defined in clause
9 (v)(III)), in the first coverage year (as de-
10 fined in clause (v)(I)) for such item or
11 service with respect to such plan or cov-
12 erage) for an item or service (including
13 with respect to provider type, or amount,
14 of claims for items or services (as deter-
15 mined by the Secretary) provided in a par-
16 ticular geographic region (other than in a
17 case with respect to which clause (ii) ap-
18 plies)) the term ‘qualifying payment
19 amount’—

20 “(I) for an item or service fur-
21 nished during 2022 (or, in the case of
22 a newly covered item or service, dur-
23 ing the first coverage year for such
24 item or service with respect to such
25 plan or coverage), means such rate for

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1 such item or service determined by
2 the sponsor or issuer, respectively,
3 through use of any database that is
4 determined, in accordance with rule-
5 making described in paragraph
6 (2)(B), to not have any conflicts of in-
7 terest and to have sufficient informa-
8 tion reflecting allowed amounts paid
9 to a health care provider or facility for
10 relevant services furnished in the ap-
11 plicable geographic region (such as a
12 State all-payer claims database);

13 “(II) for an item or service fur-
14 nished in a subsequent year (before
15 the first sufficient information year
16 (as defined in clause (v)(II)) for such
17 item or service with respect to such
18 plan or coverage), means the rate de-
19 termined under subclause (I) or this
20 subclause, as applicable, for such item
21 or service for the year previous to
22 such subsequent year, increased by
23 the percentage increase in the con-
24 sumer price index for all urban con-

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1 sumers (United States city average)
2 over such previous year;

3 “(III) for an item or service fur-
4 nished in the first sufficient informa-
5 tion year for such item or service with
6 respect to such plan or coverage, has
7 the meaning given the term qualifying
8 payment amount in clause (i)(I), ex-
9 cept that in applying such clause to
10 such item or service, the reference to
11 ‘furnished during 2022’ shall be treat-
12 ed as a reference to furnished during
13 such first sufficient information year,
14 the reference to ‘in 2019’ shall be
15 treated as a reference to such suffi-
16 cient information year, and the in-
17 crease described in such clause shall
18 not be applied; and

19 “(IV) for an item or service fur-
20 nished in any year subsequent to the
21 first sufficient information year for
22 such item or service with respect to
23 such plan or coverage, has the mean-
24 ing given such term in clause (i)(II),
25 except that in applying such clause to

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1 such item or service, the reference to
2 ‘furnished during 2023 or a subse-
3 quent year’ shall be treated as a ref-
4 erence to furnished during the year
5 after such first sufficient information
6 year or a subsequent year.

7 “(iv) INSURANCE MARKET.—For pur-
8 poses of clause (i)(I), a health insurance
9 market specified in this clause is one of the
10 following:

11 “(I) The individual market.

12 “(II) The large group market
13 (other than plans described in sub-
14 clause (IV)).

15 “(III) The small group market
16 (other than plans described in sub-
17 clause (IV)).

18 “(IV) In the case of a self-in-
19 sured group health plan, other self-in-
20 sured group health plans.

21 “(v) DEFINITIONS.—For purposes of
22 this subparagraph:

23 “(I) FIRST COVERAGE YEAR.—
24 The term ‘first coverage year’ means,
25 with respect to a group health plan or

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1 group or individual health insurance
2 coverage offered by a health insurance
3 issuer and an item or service for
4 which coverage is not offered in 2019
5 under such plan or coverage, the first
6 year after 2019 for which coverage for
7 such item or service is offered under
8 such plan or health insurance cov-
9 erage.

10 “(II) FIRST SUFFICIENT INFOR-
11 MATION YEAR.—The term ‘first suffi-
12 cient information year’ means, with
13 respect to a group health plan or
14 group or individual health insurance
15 coverage offered by a health insurance
16 issuer—

17 “(aa) in the case of an item
18 or service for which the plan or
19 coverage does not have sufficient
20 information to calculate the me-
21 dian of the contracted rates de-
22 scribed in clause (i)(I) in 2019,
23 the first year subsequent to 2022
24 for which the sponsor or issuer
25 has such sufficient information to

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1 calculate the median of such con-
2 tracted rates in the year previous
3 to such first subsequent year;
4 and

5 “(bb) in the case of a newly
6 covered item or service, the first
7 year subsequent to the first cov-
8 erage year for such item or serv-
9 ice with respect to such plan or
10 coverage for which the sponsor or
11 issuer has sufficient information
12 to calculate the median of the
13 contracted rates described in
14 clause (i)(I) in the year previous
15 to such first subsequent year.

16 “(III) NEWLY COVERED ITEM OR
17 SERVICE.—The term ‘newly covered
18 item or service’ means, with respect to
19 a group health plan or group or indi-
20 vidual health insurance issuer offering
21 health insurance coverage, an item or
22 service for which coverage was not of-
23 fered in 2019 under such plan or cov-
24 erage, but is offered under such plan
25 or coverage in a year after 2019.

1 “(F) NONPARTICIPATING EMERGENCY FA-
2 CILITY; PARTICIPATING EMERGENCY FACIL-
3 ITY.—

4 “(i) NONPARTICIPATING EMERGENCY
5 FACILITY.—The term ‘nonparticipating
6 emergency facility’ means, with respect to
7 an item or service and a group health plan
8 or group or individual health insurance
9 coverage offered by a health insurance
10 issuer, an emergency department of a hos-
11 pital, or an independent freestanding emer-
12 gency department, that does not have a
13 contractual relationship directly or indi-
14 rectly with the plan or issuer, respectively,
15 for furnishing such item or service under
16 the plan or coverage, respectively.

17 “(ii) PARTICIPATING EMERGENCY FA-
18 CILITY.—The term ‘participating emer-
19 gency facility’ means, with respect to an
20 item or service and a group health plan or
21 group or individual health insurance cov-
22 erage offered by a health insurance issuer,
23 an emergency department of a hospital, or
24 an independent freestanding emergency de-
25 partment, that has a contractual relation-

1 ship directly or indirectly with the plan or
2 issuer, respectively, with respect to the fur-
3 nishing of such an item or service at such
4 facility.

5 “(G) NONPARTICIPATING PROVIDERS; PAR-
6 TICIPATING PROVIDERS.—

7 “(i) NONPARTICIPATING PROVIDER.—

8 The term ‘nonparticipating provider’
9 means, with respect to an item or service
10 and a group health plan or group or indi-
11 vidual health insurance coverage offered by
12 a health insurance issuer, a physician or
13 other health care provider who is acting
14 within the scope of practice of that pro-
15 vider’s license or certification under appli-
16 cable State law and who does not have a
17 contractual relationship with the plan or
18 issuer, respectively, for furnishing such
19 item or service under the plan or coverage,
20 respectively.

21 “(ii) PARTICIPATING PROVIDER.—The
22 term ‘participating provider’ means, with
23 respect to an item or service and a group
24 health plan or group or individual health
25 insurance coverage offered by a health in-

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1 surance issuer, a physician or other health
2 care provider who is acting within the
3 scope of practice of that provider’s license
4 or certification under applicable State law
5 and who has a contractual relationship
6 with the plan or issuer, respectively, for
7 furnishing such item or service under the
8 plan or coverage, respectively.

9 “(H) RECOGNIZED AMOUNT.—The term
10 ‘recognized amount’ means, with respect to an
11 item or service furnished by a nonparticipating
12 provider or nonparticipating emergency facility
13 during a year and a group health plan or group
14 or individual health insurance coverage offered
15 by a health insurance issuer—

16 “(i) subject to clause (iii), in the case
17 of such item or service furnished in a State
18 that has in effect a specified State law
19 with respect to such plan, coverage, or
20 issuer, respectively; such a nonpartici-
21 pating provider or nonparticipating emer-
22 gency facility; and such an item or service,
23 the amount determined in accordance with
24 such law;

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1 “(ii) subject to clause (iii), in the case
2 of such item or service furnished in a State
3 that does not have in effect a specified
4 State law, with respect to such plan, cov-
5 erage, or issuer, respectively; such a non-
6 participating provider or nonparticipating
7 emergency facility; and such an item or
8 service, the amount that is the qualifying
9 payment amount (as defined in subpara-
10 graph (E)) for such year and determined
11 in accordance with rulemaking described in
12 paragraph (2)(B)) for such item or service;
13 or

14 “(iii) in the case of such item or serv-
15 ice furnished in a State with an All-Payer
16 Model Agreement under section 1115A of
17 the Social Security Act, the amount that
18 the State approves under such system for
19 such item or service so furnished.

20 “(I) SPECIFIED STATE LAW.—The term
21 ‘specified State law’ means, with respect to a
22 State, an item or service furnished by a non-
23 participating provider or nonparticipating emer-
24 gency facility during a year and a group health
25 plan or group or individual health insurance

1 coverage offered by a health insurance issuer, a
2 State law that provides for a method for deter-
3 mining the total amount payable under such a
4 plan, coverage, or issuer, respectively (to the ex-
5 tent such State law applies to such plan, cov-
6 erage, or issuer, subject to section 514 of the
7 Employee Retirement Income Security Act of
8 1974) in the case of a participant, beneficiary,
9 or enrollee covered under such plan or coverage
10 and receiving such item or service from such a
11 nonparticipating provider or nonparticipating
12 emergency facility.

13 “(J) STABILIZE.—The term ‘to stabilize’,
14 with respect to an emergency medical condition
15 (as defined in subparagraph (B)), has the
16 meaning give in section 1867(e)(3) of the Social
17 Security Act (42 U.S.C. 1395dd(e)(3)).

18 “(K) OUT-OF-NETWORK RATE.—The term
19 ‘out-of-network rate’ means, with respect to an
20 item or service furnished in a State during a
21 year to a participant, beneficiary, or enrollee of
22 a group health plan or group or individual
23 health insurance coverage offered by a health
24 insurance issuer receiving such item or service

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1 from a nonparticipating provider or nonparticipating emergency facility—

2 “(i) subject to clause (iii), in the case
3 of such item or service furnished in a State
4 that has in effect a specified State law
5 with respect to such plan, coverage, or
6 issuer, respectively; such a nonparticipating provider or nonparticipating emergency facility; and such an item or service,
7 the amount determined in accordance with
8 such law;

9 “(ii) subject to clause (iii), in the case
10 such State does not have in effect such a
11 law with respect to such item or service,
12 plan, and provider or facility—

13 “(I) subject to subclause (II), if
14 the provider or facility (as applicable)
15 and such plan or coverage agree on an
16 amount of payment (including if such
17 agreed on amount is the initial payment sent by the plan under subsection (a)(1)(C)(iv)(I), subsection (b)(1)(C), or section 2799A–2(a)(3)(A), as applicable, or is agreed on through open negotiations under

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1 subsection (c)(1)) with respect to such
2 item or service, such agreed on
3 amount; or

4 “(II) if such provider or facility
5 (as applicable) and such plan or cov-
6 erage enter the independent dispute
7 resolution process under subsection
8 (c) and do not so agree before the
9 date on which a certified IDR entity
10 (as defined in paragraph (4) of such
11 subsection) makes a determination
12 with respect to such item or service
13 under such subsection, the amount of
14 such determination; or

15 “(iii) in the case such State has an
16 All-Payer Model Agreement under section
17 1115A of the Social Security Act, the
18 amount that the State approves under
19 such system for such item or service so
20 furnished.

21 “(L) COST-SHARING.—The term ‘cost-
22 sharing’ includes copayments, coinsurance, and
23 deductibles.

1 “(b) COVERAGE OF NON-EMERGENCY SERVICES
2 PERFORMED BY NONPARTICIPATING PROVIDERS AT CER-
3 TAIN PARTICIPATING FACILITIES.—

4 “(1) IN GENERAL.—In the case of items or
5 services (other than emergency services to which
6 subsection (a) applies) for which any benefits are
7 provided or covered by a group health plan or health
8 insurance issuer offering group or individual health
9 insurance coverage furnished to a participant, bene-
10 ficiary, or enrollee of such plan or coverage by a
11 nonparticipating provider (as defined in subsection
12 (a)(3)(G)(i)) (and who, with respect to such items
13 and services, has not satisfied the notice and consent
14 criteria of section 2799B–2(d)) with respect to a
15 visit (as defined by the Secretary in accordance with
16 paragraph (2)(B)) at a participating health care fa-
17 cility (as defined in paragraph (2)(A)), with respect
18 to such plan or coverage, respectively, the plan or
19 coverage, respectively—

20 “(A) shall not impose on such participant,
21 beneficiary, or enrollee a cost-sharing require-
22 ment for such items and services so furnished
23 that is greater than the cost-sharing require-
24 ment that would apply under such plan or cov-
25 erage, respectively, had such items or services

1 been furnished by a participating provider (as
2 defined in subsection (a)(3)(G)(ii));

3 “(B) shall calculate such cost-sharing re-
4 quirement as if the total amount that would
5 have been charged for such items and services
6 by such participating provider were equal to the
7 recognized amount (as defined in subsection
8 (a)(3)(H)) for such items and services, plan or
9 coverage, and year;

10 “(C) not later than 30 calendar days after
11 the bill for such services is transmitted by such
12 provider, shall send to the provider an initial
13 payment or notice of denial of payment;

14 “(D) shall pay a total plan or coverage
15 payment directly, in accordance, if applica-
16 ble, with the timing requirement described in
17 subsection (e)(6), to such provider furnishing
18 such items and services to such participant,
19 beneficiary, or enrollee that is, with application
20 of any initial payment under subparagraph (C),
21 equal to the amount by which the out-of-net-
22 work rate (as defined in subsection (a)(3)(K))
23 for such items and services involved exceeds the
24 cost-sharing amount imposed under the plan or
25 coverage, respectively, for such items and serv-

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1 ices (as determined in accordance with subpara-
2 graphs (A) and (B)) and year; and

3 “(E) shall count toward any in-network de-
4 ductible and in-network out-of-pocket maxi-
5 mums (as applicable) applied under the plan or
6 coverage, respectively, any cost-sharing pay-
7 ments made by the participant, beneficiary, or
8 enrollee (and such in-network deductible and
9 out-of-pocket maximums shall be applied) with
10 respect to such items and services so furnished
11 in the same manner as if such cost-sharing pay-
12 ments were with respect to items and services
13 furnished by a participating provider.

14 “(2) DEFINITIONS.—In this section:

15 “(A) PARTICIPATING HEALTH CARE FACIL-
16 ITY.—

17 “(i) IN GENERAL.—The term ‘partici-
18 pating health care facility’ means, with re-
19 spect to an item or service and a group
20 health plan or health insurance issuer of-
21 fering group or individual health insurance
22 coverage, a health care facility described in
23 clause (ii) that has a direct or indirect con-
24 tractual relationship with the plan or
25 issuer, respectively, with respect to the fur-

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1 nishing of such an item or service at the
2 facility.

3 “(ii) HEALTH CARE FACILITY DE-
4 SCRIBED.—A health care facility described
5 in this clause, with respect to a group
6 health plan or group or individual health
7 insurance coverage, is each of the fol-
8 lowing:

9 “(I) A hospital (as defined in
10 1861(e) of the Social Security Act).

11 “(II) A hospital outpatient de-
12 partment.

13 “(III) A critical access hospital
14 (as defined in section 1861(mm)(1) of
15 such Act).

16 “(IV) An ambulatory surgical
17 center described in section
18 1833(i)(1)(A) of such Act.

19 “(V) Any other facility, specified
20 by the Secretary, that provides items
21 or services for which coverage is pro-
22 vided under the plan or coverage, re-
23 spectively.

24 “(B) VISIT.—The term ‘visit’ shall, with
25 respect to items and services furnished to an in-

1 dividual at a health care facility, include equip-
2 ment and devices, telemedicine services, imag-
3 ing services, laboratory services, preoperative
4 and postoperative services, and such other items
5 and services as the Secretary may specify, re-
6 gardless of whether or not the provider fur-
7 nishing such items or services is at the facility.

8 “(c) CERTAIN ACCESS FEES TO CERTAIN DATA-
9 BASES.—In the case of a sponsor of a group health plan
10 or health insurance issuer offering group or individual
11 health insurance coverage that, pursuant to subsection
12 (a)(3)(E)(iii), uses a database described in such sub-
13 section to determine a rate to apply under such subsection
14 for an item or service by reason of having insufficient in-
15 formation described in such subsection with respect to
16 such item or service, such sponsor or issuer shall cover
17 the cost for access to such database.”.

18 (2) TRANSFER AMENDMENT.—Part D of title
19 XXVII of the Public Health Service Act, as added
20 by paragraph (1), is amended by adding at the end
21 the following new section:

22 **“SEC. 2799A-7. OTHER PATIENT PROTECTIONS.**

23 “(a) CHOICE OF HEALTH CARE PROFESSIONAL.—If
24 a group health plan, or a health insurance issuer offering
25 group or individual health insurance coverage, requires or

1 provides for designation by a participant, beneficiary, or
2 enrollee of a participating primary care provider, then the
3 plan or issuer shall permit each participant, beneficiary,
4 and enrollee to designate any participating primary care
5 provider who is available to accept such individual.

6 “(b) ACCESS TO PEDIATRIC CARE.—

7 “(1) PEDIATRIC CARE.—In the case of a person
8 who has a child who is a participant, beneficiary, or
9 enrollee under a group health plan, or group or indi-
10 vidual health insurance coverage offered by a health
11 insurance issuer, if the plan or issuer requires or
12 provides for the designation of a participating pri-
13 mary care provider for the child, the plan or issuer
14 shall permit such person to designate a physician
15 (allopathic or osteopathic) who specializes in pediat-
16 rics as the child’s primary care provider if such pro-
17 vider participates in the network of the plan or
18 issuer.

19 “(2) CONSTRUCTION.—Nothing in paragraph
20 (1) shall be construed to waive any exclusions of cov-
21 erage under the terms and conditions of the plan or
22 health insurance coverage with respect to coverage
23 of pediatric care.

24 “(c) PATIENT ACCESS TO OBSTETRICAL AND GYNE-
25 COLOGICAL CARE.—

1 “(1) GENERAL RIGHTS.—

2 “(A) DIRECT ACCESS.—A group health
3 plan, or health insurance issuer offering group
4 or individual health insurance coverage, de-
5 scribed in paragraph (2) may not require au-
6 thorization or referral by the plan, issuer, or
7 any person (including a primary care provider
8 described in paragraph (2)(B)) in the case of a
9 female participant, beneficiary, or enrollee who
10 seeks coverage for obstetrical or gynecological
11 care provided by a participating health care
12 professional who specializes in obstetrics or
13 gynecology. Such professional shall agree to
14 otherwise adhere to such plan’s or issuer’s poli-
15 cies and procedures, including procedures re-
16 garding referrals and obtaining prior authoriza-
17 tion and providing services pursuant to a treat-
18 ment plan (if any) approved by the plan or
19 issuer.

20 “(B) OBSTETRICAL AND GYNECOLOGICAL
21 CARE.—A group health plan or health insur-
22 ance issuer described in paragraph (2) shall
23 treat the provision of obstetrical and gynecolo-
24 gical care, and the ordering of related obstet-
25 rical and gynecological items and services, pur-

1 suant to the direct access described under sub-
2 paragraph (A), by a participating health care
3 professional who specializes in obstetrics or
4 gynecology as the authorization of the primary
5 care provider.

6 “(2) APPLICATION OF PARAGRAPH.—A group
7 health plan, or health insurance issuer offering
8 group or individual health insurance coverage, de-
9 scribed in this paragraph is a group health plan or
10 health insurance coverage that—

11 “(A) provides coverage for obstetric or
12 gynecologic care; and

13 “(B) requires the designation by a partici-
14 pant, beneficiary, or enrollee of a participating
15 primary care provider.

16 “(3) CONSTRUCTION.—Nothing in paragraph
17 (1) shall be construed to—

18 “(A) waive any exclusions of coverage
19 under the terms and conditions of the plan or
20 health insurance coverage with respect to cov-
21 erage of obstetrical or gynecological care; or

22 “(B) preclude the group health plan or
23 health insurance issuer involved from requiring
24 that the obstetrical or gynecological provider

1 notify the primary care health care professional
2 or the plan or issuer of treatment decisions.”.

3 (3) CONFORMING AMENDMENTS.—

4 (A) Section 2719A of the Public Health
5 Service Act (42 U.S.C. 300gg–19a) is amended
6 by adding at the end the following new sub-
7 section:

8 “(e) APPLICATION.—The provisions of this section
9 shall not apply with respect to a group health plan, health
10 insurance issuers, or group or individual health insurance
11 coverage with respect to plan years beginning on or on
12 January 1, 2022.”.

13 (B) Section 2722 of the Public Health
14 Service Act (42 U.S.C. 300gg–21) is amend-
15 ed—

16 (i) in subsection (a)(1), by inserting
17 “and part D” after “subparts 1 and 2”;

18 (ii) in subsection (b), by inserting
19 “and part D” after “subparts 1 and 2”;

20 (iii) in subsection (c)(1), by inserting
21 “and part D” after “subparts 1 and 2”;

22 (iv) in subsection (c)(2), by inserting
23 “and part D” after “subparts 1 and 2”;

24 (v) in subsection (c)(3), by inserting
25 “and part D” after “this part”; and

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1 (vi) in subsection (d), in the matter
2 preceding paragraph (1), by inserting “and
3 part D” after “this part”.

4 (C) Section 2723 of the Public Health
5 Service Act (42 U.S.C. 300gg–22) is amend-
6 ed—

7 (i) in subsection (a)(1), by inserting
8 “and part D” after “this part”;

9 (ii) in subsection (a)(2), by inserting
10 “or part D” after “this part”;

11 (iii) in subsection (b)(1), by inserting
12 “or part D” after “this part”;

13 (iv) in subsection (b)(2)(A), by insert-
14 ing “or part D” after “this part”; and

15 (v) in subsection (b)(2)(C)(ii), by in-
16 serting “and part D” after “this part”.

17 (D) Section 2724 of the Public Health
18 Service Act (42 U.S.C. 300gg–23) is amend-
19 ed—

20 (i) in subsection (a)(1)—

21 (I) by striking “this part and
22 part C insofar as it relates to this
23 part” and inserting “this part, part
24 D, and part C insofar as it relates to
25 this part or part D”; and

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1 (II) by inserting “or part D”
2 after “requirement of this part”;
3 (ii) in subsection (a)(2), by inserting
4 “or part D” after “this part”; and
5 (iii) in subsection (c), by inserting “or
6 part D” after “this part (other than sec-
7 tion 2704)”.

8 (b) ERISA AMENDMENTS.—

9 (1) IN GENERAL.—Subpart B of part 7 of title
10 I of the Employee Retirement Income Security Act
11 of 1974 (29 U.S.C. 1185 et seq.) is amended by
12 adding at the end the following:

13 **“SEC. 716. PREVENTING SURPRISE MEDICAL BILLS.**

14 **“(a) COVERAGE OF EMERGENCY SERVICES.—**

15 **“(1) IN GENERAL.—**If a group health plan, or
16 a health insurance issuer offering group health in-
17 surance coverage, provides or covers any benefits
18 with respect to services in an emergency department
19 of a hospital or with respect to emergency services
20 in an independent freestanding emergency depart-
21 ment (as defined in paragraph (3)(D)), the plan or
22 issuer shall cover emergency services (as defined in
23 paragraph (3)(C))—

24 **“(A) without the need for any prior au-**
25 **thorization determination;**

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1 “(B) whether the health care provider fur-
2 nishing such services is a participating provider
3 or a participating emergency facility, as appli-
4 cable, with respect to such services;

5 “(C) in a manner so that, if such services
6 are provided to a participant or beneficiary by
7 a nonparticipating provider or a nonparti-
8 cating emergency facility—

9 “(i) such services will be provided
10 without imposing any requirement under
11 the plan for prior authorization of services
12 or any limitation on coverage that is more
13 restrictive than the requirements or limita-
14 tions that apply to emergency services re-
15 ceived from participating providers and
16 participating emergency facilities with re-
17 spect to such plan or coverage, respec-
18 tively;

19 “(ii) the cost-sharing requirement is
20 not greater than the requirement that
21 would apply if such services were provided
22 by a participating provider or a partici-
23 pating emergency facility;

24 “(iii) such cost-sharing requirement is
25 calculated as if the total amount that

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1 would have been charged for such services
2 by such participating provider or partici-
3 pating emergency facility were equal to the
4 recognized amount (as defined in para-
5 graph (3)(H)) for such services, plan or
6 coverage, and year;

7 “(iv) the group health plan or health
8 insurance issuer, respectively—

9 “(I) not later than 30 calendar
10 days after the bill for such services is
11 transmitted by such provider or facil-
12 ity, sends to the provider or facility,
13 as applicable, an initial payment or
14 notice of denial of payment; and

15 “(II) pays a total plan or cov-
16 erage payment directly to such pro-
17 vider or facility, respectively (in ac-
18 cordance, if applicable, with the tim-
19 ing requirement described in sub-
20 section (c)(6)) that is, with applica-
21 tion of any initial payment under sub-
22 clause (I), equal to the amount by
23 which the out-of-network rate (as de-
24 fined in paragraph (3)(K)) for such
25 services exceeds the cost-sharing

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1 amount for such services (as deter-
2 mined in accordance with clauses (ii)
3 and (iii)) and year; and

4 “(v) any cost-sharing payments made
5 by the participant or beneficiary with re-
6 spect to such emergency services so fur-
7 nished shall be counted toward any in-net-
8 work deductible or out-of-pocket maxi-
9 mums applied under the plan or coverage,
10 respectively (and such in-network deduct-
11 ible and out-of-pocket maximums shall be
12 applied) in the same manner as if such
13 cost-sharing payments were made with re-
14 spect to emergency services furnished by a
15 participating provider or a participating
16 emergency facility; and

17 “(D) without regard to any other term or
18 condition of such coverage (other than exclusion
19 or coordination of benefits, or an affiliation or
20 waiting period, permitted under section 2704 of
21 the Public Health Service Act, including as in-
22 corporated pursuant to section 715 of this Act
23 and section 9815 of the Internal Revenue Code
24 of 1986, and other than applicable cost-shar-
25 ing).

1 “(2) REGULATIONS FOR QUALIFYING PAYMENT
2 AMOUNTS.—Not later than July 1, 2021, the Sec-
3 retary, in consultation with the Secretary of the
4 Treasury and the Secretary of Health and Human
5 Services, shall establish through rulemaking—

6 “(A) the methodology the group health
7 plan or health insurance issuer offering health
8 insurance coverage in the group market shall
9 use to determine the qualifying payment
10 amount, differentiating by large group market,
11 and small group market;

12 “(B) the information such plan or issuer,
13 respectively, shall share with the nonpartici-
14 pating provider or nonparticipating facility, as
15 applicable, when making such a determination;

16 “(C) the geographic regions applied for
17 purposes of this subparagraph, taking into ac-
18 count access to items and services in rural and
19 underserved areas, including health professional
20 shortage areas, as defined in section 332 of the
21 Public Health Service Act; and

22 “(D) a process to receive complaints of vio-
23 lations of the requirements described in sub-
24 clauses (I) and (II) of subparagraph (A)(i) by
25 group health plans and health insurance issuers

1 offering health insurance coverage in the group
2 market.

3 Such rulemaking shall take into account payments
4 that are made by such plan or issuer, respectively,
5 that are not on a fee-for-service basis. Such method-
6 ology may account for relevant payment adjustments
7 that take into account quality or facility type (in-
8 cluding higher acuity settings and the case-mix of
9 various facility types) that are otherwise taken into
10 account for purposes of determining payment
11 amounts with respect to participating facilities. In
12 carrying out clause (iii), the Secretary shall consult
13 with the National Association of Insurance Commis-
14 sioners to establish the geographic regions under
15 such clause and shall periodically update such re-
16 gions, as appropriate, taking into account the find-
17 ings of the report submitted under section 109(a) of
18 the No Surprises Act.

19 “(3) DEFINITIONS.—In this subpart:

20 “(A) EMERGENCY DEPARTMENT OF A HOS-
21 PITAL.—The term ‘emergency department of a
22 hospital’ includes a hospital outpatient depart-
23 ment that provides emergency services (as de-
24 fined in subparagraph (C)(i)).

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1 “(B) EMERGENCY MEDICAL CONDITION.—

2 The term ‘emergency medical condition’ means
3 a medical condition manifesting itself by acute
4 symptoms of sufficient severity (including se-
5 vere pain) such that a prudent layperson, who
6 possesses an average knowledge of health and
7 medicine, could reasonably expect the absence
8 of immediate medical attention to result in a
9 condition described in clause (i), (ii), or (iii) of
10 section 1867(e)(1)(A) of the Social Security
11 Act.

12 “(C) EMERGENCY SERVICES.—

13 “(i) IN GENERAL.—The term ‘emer-
14 gency services’, with respect to an emer-
15 gency medical condition, means—

16 “(I) a medical screening exam-
17 ination (as required under section
18 1867 of the Social Security Act, or as
19 would be required under such section
20 if such section applied to an inde-
21 pendent freestanding emergency de-
22 partment) that is within the capability
23 of the emergency department of a hos-
24 pital or of an independent free-
25 standing emergency department, as

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1 applicable, including ancillary services
2 routinely available to the emergency
3 department to evaluate such emer-
4 gency medical condition; and

5 “(II) within the capabilities of
6 the staff and facilities available at the
7 hospital or the independent free-
8 standing emergency department, as
9 applicable, such further medical exam-
10 ination and treatment as are required
11 under section 1867 of such Act, or as
12 would be required under such section
13 if such section applied to an inde-
14 pendent freestanding emergency de-
15 partment, to stabilize the patient (re-
16 gardless of the department of the hos-
17 pital in which such further examina-
18 tion or treatment is furnished).

19 “(ii) INCLUSION OF ADDITIONAL
20 SERVICES.—

21 “(I) IN GENERAL.—For purposes
22 of this subsection and section 2799B-
23 1 of the Public Health Service Act, in
24 the case of a participant or bene-
25 ficiary who is enrolled in a group

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1 health plan or group health insurance
2 coverage offered by a health insurance
3 issuer and who is furnished services
4 described in clause (i) with respect to
5 an emergency medical condition, the
6 term ‘emergency services’ shall in-
7 clude, unless each of the conditions
8 described in subclause (II) are met, in
9 addition to the items and services de-
10 scribed in clause (i), items and serv-
11 ices—

12 “(aa) for which benefits are
13 provided or covered under the
14 plan or coverage, respectively;
15 and

16 “(bb) that are furnished by
17 a nonparticipating provider or
18 nonparticipating emergency facil-
19 ity (regardless of the department
20 of the hospital in which such
21 items or services are furnished)
22 after the participant or bene-
23 ficiary is stabilized and as part of
24 outpatient observation or an in-
25 patient or outpatient stay with

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1 respect to the visit in which the
2 services described in clause (i)
3 are furnished.

4 “(II) CONDITIONS.—For pur-
5 poses of subclause (I), the conditions
6 described in this subclause, with re-
7 spect to a participant or beneficiary
8 who is stabilized and furnished addi-
9 tional items and services described in
10 subclause (I) after such stabilization
11 by a provider or facility described in
12 subclause (I), are the following;

13 “(aa) Such provider or facil-
14 ity determines such individual is
15 able to travel using nonmedical
16 transportation or nonemergency
17 medical transportation.

18 “(bb) Such provider fur-
19 nishing such additional items and
20 services satisfies the notice and
21 consent criteria of section
22 2799B–2(d) with respect to such
23 items and services.

24 “(cc) Such individual is in a
25 condition to receive (as deter-

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1 mined in accordance with guide-
2 lines issued by the Secretary pur-
3 suant to rulemaking) the infor-
4 mation described in section
5 2799B-2 and to provide in-
6 formed consent under such sec-
7 tion, in accordance with applica-
8 ble State law.

9 “(dd) Such other conditions,
10 as specified by the Secretary,
11 such as conditions relating to co-
12 ordinating care transitions to
13 participating providers and facili-
14 ties.

15 “(D) INDEPENDENT FREESTANDING
16 EMERGENCY DEPARTMENT.—The term ‘inde-
17 pendent freestanding emergency department’
18 means a health care facility that—

19 “(i) is geographically separate and
20 distinct and licensed separately from a hos-
21 pital under applicable State law; and

22 “(ii) provides any of the emergency
23 services (as defined in subparagraph
24 (C)(i)).

25 “(E) QUALIFYING PAYMENT AMOUNT.—

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1 “(i) IN GENERAL.—The term ‘quali-
2 fying payment amount’ means, subject to
3 clauses (ii) and (iii), with respect to a
4 sponsor of a group health plan and health
5 insurance issuer offering group health in-
6 surance coverage—

7 “(I) for an item or service fur-
8 nished during 2022, the median of the
9 contracted rates recognized by the
10 plan or issuer, respectively (deter-
11 mined with respect to all such plans
12 of such sponsor or all such coverage
13 offered by such issuer that are offered
14 within the same insurance market
15 (specified in subclause (I), (II), or
16 (III) of clause (iv)) as the plan or cov-
17 erage) as the total maximum payment
18 (including the cost-sharing amount
19 imposed for such item or service and
20 the amount to be paid by the plan or
21 issuer, respectively) under such plans
22 or coverage, respectively, on January
23 31, 2019, for the same or a similar
24 item or service that is provided by a
25 provider in the same or similar spe-

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1 cialty and provided in the geographic
2 region in which the item or service is
3 furnished, consistent with the method-
4 ology established by the Secretary
5 under paragraph (2), increased by the
6 percentage increase in the consumer
7 price index for all urban consumers
8 (United States city average) over
9 2019, such percentage increase over
10 2020, and such percentage increase
11 over 2021; and

12 “(II) for an item or service fur-
13 nished during 2023 or a subsequent
14 year, the qualifying payment amount
15 determined under this clause for such
16 an item or service furnished in the
17 previous year, increased by the per-
18 centage increase in the consumer price
19 index for all urban consumers (United
20 States city average) over such pre-
21 vious year.

22 “(ii) NEW PLANS AND COVERAGE.—
23 The term ‘qualifying payment amount’
24 means, with respect to a sponsor of a
25 group health plan or health insurance

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1 issuer offering group health insurance cov-
2 erage in a geographic region in which such
3 sponsor or issuer, respectively, did not
4 offer any group health plan or health in-
5 surance coverage during 2019—

6 “(I) for the first year in which
7 such group health plan or health in-
8 surance coverage, respectively, is of-
9 fered in such region, a rate (deter-
10 mined in accordance with a method-
11 ology established by the Secretary) for
12 items and services that are covered by
13 such plan and furnished during such
14 first year; and

15 “(II) for each subsequent year
16 such group health plan or health in-
17 surance coverage, respectively, is of-
18 fered in such region, the qualifying
19 payment amount determined under
20 this clause for such items and services
21 furnished in the previous year, in-
22 creased by the percentage increase in
23 the consumer price index for all urban
24 consumers (United States city aver-
25 age) over such previous year.

1 “(iii) INSUFFICIENT INFORMATION;
2 NEWLY COVERED ITEMS AND SERVICES.—
3 In the case of a sponsor of a group health
4 plan or health insurance issuer offering
5 group health insurance coverage that does
6 not have sufficient information to calculate
7 the median of the contracted rates de-
8 scribed in clause (i)(I) in 2019 (or, in the
9 case of a newly covered item or service (as
10 defined in clause (v)(III)), in the first cov-
11 erage year (as defined in clause (v)(I)) for
12 such item or service with respect to such
13 plan or coverage) for an item or service
14 (including with respect to provider type, or
15 amount, of claims for items or services (as
16 determined by the Secretary) provided in a
17 particular geographic region (other than in
18 a case with respect to which clause (ii) ap-
19 plies)) the term ‘qualifying payment
20 amount’—

21 “(I) for an item or service fur-
22 nished during 2022 (or, in the case of
23 a newly covered item or service, dur-
24 ing the first coverage year for such
25 item or service with respect to such

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1 plan or coverage), means such rate for
2 such item or service determined by
3 the sponsor or issuer, respectively,
4 through use of any database that is
5 determined, in accordance with rule-
6 making described in paragraph (2), to
7 not have any conflicts of interest and
8 to have sufficient information reflect-
9 ing allowed amounts paid to a health
10 care provider or facility for relevant
11 services furnished in the applicable ge-
12 ographic region (such as a State all-
13 payer claims database);

14 “(II) for an item or service fur-
15 nished in a subsequent year (before
16 the first sufficient information year
17 (as defined in clause (v)(II)) for such
18 item or service with respect to such
19 plan or coverage), means the rate de-
20 termined under subclause (I) or this
21 subclause, as applicable, for such item
22 or service for the year previous to
23 such subsequent year, increased by
24 the percentage increase in the con-
25 sumer price index for all urban con-

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1 sumers (United States city average)
2 over such previous year;

3 “(III) for an item or service fur-
4 nished in the first sufficient informa-
5 tion year for such item or service with
6 respect to such plan or coverage, has
7 the meaning given the term qualifying
8 payment amount in clause (i)(I), ex-
9 cept that in applying such clause to
10 such item or service, the reference to
11 ‘furnished during 2022’ shall be treat-
12 ed as a reference to furnished during
13 such first sufficient information year,
14 the reference to ‘in 2019’ shall be
15 treated as a reference to such suffi-
16 cient information year, and the in-
17 crease described in such clause shall
18 not be applied; and

19 “(IV) for an item or service fur-
20 nished in any year subsequent to the
21 first sufficient information year for
22 such item or service with respect to
23 such plan or coverage, has the mean-
24 ing given such term in clause (i)(II),
25 except that in applying such clause to

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1 such item or service, the reference to
2 ‘furnished during 2023 or a subse-
3 quent year’ shall be treated as a ref-
4 erence to furnished during the year
5 after such first sufficient information
6 year or a subsequent year.

7 “(iv) INSURANCE MARKET.—For pur-
8 poses of clause (i)(I), a health insurance
9 market specified in this clause is one of the
10 following:

11 “(I) The large group market
12 (other than plans described in sub-
13 clause (III)).

14 “(II) The small group market
15 (other than plans described in sub-
16 clause (III)).

17 “(III) In the case of a self-in-
18 sured group health plan, other self-in-
19 sured group health plans.

20 “(v) DEFINITIONS.—For purposes of
21 this subparagraph:

22 “(I) FIRST COVERAGE YEAR.—
23 The term ‘first coverage year’ means,
24 with respect to a group health plan or
25 group health insurance coverage of-

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1 ferred by a health insurance issuer and
2 an item or service for which coverage
3 is not offered in 2019 under such plan
4 or coverage, the first year after 2019
5 for which coverage for such item or
6 service is offered under such plan or
7 health insurance coverage.

8 “(II) FIRST SUFFICIENT INFOR-
9 MATION YEAR.—The term ‘first suffi-
10 cient information year’ means, with
11 respect to a group health plan or
12 group health insurance coverage of-
13 fered by a health insurance issuer—

14 “(aa) in the case of an item
15 or service for which the plan or
16 coverage does not have sufficient
17 information to calculate the me-
18 dian of the contracted rates de-
19 scribed in clause (i)(I) in 2019,
20 the first year subsequent to 2022
21 for which such sponsor or issuer
22 has such sufficient information to
23 calculate the median of such con-
24 tracted rates in the year previous

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1 to such first subsequent year;
2 and

3 “(bb) in the case of a newly
4 covered item or service, the first
5 year subsequent to the first cov-
6 erage year for such item or serv-
7 ice with respect to such plan or
8 coverage for which the sponsor or
9 issuer has sufficient information
10 to calculate the median of the
11 contracted rates described in
12 clause (i)(I) in the year previous
13 to such first subsequent year.

14 “(III) NEWLY COVERED ITEM OR
15 SERVICE.—The term ‘newly covered
16 item or service’ means, with respect to
17 a group health plan or health insur-
18 ance issuer offering group health in-
19 surance coverage, an item or service
20 for which coverage was not offered in
21 2019 under such plan or coverage, but
22 is offered under such plan or coverage
23 in a year after 2019.

1 “(F) NONPARTICIPATING EMERGENCY FA-
2 CILITY; PARTICIPATING EMERGENCY FACIL-
3 ITY.—

4 “(i) NONPARTICIPATING EMERGENCY
5 FACILITY.—The term ‘nonparticipating
6 emergency facility’ means, with respect to
7 an item or service and a group health plan
8 or group health insurance coverage offered
9 by a health insurance issuer, an emergency
10 department of a hospital, or an inde-
11 pendent freestanding emergency depart-
12 ment, that does not have a contractual re-
13 lationship directly or indirectly with the
14 plan or issuer, respectively, for furnishing
15 such item or service under the plan or cov-
16 erage, respectively.

17 “(ii) PARTICIPATING EMERGENCY FA-
18 CILITY.—The term ‘participating emer-
19 gency facility’ means, with respect to an
20 item or service and a group health plan or
21 group health insurance coverage offered by
22 a health insurance issuer, an emergency
23 department of a hospital, or an inde-
24 pendent freestanding emergency depart-
25 ment, that has a contractual relationship

1 directly or indirectly with the plan or
2 issuer, respectively, with respect to the fur-
3 nishing of such an item or service at such
4 facility.

5 “(G) NONPARTICIPATING PROVIDERS; PAR-
6 TICIPATING PROVIDERS.—

7 “(i) NONPARTICIPATING PROVIDER.—

8 The term ‘nonparticipating provider’
9 means, with respect to an item or service
10 and a group health plan or group health
11 insurance coverage offered by a health in-
12 surance issuer, a physician or other health
13 care provider who is acting within the
14 scope of practice of that provider’s license
15 or certification under applicable State law
16 and who does not have a contractual rela-
17 tionship with the plan or issuer, respec-
18 tively, for furnishing such item or service
19 under the plan or coverage, respectively.

20 “(ii) PARTICIPATING PROVIDER.—The
21 term ‘participating provider’ means, with
22 respect to an item or service and a group
23 health plan or group health insurance cov-
24 erage offered by a health insurance issuer,
25 a physician or other health care provider

1 who is acting within the scope of practice
2 of that provider’s license or certification
3 under applicable State law and who has a
4 contractual relationship with the plan or
5 issuer, respectively, for furnishing such
6 item or service under the plan or coverage,
7 respectively.

8 “(H) RECOGNIZED AMOUNT.—The term
9 ‘recognized amount’ means, with respect to an
10 item or service furnished by a nonparticipating
11 provider or nonparticipating emergency facility
12 during a year and a group health plan or group
13 health insurance coverage offered by a health
14 insurance issuer—

15 “(i) subject to clause (iii), in the case
16 of such item or service furnished in a State
17 that has in effect a specified State law
18 with respect to such plan, coverage, or
19 issuer, respectively; such a nonparticipating
20 provider or nonparticipating emergency
21 facility; and such an item or service,
22 the amount determined in accordance with
23 such law;

24 “(ii) subject to clause (iii), in the case
25 of such item or service furnished in a State

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1 that does not have in effect a specified
2 State law, with respect to such plan, cov-
3 erage, or issuer, respectively; such a non-
4 participating provider or nonparticipating
5 emergency facility; and such an item or
6 service, the amount that is the qualifying
7 payment amount (as defined in subpara-
8 graph (E)) for such year and determined
9 in accordance with rulemaking described in
10 paragraph (2)) for such item or service; or

11 “(iii) in the case of such item or serv-
12 ice furnished in a State with an All-Payer
13 Model Agreement under section 1115A of
14 the Social Security Act, the amount that
15 the State approves under such system for
16 such item or service so furnished.

17 “(I) SPECIFIED STATE LAW.—The term
18 ‘specified State law’ means, with respect to a
19 State, an item or service furnished by a non-
20 participating provider or nonparticipating emer-
21 gency facility during a year and a group health
22 plan or group health insurance coverage offered
23 by a health insurance issuer, a State law that
24 provides for a method for determining the total
25 amount payable under such a plan, coverage, or

1 issuer, respectively (to the extent such State
2 law applies to such plan, coverage, or issuer,
3 subject to section 514) in the case of a partici-
4 pant or beneficiary covered under such plan or
5 coverage and receiving such item or service
6 from such a nonparticipating provider or non-
7 participating emergency facility.

8 “(J) STABILIZE.—The term ‘to stabilize’,
9 with respect to an emergency medical condition
10 (as defined in subparagraph (B)), has the
11 meaning give in section 1867(e)(3) of the Social
12 Security Act (42 U.S.C. 1395dd(e)(3)).

13 “(K) OUT-OF-NETWORK RATE.—The term
14 ‘out-of-network rate’ means, with respect to an
15 item or service furnished in a State during a
16 year to a participant or beneficiary of a group
17 health plan or group health insurance coverage
18 offered by a health insurance issuer receiving
19 such item or service from a nonparticipating
20 provider or nonparticipating emergency facil-
21 ity—

22 “(i) subject to clause (iii), in the case
23 of such item or service furnished in a State
24 that has in effect a specified State law
25 with respect to such plan, coverage, or

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1 issuer, respectively; such a nonpartici-
2 pating provider or nonparticipating emer-
3 gency facility; and such an item or service,
4 the amount determined in accordance with
5 such law;

6 “(ii) subject to clause (iii), in the case
7 such State does not have in effect such a
8 law with respect to such item or service,
9 plan, and provider or facility—

10 “(I) subject to subclause (II), if
11 the provider or facility (as applicable)
12 and such plan or coverage agree on an
13 amount of payment (including if such
14 agreed on amount is the initial pay-
15 ment sent by the plan under sub-
16 section (a)(1)(C)(iv)(I), subsection
17 (b)(1)(C), or section 717(a)(3)(A), as
18 applicable, or is agreed on through
19 open negotiations under subsection
20 (c)(1)) with respect to such item or
21 service, such agreed on amount; or

22 “(II) if such provider or facility
23 (as applicable) and such plan or cov-
24 erage enter the independent dispute
25 resolution process under subsection

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1 (c) and do not so agree before the
2 date on which a certified IDR entity
3 (as defined in paragraph (4) of such
4 subsection) makes a determination
5 with respect to such item or service
6 under such subsection, the amount of
7 such determination; or

8 “(iii) in the case such State has an
9 All-Payer Model Agreement under section
10 1115A of the Social Security Act, the
11 amount that the State approves under
12 such system for such item or service so
13 furnished.

14 “(L) COST-SHARING.—The term ‘cost-
15 sharing’ includes copayments, coinsurance, and
16 deductibles.

17 “(b) COVERAGE OF NON-EMERGENCY SERVICES
18 PERFORMED BY NONPARTICIPATING PROVIDERS AT CER-
19 TAIN PARTICIPATING FACILITIES.—

20 “(1) IN GENERAL.—In the case of items or
21 services (other than emergency services to which
22 subsection (a) applies) for which any benefits are
23 provided or covered by a group health plan or health
24 insurance issuer offering group health insurance cov-
25 erage furnished to a participant or beneficiary of

1 such plan or coverage by a nonparticipating provider
2 (as defined in subsection (a)(3)(G)(i)) (and who,
3 with respect to such items and services, has not sat-
4 isfied the notice and consent criteria of section
5 2799B–2(d) of the Public Health Service Act) with
6 respect to a visit (as defined by the Secretary in ac-
7 cordance with paragraph (2)(B)) at a participating
8 health care facility (as defined in paragraph (2)(A)),
9 with respect to such plan or coverage, respectively,
10 the plan or coverage, respectively—

11 “(A) shall not impose on such participant
12 or beneficiary a cost-sharing requirement for
13 such items and services so furnished that is
14 greater than the cost-sharing requirement that
15 would apply under such plan or coverage, re-
16 spectively, had such items or services been fur-
17 nished by a participating provider (as defined in
18 subsection (a)(3)(G)(ii));

19 “(B) shall calculate such cost-sharing re-
20 quirement as if the total amount that would
21 have been charged for such items and services
22 by such participating provider were equal to the
23 recognized amount (as defined in subsection
24 (a)(3)(H)) for such items and services, plan or
25 coverage, and year;

1 “(C) not later than 30 calendar days after
2 the bill for such items or services is transmitted
3 by such provider, shall send to the provider an
4 initial payment or notice of denial of payment;

5 “(D) shall pay a total plan or coverage
6 payment directly, in accordance, if applicable,
7 with the timing requirement described in sub-
8 section (c)(6), to such provider furnishing such
9 items and services to such participant or bene-
10 ficiary that is, with application of any initial
11 payment under subparagraph (C), equal to the
12 amount by which the out-of-network rate (as
13 defined in subsection (a)(3)(K)) for such items
14 and services exceeds the cost-sharing amount
15 imposed under the plan or coverage, respec-
16 tively, for such items and services (as deter-
17 mined in accordance with subparagraphs (A)
18 and (B)) and year; and

19 “(E) shall count toward any in-network de-
20 ductible and in-network out-of-pocket maxi-
21 mums (as applicable) applied under the plan or
22 coverage, respectively, any cost-sharing pay-
23 ments made by the participant or beneficiary
24 (and such in-network deductible and out-of-
25 pocket maximums shall be applied) with respect

1 to such items and services so furnished in the
2 same manner as if such cost-sharing payments
3 were with respect to items and services fur-
4 nished by a participating provider.

5 “(2) DEFINITIONS.—In this section:

6 “(A) PARTICIPATING HEALTH CARE FACIL-
7 ITY.—

8 “(i) IN GENERAL.—The term ‘partici-
9 pating health care facility’ means, with re-
10 spect to an item or service and a group
11 health plan or health insurance issuer of-
12 fering group health insurance coverage, a
13 health care facility described in clause (ii)
14 that has a direct or indirect contractual re-
15 lationship with the plan or issuer, respec-
16 tively, with respect to the furnishing of
17 such an item or service at the facility.

18 “(ii) HEALTH CARE FACILITY DE-
19 SCRIBED.—A health care facility described
20 in this clause, with respect to a group
21 health plan or group health insurance cov-
22 erage, is each of the following:

23 “(I) A hospital (as defined in
24 1861(e) of the Social Security Act).

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1 “(II) A hospital outpatient de-
2 partment.

3 “(III) A critical access hospital
4 (as defined in section 1861(mm)(1) of
5 such Act).

6 “(IV) An ambulatory surgical
7 center described in section
8 1833(i)(1)(A) of such Act.

9 “(V) Any other facility, specified
10 by the Secretary, that provides items
11 or services for which coverage is pro-
12 vided under the plan or coverage, re-
13 spectively.

14 “(B) VISIT.—The term ‘visit’ shall, with
15 respect to items and services furnished to an in-
16 dividual at a health care facility, include equip-
17 ment and devices, telemedicine services, imag-
18 ing services, laboratory services, preoperative
19 and postoperative services, and such other items
20 and services as the Secretary may specify, re-
21 gardless of whether or not the provider fur-
22 nishing such items or services is at the facility.

23 “(c) CERTAIN ACCESS FEES TO CERTAIN DATA-
24 BASES.—In the case of a sponsor of a group health plan
25 or health insurance issuer offering group health insurance

1 coverage that, pursuant to subsection (a)(3)(E)(iii), uses
2 a database described in such subsection to determine a
3 rate to apply under such subsection for an item or service
4 by reason of having insufficient information described in
5 such subsection with respect to such item or service, such
6 sponsor or issuer shall cover the cost for access to such
7 database.”.

8 (2) TRANSFER AMENDMENT.—Subpart B of
9 part 7 of title I of the Employee Retirement Income
10 Security Act of 1974 (29 U.S.C. 1185 et seq.), as
11 amended by paragraph (1), is further amended by
12 adding at the end the following:

13 **“SEC. 722. OTHER PATIENT PROTECTIONS.**

14 “(a) CHOICE OF HEALTH CARE PROFESSIONAL.—If
15 a group health plan, or a health insurance issuer offering
16 group health insurance coverage, requires or provides for
17 designation by a participant or beneficiary of a partici-
18 pating primary care provider, then the plan or issuer shall
19 permit each participant and beneficiary to designate any
20 participating primary care provider who is available to ac-
21 cept such individual.

22 “(b) ACCESS TO PEDIATRIC CARE.—

23 “(1) PEDIATRIC CARE.—In the case of a person
24 who has a child who is a participant or beneficiary
25 under a group health plan, or group health insur-

1 ance coverage offered by a health insurance issuer,
2 if the plan or issuer requires or provides for the des-
3 ignation of a participating primary care provider for
4 the child, the plan or issuer shall permit such person
5 to designate a physician (allopathic or osteopathic)
6 who specializes in pediatrics as the child’s primary
7 care provider if such provider participates in the net-
8 work of the plan or issuer.

9 “(2) CONSTRUCTION.—Nothing in paragraph
10 (1) shall be construed to waive any exclusions of cov-
11 erage under the terms and conditions of the plan or
12 health insurance coverage with respect to coverage
13 of pediatric care.

14 “(c) PATIENT ACCESS TO OBSTETRICAL AND GYNE-
15 COLOGICAL CARE.—

16 “(1) GENERAL RIGHTS.—

17 “(A) DIRECT ACCESS.—A group health
18 plan, or health insurance issuer offering group
19 health insurance coverage, described in para-
20 graph (2) may not require authorization or re-
21 ferral by the plan, issuer, or any person (includ-
22 ing a primary care provider described in para-
23 graph (2)(B)) in the case of a female partici-
24 pant or beneficiary who seeks coverage for ob-
25 stetrical or gynecological care provided by a

1 participating health care professional who spe-
2 cializes in obstetrics or gynecology. Such profes-
3 sional shall agree to otherwise adhere to such
4 plan's or issuer's policies and procedures, in-
5 cluding procedures regarding referrals and ob-
6 taining prior authorization and providing serv-
7 ices pursuant to a treatment plan (if any) ap-
8 proved by the plan or issuer.

9 “(B) OBSTETRICAL AND GYNECOLOGICAL
10 CARE.—A group health plan or health insur-
11 ance issuer described in paragraph (2) shall
12 treat the provision of obstetrical and gynecolo-
13 gical care, and the ordering of related obstet-
14 rical and gynecological items and services, pur-
15 suant to the direct access described under sub-
16 paragraph (A), by a participating health care
17 professional who specializes in obstetrics or
18 gynecology as the authorization of the primary
19 care provider.

20 “(2) APPLICATION OF PARAGRAPH.—A group
21 health plan, or health insurance issuer offering
22 group health insurance coverage, described in this
23 paragraph is a group health plan or coverage that—

24 “(A) provides coverage for obstetric or
25 gynecologic care; and

1 “(B) requires the designation by a partici-
2 pant or beneficiary of a participating primary
3 care provider.

4 “(3) CONSTRUCTION.—Nothing in paragraph
5 (1) shall be construed to—

6 “(A) waive any exclusions of coverage
7 under the terms and conditions of the plan or
8 health insurance coverage with respect to cov-
9 erage of obstetrical or gynecological care; or

10 “(B) preclude the group health plan or
11 health insurance issuer involved from requiring
12 that the obstetrical or gynecological provider
13 notify the primary care health care professional
14 or the plan or issuer of treatment decisions.”.

15 (3) CLERICAL AMENDMENT.—The table of con-
16 tents of the Employee Retirement Income Security
17 Act of 1974 is amended by inserting after the item
18 relating to section 714 the following:

“Sec. 715. Additional market reforms.

“Sec. 716. Preventing surprise medical bills.

“Sec. 722. Other patient protections.”.

19 (c) IRC AMENDMENTS.—

20 (1) IN GENERAL.—Subchapter B of chapter
21 100 of the Internal Revenue Code of 1986 is amend-
22 ed by adding at the end the following:

23 **“SEC. 9816. PREVENTING SURPRISE MEDICAL BILLS.**

24 “(a) COVERAGE OF EMERGENCY SERVICES.—

1 “(1) IN GENERAL.—If a group health plan pro-
2 vides or covers any benefits with respect to services
3 in an emergency department of a hospital or with re-
4 spect to emergency services in an independent free-
5 standing emergency department (as defined in para-
6 graph (3)(D)), the plan shall cover emergency serv-
7 ices (as defined in paragraph (3)(C))—

8 “(A) without the need for any prior au-
9 thorization determination;

10 “(B) whether the health care provider fur-
11 nishing such services is a participating provider
12 or a participating emergency facility, as appli-
13 cable, with respect to such services;

14 “(C) in a manner so that, if such services
15 are provided to a participant or beneficiary by
16 a nonparticipating provider or a nonpartici-
17 pating emergency facility—

18 “(i) such services will be provided
19 without imposing any requirement under
20 the plan for prior authorization of services
21 or any limitation on coverage that is more
22 restrictive than the requirements or limita-
23 tions that apply to emergency services re-
24 ceived from participating providers and

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1 participating emergency facilities with re-
2 spect to such plan;

3 “(ii) the cost-sharing requirement is
4 not greater than the requirement that
5 would apply if such services were provided
6 by a participating provider or a partici-
7 pating emergency facility;

8 “(iii) such cost-sharing requirement is
9 calculated as if the total amount that
10 would have been charged for such services
11 by such participating provider or partici-
12 pating emergency facility were equal to the
13 recognized amount (as defined in para-
14 graph (3)(H)) for such services, plan, and
15 year;

16 “(iv) the group health plan—

17 “(I) not later than 30 calendar
18 days after the bill for such services is
19 transmitted by such provider or facil-
20 ity, sends to the provider or facility,
21 as applicable, an initial payment or
22 notice of denial of payment; and

23 “(II) pays a total plan payment
24 directly to such provider or facility,
25 respectively (in accordance, if applica-

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1 ble, with the timing requirement de-
2 scribed in subsection (c)(6)) that is,
3 with application of any initial pay-
4 ment under subclause (I), equal to the
5 amount by which the out-of-network
6 rate (as defined in paragraph (3)(K))
7 for such services exceeds the cost-
8 sharing amount for such services (as
9 determined in accordance with clauses
10 (ii) and (iii)) and year; and

11 “(iv) any cost-sharing payments made
12 by the participant or beneficiary with re-
13 spect to such emergency services so fur-
14 nished shall be counted toward any in-net-
15 work deductible or out-of-pocket maxi-
16 mums applied under the plan (and such in-
17 network deductible and out-of-pocket maxi-
18 mums shall be applied) in the same man-
19 ner as if such cost-sharing payments were
20 made with respect to emergency services
21 furnished by a participating provider or a
22 participating emergency facility; and

23 “(D) without regard to any other term or
24 condition of such coverage (other than exclusion
25 or coordination of benefits, or an affiliation or

1 waiting period, permitted under section 2704 of
2 the Public Health Service Act, including as in-
3 corporated pursuant to section 715 of the Em-
4 ployee Retirement Income Security Act of 1974
5 and section 9815 of this Act, and other than
6 applicable cost-sharing).

7 “(2) AUDIT PROCESS AND REGULATIONS FOR
8 QUALIFYING PAYMENT AMOUNTS.—

9 “(A) AUDIT PROCESS.—

10 “(i) IN GENERAL.—Not later than Oc-
11 tober 1, 2021, the Secretary, in consulta-
12 tion with the Secretary of Health and
13 Human Services and the Secretary of
14 Labor, shall establish through rulemaking
15 a process, in accordance with clause (ii),
16 under which group health plans are au-
17 dited by the Secretary or applicable State
18 authority to ensure that—

19 “(I) such plans are in compliance
20 with the requirement of applying a
21 qualifying payment amount under this
22 section; and

23 “(II) such qualifying payment
24 amount so applied satisfies the defini-
25 tion under paragraph (3)(E) with re-

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1 spect to the year involved, including
2 with respect to a group health plan
3 described in clause (ii) of such para-
4 graph (3)(E).

5 “(ii) AUDIT SAMPLES.—Under the
6 process established pursuant to clause (i),
7 the Secretary—

8 “(I) shall conduct audits de-
9 scribed in such clause, with respect to
10 a year (beginning with 2022), of a
11 sample with respect to such year of
12 claims data from not more than 25
13 group health plans; and

14 “(II) may audit any group health
15 plan if the Secretary has received any
16 complaint or other information about
17 such plan or coverage, respectively,
18 that involves the compliance of the
19 plan with either of the requirements
20 described in subclauses (I) and (II) of
21 such clause.

22 “(iii) REPORTS.—Beginning for 2022,
23 the Secretary shall annually submit to
24 Congress a report on the number of plans
25 and issuers with respect to which audits

1 were conducted during such year pursuant
2 to this subparagraph.

3 “(B) RULEMAKING.—Not later than July
4 1, 2021, the Secretary, in consultation with the
5 Secretary of Labor and the Secretary of Health
6 and Human Services, shall establish through
7 rulemaking—

8 “(i) the methodology the group health
9 plan shall use to determine the qualifying
10 payment amount, differentiating by large
11 group market and small group market;

12 “(ii) the information such plan or
13 issuer, respectively, shall share with the
14 nonparticipating provider or nonpartici-
15 pating facility, as applicable, when making
16 such a determination;

17 “(iii) the geographic regions applied
18 for purposes of this subparagraph, taking
19 into account access to items and services in
20 rural and underserved areas, including
21 health professional shortage areas, as de-
22 fined in section 332 of the Public Health
23 Service Act; and

24 “(iv) a process to receive complaints
25 of violations of the requirements described

1 in subclauses (I) and (II) of subparagraph
2 (A)(i) by group health plans.

3 Such rulemaking shall take into account pay-
4 ments that are made by such plan that are not
5 on a fee-for-service basis. Such methodology
6 may account for relevant payment adjustments
7 that take into account quality or facility type
8 (including higher acuity settings and the case-
9 mix of various facility types) that are otherwise
10 taken into account for purposes of determining
11 payment amounts with respect to participating
12 facilities. In carrying out clause (iii), the Sec-
13 retary shall consult with the National Associa-
14 tion of Insurance Commissioners to establish
15 the geographic regions under such clause and
16 shall periodically update such regions, as appro-
17 priate, taking into account the findings of the
18 report submitted under section 109(a) of the
19 No Surprises Act.

20 “(3) DEFINITIONS.—In this subchapter:

21 “(A) EMERGENCY DEPARTMENT OF A HOS-
22 PITAL.—The term ‘emergency department of a
23 hospital’ includes a hospital outpatient depart-
24 ment that provides emergency services (as de-
25 fined in subparagraph (C)(i)).

1 “(B) EMERGENCY MEDICAL CONDITION.—
2 The term ‘emergency medical condition’ means
3 a medical condition manifesting itself by acute
4 symptoms of sufficient severity (including se-
5 vere pain) such that a prudent layperson, who
6 possesses an average knowledge of health and
7 medicine, could reasonably expect the absence
8 of immediate medical attention to result in a
9 condition described in clause (i), (ii), or (iii) of
10 section 1867(e)(1)(A) of the Social Security
11 Act.

12 “(C) EMERGENCY SERVICES.—

13 “(i) IN GENERAL.—The term ‘emer-
14 gency services’, with respect to an emer-
15 gency medical condition, means—

16 “(I) a medical screening exam-
17 ination (as required under section
18 1867 of the Social Security Act, or as
19 would be required under such section
20 if such section applied to an inde-
21 pendent freestanding emergency de-
22 partment) that is within the capability
23 of the emergency department of a hos-
24 pital or of an independent free-
25 standing emergency department, as

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1 applicable, including ancillary services
2 routinely available to the emergency
3 department to evaluate such emer-
4 gency medical condition; and

5 “(II) within the capabilities of
6 the staff and facilities available at the
7 hospital or the independent free-
8 standing emergency department, as
9 applicable, such further medical exam-
10 ination and treatment as are required
11 under section 1867 of such Act, or as
12 would be required under such section
13 if such section applied to an inde-
14 pendent freestanding emergency de-
15 partment, to stabilize the patient (re-
16 gardless of the department of the hos-
17 pital in which such further examina-
18 tion or treatment is furnished).

19 “(ii) INCLUSION OF ADDITIONAL
20 SERVICES.—

21 “(I) IN GENERAL.—For purposes
22 of this subsection and section 2799B-
23 1 of the Public Health Service Act, in
24 the case of a participant or bene-
25 ficiary who is enrolled in a group

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1 health plan and who is furnished serv-
2 ices described in clause (i) with re-
3 spect to an emergency medical condi-
4 tion, the term ‘emergency services’
5 shall include, unless each of the condi-
6 tions described in subclause (II) are
7 met, in addition to the items and serv-
8 ices described in clause (i), items and
9 services—

10 “(aa) for which benefits are
11 provided or covered under the
12 plan; and

13 “(bb) that are furnished by
14 a nonparticipating provider or
15 nonparticipating emergency facil-
16 ity (regardless of the department
17 of the hospital in which such
18 items or services are furnished)
19 after the participant or bene-
20 ficiary is stabilized and as part of
21 outpatient observation or an in-
22 patient or outpatient stay with
23 respect to the visit in which the
24 services described in clause (i)
25 are furnished.

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1 “(II) CONDITIONS.—For pur-
2 poses of subclause (I), the conditions
3 described in this subclause, with re-
4 spect to a participant or beneficiary
5 who is stabilized and furnished addi-
6 tional items and services described in
7 subclause (I) after such stabilization
8 by a provider or facility described in
9 subclause (I), are the following;

10 “(aa) Such provider or facil-
11 ity determines such individual is
12 able to travel using nonmedical
13 transportation or nonemergency
14 medical transportation.

15 “(bb) Such provider fur-
16 nishing such additional items and
17 services satisfies the notice and
18 consent criteria of section
19 2799B–2(d) with respect to such
20 items and services.

21 “(cc) Such individual is in a
22 condition to receive (as deter-
23 mined in accordance with guide-
24 lines issued by the Secretary pur-
25 suant to rulemaking) the infor-

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1 mation described in section
2 2799B-2 and to provide in-
3 formed consent under such sec-
4 tion, in accordance with applica-
5 ble State law.

6 “(dd) Such other conditions,
7 as specified by the Secretary,
8 such as conditions relating to co-
9 ordinating care transitions to
10 participating providers and facili-
11 ties.

12 “(D) INDEPENDENT FREESTANDING
13 EMERGENCY DEPARTMENT.—The term ‘inde-
14 pendent freestanding emergency department’
15 means a health care facility that—

16 “(i) is geographically separate and
17 distinct and licensed separately from a hos-
18 pital under applicable State law; and

19 “(ii) provides any of the emergency
20 services (as defined in subparagraph
21 (C)(i)).

22 “(E) QUALIFYING PAYMENT AMOUNT.—

23 “(i) IN GENERAL.—The term ‘quali-
24 fying payment amount’ means, subject to

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1 clauses (ii) and (iii), with respect to a
2 sponsor of a group health plan—

3 “(I) for an item or service fur-
4 nished during 2022, the median of the
5 contracted rates recognized by the
6 plan (determined with respect to all
7 such plans of such sponsor that are
8 offered within the same insurance
9 market (specified in subclause (I),
10 (II), or (III) of clause (iv)) as the
11 plan) as the total maximum payment
12 (including the cost-sharing amount
13 imposed for such item or service and
14 the amount to be paid by the plan)
15 under such plans on January 31,
16 2019 for the same or a similar item
17 or service that is provided by a pro-
18 vider in the same or similar specialty
19 and provided in the geographic region
20 in which the item or service is fur-
21 nished, consistent with the method-
22 ology established by the Secretary
23 under paragraph (2)(B), increased by
24 the percentage increase in the con-
25 sumer price index for all urban con-

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1 consumers (United States city average)
2 over 2019, such percentage increase
3 over 2020, and such percentage in-
4 crease over 2021; and

5 “(II) for an item or service fur-
6 nished during 2023 or a subsequent
7 year, the qualifying payment amount
8 determined under this clause for such
9 an item or service furnished in the
10 previous year, increased by the per-
11 centage increase in the consumer price
12 index for all urban consumers (United
13 States city average) over such pre-
14 vious year.

15 “(ii) NEW PLANS AND COVERAGE.—
16 The term ‘qualifying payment amount’
17 means, with respect to a sponsor of a
18 group health plan in a geographic region in
19 which such sponsor, respectively, did not
20 offer any group health plan or health in-
21 surance coverage during 2019—

22 “(I) for the first year in which
23 such group health plan is offered in
24 such region, a rate (determined in ac-
25 cordance with a methodology estab-

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1 lished by the Secretary) for items and
2 services that are covered by such plan
3 and furnished during such first year;
4 and

5 “(II) for each subsequent year
6 such group health plan is offered in
7 such region, the qualifying payment
8 amount determined under this clause
9 for such items and services furnished
10 in the previous year, increased by the
11 percentage increase in the consumer
12 price index for all urban consumers
13 (United States city average) over such
14 previous year.

15 “(iii) INSUFFICIENT INFORMATION;
16 NEWLY COVERED ITEMS AND SERVICES.—
17 In the case of a sponsor of a group health
18 plan that does not have sufficient informa-
19 tion to calculate the median of the con-
20 tracted rates described in clause (i)(I) in
21 2019 (or, in the case of a newly covered
22 item or service (as defined in clause
23 (v)(III)), in the first coverage year (as de-
24 fined in clause (v)(I)) for such item or
25 service with respect to such plan) for an

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1 item or service (including with respect to
2 provider type, or amount, of claims for
3 items or services (as determined by the
4 Secretary) provided in a particular geo-
5 graphic region (other than in a case with
6 respect to which clause (ii) applies)) the
7 term ‘qualifying payment amount’—

8 “(I) for an item or service fur-
9 nished during 2022 (or, in the case of
10 a newly covered item or service, dur-
11 ing the first coverage year for such
12 item or service with respect to such
13 plan), means such rate for such item
14 or service determined by the sponsor
15 through use of any database that is
16 determined, in accordance with rule-
17 making described in paragraph
18 (2)(B), to not have any conflicts of in-
19 terest and to have sufficient informa-
20 tion reflecting allowed amounts paid
21 to a health care provider or facility for
22 relevant services furnished in the ap-
23 plicable geographic region (such as a
24 State all-payer claims database);

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1 “(II) for an item or service fur-
2 nished in a subsequent year (before
3 the first sufficient information year
4 (as defined in clause (v)(II)) for such
5 item or service with respect to such
6 plan), means the rate determined
7 under subclause (I) or this subclause,
8 as applicable, for such item or service
9 for the year previous to such subse-
10 quent year, increased by the percent-
11 age increase in the consumer price
12 index for all urban consumers (United
13 States city average) over such pre-
14 vious year;

15 “(III) for an item or service fur-
16 nished in the first sufficient informa-
17 tion year for such item or service with
18 respect to such plan, has the meaning
19 given the term qualifying payment
20 amount in clause (i)(I), except that in
21 applying such clause to such item or
22 service, the reference to ‘furnished
23 during 2022’ shall be treated as a ref-
24 erence to furnished during such first
25 sufficient information year, the ref-

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1 erence to ‘on January 31, 2019’ shall
2 be treated as a reference to in such
3 sufficient information year, and the
4 increase described in such clause shall
5 not be applied; and

6 “(IV) for an item or service fur-
7 nished in any year subsequent to the
8 first sufficient information year for
9 such item or service with respect to
10 such plan, has the meaning given such
11 term in clause (i)(II), except that in
12 applying such clause to such item or
13 service, the reference to ‘furnished
14 during 2023 or a subsequent year’
15 shall be treated as a reference to fur-
16 nished during the year after such first
17 sufficient information year or a subse-
18 quent year.

19 “(iv) INSURANCE MARKET.—For pur-
20 poses of clause (i)(I), a health insurance
21 market specified in this clause is one of the
22 following:

23 “(I) The large group market
24 (other than plans described in sub-
25 clause (III)).

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1 “(II) The small group market
2 (other than plans described in sub-
3 clause (III)).

4 “(III) In the case of a self-in-
5 sured group health plan, other self-in-
6 sured group health plans.

7 “(v) DEFINITIONS.—For purposes of
8 this subparagraph:

9 “(I) FIRST COVERAGE YEAR.—
10 The term ‘first coverage year’ means,
11 with respect to a group health plan
12 and an item or service for which cov-
13 erage is not offered in 2019 under
14 such plan or coverage, the first year
15 after 2019 for which coverage for
16 such item or service is offered under
17 such plan.

18 “(II) FIRST SUFFICIENT INFOR-
19 MATION YEAR.—The term ‘first suffi-
20 cient information year’ means, with
21 respect to a group health plan—

22 “(aa) in the case of an item
23 or service for which the plan does
24 not have sufficient information to
25 calculate the median of the con-

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1 tracted rates described in clause
2 (i)(I) in 2019, the first year sub-
3 sequent to 2022 for which such
4 sponsor has such sufficient infor-
5 mation to calculate the median of
6 such contracted rates in the year
7 previous to such first subsequent
8 year; and

9 “(bb) in the case of a newly
10 covered item or service, the first
11 year subsequent to the first cov-
12 erage year for such item or serv-
13 ice with respect to such plan for
14 which the sponsor has sufficient
15 information to calculate the me-
16 dian of the contracted rates de-
17 scribed in clause (i)(I) in the
18 year previous to such first subse-
19 quent year.

20 “(III) NEWLY COVERED ITEM OR
21 SERVICE.—The term ‘newly covered
22 item or service’ means, with respect to
23 a group health plan, an item or serv-
24 ice for which coverage was not offered
25 in 2019 under such plan or coverage,

1 but is offered under such plan or cov-
2 erage in a year after 2019.

3 “(F) NONPARTICIPATING EMERGENCY FA-
4 CILITY; PARTICIPATING EMERGENCY FACIL-
5 ITY.—

6 “(i) NONPARTICIPATING EMERGENCY
7 FACILITY.—The term ‘nonparticipating
8 emergency facility’ means, with respect to
9 an item or service and a group health plan,
10 an emergency department of a hospital, or
11 an independent freestanding emergency de-
12 partment, that does not have a contractual
13 relationship directly or indirectly with the
14 plan for furnishing such item or service
15 under the plan.

16 “(ii) PARTICIPATING EMERGENCY FA-
17 CILITY.—The term ‘participating emer-
18 gency facility’ means, with respect to an
19 item or service and a group health plan, an
20 emergency department of a hospital, or an
21 independent freestanding emergency de-
22 partment, that has a contractual relation-
23 ship directly or indirectly with the plan,
24 with respect to the furnishing of such an
25 item or service at such facility.

1 “(G) NONPARTICIPATING PROVIDERS; PAR-
2 TICIPATING PROVIDERS.—

3 “(i) NONPARTICIPATING PROVIDER.—

4 The term ‘nonparticipating provider’
5 means, with respect to an item or service
6 and a group health plan, a physician or
7 other health care provider who is acting
8 within the scope of practice of that pro-
9 vider’s license or certification under appli-
10 cable State law and who does not have a
11 contractual relationship with the plan or
12 issuer, respectively, for furnishing such
13 item or service under the plan.

14 “(ii) PARTICIPATING PROVIDER.—The
15 term ‘participating provider’ means, with
16 respect to an item or service and a group
17 health plan, a physician or other health
18 care provider who is acting within the
19 scope of practice of that provider’s license
20 or certification under applicable State law
21 and who has a contractual relationship
22 with the plan for furnishing such item or
23 service under the plan.

24 “(H) RECOGNIZED AMOUNT.—The term
25 ‘recognized amount’ means, with respect to an

1 item or service furnished by a nonparticipating
2 provider or nonparticipating emergency facility
3 during a year and a group health plan—

4 “(i) subject to clause (iii), in the case
5 of such item or service furnished in a State
6 that has in effect a specified State law
7 with respect to such plan; such a non-
8 participating provider or nonparticipating
9 emergency facility; and such an item or
10 service, the amount determined in accord-
11 ance with such law;

12 “(ii) subject to clause (iii), in the case
13 of such item or service furnished in a State
14 that does not have in effect a specified
15 State law, with respect to such plan; such
16 a nonparticipating provider or nonpartici-
17 pating emergency facility; and such an
18 item or service, the amount that is the
19 qualifying payment amount (as defined in
20 subparagraph (E)) for such year and de-
21 termined in accordance with rulemaking
22 described in paragraph (2)(B)) for such
23 item or service; or

24 “(iii) in the case of such item or serv-
25 ice furnished in a State with an All-Payer

1 Model Agreement under section 1115A of
2 the Social Security Act, the amount that
3 the State approves under such system for
4 such item or service so furnished.

5 “(I) SPECIFIED STATE LAW.—The term
6 ‘specified State law’ means, with respect to a
7 State, an item or service furnished by a non-
8 participating provider or nonparticipating emer-
9 gency facility during a year and a group health
10 plan, a State law that provides for a method for
11 determining the total amount payable under
12 such a plan (to the extent such State law ap-
13 plies to such plan, subject to section 514) in the
14 case of a participant or beneficiary covered
15 under such plan and receiving such item or
16 service from such a nonparticipating provider or
17 nonparticipating emergency facility.

18 “(J) STABILIZE.—The term ‘to stabilize’,
19 with respect to an emergency medical condition
20 (as defined in subparagraph (B)), has the
21 meaning give in section 1867(e)(3) of the Social
22 Security Act (42 U.S.C. 1395dd(e)(3)).

23 “(K) OUT-OF-NETWORK RATE.—The term
24 ‘out-of-network rate’ means, with respect to an
25 item or service furnished in a State during a

1 year to a participant or beneficiary of a group
2 health plan receiving such item or service from
3 a nonparticipating provider or nonparticipating
4 emergency facility—

5 “(i) subject to clause (iii), in the case
6 of such item or service furnished in a State
7 that has in effect a specified State law
8 with respect to such plan; such a non-
9 participating provider or nonparticipating
10 emergency facility; and such an item or
11 service, the amount determined in accord-
12 ance with such law;

13 “(ii) subject to clause (iii), in the case
14 such State does not have in effect such a
15 law with respect to such item or service,
16 plan, and provider or facility—

17 “(I) subject to subclause (II), if
18 the provider or facility (as applicable)
19 and such plan or coverage agree on an
20 amount of payment (including if such
21 agreed on amount is the initial pay-
22 ment sent by the plan under sub-
23 section (a)(1)(C)(iv)(I), subsection
24 (b)(1)(C), or section 9817(a)(3)(A),
25 as applicable, or is agreed on through

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1 open negotiations under subsection
2 (c)(1)) with respect to such item or
3 service, such agreed on amount; or

4 “(II) if such provider or facility
5 (as applicable) and such plan or cov-
6 erage enter the independent dispute
7 resolution process under subsection
8 (c) and do not so agree before the
9 date on which a certified IDR entity
10 (as defined in paragraph (4) of such
11 subsection) makes a determination
12 with respect to such item or service
13 under such subsection, the amount of
14 such determination; or

15 “(iii) in the case such State has an
16 All-Payer Model Agreement under section
17 1115A of the Social Security Act, the
18 amount that the State approves under
19 such system for such item or service so
20 furnished.

21 “(L) COST-SHARING.—The term ‘cost-
22 sharing’ includes copayments, coinsurance, and
23 deductibles.

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1 “(b) COVERAGE OF NON-EMERGENCY SERVICES
2 PERFORMED BY NONPARTICIPATING PROVIDERS AT CER-
3 TAIN PARTICIPATING FACILITIES.—

4 “(1) IN GENERAL.—In the case of items or
5 services (other than emergency services to which
6 subsection (a) applies) for which any benefits are
7 provided or covered by a group health plan furnished
8 to a participant or beneficiary of such plan by a
9 nonparticipating provider (as defined in subsection
10 (a)(3)(G)(i)) (and who, with respect to such items
11 and services, has not satisfied the notice and consent
12 criteria of section 2799B–2(d) of the Public Health
13 Service Act) with respect to a visit (as defined by
14 the Secretary in accordance with paragraph (2)(B))
15 at a participating health care facility (as defined in
16 paragraph (2)(A)), with respect to such plan, the
17 plan—

18 “(A) shall not impose on such participant
19 or beneficiary a cost-sharing requirement for
20 such items and services so furnished that is
21 greater than the cost-sharing requirement that
22 would apply under such plan had such items or
23 services been furnished by a participating pro-
24 vider (as defined in subsection (a)(3)(G)(ii));

1 “(B) shall calculate such cost-sharing re-
2 quirement as if the total amount that would
3 have been charged for such items and services
4 by such participating provider were equal to the
5 recognized amount (as defined in subsection
6 (a)(3)(H)) for such items and services, plan,
7 and year;

8 “(C) not later than 30 calendar days after
9 the bill for such items or services is transmitted
10 by such provider, shall send to the provider an
11 initial payment or notice of denial of payment;

12 “(D) shall pay a total plan payment di-
13 rectly, in accordance, if applicable, with the
14 timing requirement described in subsection
15 (c)(6), to such provider furnishing such items
16 and services to such participant or beneficiary
17 that is, with application of any initial payment
18 under subparagraph (C), equal to the amount
19 by which the out-of-network rate (as defined in
20 subsection (a)(3)(K)) for such items and serv-
21 ices exceeds the cost-sharing amount imposed
22 under the plan for such items and services (as
23 determined in accordance with subparagraphs
24 (A) and (B)) and year; and

1 “(E) shall count toward any in-network de-
2 ductible and in-network out-of-pocket maxi-
3 mums (as applicable) applied under the plan,
4 any cost-sharing payments made by the partici-
5 pant or beneficiary (and such in-network de-
6 ductible and out-of-pocket maximums shall be
7 applied) with respect to such items and services
8 so furnished in the same manner as if such
9 cost-sharing payments were with respect to
10 items and services furnished by a participating
11 provider.

12 “(2) DEFINITIONS.—In this section:

13 “(A) PARTICIPATING HEALTH CARE FACIL-
14 ITY.—

15 “(i) IN GENERAL.—The term ‘partici-
16 pating health care facility’ means, with re-
17 spect to an item or service and a group
18 health plan, a health care facility described
19 in clause (ii) that has a direct or indirect
20 contractual relationship with the plan, with
21 respect to the furnishing of such an item
22 or service at the facility.

23 “(ii) HEALTH CARE FACILITY DE-
24 SCRIBED.—A health care facility described
25 in this clause, with respect to a group

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1 health plan or health insurance coverage
2 offered in the group or individual market,
3 is each of the following:

4 “(I) A hospital (as defined in
5 1861(e) of the Social Security Act).

6 “(II) A hospital outpatient de-
7 partment.

8 “(III) A critical access hospital
9 (as defined in section 1861(mm)(1) of
10 such Act).

11 “(IV) An ambulatory surgical
12 center described in section
13 1833(i)(1)(A) of such Act.

14 “(V) Any other facility, specified
15 by the Secretary, that provides items
16 or services for which coverage is pro-
17 vided under the plan or coverage, re-
18 spectively.

19 “(B) VISIT.—The term ‘visit’ shall, with
20 respect to items and services furnished to an in-
21 dividual at a health care facility, include equip-
22 ment and devices, telemedicine services, imag-
23 ing services, laboratory services, preoperative
24 and postoperative services, and such other items
25 and services as the Secretary may specify, re-

1 regardless of whether or not the provider fur-
2 nishing such items or services is at the facility.

3 “(c) CERTAIN ACCESS FEES TO CERTAIN DATA-
4 BASES.—In the case of a sponsor of a group health plan
5 that, pursuant to subsection (a)(3)(E)(iii), uses a data-
6 base described in such subsection to determine a rate to
7 apply under such subsection for an item or service by rea-
8 son of having insufficient information described in such
9 subsection with respect to such item or service, such spon-
10 sor shall cover the cost for access to such database.”.

11 (2) TRANSFER AMENDMENT.—Subchapter B of
12 chapter 100 of the Internal Revenue Code of 1986,
13 as amended by paragraph (1), is further amended by
14 adding at the end the following:

15 **“SEC. 9822. OTHER PATIENT PROTECTIONS.**

16 “(a) CHOICE OF HEALTH CARE PROFESSIONAL.—If
17 a group health plan requires or provides for designation
18 by a participant or beneficiary of a participating primary
19 care provider, then the plan shall permit each participant
20 and beneficiary to designate any participating primary
21 care provider who is available to accept such individual.

22 “(b) ACCESS TO PEDIATRIC CARE.—

23 “(1) PEDIATRIC CARE.—In the case of a person
24 who has a child who is a participant or beneficiary
25 under a group health plan if the plan requires or

1 provides for the designation of a participating pri-
2 mary care provider for the child, the plan shall per-
3 mit such person to designate a physician (allopathic
4 or osteopathic) who specializes in pediatrics as the
5 child's primary care provider if such provider par-
6 ticipates in the network of the plan.

7 “(2) CONSTRUCTION.—Nothing in paragraph
8 (1) shall be construed to waive any exclusions of cov-
9 erage under the terms and conditions of the plan
10 with respect to coverage of pediatric care.

11 “(c) PATIENT ACCESS TO OBSTETRICAL AND GYNE-
12 COLOGICAL CARE.—

13 “(1) GENERAL RIGHTS.—

14 “(A) DIRECT ACCESS.—A group health
15 plan described in paragraph (2) may not re-
16 quire authorization or referral by the plan,
17 issuer, or any person (including a primary care
18 provider described in paragraph (2)(B)) in the
19 case of a female participant or beneficiary who
20 seeks coverage for obstetrical or gynecological
21 care provided by a participating health care
22 professional who specializes in obstetrics or
23 gynecology. Such professional shall agree to
24 otherwise adhere to such plan's policies and
25 procedures, including procedures regarding re-

1 ferrals and obtaining prior authorization and
2 providing services pursuant to a treatment plan
3 (if any) approved by the plan.

4 “(B) OBSTETRICAL AND GYNECOLOGICAL
5 CARE.—A group health plan described in para-
6 graph (2) shall treat the provision of obstetrical
7 and gynecological care, and the ordering of re-
8 lated obstetrical and gynecological items and
9 services, pursuant to the direct access described
10 under subparagraph (A), by a participating
11 health care professional who specializes in ob-
12 stetrics or gynecology as the authorization of
13 the primary care provider.

14 “(2) APPLICATION OF PARAGRAPH.—A group
15 health plan described in this paragraph is a group
16 health plan that—

17 “(A) provides coverage for obstetric or
18 gynecologic care; and

19 “(B) requires the designation by a partici-
20 pant or beneficiary of a participating primary
21 care provider.

22 “(3) CONSTRUCTION.—Nothing in paragraph
23 (1) shall be construed to—

24 “(A) waive any exclusions of coverage
25 under the terms and conditions of the plan with

1 respect to coverage of obstetrical or gynecological care; or

2
3 “(B) preclude the group health plan involved from requiring that the obstetrical or
4 gynecological provider notify the primary care
5 health care professional or the plan or issuer of
6 treatment decisions.”.

7
8 (3) CLERICAL AMENDMENT.—The table of sections for subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended by adding at
9 the end the following new item:
10
11

“Sec. 9815. Additional market reforms.

“Sec. 9816. Preventing surprise medical bills.

“Sec. 9822. Other patient protections.”.

12 (4) CONFORMING AMENDMENTS.—

13 (A) IN GENERAL.—Section 223(c) of the
14 Internal Revenue Code of 1986 is amended—

15 (i) in paragraph (1), by adding at the
16 end the following:

17 “(D) SPECIAL RULE FOR INDIVIDUALS RECEIVING BENEFITS SUBJECT TO SURPRISE
18 BILLING STATUTES.—An individual shall not
19 fail to be treated as an eligible individual for
20 any period merely because the individual receives benefits for medical care subject to and
21 in accordance with section 9816 or 9817, section 2799A–1 or 2799A–2 of the Public Health
22
23
24

1 Service Act, or section 716 or 717 of the Em-
2 ployee Retirement Income Security Act of 1974,
3 or any State law providing similar protections
4 to such individual.”; and

5 (ii) in paragraph (2), by adding at the
6 end the following:

7 “(F) SPECIAL RULE FOR SURPRISE BILL-
8 ING.—A plan shall not fail to be treated as a
9 high deductible health plan by reason of pro-
10 viding benefits for medical care in accordance
11 with section 9816 or 9817, section 2799A–1 or
12 2799A–2 of the Public Health Service Act, or
13 section 716 or 717 of the Employee Retirement
14 Income Security Act of 1974, or any State law
15 providing similar protections to individuals,
16 prior to the satisfaction of the deductible under
17 paragraph (2)(A)(i).”.

18 (B) EFFECTIVE DATE.—The amendments
19 made by subparagraph (A) shall apply for plan
20 years beginning on or after January 1, 2022.

21 (d) ADDITIONAL APPLICATION PROVISIONS.—

22 (1) APPLICATION TO FEHB.—Section 8902 of
23 title 5, United States Code, is amended by adding
24 at the end the following new subsection:

1 “(p) Each contract under this chapter shall require
2 the carrier to comply with requirements described in the
3 provisions of sections 2799A–1, 2799A–2, and 2799A–7
4 of the Public Health Service Act, sections 716, 717, and
5 722 of the Employee Retirement Income Security Act of
6 1974, and sections 9816, 9817, and 9822 of the Internal
7 Revenue Code of 1986 (as applicable) in the same manner
8 as such provisions apply to a group health plan or health
9 insurance issuer offering group or individual health insur-
10 ance coverage, as described in such sections. The provi-
11 sions of sections 2799B–1, 2799B–2, 2799B–3, and
12 2799B–5 of the Public Health Service Act shall apply to
13 a health care provider and facility and an air ambulance
14 provider described in such respective sections with respect
15 to an enrollee in a health benefits plan under this chapter
16 in the same manner as such provisions apply to such a
17 provider and facility with respect to an enrollee in a group
18 health plan or group or individual health insurance cov-
19 erage offered by a health insurance issuer, as described
20 in such sections.”.

21 (2) APPLICATION TO GRANDFATHERED
22 PLANS.—Section 1251(a) of the Patient Protection
23 and Affordable Care Act (42 U.S.C. 18011(a)) is
24 amended by adding at the end the following:

1 “(5) APPLICATION OF ADDITIONAL PROVI-
2 SIONS.—Sections 2799A–1, 2799A–2, and 2799A–7
3 of the Public Health Service Act shall apply to
4 grandfathered health plans for plan years beginning
5 on or after January 1, 2022.”.

6 (3) RULE OF CONSTRUCTION.—Nothing in this
7 title, including the amendments made by this title
8 may be construed as modifying, reducing, or elimi-
9 nating—

10 (A) the protections under section 222 of
11 the Indian Health Care Improvement Act (25
12 U.S.C. 1621u) and under subpart I of part 136
13 of title 42, Code of Federal Regulations (or any
14 successor regulation), against payment liability
15 for a patient who receives contract health serv-
16 ices that are authorized by the Indian Health
17 Service; or

18 (B) the requirements under section
19 1866(a)(1)(U) of the Social Security Act (42
20 U.S.C. 1395cc(a)(1)(U)).

21 (e) EFFECTIVE DATE.—The amendments made by
22 this section shall apply with respect to plan years (or, in
23 the case of the amendment made by subsection (d)(1),
24 with respect to contracts entered into or renewed for con-
25 tract years) beginning on or after January 1, 2022.

1 **SEC. 103. DETERMINATION OF OUT-OF-NETWORK RATES TO**
2 **BE PAID BY HEALTH PLANS; INDEPENDENT**
3 **DISPUTE RESOLUTION PROCESS.**

4 (a) PHSA.—Section 2799A–1, as added by section
5 102, is amended—

6 (1) by redesignating subsection (c) as sub-
7 section (d); and

8 (2) by inserting after subsection (b) the fol-
9 lowing new subsection:

10 “(c) DETERMINATION OF OUT-OF-NETWORK RATES
11 TO BE PAID BY HEALTH PLANS; INDEPENDENT DISPUTE
12 RESOLUTION PROCESS.—

13 “(1) DETERMINATION THROUGH OPEN NEGO-
14 TIATION.—

15 “(A) IN GENERAL.—With respect to an
16 item or service furnished in a year by a non-
17 participating provider or a nonparticipating fa-
18 cility, with respect to a group health plan or
19 health insurance issuer offering group or indi-
20 vidual health insurance coverage, in a State de-
21 scribed in subsection (a)(3)(K)(ii) with respect
22 to such plan or coverage and provider or facil-
23 ity, and for which a payment is required to be
24 made by the plan or coverage pursuant to sub-
25 section (a)(1) or (b)(1), the provider or facility
26 (as applicable) or plan or coverage may, during

1 the 30-day period beginning on the day the pro-
2 vider or facility receives an initial payment or
3 a notice of denial of payment from the plan or
4 coverage regarding a claim for payment for
5 such item or service, initiate open negotiations
6 under this paragraph between such provider or
7 facility and plan or coverage for purposes of de-
8 termining, during the open negotiation period,
9 an amount agreed on by such provider or facil-
10 ity, respectively, and such plan or coverage for
11 payment (including any cost-sharing) for such
12 item or service. For purposes of this subsection,
13 the open negotiation period, with respect to an
14 item or service, is the 30-day period beginning
15 on the date of initiation of the negotiations with
16 respect to such item or service.

17 “(B) ACCESSING INDEPENDENT DISPUTE
18 RESOLUTION PROCESS IN CASE OF FAILED NE-
19 GOTIATIONS.—In the case of open negotiations
20 pursuant to subparagraph (A), with respect to
21 an item or service, that do not result in a deter-
22 mination of an amount of payment for such
23 item or service by the last day of the open nego-
24 tiation period described in such subparagraph
25 with respect to such item or service, the pro-

1 vider or facility (as applicable) or group health
2 plan or health insurance issuer offering group
3 or individual health insurance coverage that was
4 party to such negotiations may, during the 4-
5 day period beginning on the day after such
6 open negotiation period, initiate the inde-
7 pendent dispute resolution process under para-
8 graph (2) with respect to such item or service.
9 The independent dispute resolution process
10 shall be initiated by a party pursuant to the
11 previous sentence by submission to the other
12 party and to the Secretary of a notification
13 (containing such information as specified by the
14 Secretary) and for purposes of this subsection,
15 the date of initiation of such process shall be
16 the date of such submission or such other date
17 specified by the Secretary pursuant to regula-
18 tions that is not later than the date of receipt
19 of such notification by both the other party and
20 the Secretary.

21 “(2) INDEPENDENT DISPUTE RESOLUTION
22 PROCESS AVAILABLE IN CASE OF FAILED OPEN NE-
23 GOTIATIONS.—

24 “(A) ESTABLISHMENT.—Not later than 1
25 year after the date of the enactment of this

1 subsection, the Secretary, jointly with the Sec-
2 retary of Labor and the Secretary of the Treas-
3 ury, shall establish by regulation one inde-
4 pendent dispute resolution process (referred to
5 in this subsection as the ‘IDR process’) under
6 which, in the case of an item or service with re-
7 spect to which a provider or facility (as applica-
8 ble) or group health plan or health insurance
9 issuer offering group or individual health insur-
10 ance coverage submits a notification under
11 paragraph (1)(B) (in this subsection referred to
12 as a ‘qualified IDR item or service’), a certified
13 IDR entity under paragraph (4) determines,
14 subject to subparagraph (B) and in accordance
15 with the succeeding provisions of this sub-
16 section, the amount of payment under the plan
17 or coverage for such item or service furnished
18 by such provider or facility.

19 “(B) AUTHORITY TO CONTINUE NEGOTIA-
20 TIONS.—Under the independent dispute resolu-
21 tion process, in the case that the parties to a
22 determination for a qualified IDR item or serv-
23 ice agree on a payment amount for such item
24 or service during such process but before the
25 date on which the entity selected with respect to

1 such determination under paragraph (4) makes
2 such determination under paragraph (5), such
3 amount shall be treated for purposes of sub-
4 section (a)(3)(K)(ii) as the amount agreed to by
5 such parties for such item or service. In the
6 case of an agreement described in the previous
7 sentence, the independent dispute resolution
8 process shall provide for a method to determine
9 how to allocate between the parties to such de-
10 termination the payment of the compensation of
11 the entity selected with respect to such deter-
12 mination.

13 “(C) CLARIFICATION.—A nonparticipating
14 provider may not, with respect to an item or
15 service furnished by such provider, submit a no-
16 tification under paragraph (1)(B) if such pro-
17 vider is exempt from the requirement under
18 subsection (a) of section 2799B–2 with respect
19 to such item or service pursuant to subsection
20 (b) of such section.

21 “(3) TREATMENT OF BATCHING OF ITEMS AND
22 SERVICES.—

23 “(A) IN GENERAL.—Under the IDR proc-
24 ess, the Secretary shall specify criteria under
25 which multiple qualified IDR dispute items and

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1 services are permitted to be considered jointly
2 as part of a single determination by an entity
3 for purposes of encouraging the efficiency (in-
4 cluding minimizing costs) of the IDR process.
5 Such items and services may be so considered
6 only if—

7 “(i) such items and services to be in-
8 cluded in such determination are furnished
9 by the same provider or facility;

10 “(ii) payment for such items and serv-
11 ices is required to be made by the same
12 group health plan or health insurance
13 issuer;

14 “(iii) such items and services are re-
15 lated to the treatment of a similar condi-
16 tion; and

17 “(iv) such items and services were
18 furnished during the 30 day period fol-
19 lowing the date on which the first item or
20 service included with respect to such deter-
21 mination was furnished or an alternative
22 period as determined by the Secretary, for
23 use in limited situations, such as by the
24 consent of the parties or in the case of low-
25 volume items and services, to encourage

1 procedural efficiency and minimize health
2 plan and provider administrative costs.

3 “(B) TREATMENT OF BUNDLED PAY-
4 MENTS.—In carrying out subparagraph (A), the
5 Secretary shall provide that, in the case of
6 items and services which are included by a pro-
7 vider or facility as part of a bundled payment,
8 such items and services included in such bun-
9 dled payment may be part of a single deter-
10 mination under this subsection.

11 “(4) CERTIFICATION AND SELECTION OF IDR
12 ENTITIES.—

13 “(A) IN GENERAL.—The Secretary, in con-
14 sultation with the Secretary of Labor and Sec-
15 retary of the Treasury, shall establish a process
16 to certify (including to recertify) entities under
17 this paragraph. Such process shall ensure that
18 an entity so certified—

19 “(i) has (directly or through contracts
20 or other arrangements) sufficient medical,
21 legal, and other expertise and sufficient
22 staffing to make determinations described
23 in paragraph (5) on a timely basis;

24 “(ii) is not—

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1 “(I) a group health plan or
2 health insurance issuer offering group
3 or individual health insurance cov-
4 erage, provider, or facility;

5 “(II) an affiliate or a subsidiary
6 of such a group health plan or health
7 insurance issuer, provider, or facility;
8 or

9 “(III) an affiliate or subsidiary of
10 a professional or trade association of
11 such group health plans or health in-
12 surance issuers or of providers or fa-
13 cilities;

14 “(iii) carries out the responsibilities of
15 such an entity in accordance with this sub-
16 section;

17 “(iv) meets appropriate indicators of
18 fiscal integrity;

19 “(v) maintains the confidentiality (in
20 accordance with regulations promulgated
21 by the Secretary) of individually identifi-
22 able health information obtained in the
23 course of conducting such determinations;

24 “(vi) does not under the IDR process
25 carry out any determination with respect

1 to which the entity would not pursuant to
2 subclause (I), (II), or (III) of subpara-
3 graph (F)(i) be eligible for selection; and

4 “(vii) meets such other requirements
5 as determined appropriate by the Sec-
6 retary.

7 “(B) PERIOD OF CERTIFICATION.—Subject
8 to subparagraph (C), each certification (includ-
9 ing a recertification) of an entity under the
10 process described in subparagraph (A) shall be
11 for a 5-year period.

12 “(C) REVOCATION.—A certification of an
13 entity under this paragraph may be revoked
14 under the process described in subparagraph
15 (A) if the entity has a pattern or practice of
16 noncompliance with any of the requirements de-
17 scribed in such subparagraph.

18 “(D) PETITION FOR DENIAL OR WITH-
19 DRAWAL.—The process described in subpara-
20 graph (A) shall ensure that an individual, pro-
21 vider, facility, or group health plan or health in-
22 surance issuer offering group or individual
23 health insurance coverage may petition for a de-
24 nial of a certification or a revocation of a cer-
25 tification with respect to an entity under this

1 paragraph for failure of meeting a requirement
2 of this subsection.

3 “(E) SUFFICIENT NUMBER OF ENTI-
4 TIES.—The process described in subparagraph
5 (A) shall ensure that a sufficient number of en-
6 tities are certified under this paragraph to en-
7 sure the timely and efficient provision of deter-
8 minations described in paragraph (5).

9 “(F) SELECTION OF CERTIFIED IDR ENTI-
10 TY.—The Secretary shall, with respect to the
11 determination of the amount of payment under
12 this subsection of an item or service, provide for
13 a method—

14 “(i) that allows for the group health
15 plan or health insurance issuer offering
16 group or individual health insurance cov-
17 erage and the nonparticipating provider or
18 the nonparticipating emergency facility (as
19 applicable) involved in a notification under
20 paragraph (1)(B) to jointly select, not later
21 than the last day of the 3-business day pe-
22 riod following the date of the initiation of
23 the process with respect to such item or
24 service, for purposes of making such deter-

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1 mination, an entity certified under this
2 paragraph that—

3 “(I) is not a party to such deter-
4 mination or an employee or agent of
5 such a party;

6 “(II) does not have a material fa-
7 miliar, financial, or professional rela-
8 tionship with such a party; and

9 “(III) does not otherwise have a
10 conflict of interest with such a party
11 (as determined by the Secretary); and

12 “(ii) that requires, in the case such
13 parties do not make such selection by such
14 last day, the Secretary to, not later than 6
15 business days after such date of initi-
16 ation—

17 “(I) select such an entity that
18 satisfies subclauses (I) through (III)
19 of clause (i)); and

20 “(II) provide notification of such
21 selection to the provider or facility (as
22 applicable) and the plan or issuer (as
23 applicable) party to such determina-
24 tion.

1 An entity selected pursuant to the previous sentence to
2 make a determination described in such sentence shall be
3 referred to in this subsection as the ‘certified IDR entity’
4 with respect to such determination.

5 “(5) PAYMENT DETERMINATION.—

6 “(A) IN GENERAL.—Not later than 30
7 days after the date of selection of the certified
8 IDR entity with respect to a determination for
9 a qualified IDR item or service, the certified
10 IDR entity shall—

11 “(i) taking into account the consider-
12 ations specified in subparagraph (C), select
13 one of the offers submitted under subpara-
14 graph (B) to be the amount of payment for
15 such item or service determined under this
16 subsection for purposes of subsection
17 (a)(1) or (b)(1), as applicable; and

18 “(ii) notify the provider or facility and
19 the group health plan or health insurance
20 issuer offering group or individual health
21 insurance coverage party to such deter-
22 mination of the offer selected under clause
23 (i).

24 “(B) SUBMISSION OF OFFERS.—Not later
25 than 10 days after the date of selection of the

1 certified IDR entity with respect to a deter-
2 mination for a qualified IDR item or service,
3 the provider or facility and the group health
4 plan or health insurance issuer offering group
5 or individual health insurance coverage party to
6 such determination—

7 “(i) shall each submit to the certified
8 IDR entity with respect to such determina-
9 tion—

10 “(I) an offer for a payment
11 amount for such item or service fur-
12 nished by such provider or facility;
13 and

14 “(II) such information as re-
15 quested by the certified IDR entity re-
16 lating to such offer; and

17 “(ii) may each submit to the certified
18 IDR entity with respect to such determina-
19 tion any information relating to such offer
20 submitted by either party, including infor-
21 mation relating to any circumstance de-
22 scribed in subparagraph (C)(ii).

23 “(C) CONSIDERATIONS IN DETERMINA-
24 TION.—

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1 “(i) IN GENERAL.—In determining
2 which offer is the payment to be applied
3 pursuant to this paragraph, the certified
4 IDR entity, with respect to the determina-
5 tion for a qualified IDR item or service
6 shall consider—

7 “(I) the qualifying payment
8 amounts (as defined in subsection
9 (a)(3)(E)) for the applicable year for
10 items or services that are comparable
11 to the qualified IDR item or service
12 and that are furnished in the same
13 geographic region (as defined by the
14 Secretary for purposes of such sub-
15 section) as such qualified IDR item or
16 service; and

17 “(II) subject to subparagraph
18 (D), information on any circumstance
19 described in clause (ii), such informa-
20 tion as requested in subparagraph
21 (B)(i)(II), and any additional infor-
22 mation provided in subparagraph
23 (B)(ii).

24 “(ii) ADDITIONAL CIRCUMSTANCES.—
25 For purposes of clause (i)(II), the cir-

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1 cumstances described in this clause are,
2 with respect to a qualified IDR item or
3 service of a nonparticipating provider, non-
4 participating emergency facility, group
5 health plan, or health insurance issuer of
6 group or individual health insurance cov-
7 erage the following:

8 “(I) The level of training, experi-
9 ence, and quality and outcomes meas-
10 urements of the provider or facility
11 that furnished such item or service
12 (such as those endorsed by the con-
13 sensus-based entity authorized in sec-
14 tion 1890 of the Social Security Act).

15 “(II) The market share held by
16 the nonparticipating provider or facil-
17 ity or that of the plan or issuer in the
18 geographic region in which the item or
19 service was provided.

20 “(III) The acuity of the indi-
21 vidual receiving such item or service
22 or the complexity of furnishing such
23 item or service to such individual.

24 “(IV) The teaching status, case
25 mix, and scope of services of the non-

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1 participating facility that furnished
2 such item or service.

3 “(V) Demonstrations of good
4 faith efforts (or lack of good faith ef-
5 forts) made by the nonparticipating
6 provider or nonparticipating facility or
7 the plan or issuer to enter into net-
8 work agreements and, if applicable,
9 contracted rates between the provider
10 or facility, as applicable, and the plan
11 or issuer, as applicable, during the
12 previous 4 plan years.

13 “(D) PROHIBITION ON CONSIDERATION OF
14 CERTAIN FACTORS.—In determining which offer
15 is the payment to be applied with respect to
16 qualified IDR items and services furnished by a
17 provider or facility, the certified IDR entity
18 with respect to a determination shall not con-
19 sider usual and customary charges, the amount
20 that would have been billed by such provider or
21 facility with respect to such items and services
22 had the provisions of section 2799B–1 or
23 2799B–2 (as applicable) not applied, or the
24 payment or reimbursement rate for such items
25 and services furnished by such provider or facil-

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1 ity payable by a public payor, including under
2 the Medicare program under title XVIII of the
3 Social Security Act, under the Medicaid pro-
4 gram under title XIX of such Act, under the
5 Children’s Health Insurance Program under
6 title XXI of such Act, under the TRICARE
7 program under chapter 55 of title 10, United
8 States Code, or under chapter 17 of title 38,
9 United States Code.

10 “(E) EFFECTS OF DETERMINATION.—

11 “(i) IN GENERAL.—A determination
12 of a certified IDR entity under subpara-
13 graph (A)—

14 “(I) shall be binding upon the
15 parties involved, in the absence of a
16 fraudulent claim or evidence of mis-
17 representation of facts presented to
18 the IDR entity involved regarding
19 such claim; and

20 “(II) shall not be subject to judi-
21 cial review, except in a case described
22 in any of paragraphs (1) through (4)
23 of section 10(a) of title 9, United
24 States Code.

1 “(ii) SUSPENSION OF CERTAIN SUBSE-
2 QUENT IDR REQUESTS.—In the case of a
3 determination of a certified IDR entity
4 under subparagraph (A), with respect to
5 an initial notification submitted under
6 paragraph (1)(B) with respect to qualified
7 IDR items and services and the two par-
8 ties involved with such notification, the
9 party that submitted such notification may
10 not submit during the 90-day period fol-
11 lowing such determination a subsequent
12 notification under such paragraph involv-
13 ing the same other party to such notifica-
14 tion with respect to such an item or service
15 that was the subject of such initial notifi-
16 cation.

17 “(iii) SUBSEQUENT SUBMISSION OF
18 REQUESTS PERMITTED.—In the case of a
19 notification that pursuant to clause (ii) is
20 not permitted to be submitted under para-
21 graph (1)(B) during a 90-day period speci-
22 fied in such clause, if the end of the open
23 negotiation period specified in paragraph
24 (1)(A), that but for this clause would oth-
25 erwise apply with respect to such notifica-

1 tion, occurs during such 90-day period,
2 such paragraph (1)(B) shall be applied as
3 if the reference in such paragraph to the
4 4-day period beginning on the day after
5 such open negotiation period were instead
6 a reference to the 30-day period beginning
7 on the day after the last day of such 90-
8 day period.

9 “(iv) REPORTS.—The Secretary, joint-
10 ly with the Secretary of Labor and the
11 Secretary of the Treasury, shall examine
12 the impact of the application of clause (ii)
13 and whether the application of such clause
14 delays payment determinations or impacts
15 early, alternative resolution of claims (such
16 as through open negotiations), and shall
17 submit to Congress, not later than 2 years
18 after the date of implementation of such
19 clause an interim report (and not later
20 than 4 years after such date of implemen-
21 tation, a final report) on whether any
22 group health plans or health insurance
23 issuers offering group or individual health
24 insurance coverage or types of such plans
25 or coverage have a pattern or practice of

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1 routine denial, low payment, or down-cod-
2 ing of claims, or otherwise abuse the 90-
3 day period described in such clause, includ-
4 ing recommendations on ways to discour-
5 age such a pattern or practice.

6 “(F) COSTS OF INDEPENDENT DISPUTE
7 RESOLUTION PROCESS.—In the case of a notifi-
8 cation under paragraph (1)(B) submitted by a
9 nonparticipating provider, nonparticipating
10 emergency facility, group health plan, or health
11 insurance issuer offering group or individual
12 health insurance coverage and submitted to a
13 certified IDR entity—

14 “(i) if such entity makes a determina-
15 tion with respect to such notification under
16 subparagraph (A), the party whose offer is
17 not chosen under such subparagraph shall
18 be responsible for paying all fees charged
19 by such entity; and

20 “(ii) if the parties reach a settlement
21 with respect to such notification prior to
22 such a determination, each party shall pay
23 half of all fees charged by such entity, un-
24 less the parties otherwise agree.

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1 “(6) TIMING OF PAYMENT.—The total plan or
2 coverage payment required pursuant to subsection
3 (a)(1) or (b)(1), with respect to a qualified IDR
4 item or service for which a determination is made
5 under paragraph (5)(A) or with respect to an item
6 or service for which a payment amount is deter-
7 mined under open negotiations under paragraph (1),
8 shall be made directly to the nonparticipating pro-
9 vider or facility not later than 30 days after the date
10 on which such determination is made.

11 “(7) PUBLICATION OF INFORMATION RELATING
12 TO THE IDR PROCESS.—

13 “(A) PUBLICATION OF INFORMATION.—
14 For each calendar quarter in 2022 and each
15 calendar quarter in a subsequent year, the Sec-
16 retary shall make available on the public
17 website of the Department of Health and
18 Human Services—

19 “(i) the number of notifications sub-
20 mitted under paragraph (1)(B) during
21 such calendar quarter;

22 “(ii) the size of the provider practices
23 and the size of the facilities submitting no-
24 tifications under paragraph (1)(B) during
25 such calendar quarter;

1 “(iii) the number of such notifications
2 with respect to which a determination was
3 made under paragraph (5)(A);

4 “(iv) the information described in sub-
5 paragraph (B) with respect to each notifi-
6 cation with respect to which such a deter-
7 mination was so made;

8 “(v) the number of times the payment
9 amount determined (or agreed to) under
10 this subsection exceeds the qualifying pay-
11 ment amount, specified by items and serv-
12 ices;

13 “(vi) the amount of expenditures
14 made by the Secretary during such cal-
15 endar quarter to carry out the IDR proc-
16 ess;

17 “(vii) the total amount of fees paid
18 under paragraph (8) during such calendar
19 quarter; and

20 “(viii) the total amount of compensa-
21 tion paid to certified IDR entities under
22 paragraph (5)(F) during such calendar
23 quarter.

24 “(B) INFORMATION.—For purposes of sub-
25 paragraph (A), the information described in

1 this subparagraph is, with respect to a notifica-
2 tion under paragraph (1)(B) by a nonpartici-
3 pating provider, nonparticipating emergency fa-
4 cility, group health plan, or health insurance
5 issuer offering group or individual health insur-
6 ance coverage—

7 “(i) a description of each item and
8 service included with respect to such notifi-
9 cation;

10 “(ii) the geography in which the items
11 and services with respect to such notifica-
12 tion were provided;

13 “(iii) the amount of the offer sub-
14 mitted under paragraph (5)(B) by the
15 group health plan or health insurance
16 issuer (as applicable) and by the non-
17 participating provider or nonparticipating
18 emergency facility (as applicable) expressed
19 as a percentage of the qualifying payment
20 amount;

21 “(iv) whether the offer selected by the
22 certified IDR entity under paragraph (5)
23 to be the payment applied was the offer
24 submitted by such plan or issuer (as appli-
25 cable) or by such provider or facility (as

1 applicable) and the amount of such offer
2 so selected expressed as a percentage of
3 the qualifying payment amount;

4 “(v) the category and practice spe-
5 cialty of each such provider or facility in-
6 volved in furnishing such items and serv-
7 ices;

8 “(vi) the identity of the health plan or
9 health insurance issuer, provider, or facil-
10 ity, with respect to the notification;

11 “(vii) the length of time in making
12 each determination;

13 “(viii) the compensation paid to the
14 certified IDR entity with respect to the
15 settlement or determination; and

16 “(ix) any other information specified
17 by the Secretary.

18 “(C) IDR ENTITY REQUIREMENTS.—For
19 2022 and each subsequent year, an IDR entity,
20 as a condition of certification as an IDR entity,
21 shall submit to the Secretary such information
22 as the Secretary determines necessary to carry
23 out the provisions of this subsection.

24 “(D) CLARIFICATION.—The Secretary
25 shall ensure the public reporting under this

1 paragraph does not contain information that
2 would disclose privileged or confidential infor-
3 mation of a group health plan or health insur-
4 ance issuer offering group or individual health
5 insurance coverage or of a provider or facility.

6 “(8) ADMINISTRATIVE FEE.—

7 “(A) IN GENERAL.—Each party to a deter-
8 mination under paragraph (5) to which an enti-
9 ty is selected under paragraph (3) in a year
10 shall pay to the Secretary, at such time and in
11 such manner as specified by the Secretary, a
12 fee for participating in the IDR process with re-
13 spect to such determination in an amount de-
14 scribed in subparagraph (B) for such year.

15 “(B) AMOUNT OF FEE.—The amount de-
16 scribed in this subparagraph for a year is an
17 amount established by the Secretary in a man-
18 ner such that the total amount of fees paid
19 under this paragraph for such year is estimated
20 to be equal to the amount of expenditures esti-
21 mated to be made by the Secretary for such
22 year in carrying out the IDR process.

23 “(9) WAIVER AUTHORITY.—The Secretary may
24 modify any deadline or other timing requirement
25 specified under this subsection (other than the es-

1 establishment date for the IDR process under para-
2 graph (2)(A) and other than under paragraph (6))
3 in cases of extenuating circumstances, as specified
4 by the Secretary, or to ensure that all claims that
5 occur during a 90-day period described in paragraph
6 (5)(E)(ii), but with respect to which a notification is
7 not permitted by reason of such paragraph to be
8 submitted under paragraph (1)(B) during such pe-
9 riod, are eligible for the IDR process.”.

10 (b) ERISA.—Section 716 of the Employee Retire-
11 ment Income Security Act of 1974, as added by section
12 102, is amended—

13 (1) by redesignating subsection (c) as sub-
14 section (d); and

15 (2) by inserting after subsection (b) the fol-
16 lowing new subsection:

17 “(c) DETERMINATION OF OUT-OF-NETWORK RATES
18 TO BE PAID BY HEALTH PLANS; INDEPENDENT DISPUTE
19 RESOLUTION PROCESS.—

20 “(1) DETERMINATION THROUGH OPEN NEGO-
21 TIATION.—

22 “(A) IN GENERAL.—With respect to an
23 item or service furnished in a year by a non-
24 participating provider or a nonparticipating fa-
25 cility, with respect to a group health plan or

1 health insurance issuer offering group health
2 insurance coverage, in a State described in sub-
3 section (a)(3)(K)(ii) with respect to such plan
4 or coverage and provider or facility, and for
5 which a payment is required to be made by the
6 plan or coverage pursuant to subsection (a)(1)
7 or (b)(1), the provider or facility (as applicable)
8 or plan or coverage may, during the 30-day pe-
9 riod beginning on the day the provider or facil-
10 ity receives an initial payment or a notice of de-
11 nial of payment from the plan or coverage re-
12 garding a claim for payment for such item or
13 service, initiate open negotiations under this
14 paragraph between such provider or facility and
15 plan or coverage for purposes of determining,
16 during the open negotiation period, an amount
17 agreed on by such provider or facility, respec-
18 tively, and such plan or coverage for payment
19 (including any cost-sharing) for such item or
20 service. For purposes of this subsection, the
21 open negotiation period, with respect to an item
22 or service, is the 30-day period beginning on
23 the date of initiation of the negotiations with
24 respect to such item or service.

1 “(B) ACCESSING INDEPENDENT DISPUTE
2 RESOLUTION PROCESS IN CASE OF FAILED NE-
3 GOTIATIONS.—In the case of open negotiations
4 pursuant to subparagraph (A), with respect to
5 an item or service, that do not result in a deter-
6 mination of an amount of payment for such
7 item or service by the last day of the open nego-
8 tiation period described in such subparagraph
9 with respect to such item or service, the pro-
10 vider or facility (as applicable) or group health
11 plan or health insurance issuer offering group
12 health insurance coverage that was party to
13 such negotiations may, during the 4-day period
14 beginning on the day after such open negotia-
15 tion period, initiate the independent dispute res-
16 olution process under paragraph (2) with re-
17 spect to such item or service. The independent
18 dispute resolution process shall be initiated by
19 a party pursuant to the previous sentence by
20 submission to the other party and to the Sec-
21 retary of a notification (containing such infor-
22 mation as specified by the Secretary) and for
23 purposes of this subsection, the date of initi-
24 ation of such process shall be the date of such
25 submission or such other date specified by the

1 Secretary pursuant to regulations that is not
2 later than the date of receipt of such notifica-
3 tion by both the other party and the Secretary.

4 “(2) INDEPENDENT DISPUTE RESOLUTION
5 PROCESS AVAILABLE IN CASE OF FAILED OPEN NE-
6 GOTIATIONS.—

7 “(A) ESTABLISHMENT.—Not later than 1
8 year after the date of the enactment of this
9 subsection, the Secretary, jointly with the Sec-
10 retary of Health and Human Services and the
11 Secretary of the Treasury, shall establish by
12 regulation one independent dispute resolution
13 process (referred to in this subsection as the
14 ‘IDR process’) under which, in the case of an
15 item or service with respect to which a provider
16 or facility (as applicable) or group health plan
17 or health insurance issuer offering group health
18 insurance coverage submits a notification under
19 paragraph (1)(B) (in this subsection referred to
20 as a ‘qualified IDR item or service’), a certified
21 IDR entity under paragraph (4) determines,
22 subject to subparagraph (B) and in accordance
23 with the succeeding provisions of this sub-
24 section, the amount of payment under the plan

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1 or coverage for such item or service furnished
2 by such provider or facility.

3 “(B) AUTHORITY TO CONTINUE NEGOTIA-
4 TIONS.—Under the independent dispute resolu-
5 tion process, in the case that the parties to a
6 determination for a qualified IDR item or serv-
7 ice agree on a payment amount for such item
8 or service during such process but before the
9 date on which the entity selected with respect to
10 such determination under paragraph (4) makes
11 such determination under paragraph (5), such
12 amount shall be treated for purposes of sub-
13 section (a)(3)(K)(ii) as the amount agreed to by
14 such parties for such item or service. In the
15 case of an agreement described in the previous
16 sentence, the independent dispute resolution
17 process shall provide for a method to determine
18 how to allocate between the parties to such de-
19 termination the payment of the compensation of
20 the entity selected with respect to such deter-
21 mination.

22 “(C) CLARIFICATION.—A nonparticipating
23 provider may not, with respect to an item or
24 service furnished by such provider, submit a no-
25 tification under paragraph (1)(B) if such pro-

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1 vider is exempt from the requirement under
2 subsection (a) of section 2799B–2 of the Public
3 Health Service Act with respect to such item or
4 service pursuant to subsection (b) of such sec-
5 tion.

6 “(3) TREATMENT OF BATCHING OF ITEMS AND
7 SERVICES.—

8 “(A) IN GENERAL.—Under the IDR proc-
9 ess, the Secretary shall specify criteria under
10 which multiple qualified IDR dispute items and
11 services are permitted to be considered jointly
12 as part of a single determination by an entity
13 for purposes of encouraging the efficiency (in-
14 cluding minimizing costs) of the IDR process.
15 Such items and services may be so considered
16 only if—

17 “(i) such items and services to be in-
18 cluded in such determination are furnished
19 by the same provider or facility;

20 “(ii) payment for such items and serv-
21 ices is required to be made by the same
22 group health plan or health insurance
23 issuer;

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1 “(iii) such items and services are re-
2 lated to the treatment of a similar condi-
3 tion; and

4 “(iv) such items and services were
5 furnished during the 30 day period fol-
6 lowing the date on which the first item or
7 service included with respect to such deter-
8 mination was furnished or an alternative
9 period as determined by the Secretary, for
10 use in limited situations, such as by the
11 consent of the parties or in the case of low-
12 volume items and services, to encourage
13 procedural efficiency and minimize health
14 plan and provider administrative costs.

15 “(B) TREATMENT OF BUNDLED PAY-
16 MENTS.—In carrying out subparagraph (A), the
17 Secretary shall provide that, in the case of
18 items and services which are included by a pro-
19 vider or facility as part of a bundled payment,
20 such items and services included in such bun-
21 dled payment may be part of a single deter-
22 mination under this subsection.

23 “(4) CERTIFICATION AND SELECTION OF IDR
24 ENTITIES.—

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1 “(A) IN GENERAL.—The Secretary, jointly
2 with the Secretary of Health and Human Serv-
3 ices and Secretary of the Treasury, shall estab-
4 lish a process to certify (including to recertify)
5 entities under this paragraph. Such process
6 shall ensure that an entity so certified—

7 “(i) has (directly or through contracts
8 or other arrangements) sufficient medical,
9 legal, and other expertise and sufficient
10 staffing to make determinations described
11 in paragraph (5) on a timely basis;

12 “(ii) is not—

13 “(I) a group health plan or
14 health insurance issuer offering group
15 health insurance coverage, provider,
16 or facility;

17 “(II) an affiliate or a subsidiary
18 of such a group health plan or health
19 insurance issuer, provider, or facility;
20 or

21 “(III) an affiliate or subsidiary of
22 a professional or trade association of
23 such group health plans or health in-
24 surance issuers or of providers or fa-
25 cilities;

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1 “(iii) carries out the responsibilities of
2 such an entity in accordance with this sub-
3 section;

4 “(iv) meets appropriate indicators of
5 fiscal integrity;

6 “(v) maintains the confidentiality (in
7 accordance with regulations promulgated
8 by the Secretary) of individually identifi-
9 able health information obtained in the
10 course of conducting such determinations;

11 “(vi) does not under the IDR process
12 carry out any determination with respect
13 to which the entity would not pursuant to
14 subclause (I), (II), or (III) of subpara-
15 graph (F)(i) be eligible for selection; and

16 “(vii) meets such other requirements
17 as determined appropriate by the Sec-
18 retary.

19 “(B) PERIOD OF CERTIFICATION.—Subject
20 to subparagraph (C), each certification (includ-
21 ing a recertification) of an entity under the
22 process described in subparagraph (A) shall be
23 for a 5-year period.

24 “(C) REVOCATION.—A certification of an
25 entity under this paragraph may be revoked

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1 under the process described in subparagraph
2 (A) if the entity has a pattern or practice of
3 noncompliance with any of the requirements de-
4 scribed in such subparagraph.

5 “(D) PETITION FOR DENIAL OR WITH-
6 DRAWAL.—The process described in subpara-
7 graph (A) shall ensure that an individual, pro-
8 vider, facility, or group health plan or health in-
9 surance issuer offering group health insurance
10 coverage may petition for a denial of a certifi-
11 cation or a revocation of a certification with re-
12 spect to an entity under this paragraph for fail-
13 ure of meeting a requirement of this subsection.

14 “(E) SUFFICIENT NUMBER OF ENTI-
15 TIES.—The process described in subparagraph
16 (A) shall ensure that a sufficient number of en-
17 tities are certified under this paragraph to en-
18 sure the timely and efficient provision of deter-
19 minations described in paragraph (5).

20 “(F) SELECTION OF CERTIFIED IDR ENTI-
21 TY.—The Secretary shall, with respect to the
22 determination of the amount of payment under
23 this subsection of an item or service, provide for
24 a method—

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1 “(i) that allows for the group health
2 plan or health insurance issuer offering
3 group health insurance coverage and the
4 nonparticipating provider or the non-
5 participating emergency facility (as appli-
6 cable) involved in a notification under
7 paragraph (1)(B) to jointly select, not later
8 than the last day of the 3-business day pe-
9 riod following the date of the initiation of
10 the process with respect to such item or
11 service, for purposes of making such deter-
12 mination, an entity certified under this
13 paragraph that—

14 “(I) is not a party to such deter-
15 mination or an employee or agent of
16 such a party;

17 “(II) does not have a material fa-
18 milial, financial, or professional rela-
19 tionship with such a party; and

20 “(III) does not otherwise have a
21 conflict of interest with such a party
22 (as determined by the Secretary); and

23 “(ii) that requires, in the case such
24 parties do not make such selection by such
25 last day, the Secretary to, not later than 6

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1 business days after such date of initi-
2 ation—

3 “(I) select such an entity that
4 satisfies subclauses (I) through (III)
5 of clause (i)); and

6 “(II) provide notification of such
7 selection to the provider or facility (as
8 applicable) and the plan or issuer (as
9 applicable) party to such determina-
10 tion.

11 An entity selected pursuant to the previous sentence to
12 make a determination described in such sentence shall be
13 referred to in this subsection as the ‘certified IDR entity’
14 with respect to such determination.

15 “(5) PAYMENT DETERMINATION.—

16 “(A) IN GENERAL.—Not later than 30
17 days after the date of selection of the certified
18 IDR entity with respect to a determination for
19 a qualified IDR item or service, the certified
20 IDR entity shall—

21 “(i) taking into account the consider-
22 ations specified in subparagraph (C), select
23 one of the offers submitted under subpara-
24 graph (B) to be the amount of payment for
25 such item or service determined under this

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1 subsection for purposes of subsection
2 (a)(1) or (b)(1), as applicable; and

3 “(ii) notify the provider or facility and
4 the group health plan or health insurance
5 issuer offering group health insurance cov-
6 erage party to such determination of the
7 offer selected under clause (i).

8 “(B) SUBMISSION OF OFFERS.—Not later
9 than 10 days after the date of selection of the
10 certified IDR entity with respect to a deter-
11 mination for a qualified IDR item or service,
12 the provider or facility and the group health
13 plan or health insurance issuer offering group
14 health insurance coverage party to such deter-
15 mination—

16 “(i) shall each submit to the certified
17 IDR entity with respect to such determina-
18 tion—

19 “(I) an offer for a payment
20 amount for such item or service fur-
21 nished by such provider or facility;
22 and

23 “(II) such information as re-
24 quested by the certified IDR entity re-
25 lating to such offer; and

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1 “(ii) may each submit to the certified
2 IDR entity with respect to such determina-
3 tion any information relating to such offer
4 submitted by either party, including infor-
5 mation relating to any circumstance de-
6 scribed in subparagraph (C)(ii).

7 “(C) CONSIDERATIONS IN DETERMINA-
8 TION.—

9 “(i) IN GENERAL.—In determining
10 which offer is the payment to be applied
11 pursuant to this paragraph, the certified
12 IDR entity, with respect to the determina-
13 tion for a qualified IDR item or service
14 shall consider—

15 “(I) the qualifying payment
16 amounts (as defined in subsection
17 (a)(3)(E)) for the applicable year for
18 items or services that are comparable
19 to the qualified IDR item or service
20 and that are furnished in the same
21 geographic region (as defined by the
22 Secretary for purposes of such sub-
23 section) as such qualified IDR item or
24 service; and

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1 “(II) subject to subparagraph
2 (D), information on any circumstance
3 described in clause (ii), such informa-
4 tion as requested in subparagraph
5 (B)(i)(II), and any additional infor-
6 mation provided in subparagraph
7 (B)(ii).

8 “(ii) ADDITIONAL CIRCUMSTANCES.—
9 For purposes of clause (i)(II), the cir-
10 cumstances described in this clause are,
11 with respect to a qualified IDR item or
12 service of a nonparticipating provider, non-
13 participating emergency facility, group
14 health plan, or health insurance issuer of
15 group health insurance coverage the fol-
16 lowing:

17 “(I) The level of training, experi-
18 ence, and quality and outcomes meas-
19 urements of the provider or facility
20 that furnished such item or service
21 (such as those endorsed by the con-
22 sensus-based entity authorized in sec-
23 tion 1890 of the Social Security Act).

24 “(II) The market share held by
25 the nonparticipating provider or facil-

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1 ity or that of the plan or issuer in the
2 geographic region in which the item or
3 service was provided.

4 “(III) The acuity of the indi-
5 vidual receiving such item or service
6 or the complexity of furnishing such
7 item or service to such individual.

8 “(IV) The teaching status, case
9 mix, and scope of services of the non-
10 participating facility that furnished
11 such item or service.

12 “(V) Demonstrations of good
13 faith efforts (or lack of good faith ef-
14 forts) made by the nonparticipating
15 provider or nonparticipating facility or
16 the plan or issuer to enter into net-
17 work agreements and, if applicable,
18 contracted rates between the provider
19 or facility, as applicable, and the plan
20 or issuer, as applicable, during the
21 previous 4 plan years.

22 “(D) PROHIBITION ON CONSIDERATION OF
23 CERTAIN FACTORS.—In determining which offer
24 is the payment to be applied with respect to
25 qualified IDR items and services furnished by a

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1 provider or facility, the certified IDR entity
2 with respect to a determination shall not con-
3 sider usual and customary charges, the amount
4 that would have been billed by such provider or
5 facility with respect to such items and services
6 had the provisions of section 2799B–1 of the
7 Public Health Service Act or 2799B–2 of such
8 Act (as applicable) not applied, or the payment
9 or reimbursement rate for such items and serv-
10 ices furnished by such provider or facility pay-
11 able by a public payor, including under the
12 Medicare program under title XVIII of the So-
13 cial Security Act, under the Medicaid program
14 under title XIX of such Act, under the Chil-
15 dren’s Health Insurance Program under title
16 XXI of such Act, under the TRICARE program
17 under chapter 55 of title 10, United States
18 Code, or under chapter 17 of title 38, United
19 States Code.

20 “(E) EFFECTS OF DETERMINATION.—

21 “(i) IN GENERAL.—A determination
22 of a certified IDR entity under subpara-
23 graph (A)—

24 “(I) shall be binding upon the
25 parties involved, in the absence of a

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1 fraudulent claim or evidence of mis-
2 representation of facts presented to
3 the IDR entity involved regarding
4 such claim; and

5 “(II) shall not be subject to judi-
6 cial review, except in a case described
7 in any of paragraphs (1) through (4)
8 of section 10(a) of title 9, United
9 States Code.

10 “(ii) SUSPENSION OF CERTAIN SUBSE-
11 QUENT IDR REQUESTS.—In the case of a
12 determination of a certified IDR entity
13 under subparagraph (A), with respect to
14 an initial notification submitted under
15 paragraph (1)(B) with respect to qualified
16 IDR items and services and the two par-
17 ties involved with such notification, the
18 party that submitted such notification may
19 not submit during the 90-day period fol-
20 lowing such determination a subsequent
21 notification under such paragraph involv-
22 ing the same other party to such notifica-
23 tion with respect to such an item or service
24 that was the subject of such initial notifi-
25 cation.

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1 “(iii) SUBSEQUENT SUBMISSION OF
2 REQUESTS PERMITTED.—In the case of a
3 notification that pursuant to clause (ii) is
4 not permitted to be submitted under para-
5 graph (1)(B) during a 90-day period speci-
6 fied in such clause, if the end of the open
7 negotiation period specified in paragraph
8 (1)(A), that but for this clause would oth-
9 erwise apply with respect to such notifica-
10 tion, occurs during such 90-day period,
11 such paragraph (1)(B) shall be applied as
12 if the reference in such paragraph to the
13 4-day period beginning on the day after
14 such open negotiation period were instead
15 a reference to the 30-day period beginning
16 on the day after the last day of such 90-
17 day period.

18 “(iv) REPORTS.—The Secretary, joint-
19 ly with the Secretary of Health and
20 Human Services and the Secretary of the
21 Treasury, shall examine the impact of the
22 application of clause (ii) and whether the
23 application of such clause delays payment
24 determinations or impacts early, alter-
25 native resolution of claims (such as

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1 through open negotiations), and shall sub-
2 mit to Congress, not later than 2 years
3 after the date of implementation of such
4 clause an interim report (and not later
5 than 4 years after such date of implemen-
6 tation, a final report) on whether any
7 group health plans or health insurance
8 issuers offering group or individual health
9 insurance coverage or types of such plans
10 or coverage have a pattern or practice of
11 routine denial, low payment, or down-cod-
12 ing of claims, or otherwise abuse the 90-
13 day period described in such clause, includ-
14 ing recommendations on ways to discour-
15 age such a pattern or practice.

16 “(F) COSTS OF INDEPENDENT DISPUTE
17 RESOLUTION PROCESS.—In the case of a notifi-
18 cation under paragraph (1)(B) submitted by a
19 nonparticipating provider, nonparticipating
20 emergency facility, group health plan, or health
21 insurance issuer offering group health insur-
22 ance coverage and submitted to a certified IDR
23 entity—

24 “(i) if such entity makes a determina-
25 tion with respect to such notification under

1 subparagraph (A), the party whose offer is
2 not chosen under such subparagraph shall
3 be responsible for paying all fees charged
4 by such entity; and

5 “(ii) if the parties reach a settlement
6 with respect to such notification prior to
7 such a determination, each party shall pay
8 half of all fees charged by such entity, un-
9 less the parties otherwise agree.

10 “(6) TIMING OF PAYMENT.—The total plan or
11 coverage payment required pursuant to subsection
12 (a)(1) or (b)(1), with respect to a qualified IDR
13 item or service for which a determination is made
14 under paragraph (5)(A) or with respect to an item
15 or service for which a payment amount is deter-
16 mined under open negotiations under paragraph (1),
17 shall be made directly to the nonparticipating pro-
18 vider or facility not later than 30 days after the date
19 on which such determination is made.

20 “(7) PUBLICATION OF INFORMATION RELATING
21 TO THE IDR PROCESS.—

22 “(A) PUBLICATION OF INFORMATION.—
23 For each calendar quarter in 2022 and each
24 calendar quarter in a subsequent year, the Sec-

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1 retary shall make available on the public
2 website of the Department of Labor—

3 “(i) the number of notifications sub-
4 mitted under paragraph (1)(B) during
5 such calendar quarter;

6 “(ii) the size of the provider practices
7 and the size of the facilities submitting no-
8 tifications under paragraph (1)(B) during
9 such calendar quarter;

10 “(iii) the number of such notifications
11 with respect to which a determination was
12 made under paragraph (5)(A);

13 “(iv) the information described in sub-
14 paragraph (B) with respect to each notifi-
15 cation with respect to which such a deter-
16 mination was so made;

17 “(v) the number of times the payment
18 amount determined (or agreed to) under
19 this subsection exceeds the qualifying pay-
20 ment amount, specified by items and serv-
21 ices;

22 “(vi) the amount of expenditures
23 made by the Secretary during such cal-
24 endar quarter to carry out the IDR proc-
25 ess;

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1 “(vii) the total amount of fees paid
2 under paragraph (8) during such calendar
3 quarter; and

4 “(viii) the total amount of compensa-
5 tion paid to certified IDR entities under
6 paragraph (5)(F) during such calendar
7 quarter.

8 “(B) INFORMATION.—For purposes of sub-
9 paragraph (A), the information described in
10 this subparagraph is, with respect to a notifica-
11 tion under paragraph (1)(B) by a nonpartici-
12 pating provider, nonparticipating emergency fa-
13 cility, group health plan, or health insurance
14 issuer offering group health insurance cov-
15 erage—

16 “(i) a description of each item and
17 service included with respect to such notifi-
18 cation;

19 “(ii) the geography in which the items
20 and services with respect to such notifica-
21 tion were provided;

22 “(iii) the amount of the offer sub-
23 mitted under paragraph (5)(B) by the
24 group health plan or health insurance
25 issuer (as applicable) and by the non-

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1 participating provider or nonparticipating
2 emergency facility (as applicable) expressed
3 as a percentage of the qualifying payment
4 amount;

5 “(iv) whether the offer selected by the
6 certified IDR entity under paragraph (5)
7 to be the payment applied was the offer
8 submitted by such plan or issuer (as appli-
9 cable) or by such provider or facility (as
10 applicable) and the amount of such offer
11 so selected expressed as a percentage of
12 the qualifying payment amount;

13 “(v) the category and practice spe-
14 cialty of each such provider or facility in-
15 volved in furnishing such items and serv-
16 ices;

17 “(vi) the identity of the health plan or
18 health insurance issuer, provider, or facil-
19 ity, with respect to the notification;

20 “(vii) the length of time in making
21 each determination;

22 “(viii) the compensation paid to the
23 certified IDR entity with respect to the
24 settlement or determination; and

1 “(ix) any other information specified
2 by the Secretary.

3 “(C) IDR ENTITY REQUIREMENTS.—For
4 2022 and each subsequent year, an IDR entity,
5 as a condition of certification as an IDR entity,
6 shall submit to the Secretary such information
7 as the Secretary determines necessary to carry
8 out the provisions of this subsection.

9 “(D) CLARIFICATION.—The Secretary
10 shall ensure the public reporting under this
11 paragraph does not contain information that
12 would disclose privileged or confidential infor-
13 mation of a group health plan or health insur-
14 ance issuer offering group or individual health
15 insurance coverage or of a provider or facility.

16 “(8) ADMINISTRATIVE FEE.—

17 “(A) IN GENERAL.—Each party to a deter-
18 mination under paragraph (5) to which an enti-
19 ty is selected under paragraph (3) in a year
20 shall pay to the Secretary, at such time and in
21 such manner as specified by the Secretary, a
22 fee for participating in the IDR process with re-
23 spect to such determination in an amount de-
24 scribed in subparagraph (B) for such year.

1 “(B) AMOUNT OF FEE.—The amount de-
2 scribed in this subparagraph for a year is an
3 amount established by the Secretary in a man-
4 ner such that the total amount of fees paid
5 under this paragraph for such year is estimated
6 to be equal to the amount of expenditures esti-
7 mated to be made by the Secretary for such
8 year in carrying out the IDR process.

9 “(9) WAIVER AUTHORITY.—The Secretary may
10 modify any deadline or other timing requirement
11 specified under this subsection (other than the es-
12 tablishment date for the IDR process under para-
13 graph (2)(A) and other than under paragraph (6))
14 in cases of extenuating circumstances, as specified
15 by the Secretary, or to ensure that all claims that
16 occur during a 90-day period described in paragraph
17 (5)(E)(ii), but with respect to which a notification is
18 not permitted by reason of such paragraph to be
19 submitted under paragraph (1)(B) during such pe-
20 riod, are eligible for the IDR process.”.

21 (c) IRC.—Section 9816 of the Internal Revenue Code
22 of 1986, as added by section 102, is amended—

23 (1) by redesignating subsection (c) as sub-
24 section (d); and

1 (2) by inserting after subsection (b) the fol-
2 lowing new subsection:

3 “(c) DETERMINATION OF OUT-OF-NETWORK RATES
4 TO BE PAID BY HEALTH PLANS; INDEPENDENT DISPUTE
5 RESOLUTION PROCESS.—

6 “(1) DETERMINATION THROUGH OPEN NEGO-
7 TIATION.—

8 “(A) IN GENERAL.—With respect to an
9 item or service furnished in a year by a non-
10 participating provider or a nonparticipating fa-
11 cility, with respect to a group health plan, in a
12 State described in subsection (a)(3)(K)(ii) with
13 respect to such plan and provider or facility,
14 and for which a payment is required to be made
15 by the plan pursuant to subsection (a)(1) or
16 (b)(1), the provider or facility (as applicable) or
17 plan may, during the 30-day period beginning
18 on the day the provider or facility receives an
19 initial payment or a notice of denial of payment
20 from the plan regarding a claim for payment
21 for such item or service, initiate open negotia-
22 tions under this paragraph between such pro-
23 vider or facility and plan for purposes of deter-
24 mining, during the open negotiation period, an
25 amount agreed on by such provider or facility,

1 respectively, and such plan for payment (includ-
2 ing any cost-sharing) for such item or service.
3 For purposes of this subsection, the open nego-
4 tiation period, with respect to an item or serv-
5 ice, is the 30-day period beginning on the date
6 of initiation of the negotiations with respect to
7 such item or service.

8 “(B) ACCESSING INDEPENDENT DISPUTE
9 RESOLUTION PROCESS IN CASE OF FAILED NE-
10 GOTIATIONS.—In the case of open negotiations
11 pursuant to subparagraph (A), with respect to
12 an item or service, that do not result in a deter-
13 mination of an amount of payment for such
14 item or service by the last day of the open nego-
15 tiation period described in such subparagraph
16 with respect to such item or service, the pro-
17 vider or facility (as applicable) or group health
18 plan that was party to such negotiations may,
19 during the 4-day period beginning on the day
20 after such open negotiation period, initiate the
21 independent dispute resolution process under
22 paragraph (2) with respect to such item or
23 service. The independent dispute resolution
24 process shall be initiated by a party pursuant to
25 the previous sentence by submission to the

1 other party and to the Secretary of a notifica-
2 tion (containing such information as specified
3 by the Secretary) and for purposes of this sub-
4 section, the date of initiation of such process
5 shall be the date of such submission or such
6 other date specified by the Secretary pursuant
7 to regulations that is not later than the date of
8 receipt of such notification by both the other
9 party and the Secretary.

10 “(2) INDEPENDENT DISPUTE RESOLUTION
11 PROCESS AVAILABLE IN CASE OF FAILED OPEN NE-
12 GOTIATIONS.—

13 “(A) ESTABLISHMENT.—Not later than 1
14 year after the date of the enactment of this
15 subsection, the Secretary, jointly with the Sec-
16 retary of Health and Human Services and the
17 Secretary of Labor, shall establish by regulation
18 one independent dispute resolution process (re-
19 ferred to in this subsection as the ‘IDR proc-
20 ess’) under which, in the case of an item or
21 service with respect to which a provider or facil-
22 ity (as applicable) or group health plan submits
23 a notification under paragraph (1)(B) (in this
24 subsection referred to as a ‘qualified IDR item
25 or service’), a certified IDR entity under para-

1 graph (4) determines, subject to subparagraph
2 (B) and in accordance with the succeeding pro-
3 visions of this subsection, the amount of pay-
4 ment under the plan for such item or service
5 furnished by such provider or facility.

6 “(B) AUTHORITY TO CONTINUE NEGOTIA-
7 TIONS.—Under the independent dispute resolu-
8 tion process, in the case that the parties to a
9 determination for a qualified IDR item or serv-
10 ice agree on a payment amount for such item
11 or service during such process but before the
12 date on which the entity selected with respect to
13 such determination under paragraph (4) makes
14 such determination under paragraph (5), such
15 amount shall be treated for purposes of sub-
16 section (a)(3)(K)(ii) as the amount agreed to by
17 such parties for such item or service. In the
18 case of an agreement described in the previous
19 sentence, the independent dispute resolution
20 process shall provide for a method to determine
21 how to allocate between the parties to such de-
22 termination the payment of the compensation of
23 the entity selected with respect to such deter-
24 mination.

1 “(C) CLARIFICATION.—A nonparticipating
2 provider may not, with respect to an item or
3 service furnished by such provider, submit a no-
4 tification under paragraph (1)(B) if such pro-
5 vider is exempt from the requirement under
6 subsection (a) of section 2799B–2 of the Public
7 Health Service Act with respect to such item or
8 service pursuant to subsection (b) of such sec-
9 tion.

10 “(3) TREATMENT OF BATCHING OF ITEMS AND
11 SERVICES.—

12 “(A) IN GENERAL.—Under the IDR proc-
13 ess, the Secretary shall specify criteria under
14 which multiple qualified IDR dispute items and
15 services are permitted to be considered jointly
16 as part of a single determination by an entity
17 for purposes of encouraging the efficiency (in-
18 cluding minimizing costs) of the IDR process.
19 Such items and services may be so considered
20 only if—

21 “(i) such items and services to be in-
22 cluded in such determination are furnished
23 by the same provider or facility;

24 “(ii) payment for such items and serv-
25 ices is required to be made by the same

1 group health plan or health insurance
2 issuer;

3 “(iii) such items and services are re-
4 lated to the treatment of a similar condi-
5 tion; and

6 “(iv) such items and services were
7 furnished during the 30 day period fol-
8 lowing the date on which the first item or
9 service included with respect to such deter-
10 mination was furnished or an alternative
11 period as determined by the Secretary, for
12 use in limited situations, such as by the
13 consent of the parties or in the case of low-
14 volume items and services, to encourage
15 procedural efficiency and minimize health
16 plan and provider administrative costs.

17 “(B) TREATMENT OF BUNDLED PAY-
18 MENTS.—In carrying out subparagraph (A), the
19 Secretary shall provide that, in the case of
20 items and services which are included by a pro-
21 vider or facility as part of a bundled payment,
22 such items and services included in such bun-
23 dled payment may be part of a single deter-
24 mination under this subsection.

1 “(4) CERTIFICATION AND SELECTION OF IDR
2 ENTITIES.—

3 “(A) IN GENERAL.—The Secretary, jointly
4 with the Secretary of Health and Human Serv-
5 ices and the Secretary of Labor, shall establish
6 a process to certify (including to recertify) enti-
7 ties under this paragraph. Such process shall
8 ensure that an entity so certified—

9 “(i) has (directly or through contracts
10 or other arrangements) sufficient medical,
11 legal, and other expertise and sufficient
12 staffing to make determinations described
13 in paragraph (5) on a timely basis;

14 “(ii) is not—

15 “(I) a group health plan, pro-
16 vider, or facility;

17 “(II) an affiliate or a subsidiary
18 of such a group health plan, provider,
19 or facility; or

20 “(III) an affiliate or subsidiary of
21 a professional or trade association of
22 such group health plans or of pro-
23 viders or facilities;

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1 “(iii) carries out the responsibilities of
2 such an entity in accordance with this sub-
3 section;

4 “(iv) meets appropriate indicators of
5 fiscal integrity;

6 “(v) maintains the confidentiality (in
7 accordance with regulations promulgated
8 by the Secretary) of individually identifi-
9 able health information obtained in the
10 course of conducting such determinations;

11 “(vi) does not under the IDR process
12 carry out any determination with respect
13 to which the entity would not pursuant to
14 subclause (I), (II), or (III) of subpara-
15 graph (F)(i) be eligible for selection; and

16 “(vii) meets such other requirements
17 as determined appropriate by the Sec-
18 retary.

19 “(B) PERIOD OF CERTIFICATION.—Subject
20 to subparagraph (C), each certification (includ-
21 ing a recertification) of an entity under the
22 process described in subparagraph (A) shall be
23 for a 5-year period.

24 “(C) REVOCATION.—A certification of an
25 entity under this paragraph may be revoked

1 under the process described in subparagraph
2 (A) if the entity has a pattern or practice of
3 noncompliance with any of the requirements de-
4 scribed in such subparagraph.

5 “(D) PETITION FOR DENIAL OR WITH-
6 DRAWAL.—The process described in subpara-
7 graph (A) shall ensure that an individual, pro-
8 vider, facility, or group health plan may petition
9 for a denial of a certification or a revocation of
10 a certification with respect to an entity under
11 this paragraph for failure of meeting a require-
12 ment of this subsection.

13 “(E) SUFFICIENT NUMBER OF ENTI-
14 TIES.—The process described in subparagraph
15 (A) shall ensure that a sufficient number of en-
16 tities are certified under this paragraph to en-
17 sure the timely and efficient provision of deter-
18 minations described in paragraph (5).

19 “(F) SELECTION OF CERTIFIED IDR ENTI-
20 TY.—The Secretary shall, with respect to the
21 determination of the amount of payment under
22 this subsection of an item or service, provide for
23 a method—

24 “(i) that allows for the group health
25 plan and the nonparticipating provider or

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1 the nonparticipating emergency facility (as
2 applicable) involved in a notification under
3 paragraph (1)(B) to jointly select, not later
4 than the last day of the 3-business day pe-
5 riod following the date of the initiation of
6 the process with respect to such item or
7 service, for purposes of making such deter-
8 mination, an entity certified under this
9 paragraph that—

10 “(I) is not a party to such deter-
11 mination or an employee or agent of
12 such a party;

13 “(II) does not have a material fa-
14 milial, financial, or professional rela-
15 tionship with such a party; and

16 “(III) does not otherwise have a
17 conflict of interest with such a party
18 (as determined by the Secretary); and

19 “(ii) that requires, in the case such
20 parties do not make such selection by such
21 last day, the Secretary to, not later than 6
22 business days after such date of initi-
23 ation—

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1 “(I) select such an entity that
2 satisfies subclauses (I) through (III)
3 of clause (i)); and

4 “(II) provide notification of such
5 selection to the provider or facility (as
6 applicable) and the plan or issuer (as
7 applicable) party to such determina-
8 tion.

9 An entity selected pursuant to the previous sentence to
10 make a determination described in such sentence shall be
11 referred to in this subsection as the ‘certified IDR entity’
12 with respect to such determination.

13 “(5) PAYMENT DETERMINATION.—

14 “(A) IN GENERAL.—Not later than 30
15 days after the date of selection of the certified
16 IDR entity with respect to a determination for
17 a qualified IDR item or service, the certified
18 IDR entity shall—

19 “(i) taking into account the consider-
20 ations specified in subparagraph (C), select
21 one of the offers submitted under subpara-
22 graph (B) to be the amount of payment for
23 such item or service determined under this
24 subsection for purposes of subsection
25 (a)(1) or (b)(1), as applicable; and

1 “(ii) notify the provider or facility and
2 the group health plan party to such deter-
3 mination of the offer selected under clause
4 (i).

5 “(B) SUBMISSION OF OFFERS.—Not later
6 than 10 days after the date of selection of the
7 certified IDR entity with respect to a determina-
8 tion for a qualified IDR item or service, the
9 provider or facility and the group health plan
10 party to such determination—

11 “(i) shall each submit to the certified
12 IDR entity with respect to such determina-
13 tion—

14 “(I) an offer for a payment
15 amount for such item or service fur-
16 nished by such provider or facility;
17 and

18 “(II) such information as re-
19 quested by the certified IDR entity re-
20 lating to such offer; and

21 “(ii) may each submit to the certified
22 IDR entity with respect to such determina-
23 tion any information relating to such offer
24 submitted by either party, including infor-

1 mation relating to any circumstance de-
2 scribed in subparagraph (C)(ii).

3 “(C) CONSIDERATIONS IN DETERMINA-
4 TION.—

5 “(i) IN GENERAL.—In determining
6 which offer is the payment to be applied
7 pursuant to this paragraph, the certified
8 IDR entity, with respect to the determina-
9 tion for a qualified IDR item or service
10 shall consider—

11 “(I) the qualifying payment
12 amounts (as defined in subsection
13 (a)(3)(E)) for the applicable year for
14 items or services that are comparable
15 to the qualified IDR item or service
16 and that are furnished in the same
17 geographic region (as defined by the
18 Secretary for purposes of such sub-
19 section) as such qualified IDR item or
20 service; and

21 “(II) subject to subparagraph
22 (D), information on any circumstance
23 described in clause (ii), such informa-
24 tion as requested in subparagraph
25 (B)(i)(II), and any additional infor-

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1 mation provided in subparagraph
2 (B)(ii).

3 “(ii) ADDITIONAL CIRCUMSTANCES.—
4 For purposes of clause (i)(II), the cir-
5 cumstances described in this clause are,
6 with respect to a qualified IDR item or
7 service of a nonparticipating provider, non-
8 participating emergency facility, or group
9 health plan, the following:

10 “(I) The level of training, experi-
11 ence, and quality and outcomes meas-
12 urements of the provider or facility
13 that furnished such item or service
14 (such as those endorsed by the con-
15 sensus-based entity authorized in sec-
16 tion 1890 of the Social Security Act).

17 “(II) The market share held by
18 the nonparticipating provider or facil-
19 ity or that of the plan or issuer in the
20 geographic region in which the item or
21 service was provided.

22 “(III) The acuity of the indi-
23 vidual receiving such item or service
24 or the complexity of furnishing such
25 item or service to such individual.

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1 “(IV) The teaching status, case
2 mix, and scope of services of the non-
3 participating facility that furnished
4 such item or service.

5 “(V) Demonstrations of good
6 faith efforts (or lack of good faith ef-
7 forts) made by the nonparticipating
8 provider or nonparticipating facility or
9 the plan or issuer to enter into net-
10 work agreements and, if applicable,
11 contracted rates between the provider
12 or facility, as applicable, and the plan
13 or issuer, as applicable, during the
14 previous 4 plan years.

15 “(D) PROHIBITION ON CONSIDERATION OF
16 CERTAIN FACTORS.—In determining which offer
17 is the payment to be applied with respect to
18 qualified IDR items and services furnished by a
19 provider or facility, the certified IDR entity
20 with respect to a determination shall not con-
21 sider usual and customary charges, the amount
22 that would have been billed by such provider or
23 facility with respect to such items and services
24 had the provisions of section 2799B–1 of the
25 Public Health Service Act or 2799B–2 of such

1 Act (as applicable) not applied, or the payment
2 or reimbursement rate for such items and serv-
3 ices furnished by such provider or facility pay-
4 able by a public payor, including under the
5 Medicare program under title XVIII of the So-
6 cial Security Act, under the Medicaid program
7 under title XIX of such Act, under the Chil-
8 dren’s Health Insurance Program under title
9 XXI of such Act, under the TRICARE program
10 under chapter 55 of title 10, United States
11 Code, or under chapter 17 of title 38, United
12 States Code.

13 “(E) EFFECTS OF DETERMINATION.—

14 “(i) IN GENERAL.—A determination
15 of a certified IDR entity under subpara-
16 graph (A)—

17 “(I) shall be binding upon the
18 parties involved, in the absence of a
19 fraudulent claim or evidence of mis-
20 representation of facts presented to
21 the IDR entity involved regarding
22 such claim; and

23 “(II) shall not be subject to judi-
24 cial review, except in a case described
25 in any of paragraphs (1) through (4)

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1 of section 10(a) of title 9, United
2 States Code.

3 “(ii) SUSPENSION OF CERTAIN SUBSE-
4 QUENT IDR REQUESTS.—In the case of a
5 determination of a certified IDR entity
6 under subparagraph (A), with respect to
7 an initial notification submitted under
8 paragraph (1)(B) with respect to qualified
9 IDR items and services and the two par-
10 ties involved with such notification, the
11 party that submitted such notification may
12 not submit during the 90-day period fol-
13 lowing such determination a subsequent
14 notification under such paragraph involv-
15 ing the same other party to such notifica-
16 tion with respect to such an item or service
17 that was the subject of such initial notifi-
18 cation.

19 “(iii) SUBSEQUENT SUBMISSION OF
20 REQUESTS PERMITTED.—In the case of a
21 notification that pursuant to clause (ii) is
22 not permitted to be submitted under para-
23 graph (1)(B) during a 90-day period speci-
24 fied in such clause, if the end of the open
25 negotiation period specified in paragraph

1 (1)(A), that but for this clause would oth-
2 erwise apply with respect to such notifica-
3 tion, occurs during such 90-day period,
4 such paragraph (1)(B) shall be applied as
5 if the reference in such paragraph to the
6 4-day period beginning on the day after
7 such open negotiation period were instead
8 a reference to the 30-day period beginning
9 on the day after the last day of such 90-
10 day period.

11 “(iv) REPORTS.—The Secretary, joint-
12 ly with the Secretary of Labor and the
13 Secretary of the Health and Human Serv-
14 ices, shall examine the impact of the appli-
15 cation of clause (ii) and whether the appli-
16 cation of such clause delays payment deter-
17 minations or impacts early, alternative res-
18 olution of claims (such as through open ne-
19 gotiations), and shall submit to Congress,
20 not later than 2 years after the date of im-
21 plementation of such clause an interim re-
22 port (and not later than 4 years after such
23 date of implementation, a final report) on
24 whether any group health plans or health
25 insurance issuers offering group or indi-

1 vidual health insurance coverage or types
2 of such plans or coverage have a pattern or
3 practice of routine denial, low payment, or
4 down-coding of claims, or otherwise abuse
5 the 90-day period described in such clause,
6 including recommendations on ways to dis-
7 courage such a pattern or practice.

8 “(F) COSTS OF INDEPENDENT DISPUTE
9 RESOLUTION PROCESS.—In the case of a notifi-
10 cation under paragraph (1)(B) submitted by a
11 nonparticipating provider, nonparticipating
12 emergency facility, or group health plan and
13 submitted to a certified IDR entity—

14 “(i) if such entity makes a determina-
15 tion with respect to such notification under
16 subparagraph (A), the party whose offer is
17 not chosen under such subparagraph shall
18 be responsible for paying all fees charged
19 by such entity; and

20 “(ii) if the parties reach a settlement
21 with respect to such notification prior to
22 such a determination, each party shall pay
23 half of all fees charged by such entity, un-
24 less the parties otherwise agree.

1 “(6) TIMING OF PAYMENT.—The total plan
2 payment required pursuant to subsection (a)(1) or
3 (b)(1), with respect to a qualified IDR item or serv-
4 ice for which a determination is made under para-
5 graph (5)(A) or with respect to an item or service
6 for which a payment amount is determined under
7 open negotiations under paragraph (1), shall be
8 made directly to the nonparticipating provider or fa-
9 cility not later than 30 days after the date on which
10 such determination is made.

11 “(7) PUBLICATION OF INFORMATION RELATING
12 TO THE IDR PROCESS.—

13 “(A) PUBLICATION OF INFORMATION.—
14 For each calendar quarter in 2022 and each
15 calendar quarter in a subsequent year, the Sec-
16 retary shall make available on the public
17 website of the Department of the Treasury—

18 “(i) the number of notifications sub-
19 mitted under paragraph (1)(B) during
20 such calendar quarter;

21 “(ii) the size of the provider practices
22 and the size of the facilities submitting no-
23 tifications under paragraph (1)(B) during
24 such calendar quarter;

1 “(iii) the number of such notifications
2 with respect to which a determination was
3 made under paragraph (5)(A);

4 “(iv) the information described in sub-
5 paragraph (B) with respect to each notifi-
6 cation with respect to which such a deter-
7 mination was so made;

8 “(v) the number of times the payment
9 amount determined (or agreed to) under
10 this subsection exceeds the qualifying pay-
11 ment amount, specified by items and serv-
12 ices;

13 “(vi) the amount of expenditures
14 made by the Secretary during such cal-
15 endar quarter to carry out the IDR proc-
16 ess;

17 “(vii) the total amount of fees paid
18 under paragraph (8) during such calendar
19 quarter; and

20 “(viii) the total amount of compensa-
21 tion paid to certified IDR entities under
22 paragraph (5)(F) during such calendar
23 quarter.

24 “(B) INFORMATION.—For purposes of sub-
25 paragraph (A), the information described in

1 this subparagraph is, with respect to a notifica-
2 tion under paragraph (1)(B) by a nonpartici-
3 pating provider, nonparticipating emergency fa-
4 cility, or group health plan—

5 “(i) a description of each item and
6 service included with respect to such notifi-
7 cation;

8 “(ii) the geography in which the items
9 and services with respect to such notifica-
10 tion were provided;

11 “(iii) the amount of the offer sub-
12 mitted under paragraph (5)(B) by the
13 group health plan and by the nonpartici-
14 pating provider or nonparticipating emer-
15 gency facility (as applicable) expressed as
16 a percentage of the qualifying payment
17 amount;

18 “(iv) whether the offer selected by the
19 certified IDR entity under paragraph (5)
20 to be the payment applied was the offer
21 submitted by such plan or by such provider
22 or facility (as applicable) and the amount
23 of such offer so selected expressed as a
24 percentage of the qualifying payment
25 amount;

1 “(v) the category and practice spe-
2 cialty of each such provider or facility in-
3 volved in furnishing such items and serv-
4 ices;

5 “(vi) the identity of the group health
6 plan, provider, or facility, with respect to
7 the notification;

8 “(vii) the length of time in making
9 each determination;

10 “(viii) the compensation paid to the
11 certified IDR entity with respect to the
12 settlement or determination; and

13 “(ix) any other information specified
14 by the Secretary.

15 “(C) IDR ENTITY REQUIREMENTS.—For
16 2022 and each subsequent year, an IDR entity,
17 as a condition of certification as an IDR entity,
18 shall submit to the Secretary such information
19 as the Secretary determines necessary to carry
20 out the provisions of this subsection.

21 “(D) CLARIFICATION.—The Secretary
22 shall ensure the public reporting under this
23 paragraph does not contain information that
24 would disclose privileged or confidential infor-
25 mation of a group health plan or health insur-

1 ance issuer offering group or individual health
2 insurance coverage or of a provider or facility.

3 “(8) ADMINISTRATIVE FEE.—

4 “(A) IN GENERAL.—Each party to a deter-
5 mination under paragraph (5) to which an enti-
6 ty is selected under paragraph (3) in a year
7 shall pay to the Secretary, at such time and in
8 such manner as specified by the Secretary, a
9 fee for participating in the IDR process with re-
10 spect to such determination in an amount de-
11 scribed in subparagraph (B) for such year.

12 “(B) AMOUNT OF FEE.—The amount de-
13 scribed in this subparagraph for a year is an
14 amount established by the Secretary in a man-
15 ner such that the total amount of fees paid
16 under this paragraph for such year is estimated
17 to be equal to the amount of expenditures esti-
18 mated to be made by the Secretary for such
19 year in carrying out the IDR process.

20 “(9) WAIVER AUTHORITY.—The Secretary may
21 modify any deadline or other timing requirement
22 specified under this subsection (other than the es-
23 tablishment date for the IDR process under para-
24 graph (2)(A) and other than under paragraph (6))
25 in cases of extenuating circumstances, as specified

1 by the Secretary, or to ensure that all claims that
2 occur during a 90-day period described in paragraph
3 (5)(E)(ii), but with respect to which a notification is
4 not permitted by reason of such paragraph to be
5 submitted under paragraph (1)(B) during such pe-
6 riod, are eligible for the IDR process.”.

7 **SEC. 104. HEALTH CARE PROVIDER REQUIREMENTS RE-**
8 **GARDING SURPRISE MEDICAL BILLING.**

9 (a) IN GENERAL.—Title XXVII of the Public Health
10 Service Act (42 U.S.C. 300gg et seq.) is amended by in-
11 serting after part D, as added by section 102, the fol-
12 lowing:

13 **“PART E—HEALTH CARE PROVIDER**
14 **REQUIREMENTS**
15 **“SEC. 2799B-1. BALANCE BILLING IN CASES OF EMERGENCY**
16 **SERVICES.**

17 “(a) IN GENERAL.—In the case of a participant, ben-
18 eficiary, or enrollee with benefits under a group health
19 plan or group or individual health insurance coverage of-
20 fered by a health insurance issuer and who is furnished
21 during a plan year beginning on or after January 1, 2022,
22 emergency services (for which benefits are provided under
23 the plan or coverage) with respect to an emergency med-
24 ical condition with respect to a visit at an emergency de-

1 partment of a hospital or an independent freestanding
2 emergency department—

3 “(1) in the case that the hospital or inde-
4 pendent freestanding emergency department is a
5 nonparticipating emergency facility, the emergency
6 department of a hospital or independent free-
7 standing emergency department shall not bill, and
8 shall not hold liable, the participant, beneficiary, or
9 enrollee for a payment amount for such emergency
10 services so furnished that is more than the cost-
11 sharing requirement for such services (as determined
12 in accordance with clauses (ii) and (iii) of section
13 2799A–1(a)(1)(C), of section 9816(a)(1)(C) of the
14 Internal Revenue Code of 1986, and of section
15 716(a)(1)(C) of the Employee Retirement Income
16 Security Act of 1974, as applicable); and

17 “(2) in the case that such services are furnished
18 by a nonparticipating provider, the health care pro-
19 vider shall not bill, and shall not hold liable, such
20 participant, beneficiary, or enrollee for a payment
21 amount for an emergency service furnished to such
22 individual by such provider with respect to such
23 emergency medical condition and visit for which the
24 individual receives emergency services at the hospital
25 or emergency department that is more than the cost-

1 sharing requirement for such services furnished by
2 the provider (as determined in accordance with
3 clauses (ii) and (iii) of section 2799A–1(a)(1)(C), of
4 section 9816(a)(1)(C) of the Internal Revenue Code
5 of 1986, and of section 716(a)(1)(C) of the Em-
6 ployee Retirement Income Security Act of 1974, as
7 applicable).

8 “(b) DEFINITION.—In this section, the term ‘visit’
9 shall have such meaning as applied to such term for pur-
10 poses of section 2799A–1(b).

11 **“SEC. 2799B–2. BALANCE BILLING IN CASES OF NON-EMER-**
12 **GENCY SERVICES PERFORMED BY NON-**
13 **PARTICIPATING PROVIDERS AT CERTAIN**
14 **PARTICIPATING FACILITIES.**

15 “(a) IN GENERAL.—Subject to subsection (b), in the
16 case of a participant, beneficiary, or enrollee with benefits
17 under a group health plan or group or individual health
18 insurance coverage offered by a health insurance issuer
19 and who is furnished during a plan year beginning on or
20 after January 1, 2022, items or services (other than emer-
21 gency services to which section 2799B–1 applies) for
22 which benefits are provided under the plan or coverage
23 at a participating health care facility by a nonparticipating
24 provider, such provider shall not bill, and shall not hold
25 liable, such participant, beneficiary, or enrollee for a pay-

1 ment amount for such an item or service furnished by such
2 provider with respect to a visit at such facility that is more
3 than the cost-sharing requirement for such item or service
4 (as determined in accordance with subparagraphs (A) and
5 (B) of section 2799A–1(b)(1) of section 9816(b)(1) of the
6 Internal Revenue Code of 1986, and of section 716(b)(1)
7 of the Employee Retirement Income Security Act of 1974,
8 as applicable).

9 “(b) EXCEPTION.—

10 “(1) IN GENERAL.—Subsection (a) shall not
11 apply with respect to items or services (other than
12 ancillary services described in paragraph (2)) fur-
13 nished by a nonparticipating provider to a partici-
14 pant, beneficiary, or enrollee of a group health plan
15 or group or individual health insurance coverage of-
16 fered by a health insurance issuer, if the provider
17 satisfies the notice and consent criteria of subsection
18 (d).

19 “(2) ANCILLARY SERVICES DESCRIBED.—For
20 purposes of paragraph (1), ancillary services de-
21 scribed in this paragraph are, with respect to a par-
22 ticipating health care facility—

23 “(A) subject to paragraph (3), items and
24 services related to emergency medicine, anesthe-
25 siology, pathology, radiology, and neonatology,

1 whether or not provided by a physician or non-
2 physician practitioner, and items and services
3 provided by assistant surgeons, hospitalists, and
4 intensivists;

5 “(B) subject to paragraph (3), diagnostic
6 services (including radiology and laboratory
7 services);

8 “(C) items and services provided by such
9 other specialty practitioners, as the Secretary
10 specifies through rulemaking; and

11 “(D) items and services provided by a non-
12 participating provider if there is no partici-
13 pating provider who can furnish such item or
14 service at such facility.

15 “(3) EXCEPTION.—The Secretary may, through
16 rulemaking, establish a list (and update such list pe-
17 riodically) of advanced diagnostic laboratory tests,
18 which shall not be included as an ancillary service
19 described in paragraph (2) and with respect to
20 which subsection (a) would apply.

21 “(c) CLARIFICATION.—In the case of a nonpartici-
22 pating provider that satisfies the notice and consent cri-
23 teria of subsection (d) with respect to an item or service
24 (referred to in this subsection as a ‘covered item or serv-
25 ice’), such notice and consent criteria may not be con-

1 strued as applying with respect to any item or service that
2 is furnished as a result of unforeseen, urgent medical
3 needs that arise at the time such covered item or service
4 is furnished. For purposes of the previous sentence, a cov-
5 ered item or service shall not include an ancillary service
6 described in subsection (b)(2).

7 “(d) NOTICE AND CONSENT TO BE TREATED BY A
8 NONPARTICIPATING PROVIDER OR NONPARTICIPATING
9 FACILITY.—

10 “(1) IN GENERAL.—A nonparticipating provider
11 or nonparticipating facility satisfies the notice and
12 consent criteria of this subsection, with respect to
13 items or services furnished by the provider or facility
14 to a participant, beneficiary, or enrollee of a group
15 health plan or group or individual health insurance
16 coverage offered by a health insurance issuer, if the
17 provider (or, if applicable, the participating health
18 care facility on behalf of such provider) or non-
19 participating facility—

20 “(A) in the case that the participant, bene-
21 ficiary, or enrollee makes an appointment to be
22 furnished such items or services at least 72
23 hours prior to the date on which the individual
24 is to be furnished such items or services, pro-
25 vides to the participant, beneficiary, or enrollee

1 (or to an authorized representative of the par-
2 ticipant, beneficiary, or enrollee) not later than
3 72 hours prior to the date on which the indi-
4 vidual is furnished such items or services (or, in
5 the case that the participant, beneficiary, or en-
6 rollee makes such an appointment within 72
7 hours of when such items or services are to be
8 furnished, provides to the participant, bene-
9 ficiary, or enrollee (or to an authorized rep-
10 resentative of the participant, beneficiary, or
11 enrollee) on such date the appointment is
12 made), a written notice in paper or electronic
13 form, as selected by the participant, beneficiary,
14 or enrollee, (and including electronic notifica-
15 tion, as practicable) specified by the Secretary,
16 not later than July 1, 2021, through guidance
17 (which shall be updated as determined nec-
18 essary by the Secretary) that—

19 “(i) contains the information required
20 under paragraph (2);

21 “(ii) clearly states that consent to re-
22 ceive such items and services from such
23 nonparticipating provider or nonpartici-
24 pating facility is optional and that the par-
25 ticipant, beneficiary, or enrollee may in-

1 stead seek care from a participating pro-
2 vider or at a participating facility, with re-
3 spect to such plan or coverage, as applica-
4 ble, in which case the cost-sharing respon-
5 sibility of the participant, beneficiary, or
6 enrollee would not exceed such responsi-
7 bility that would apply with respect to such
8 an item or service that is furnished by a
9 participating provider or participating fa-
10 cility, as applicable with respect to such
11 plan; and

12 “(iii) is available in the 15 most com-
13 mon languages in the geographic region of
14 the applicable facility;

15 “(B) obtains from the participant, bene-
16 ficiary, or enrollee (or from such an authorized
17 representative) the consent described in para-
18 graph (3) to be treated by a nonparticipating
19 provider or nonparticipating facility; and

20 “(C) provides a signed copy of such con-
21 sent to the participant, beneficiary, or enrollee
22 through mail or email (as selected by the par-
23 ticipant, beneficiary, or enrollee).

24 “(2) INFORMATION REQUIRED UNDER WRITTEN
25 NOTICE.—For purposes of paragraph (1)(A)(i), the

1 information described in this paragraph, with re-
2 spect to a nonparticipating provider or nonpartici-
3 pating facility and a participant, beneficiary, or en-
4 rollee of a group health plan or group or individual
5 health insurance coverage offered by a health insur-
6 ance issuer, is each of the following:

7 “(A) Notification, as applicable, that the
8 health care provider is a nonparticipating pro-
9 vider with respect to the health plan or the
10 health care facility is a nonparticipating facility
11 with respect to the health plan.

12 “(B) Notification of the good faith esti-
13 mated amount that such provider or facility
14 may charge the participant, beneficiary, or en-
15 rollee for such items and services involved, in-
16 cluding a notification that the provision of such
17 estimate or consent to be treated under para-
18 graph (3) does not constitute a contract with
19 respect to the charges estimated for such items
20 and services.

21 “(C) In the case of a participating facility
22 and a nonparticipating provider, a list of any
23 participating providers at the facility who are
24 able to furnish such items and services involved
25 and notification that the participant, bene-

1 ficiary, or enrollee may be referred, at their op-
2 tion, to such a participating provider.

3 “(D) Information about whether prior au-
4 thorization or other care management limita-
5 tions may be required in advance of receiving
6 such items or services at the facility.

7 “(3) CONSENT DESCRIBED TO BE TREATED BY
8 A NONPARTICIPATING PROVIDER OR NONPARTICI-
9 PATING FACILITY.—For purposes of paragraph
10 (1)(B), the consent described in this paragraph, with
11 respect to a participant, beneficiary, or enrollee of a
12 group health plan or group or individual health in-
13 surance coverage offered by a health insurance
14 issuer who is to be furnished items or services by a
15 nonparticipating provider or nonparticipating facil-
16 ity, is a document specified by the Secretary, in con-
17 sultation with the Secretary of Labor, through guid-
18 ance that shall be signed by the participant, bene-
19 ficiary, or enrollee before such items or services are
20 furnished and that —

21 “(A) acknowledges (in clear and under-
22 standable language) that the participant, bene-
23 ficiary, or enrollee has been—

24 “(i) provided with the written notice
25 under paragraph (1)(A);

1 “(ii) informed that the payment of
2 such charge by the participant, beneficiary,
3 or enrollee may not accrue toward meeting
4 any limitation that the plan or coverage
5 places on cost-sharing, including an expla-
6 nation that such payment may not apply to
7 an in-network deductible applied under the
8 plan or coverage; and

9 “(iii) provided the opportunity to re-
10 ceive the written notice under paragraph
11 (1)(A) in the form selected by the partici-
12 pant, beneficiary or enrollee; and

13 “(B) documents the date on which the par-
14 ticipant, beneficiary, or enrollee received the
15 written notice under paragraph (1)(A) and the
16 date on which the individual signed such con-
17 sent to be furnished such items or services by
18 such provider or facility.

19 “(4) RULE OF CONSTRUCTION.—The consent
20 described in paragraph (3), with respect to a partici-
21 pant, beneficiary, or enrollee of a group health plan
22 or group or individual health insurance coverage of-
23 fered by a health insurance issuer, shall constitute
24 only consent to the receipt of the information pro-
25 vided pursuant to this subsection and shall not con-

1 stitute a contractual agreement of the participant,
2 beneficiary, or enrollee to any estimated charge or
3 amount included in such information.

4 “(e) RETENTION OF CERTAIN DOCUMENTS.—A non-
5 participating facility (with respect to such facility or any
6 nonparticipating provider at such facility) or a partici-
7 pating facility (with respect to nonparticipating providers
8 at such facility) that obtains from a participant, bene-
9 ficiary, or enrollee of a group health plan or group or indi-
10 vidual health insurance coverage offered by a health insur-
11 ance issuer (or an authorized representative of such par-
12 ticipant, beneficiary, or enrollee) a written notice in ac-
13 cordance with subsection (d)(1)(B), with respect to fur-
14 nishing an item or service to such participant, beneficiary,
15 or enrollee, shall retain such notice for at least a 7-year
16 period after the date on which such item or service is so
17 furnished.

18 “(f) DEFINITIONS.—In this section:

19 “(1) The terms ‘nonparticipating provider’ and
20 ‘participating provider’ have the meanings given
21 such terms, respectively, in subsection (a)(3) of sec-
22 tion 2799A–1.

23 “(2) The term ‘participating health care facil-
24 ity’ has the meaning given such term in subsection
25 (b)(2) of section 2799A–1.

1 “(3) The term ‘nonparticipating facility’
2 means—

3 “(A) with respect to emergency services (as
4 defined in section 2799A–1(a)(3)(C)(i)) and a
5 group health plan or group or individual health
6 insurance coverage offered by a health insur-
7 ance issuer, an emergency department of a hos-
8 pital, or an independent freestanding emergency
9 department, that does not have a contractual
10 relationship with the plan or issuer, respec-
11 tively, with respect to the furnishing of such
12 services under the plan or coverage, respec-
13 tively; and

14 “(B) with respect to services described in
15 section 2799A–1(a)(3)(C)(ii) and a group
16 health plan or group or individual health insur-
17 ance coverage offered by a health insurance
18 issuer, a hospital or an independent free-
19 standing emergency department, that does not
20 have a contractual relationship with the plan or
21 issuer, respectively, with respect to the fur-
22 nishing of such services under the plan or cov-
23 erage, respectively.

24 “(4) The term ‘participating facility’ means—

1 “(A) with respect to emergency services (as
2 defined in clause (i) of section 2799A–
3 1(a)(3)(C)) that are not described in clause(ii)
4 of such section and a group health plan or
5 group or individual health insurance coverage
6 offered by a health insurance issuer, an emer-
7 gency department of a hospital, or an inde-
8 pendent freestanding emergency department,
9 that has a direct or indirect contractual rela-
10 tionship with the plan or issuer, respectively,
11 with respect to the furnishing of such services
12 under the plan or coverage, respectively; and

13 “(B) with respect to services that pursuant
14 to clause (ii) of section 2799A–1(a)(3)(C), of
15 section 9816(a)(3) of the Internal Revenue
16 Code of 1986, and of section 716(a)(3) of the
17 Employee Retirement Income Security Act of
18 1974, as applicable are included as emergency
19 services (as defined in clause (i) of such section
20 and a group health plan or group or individual
21 health insurance coverage offered by a health
22 insurance issuer, a hospital or an independent
23 freestanding emergency department, that has a
24 contractual relationship with the plan or cov-
25 erage, respectively, with respect to the fur-

1 nishing of such services under the plan or cov-
2 erage, respectively.

3 **“SEC. 2799B-3. PROVIDER REQUIREMENTS WITH RESPECT**
4 **TO DISCLOSURE ON PATIENT PROTECTIONS**
5 **AGAINST BALANCE BILLING.**

6 “Beginning not later than January 1, 2022, each
7 health care provider and health care facility shall make
8 publicly available, and (if applicable) post on a public
9 website of such provider or facility and provide to individ-
10 uals who are participants, beneficiaries, or enrollees of a
11 group health plan or group or individual health insurance
12 coverage offered by a health insurance issuer a one-page
13 notice (either postal or electronic mail, as specified by the
14 participant, beneficiary, or enrollee) in clear and under-
15 standable language containing information on—

16 “(1) the requirements and prohibitions of such
17 provider or facility under sections 2799B-1 and
18 2799B-2 (relating to prohibitions on balance billing
19 in certain circumstances);

20 “(2) any other applicable State law require-
21 ments on such provider or facility regarding the
22 amounts such provider or facility may, with respect
23 to an item or service, charge a participant, bene-
24 ficiary, or enrollee of a group health plan or group
25 or individual health insurance coverage offered by a

1 health insurance issuer with respect to which such
2 provider or facility does not have a contractual rela-
3 tionship for furnishing such item or service under
4 the plan or coverage, respectively, after receiving
5 payment from the plan or coverage, respectively, for
6 such item or service and any applicable cost-sharing
7 payment from such participant, beneficiary, or en-
8 rollee; and

9 “(3) information on contacting appropriate
10 State and Federal agencies in the case that an indi-
11 vidual believes that such provider or facility has vio-
12 lated any requirement described in paragraph (1) or
13 (2) with respect to such individual.

14 **“SEC. 2799B-4. ENFORCEMENT.**

15 “(a) STATE ENFORCEMENT.—

16 “(1) STATE AUTHORITY.—Each State may re-
17 quire a provider or health care facility (including a
18 provider of air ambulance services) subject to the re-
19 quirements of this part to satisfy such requirements
20 applicable to the provider or facility.

21 “(2) FAILURE TO IMPLEMENT REQUIRE-
22 MENTS.—In the case of a determination by the Sec-
23 retary that a State has failed to substantially en-
24 force the requirements to which paragraph (1) ap-
25 plies with respect to applicable providers and facili-

1 ties in the State, the Secretary shall enforce such re-
2 quirements under subsection (b) insofar as they re-
3 late to violations of such requirements occurring in
4 such State.

5 “(3) NOTIFICATION OF APPLICABLE SEC-
6 RETARY.—A State may notify the Secretary of
7 Labor, Secretary of Health and Human Services, or
8 the Secretary of the Treasury, as applicable, of in-
9 stances of violations of sections 2799B–1, 2799B–2,
10 or 2799B–5 with respect to participants, bene-
11 ficiaries, or enrollees under a group health plan or
12 group or individual health insurance coverage, as ap-
13 plicable offered by a health insurance issuer and any
14 enforcement actions taken against providers or fa-
15 cilities as a result of such violations, including the
16 disposition of any such enforcement actions.

17 “(b) SECRETARIAL ENFORCEMENT AUTHORITY.—

18 “(1) IN GENERAL.—If a provider or facility is
19 found by the Secretary to be in violation of a re-
20 quirement to which subsection (a)(1) applies, the
21 Secretary may apply a civil monetary penalty with
22 respect to such provider or facility (including, as ap-
23 plicable, a provider of air ambulance services) in an
24 amount not to exceed \$10,000 per violation. The
25 provisions of subsections (c) (with the exception of

1 the first sentence of paragraph (1) of such sub-
2 section), (d), (e), (g), (h), (k), and (l) of section
3 1128A of the Social Security Act shall apply to a
4 civil monetary penalty or assessment under this sub-
5 section in the same manner as such provisions apply
6 to a penalty, assessment, or proceeding under sub-
7 section (a) of such section.

8 “(2) LIMITATION.—The provisions of para-
9 graph (1) shall apply to enforcement of a provision
10 (or provisions) specified in subsection (a)(1) only as
11 provided under subsection (a)(2).

12 “(3) COMPLAINT PROCESS.—The Secretary
13 shall, through rulemaking, establish a process to re-
14 ceive consumer complaints of violations of such pro-
15 visions and provide a response to such complaints
16 within 60 days of receipt of such complaints.

17 “(4) EXCEPTION.—The Secretary shall waive
18 the penalties described under paragraph (1) with re-
19 spect to a facility or provider (including a provider
20 of air ambulance services) who does not knowingly
21 violate, and should not have reasonably known it vio-
22 lated, section 2799B–1 or 2799B–2 (or, in the case
23 of a provider of air ambulance services, section
24 2799B–5) with respect to a participant, beneficiary,
25 or enrollee, if such facility or provider, within 30

1 days of the violation, withdraws the bill that was in
2 violation of such provision and reimburses the health
3 plan or enrollee, as applicable, in an amount equal
4 to the difference between the amount billed and the
5 amount allowed to be billed under the provision, plus
6 interest, at an interest rate determined by the Sec-
7 retary.

8 “(5) HARDSHIP EXEMPTION.—The Secretary
9 may establish a hardship exemption to the penalties
10 under this subsection.

11 “(c) CONTINUED APPLICABILITY OF STATE LAW.—
12 The sections specified in subsection (a)(1) shall not be
13 construed to supersede any provision of State law which
14 establishes, implements, or continues in effect any require-
15 ment or prohibition except to the extent that such require-
16 ment or prohibition prevents the application of a require-
17 ment or prohibition of such a section.”.

18 (b) SECRETARY OF LABOR ENFORCEMENT.—

19 (1) IN GENERAL.—Part 5 of subtitle B of title
20 I of the Employee Retirement Income Security Act
21 of 1974 (29 U.S.C. 1131 et seq.) is amended by
22 adding at the end the following new section:

1 **“SEC. 522. COORDINATION OF ENFORCEMENT REGARDING**
2 **VIOLATIONS OF CERTAIN HEALTH CARE PRO-**
3 **VIDER REQUIREMENTS; COMPLAINT PROC-**
4 **ESS.**

5 “(a) INVESTIGATING VIOLATIONS.—Upon receiving a
6 notice from a State or the Secretary of Health and Human
7 Services of violations of sections 2799B–1, 2799B–2, or
8 2799B–5 of the Public Health Service Act, the Secretary
9 of Labor shall identify patterns of such violations with re-
10 spect to participants or beneficiaries under a group health
11 plan or group health insurance coverage offered by a
12 health insurance issuer and conduct an investigation pur-
13 suant to section 504 where appropriate, as determined by
14 the Secretary. The Secretary shall coordinate with States
15 and the Secretary of Health and Human Services, in ac-
16 cordance with section 506 and with section 104 of Health
17 Insurance Portability and Accountability Act of 1996,
18 where appropriate, as determined by the Secretary, to en-
19 sure that appropriate measures have been taken to correct
20 such violations retrospectively and prospectively with re-
21 spect to participants or beneficiaries under a group health
22 plan or group health insurance coverage offered by a
23 health insurance issuer.

24 “(b) COMPLAINT PROCESS.— Not later than January
25 1, 2022, the Secretary shall ensure a process under which
26 the Secretary—

1 “(1) may receive complaints from participants
2 and beneficiaries of group health plans or group
3 health insurance coverage offered by a health insur-
4 ance issuer relating to alleged violations of the sec-
5 tions specified in subsection (a); and

6 “(2) transmits such complaints to States or the
7 Secretary of Health and Human Services (as deter-
8 mined appropriate by the Secretary) for potential
9 enforcement actions.”.

10 (2) TECHNICAL AMENDMENT.—The table of
11 contents in section 1 of the Employee Retirement
12 Income Security Act of 1974 (29 U.S.C. 1001 et
13 seq.) is amended by inserting after the item relating
14 to section 521 the following new item:

 “Sec. 522. Coordination of enforcement regarding violations of certain health
 care provider requirements; complaint process.”.

15 **SEC. 105. ENDING SURPRISE AIR AMBULANCE BILLS.**

16 (a) GROUP HEALTH PLANS AND INDIVIDUAL AND
17 GROUP HEALTH INSURANCE COVERAGE.—

18 (1) PHSA AMENDMENTS.—Part D of title
19 XXVII of the Public Health Service Act, as added
20 and amended by section 102 and further amended
21 by the previous provisions of this title, is further
22 amended by inserting after section 2799A–1 the fol-
23 lowing:

1 **“SEC. 2799A-2. ENDING SURPRISE AIR AMBULANCE BILLS.**

2 “(a) IN GENERAL.—In the case of a participant, ben-
3 eficiary, or enrollee who is in a group health plan or group
4 or individual health insurance coverage offered by a health
5 insurance issuer and who receives air ambulance services
6 from a nonparticipating provider (as defined in section
7 2799A-1(a)(3)(G)) with respect to such plan or coverage,
8 if such services would be covered if provided by a partici-
9 pating provider (as defined in such section) with respect
10 to such plan or coverage—

11 “(1) the cost-sharing requirement with respect
12 to such services shall be the same requirement that
13 would apply if such services were provided by such
14 a participating provider, and any coinsurance or de-
15 ductible shall be based on rates that would apply for
16 such services if they were furnished by such a par-
17 ticipating provider;

18 “(2) such cost-sharing amounts shall be count-
19 ed towards the in-network deductible and in-network
20 out-of-pocket maximum amount under the plan or
21 coverage for the plan year (and such in-network de-
22 ductible shall be applied) with respect to such items
23 and services so furnished in the same manner as if
24 such cost-sharing payments were with respect to
25 items and services furnished by a participating pro-
26 vider; and

1 “(3) the group health plan or health insurance
2 issuer, respectively, shall—

3 “(A) not later than 30 calendar days after
4 the bill for such services is transmitted by such
5 provider, send to the provider, an initial pay-
6 ment or notice of denial of payment; and

7 “(B) pay a total plan or coverage payment,
8 in accordance with, if applicable, subsection
9 (b)(6), directly to such provider furnishing such
10 services to such participant, beneficiary, or en-
11 rollee that is, with application of any initial
12 payment under subparagraph (A), equal to the
13 amount by which the out-of-network rate (as
14 defined in section 2799A–1(a)(3)(K)) for such
15 services and year involved exceeds the cost-shar-
16 ing amount imposed under the plan or cov-
17 erage, respectively, for such services (as deter-
18 mined in accordance with paragraphs (1) and
19 (2)).

20 “(b) DETERMINATION OF OUT-OF-NETWORK RATES
21 TO BE PAID BY HEALTH PLANS; INDEPENDENT DISPUTE
22 RESOLUTION PROCESS.—

23 “(1) DETERMINATION THROUGH OPEN NEGO-
24 TATION.—

1 “(A) IN GENERAL.—With respect to air
2 ambulance services furnished in a year by a
3 nonparticipating provider, with respect to a
4 group health plan or health insurance issuer of-
5 fering group or individual health insurance cov-
6 erage, and for which a payment is required to
7 be made by the plan or coverage pursuant to
8 subsection (a)(3), the provider or plan or cov-
9 erage may, during the 30-day period beginning
10 on the day the provider receives an initial pay-
11 ment or a notice of denial of payment from the
12 plan or coverage regarding a claim for payment
13 for such service, initiate open negotiations
14 under this paragraph between such provider
15 and plan or coverage for purposes of deter-
16 mining, during the open negotiation period, an
17 amount agreed on by such provider, and such
18 plan or coverage for payment (including any
19 cost-sharing) for such service. For purposes of
20 this subsection, the open negotiation period,
21 with respect to air ambulance services, is the
22 30-day period beginning on the date of initi-
23 ation of the negotiations with respect to such
24 services.

1 “(B) ACCESSING INDEPENDENT DISPUTE
2 RESOLUTION PROCESS IN CASE OF FAILED NE-
3 GOTIATIONS.—In the case of open negotiations
4 pursuant to subparagraph (A), with respect to
5 air ambulance services, that do not result in a
6 determination of an amount of payment for
7 such services by the last day of the open nego-
8 tiation period described in such subparagraph
9 with respect to such services, the provider or
10 group health plan or health insurance issuer of-
11 fering group or individual health insurance cov-
12 erage that was party to such negotiations may,
13 during the 4-day period beginning on the day
14 after such open negotiation period, initiate the
15 independent dispute resolution process under
16 paragraph (2) with respect to such item or
17 service. The independent dispute resolution
18 process shall be initiated by a party pursuant to
19 the previous sentence by submission to the
20 other party and to the Secretary of a notifica-
21 tion (containing such information as specified
22 by the Secretary) and for purposes of this sub-
23 section, the date of initiation of such process
24 shall be the date of such submission or such
25 other date specified by the Secretary pursuant

1 to regulations that is not later than the date of
2 receipt of such notification by both the other
3 party and the Secretary.

4 “(2) INDEPENDENT DISPUTE RESOLUTION
5 PROCESS AVAILABLE IN CASE OF FAILED OPEN NE-
6 GOTIATIONS.—

7 “(A) ESTABLISHMENT.—Not later than 1
8 year after the date of the enactment of this
9 subsection, the Secretary, jointly with the Sec-
10 retary of Labor and the Secretary of the Treas-
11 ury, shall establish by regulation one inde-
12 pendent dispute resolution process (referred to
13 in this subsection as the ‘IDR process’) under
14 which, in the case of air ambulance services
15 with respect to which a provider or group
16 health plan or health insurance issuer offering
17 group or individual health insurance coverage
18 submits a notification under paragraph (1)(B)
19 (in this subsection referred to as a ‘qualified
20 IDR air ambulance services’), a certified IDR
21 entity under paragraph (4) determines, subject
22 to subparagraph (B) and in accordance with
23 the succeeding provisions of this subsection, the
24 amount of payment under the plan or coverage
25 for such services furnished by such provider.

1 “(B) AUTHORITY TO CONTINUE NEGOTIA-
2 TIONS.—Under the independent dispute resolu-
3 tion process, in the case that the parties to a
4 determination for qualified IDR air ambulance
5 services agree on a payment amount for such
6 services during such process but before the date
7 on which the entity selected with respect to
8 such determination under paragraph (4) makes
9 such determination under paragraph (5), such
10 amount shall be treated for purposes of section
11 2799A–1(a)(3)(K)(ii) as the amount agreed to
12 by such parties for such services. In the case of
13 an agreement described in the previous sen-
14 tence, the independent dispute resolution proc-
15 ess shall provide for a method to determine how
16 to allocate between the parties to such deter-
17 mination the payment of the compensation of
18 the entity selected with respect to such deter-
19 mination.

20 “(C) CLARIFICATION.—A nonparticipating
21 provider may not, with respect to an item or
22 service furnished by such provider, submit a no-
23 tification under paragraph (1)(B) if such pro-
24 vider is exempt from the requirement under
25 subsection (a) of section 2799B–2 with respect

1 to such item or service pursuant to subsection
2 (b) of such section.

3 “(3) TREATMENT OF BATCHING OF SERV-
4 ICES.—The provisions of section 2799A–1(c)(3)
5 shall apply with respect to a notification submitted
6 under this subsection with respect to air ambulance
7 services in the same manner and to the same extent
8 such provisions apply with respect to a notification
9 submitted under section 2799A–1(c) with respect to
10 items and services described in such section.

11 “(4) IDR ENTITIES.—

12 “(A) ELIGIBILITY.—An IDR entity cer-
13 tified under this subsection is an IDR entity
14 certified under section 2799A–1(c)(4).

15 “(B) SELECTION OF CERTIFIED IDR ENTI-
16 TY.—The provisions of subparagraph (F) of
17 section 2799A–1(c)(4) shall apply with respect
18 to selecting an IDR entity certified pursuant to
19 subparagraph (A) with respect to the deter-
20 mination of the amount of payment under this
21 subsection of air ambulance services in the
22 same manner as such provisions apply with re-
23 spect to selecting an IDR entity certified under
24 such section with respect to the determination
25 of the amount of payment under section

1 2799A–1(c) of an item or service. An entity se-
2 lected pursuant to the previous sentence to
3 make a determination described in such sen-
4 tence shall be referred to in this subsection as
5 the ‘certified IDR entity’ with respect to such
6 determination.

7 “(5) PAYMENT DETERMINATION.—

8 “(A) IN GENERAL.—Not later than 30
9 days after the date of selection of the certified
10 IDR entity with respect to a determination for
11 qualified IDR ambulance services, the certified
12 IDR entity shall—

13 “(i) taking into account the consider-
14 ations specified in subparagraph (C), select
15 one of the offers submitted under subpara-
16 graph (B) to be the amount of payment for
17 such services determined under this sub-
18 section for purposes of subsection (a)(3);
19 and

20 “(ii) notify the provider or facility and
21 the group health plan or health insurance
22 issuer offering group or individual health
23 insurance coverage party to such deter-
24 mination of the offer selected under clause
25 (i).

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1 “(B) SUBMISSION OF OFFERS.—Not later
2 than 10 days after the date of selection of the
3 certified IDR entity with respect to a deter-
4 mination for qualified IDR air ambulance serv-
5 ices, the provider and the group health plan or
6 health insurance issuer offering group or indi-
7 vidual health insurance coverage party to such
8 determination—

9 “(i) shall each submit to the certified
10 IDR entity with respect to such determina-
11 tion—

12 “(I) an offer for a payment
13 amount for such services furnished by
14 such provider; and

15 “(II) such information as re-
16 quested by the certified IDR entity re-
17 lating to such offer; and

18 “(ii) may each submit to the certified
19 IDR entity with respect to such determina-
20 tion any information relating to such offer
21 submitted by either party, including infor-
22 mation relating to any circumstance de-
23 scribed in subparagraph (C)(ii).

24 “(C) CONSIDERATIONS IN DETERMINA-
25 TION.—

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1 “(i) IN GENERAL.—In determining
2 which offer is the payment to be applied
3 pursuant to this paragraph, the certified
4 IDR entity, with respect to the determina-
5 tion for a qualified IDR air ambulance
6 service shall consider—

7 “(I) the qualifying payment
8 amounts (as defined in section
9 2799A–1(a)(3)(E)) for the applicable
10 year for items or services that are
11 comparable to the qualified IDR air
12 ambulance service and that are fur-
13 nished in the same geographic region
14 (as defined by the Secretary for pur-
15 poses of such subsection) as such
16 qualified IDR air ambulance service;
17 and

18 “(II) subject to clause (iii), infor-
19 mation on any circumstance described
20 in clause (ii), such information as re-
21 quested in subparagraph (B)(i)(II),
22 and any additional information pro-
23 vided in subparagraph (B)(ii).

24 “(ii) ADDITIONAL CIRCUMSTANCES.—
25 For purposes of clause (i)(II), the cir-

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1 cumstances described in this clause are,
2 with respect to air ambulance services in-
3 cluded in the notification submitted under
4 paragraph (1)(B) of a nonparticipating
5 provider, group health plan, or health in-
6 surance issuer the following:

7 “(I) The quality and outcomes
8 measurements of the provider that
9 furnished such services.

10 “(II) The acuity of the individual
11 receiving such services or the com-
12 plexity of furnishing such services to
13 such individual.

14 “(III) The training, experience,
15 and quality of the medical personnel
16 that furnished such services.

17 “(IV) Ambulance vehicle type, in-
18 cluding the clinical capability level of
19 such vehicle.

20 “(V) Population density of the
21 pick up location (such as urban, sub-
22 urban, rural, or frontier).

23 “(VI) Demonstrations of good
24 faith efforts (or lack of good faith ef-
25 forts) made by the nonparticipating

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1 provider or nonparticipating facility or
2 the plan or issuer to enter into net-
3 work agreements and, if applicable,
4 contracted rates between the provider
5 and the plan or issuer, as applicable,
6 during the previous 4 plan years.

7 “(iii) PROHIBITION ON CONSIDER-
8 ATION OF CERTAIN FACTORS.—In deter-
9 mining which offer is the payment amount
10 to be applied with respect to qualified IDR
11 air ambulance services furnished by a pro-
12 vider, the certified IDR entity with respect
13 to such determination shall not consider
14 usual and customary charges, the amount
15 that would have been billed by such pro-
16 vider with respect to such services had the
17 provisions of section 2799B–5 not applied,
18 or the payment or reimbursement rate for
19 such services furnished by such provider
20 payable by a public payor, including under
21 the Medicare program under title XVIII of
22 the Social Security Act, under the Med-
23 icaid program under title XIX of such Act,
24 under the Children’s Health Insurance
25 Program under title XXI of such Act,

1 under the TRICARE program under chap-
2 ter 55 of title 10, United States Code, or
3 under chapter 17 of title 38, United States
4 Code.

5 “(D) EFFECTS OF DETERMINATION.—The
6 provisions of section 2799A–1(c)(5)(E)) shall
7 apply with respect to a determination of a cer-
8 tified IDR entity under subparagraph (A), the
9 notification submitted with respect to such de-
10 termination, the services with respect to such
11 notification, and the parties to such notification
12 in the same manner as such provisions apply
13 with respect to a determination of a certified
14 IDR entity under section 2799A–1(c)(5)(E),
15 the notification submitted with respect to such
16 determination, the items and services with re-
17 spect to such notification, and the parties to
18 such notification.

19 “(E) COSTS OF INDEPENDENT DISPUTE
20 RESOLUTION PROCESS.—The provisions of sec-
21 tion 2799A–1(c)(5)(F) shall apply to a notifica-
22 tion made under this subsection, the parties to
23 such notification, and a determination under
24 subparagraph (A) in the same manner and to
25 the same extent such provisions apply to a noti-

1 fication under section 2799A–1(c), the parties
2 to such notification and a determination made
3 under section 2799A–1(c)(5)(A).

4 “(6) TIMING OF PAYMENT.—The total plan or
5 coverage payment required pursuant to subsection
6 (a)(3), with respect to qualified IDR air ambulance
7 services for which a determination is made under
8 paragraph (5)(A) or with respect to an air ambu-
9 lance service for which a payment amount is deter-
10 mined under open negotiations under paragraph (1),
11 shall be made directly to the nonparticipating pro-
12 vider not later than 30 days after the date on which
13 such determination is made.

14 “(7) PUBLICATION OF INFORMATION RELATING
15 TO THE IDR PROCESS.—

16 “(A) IN GENERAL.—For each calendar
17 quarter in 2022 and each calendar quarter in a
18 subsequent year, the Secretary shall publish on
19 the public website of the Department of Health
20 and Human Services—

21 “(i) the number of notifications sub-
22 mitted under the IDR process during such
23 calendar quarter;

1 “(ii) the number of such notifications
2 with respect to which a final determination
3 was made under paragraph (5)(A);

4 “(iii) the information described in
5 subparagraph (B) with respect to each no-
6 tification with respect to which such a de-
7 termination was so made.

8 “(iv) the number of times the pay-
9 ment amount determined (or agreed to)
10 under this subsection exceeds the quali-
11 fying payment amount;

12 “(v) the amount of expenditures made
13 by the Secretary during such calendar
14 quarter to carry out the IDR process;

15 “(vi) the total amount of fees paid
16 under paragraph (8) during such calendar
17 quarter; and

18 “(vii) the total amount of compensa-
19 tion paid to certified IDR entities under
20 paragraph (5)(E) during such calendar
21 quarter.

22 “(B) INFORMATION WITH RESPECT TO RE-
23 QUESTS.—For purposes of subparagraph (A),
24 the information described in this subparagraph
25 is, with respect to a notification under the IDR

1 process of a nonparticipating provider, group
2 health plan, or health insurance issuer offering
3 group or individual health insurance coverage—

4 “(i) a description of each air ambu-
5 lance service included in such notification;

6 “(ii) the geography in which the serv-
7 ices included in such notification were pro-
8 vided;

9 “(iii) the amount of the offer sub-
10 mitted under paragraph (2) by the group
11 health plan or health insurance issuer (as
12 applicable) and by the nonparticipating
13 provider expressed as a percentage of the
14 qualifying payment amount;

15 “(iv) whether the offer selected by the
16 certified IDR entity under paragraph (5)
17 to be the payment applied was the offer
18 submitted by such plan or issuer (as appli-
19 cable) or by such provider and the amount
20 of such offer so selected expressed as a
21 percentage of the qualifying payment
22 amount;

23 “(v) ambulance vehicle type, including
24 the clinical capability level of such vehicle;

1 “(vi) the identity of the group health
2 plan or health insurance issuer or air am-
3 bulance provider with respect to such noti-
4 fication;

5 “(vii) the length of time in making
6 each determination;

7 “(viii) the compensation paid to the
8 certified IDR entity with respect to the
9 settlement or determination; and

10 “(ix) any other information specified
11 by the Secretary.

12 “(C) IDR ENTITY REQUIREMENTS.—For
13 2022 and each subsequent year, an IDR entity,
14 as a condition of certification as an IDR entity,
15 shall submit to the Secretary such information
16 as the Secretary determines necessary for the
17 Secretary to carry out the provisions of this
18 paragraph.

19 “(D) CLARIFICATION.—The Secretary
20 shall ensure the public reporting under this
21 paragraph does not contain information that
22 would disclose privileged or confidential infor-
23 mation of a group health plan or health insur-
24 ance issuer offering group or individual health
25 insurance coverage or of a provider or facility.

1 “(8) ADMINISTRATIVE FEE.—

2 “(A) IN GENERAL.—Each party to a deter-
3 mination under paragraph (5) to which an enti-
4 ty is selected under paragraph (4) in a year
5 shall pay to the Secretary, at such time and in
6 such manner as specified by the Secretary, a
7 fee for participating in the IDR process with re-
8 spect to such determination in an amount de-
9 scribed in subparagraph (B) for such year.

10 “(B) AMOUNT OF FEE.—The amount de-
11 scribed in this subparagraph for a year is an
12 amount established by the Secretary in a man-
13 ner such that the total amount of fees paid
14 under this paragraph for such year is estimated
15 to be equal to the amount of expenditures esti-
16 mated to be made by the Secretary for such
17 year in carrying out the IDR process.

18 “(9) WAIVER AUTHORITY.—The Secretary may
19 modify any deadline or other timing requirement
20 specified under this subsection (other than the es-
21 tablishment date for the IDR process under para-
22 graph (2)(A) and other than under paragraph (6))
23 in cases of extenuating circumstances, as specified
24 by the Secretary, or to ensure that all claims that
25 occur during a 90-day period applied through para-

1 graph (5)(D), but with respect to which a notifica-
2 tion is not permitted by reason of such paragraph to
3 be submitted under paragraph (1)(B) during such
4 period, are eligible for the IDR process.

5 “(c) DEFINITIONS.—For purposes of this section:

6 “(1) AIR AMBULANCE SERVICE.—The term ‘air
7 ambulance service’ means medical transport by heli-
8 copter or airplane for patients.

9 “(2) QUALIFYING PAYMENT AMOUNT.—The
10 term ‘qualifying payment amount’ has the meaning
11 given such term in section 2799A–1(a)(3).

12 “(3) NONPARTICIPATING PROVIDER.—The term
13 ‘nonparticipating provider’ has the meaning given
14 such term in section 2799A–1(a)(3).”.

15 (2) ERISA AMENDMENT.—

16 (A) IN GENERAL.—Subpart B of part 7 of
17 title I of the Employee Retirement Income Se-
18 curity Act of 1974 (29 U.S.C. 1185 et seq.), as
19 amended by section 102(b) and further amend-
20 ed by the previous provisions of this title, is fur-
21 ther amended by inserting after section 716 the
22 following:

23 **“SEC. 717. ENDING SURPRISE AIR AMBULANCE BILLS.**

24 “(a) IN GENERAL.—In the case of a participant or
25 beneficiary who is in a group health plan or group health

1 insurance coverage offered by a health insurance issuer
2 and who receives air ambulance services from a nonpartici-
3 pating provider (as defined in section 716(a)(3)(G)) with
4 respect to such plan or coverage, if such services would
5 be covered if provided by a participating provider (as de-
6 fined in such section) with respect to such plan or cov-
7 erage—

8 “(1) the cost-sharing requirement with respect
9 to such services shall be the same requirement that
10 would apply if such services were provided by such
11 a participating provider, and any coinsurance or de-
12 ductible shall be based on rates that would apply for
13 such services if they were furnished by such a par-
14 ticipating provider;

15 “(2) such cost-sharing amounts shall be count-
16 ed towards the in-network deductible and in-network
17 out-of-pocket maximum amount under the plan or
18 coverage for the plan year (and such in-network de-
19 ductible shall be applied) with respect to such items
20 and services so furnished in the same manner as if
21 such cost-sharing payments were with respect to
22 items and services furnished by a participating pro-
23 vider; and

24 “(3) the group health plan or health insurance
25 issuer, respectively, shall—

1 “(A) not later than 30 calendar days after
2 the bill for such services is transmitted by such
3 provider, send to the provider, an initial pay-
4 ment or notice of denial of payment; and

5 “(B) pay a total plan or coverage payment,
6 in accordance with, if applicable, subsection
7 (b)(6), directly to such provider furnishing such
8 services to such participant, beneficiary, or en-
9 rollee that is, with application of any initial
10 payment under subparagraph (A), equal to the
11 amount by which the out-of-network rate (as
12 defined in section 716(a)(3)(K)) for such serv-
13 ices and year involved exceeds the cost-sharing
14 amount imposed under the plan or coverage, re-
15 spectively, for such services (as determined in
16 accordance with paragraphs (1) and (2)).

17 “(b) DETERMINATION OF OUT-OF-NETWORK RATES
18 TO BE PAID BY HEALTH PLANS; INDEPENDENT DISPUTE
19 RESOLUTION PROCESS.—

20 “(1) DETERMINATION THROUGH OPEN NEGO-
21 TIATION.—

22 “(A) IN GENERAL.—With respect to air
23 ambulance services furnished in a year by a
24 nonparticipating provider, with respect to a
25 group health plan or health insurance issuer of-

1 fering group health insurance coverage, and for
2 which a payment is required to be made by the
3 plan or coverage pursuant to subsection (a)(3),
4 the provider or plan or coverage may, during
5 the 30-day period beginning on the day the pro-
6 vider receives a payment or a statement of de-
7 nial of payment from the plan or coverage re-
8 garding a claim for payment for such service,
9 initiate open negotiations under this paragraph
10 between such provider and plan or coverage for
11 purposes of determining, during the open nego-
12 tiation period, an amount agreed on by such
13 provider, and such plan or coverage for pay-
14 ment (including any cost-sharing) for such serv-
15 ice. For purposes of this subsection, the open
16 negotiation period, with respect to air ambu-
17 lance services, is the 30-day period beginning
18 on the date of initiation of the negotiations with
19 respect to such services.

20 “(B) ACCESSING INDEPENDENT DISPUTE
21 RESOLUTION PROCESS IN CASE OF FAILED NE-
22 GOTIATIONS.—In the case of open negotiations
23 pursuant to subparagraph (A), with respect to
24 air ambulance services, that do not result in a
25 determination of an amount of payment for

1 such services by the last day of the open nego-
2 tiation period described in such subparagraph
3 with respect to such services, the provider or
4 group health plan or health insurance issuer of-
5 fering group health insurance coverage that was
6 party to such negotiations may, during the 4-
7 day period beginning on the day after such
8 open negotiation period, initiate the inde-
9 pendent dispute resolution process under para-
10 graph (2) with respect to such item or service.
11 The independent dispute resolution process
12 shall be initiated by a party pursuant to the
13 previous sentence by submission to the other
14 party and to the Secretary of a notification
15 (containing such information as specified by the
16 Secretary) and for purposes of this subsection,
17 the date of initiation of such process shall be
18 the date of such submission or such other date
19 specified by the Secretary pursuant to regula-
20 tions that is not later than the date of receipt
21 of such notification by both the other party and
22 the Secretary.

23 “(2) INDEPENDENT DISPUTE RESOLUTION
24 PROCESS AVAILABLE IN CASE OF FAILED OPEN NE-
25 GOTIATIONS.—

1 “(A) ESTABLISHMENT.—Not later than 1
2 year after the date of the enactment of this
3 subsection, the Secretary, jointly with the Sec-
4 retary of Health and Human Services and the
5 Secretary of the Treasury, shall establish by
6 regulation one independent dispute resolution
7 process (referred to in this subsection as the
8 ‘IDR process’) under which, in the case of air
9 ambulance services with respect to which a pro-
10 vider or group health plan or health insurance
11 issuer offering group health insurance coverage
12 submits a notification under paragraph (1)(B)
13 (in this subsection referred to as a ‘qualified
14 IDR air ambulance services’), a certified IDR
15 entity under paragraph (4) determines, subject
16 to subparagraph (B) and in accordance with
17 the succeeding provisions of this subsection, the
18 amount of payment under the plan or coverage
19 for such services furnished by such provider.

20 “(B) AUTHORITY TO CONTINUE NEGOTIA-
21 TIONS.—Under the independent dispute resolu-
22 tion process, in the case that the parties to a
23 determination for qualified IDR air ambulance
24 services agree on a payment amount for such
25 services during such process but before the date

1 on which the entity selected with respect to
2 such determination under paragraph (4) makes
3 such determination under paragraph (5), such
4 amount shall be treated for purposes of section
5 716(a)(3)(K)(ii) as the amount agreed to by
6 such parties for such services. In the case of an
7 agreement described in the previous sentence,
8 the independent dispute resolution process shall
9 provide for a method to determine how to allo-
10 cate between the parties to such determination
11 the payment of the compensation of the entity
12 selected with respect to such determination.

13 “(C) CLARIFICATION.—A nonparticipating
14 provider may not, with respect to an item or
15 service furnished by such provider, submit a no-
16 tification under paragraph (1)(B) if such pro-
17 vider is exempt from the requirement under
18 subsection (a) of section 2799B–2 of the Public
19 Health Service Act with respect to such item or
20 service pursuant to subsection (b) of such sec-
21 tion.

22 “(3) TREATMENT OF BATCHING OF SERV-
23 ICES.—The provisions of section 716(c)(3) shall
24 apply with respect to a notification submitted under
25 this subsection with respect to air ambulance serv-

1 ices in the same manner and to the same extent
2 such provisions apply with respect to a notification
3 submitted under section 716(c) with respect to items
4 and services described in such section.

5 “(4) IDR ENTITIES.—

6 “(A) ELIGIBILITY.—An IDR entity cer-
7 tified under this subsection is an IDR entity
8 certified under section 716(c)(4).

9 “(B) SELECTION OF CERTIFIED IDR ENTI-
10 TY.—The provisions of subparagraph (F) of
11 section 716(c)(4) shall apply with respect to se-
12 lecting an IDR entity certified pursuant to sub-
13 paragraph (A) with respect to the determina-
14 tion of the amount of payment under this sub-
15 section of air ambulance services in the same
16 manner as such provisions apply with respect to
17 selecting an IDR entity certified under such
18 section with respect to the determination of the
19 amount of payment under section 716(c) of an
20 item or service. An entity selected pursuant to
21 the previous sentence to make a determination
22 described in such sentence shall be referred to
23 in this subsection as the ‘certified IDR entity’
24 with respect to such determination.

25 “(5) PAYMENT DETERMINATION.—

1 “(A) IN GENERAL.—Not later than 30
2 days after the date of selection of the certified
3 IDR entity with respect to a determination for
4 qualified IDR ambulance services, the certified
5 IDR entity shall—

6 “(i) taking into account the consider-
7 ations specified in subparagraph (C), select
8 one of the offers submitted under subpara-
9 graph (B) to be the amount of payment for
10 such services determined under this sub-
11 section for purposes of subsection (a)(3);
12 and

13 “(ii) notify the provider or facility and
14 the group health plan or health insurance
15 issuer offering group health insurance cov-
16 erage party to such determination of the
17 offer selected under clause (i).

18 “(B) SUBMISSION OF OFFERS.—Not later
19 than 10 days after the date of selection of the
20 certified IDR entity with respect to a deter-
21 mination for qualified IDR air ambulance serv-
22 ices, the provider and the group health plan or
23 health insurance issuer offering group health
24 insurance coverage party to such determina-
25 tion—

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1 “(i) shall each submit to the certified
2 IDR entity with respect to such determina-
3 tion—

4 “(I) an offer for a payment
5 amount for such services furnished by
6 such provider; and

7 “(II) such information as re-
8 quested by the certified IDR entity re-
9 lating to such offer; and

10 “(ii) may each submit to the certified
11 IDR entity with respect to such determina-
12 tion any information relating to such offer
13 submitted by either party, including infor-
14 mation relating to any circumstance de-
15 scribed in subparagraph (C)(ii).

16 “(C) CONSIDERATIONS IN DETERMINA-
17 TION.—

18 “(i) IN GENERAL.—In determining
19 which offer is the payment to be applied
20 pursuant to this paragraph, the certified
21 IDR entity, with respect to the determina-
22 tion for a qualified IDR air ambulance
23 service shall consider—

24 “(I) the qualifying payment
25 amounts (as defined in section

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1 716(a)(3)(E)) for the applicable year
2 for items and services that are com-
3 parable to the qualified IDR air am-
4 bulance service and that are furnished
5 in the same geographic region (as de-
6 fined by the Secretary for purposes of
7 such subsection) as such qualified
8 IDR air ambulance service; and

9 “(II) subject to clause (iii), infor-
10 mation on any circumstance described
11 in clause (ii), such information as re-
12 quested in subparagraph (B)(i)(II),
13 and any additional information pro-
14 vided in subparagraph (B)(ii).

15 “(ii) ADDITIONAL CIRCUMSTANCES.—
16 For purposes of clause (i)(II), the cir-
17 cumstances described in this clause are,
18 with respect to air ambulance services in-
19 cluded in the notification submitted under
20 paragraph (1)(B) of a nonparticipating
21 provider, group health plan, or health in-
22 surance issuer the following:

23 “(I) The quality and outcomes
24 measurements of the provider that
25 furnished such services.

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1 “(II) The acuity of the individual
2 receiving such services or the com-
3 plexity of furnishing such services to
4 such individual.

5 “(III) The training, experience,
6 and quality of the medical personnel
7 that furnished such services.

8 “(IV) Ambulance vehicle type, in-
9 cluding the clinical capability level of
10 such vehicle.

11 “(V) Population density of the
12 pick up location (such as urban, sub-
13 urban, rural, or frontier).

14 “(VI) Demonstrations of good
15 faith efforts (or lack of good faith ef-
16 forts) made by the nonparticipating
17 provider or nonparticipating facility or
18 the plan or issuer to enter into net-
19 work agreements and, if applicable,
20 contracted rates between the provider
21 and the plan or issuer, as applicable,
22 during the previous 4 plan years.

23 “(iii) PROHIBITION ON CONSIDER-
24 ATION OF CERTAIN FACTORS.—In deter-
25 mining which offer is the payment amount

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1 to be applied with respect to qualified IDR
2 air ambulance services furnished by a pro-
3 vider, the certified IDR entity with respect
4 to such determination shall not consider
5 usual and customary charges, the amount
6 that would have been billed by such pro-
7 vider with respect to such services had the
8 provisions of section 2799B-5 of the Pub-
9 lic Health Service Act not applied, or the
10 payment or reimbursement rate for such
11 services furnished by such provider payable
12 by a public payor, including under the
13 Medicare program under title XVIII of the
14 Social Security Act, under the Medicaid
15 program under title XIX of such Act,
16 under the Children's Health Insurance
17 Program under title XXI of such Act,
18 under the TRICARE program under chap-
19 ter 55 of title 10, United States Code, or
20 under chapter 17 of title 38, United States
21 Code.

22 “(D) EFFECTS OF DETERMINATION.—The
23 provisions of section 716(c)(5)(E)) shall apply
24 with respect to a determination of a certified
25 IDR entity under subparagraph (A), the notifi-

1 cation submitted with respect to such deter-
2 mination, the services with respect to such noti-
3 fication, and the parties to such notification in
4 the same manner as such provisions apply with
5 respect to a determination of a certified IDR
6 entity under section 716(c)(5)(E), the notifica-
7 tion submitted with respect to such determina-
8 tion, the items and services with respect to such
9 notification, and the parties to such notifica-
10 tion.

11 “(E) COSTS OF INDEPENDENT DISPUTE
12 RESOLUTION PROCESS.—The provisions of sec-
13 tion 716(c)(5)(F) shall apply to a notification
14 made under this subsection, the parties to such
15 notification, and a determination under sub-
16 paragraph (A) in the same manner and to the
17 same extent such provisions apply to a notifica-
18 tion under section 716(c), the parties to such
19 notification and a determination made under
20 section 716(c)(5)(A).

21 “(6) TIMING OF PAYMENT.—The total plan or
22 coverage payment required pursuant to subsection
23 (a)(3), with respect to qualified IDR air ambulance
24 services for which a determination is made under
25 paragraph (5)(A) or with respect to air ambulance

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1 services for which a payment amount is determined
2 under open negotiations under paragraph (1), shall
3 be made directly to the nonparticipating provider not
4 later than 30 days after the date on which such de-
5 termination is made.

6 “(7) PUBLICATION OF INFORMATION RELATING
7 TO THE IDR PROCESS.—

8 “(A) IN GENERAL.—For each calendar
9 quarter in 2022 and each calendar quarter in a
10 subsequent year, the Secretary shall publish on
11 the public website of the Department of
12 Labor—

13 “(i) the number of notifications sub-
14 mitted under the IDR process during such
15 calendar quarter;

16 “(ii) the number of such notifications
17 with respect to which a final determination
18 was made under paragraph (5)(A);

19 “(iii) the information described in
20 subparagraph (B) with respect to each no-
21 tification with respect to which such a de-
22 termination was so made.

23 “(iv) the number of times the pay-
24 ment amount determined (or agreed to)

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1 under this subsection exceeds the quali-
2 fying payment amount;

3 “(v) the amount of expenditures made
4 by the Secretary during such calendar
5 quarter to carry out the IDR process;

6 “(vi) the total amount of fees paid
7 under paragraph (8) during such calendar
8 quarter; and

9 “(vii) the total amount of compensa-
10 tion paid to certified IDR entities under
11 paragraph (5)(E) during such calendar
12 quarter.

13 “(B) INFORMATION WITH RESPECT TO RE-
14 QUESTS.—For purposes of subparagraph (A),
15 the information described in this subparagraph
16 is, with respect to a notification under the IDR
17 process of a nonparticipating provider, group
18 health plan, or health insurance issuer offering
19 group health insurance coverage—

20 “(i) a description of each air ambu-
21 lance service included in such notification;

22 “(ii) the geography in which the serv-
23 ices included in such notification were pro-
24 vided;

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1 “(iii) the amount of the offer sub-
2 mitted under paragraph (2) by the group
3 health plan or health insurance issuer (as
4 applicable) and by the nonparticipating
5 provider expressed as a percentage of the
6 qualifying payment amount;

7 “(iv) whether the offer selected by the
8 certified IDR entity under paragraph (5)
9 to be the payment applied was the offer
10 submitted by such plan or issuer (as appli-
11 cable) or by such provider and the amount
12 of such offer so selected expressed as a
13 percentage of the qualifying payment
14 amount;

15 “(v) ambulance vehicle type, including
16 the clinical capability level of such vehicle;

17 “(vi) the identity of the group health
18 plan or health insurance issuer or air am-
19 bulance provider with respect to such noti-
20 fication;

21 “(vii) the length of time in making
22 each determination;

23 “(viii) the compensation paid to the
24 certified IDR entity with respect to the
25 settlement or determination; and

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1 “(ix) any other information specified
2 by the Secretary.

3 “(C) IDR ENTITY REQUIREMENTS.—For
4 2022 and each subsequent year, an IDR entity,
5 as a condition of certification as an IDR entity,
6 shall submit to the Secretary such information
7 as the Secretary determines necessary for the
8 Secretary to carry out the provisions of this
9 paragraph.

10 “(D) CLARIFICATION.—The Secretary
11 shall ensure the public reporting under this
12 paragraph does not contain information that
13 would disclose privileged or confidential infor-
14 mation of a group health plan or health insur-
15 ance issuer offering group or individual health
16 insurance coverage or of a provider or facility.

17 “(8) ADMINISTRATIVE FEE.—

18 “(A) IN GENERAL.—Each party to a deter-
19 mination under paragraph (5) to which an enti-
20 ty is selected under paragraph (4) in a year
21 shall pay to the Secretary, at such time and in
22 such manner as specified by the Secretary, a
23 fee for participating in the IDR process with re-
24 spect to such determination in an amount de-
25 scribed in subparagraph (B) for such year.

1 “(B) AMOUNT OF FEE.—The amount de-
2 scribed in this subparagraph for a year is an
3 amount established by the Secretary in a man-
4 ner such that the total amount of fees paid
5 under this paragraph for such year is estimated
6 to be equal to the amount of expenditures esti-
7 mated to be made by the Secretary for such
8 year in carrying out the IDR process.

9 “(9) WAIVER AUTHORITY.—The Secretary may
10 modify any deadline or other timing requirement
11 specified under this subsection (other than the es-
12 tablishment date for the IDR process under para-
13 graph (2)(A) and other than under paragraph (6))
14 in cases of extenuating circumstances, as specified
15 by the Secretary, or to ensure that all claims that
16 occur during a 90-day period applied through para-
17 graph (5)(D), but with respect to which a notifica-
18 tion is not permitted by reason of such paragraph to
19 be submitted under paragraph (1)(B) during such
20 period, are eligible for the IDR process.

21 “(c) DEFINITION.—For purposes of this section:

22 “(1) AIR AMBULANCE SERVICES.—The term
23 ‘air ambulance service’ means medical transport by
24 helicopter or airplane for patients.

1 “(2) QUALIFYING PAYMENT AMOUNT.—The
2 term ‘qualifying payment amount’ has the meaning
3 given such term in section 716(a)(3).

4 “(3) NONPARTICIPATING PROVIDER.—The term
5 ‘nonparticipating provider’ has the meaning given
6 such term in section 716(a)(3).”.

7 (3) IRC AMENDMENTS.—

8 (A) IN GENERAL.—Subchapter B of chap-
9 ter 100 of the Internal Revenue Code of 1986,
10 as amended by section 102(c) and further
11 amended by the previous provisions of this title,
12 is further amended by inserting after section
13 9816 the following:

14 **“SEC. 9817. ENDING SURPRISE AIR AMBULANCE BILLS.**

15 “(a) IN GENERAL.—In the case of a participant or
16 beneficiary in a group health plan who receives air ambu-
17 lance services from a nonparticipating provider (as defined
18 in section 9816(a)(3)(G)) with respect to such plan, if
19 such services would be covered if provided by a partici-
20 pating provider (as defined in such section) with respect
21 to such plan—

22 “(1) the cost-sharing requirement with respect
23 to such services shall be the same requirement that
24 would apply if such services were provided by such
25 a participating provider, and any coinsurance or de-

1 ductible shall be based on rates that would apply for
2 such services if they were furnished by such a par-
3 ticipating provider;

4 “(2) such cost-sharing amounts shall be count-
5 ed towards the in-network deductible and in-network
6 out-of-pocket maximum amount under the plan for
7 the plan year (and such in-network deductible shall
8 be applied) with respect to such items and services
9 so furnished in the same manner as if such cost-
10 sharing payments were with respect to items and
11 services furnished by a participating provider; and

12 “(3) the group health plan shall—

13 “(A) not later than 30 calendar days after
14 the bill for such services is transmitted by such
15 provider, send to the provider, an initial pay-
16 ment or notice of denial of payment; and

17 “(B) pay a total plan payment, in accord-
18 ance with, if applicable, subsection (b)(6), di-
19 rectly to such provider furnishing such services
20 to such participant, beneficiary, or enrollee that
21 is, with application of any initial payment under
22 subparagraph (A), equal to the amount by
23 which the out-of-network rate (as defined in
24 section 9816(a)(3)(K)) for such services and
25 year involved exceeds the cost-sharing amount

1 imposed under the plan for such services (as de-
2 termined in accordance with paragraphs (1)
3 and (2)).

4 “(b) DETERMINATION OF OUT-OF-NETWORK RATES
5 TO BE PAID BY HEALTH PLANS; INDEPENDENT DISPUTE
6 RESOLUTION PROCESS.—

7 “(1) DETERMINATION THROUGH OPEN NEGO-
8 TATION.—

9 “(A) IN GENERAL.—With respect to air
10 ambulance services furnished in a year by a
11 nonparticipating provider, with respect to a
12 group health plan, and for which a payment is
13 required to be made by the plan pursuant to
14 subsection (a)(3), the provider or plan may,
15 during the 30-day period beginning on the day
16 the provider receives a payment or a statement
17 of denial of payment from the plan regarding a
18 claim for payment for such service, initiate open
19 negotiations under this paragraph between such
20 provider and plan for purposes of determining,
21 during the open negotiation period, an amount
22 agreed on by such provider, and such plan for
23 payment (including any cost-sharing) for such
24 service. For purposes of this subsection, the
25 open negotiation period, with respect to air am-

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1 balance services, is the 30-day period beginning
2 on the date of initiation of the negotiations with
3 respect to such services.

4 “(B) ACCESSING INDEPENDENT DISPUTE
5 RESOLUTION PROCESS IN CASE OF FAILED NE-
6 GOTIATIONS.—In the case of open negotiations
7 pursuant to subparagraph (A), with respect to
8 air ambulance services, that do not result in a
9 determination of an amount of payment for
10 such services by the last day of the open nego-
11 tiation period described in such subparagraph
12 with respect to such services, the provider or
13 group health plan that was party to such nego-
14 tiations may, during the 4-day period beginning
15 on the day after such open negotiation period,
16 initiate the independent dispute resolution proc-
17 ess under paragraph (2) with respect to such
18 services. The independent dispute resolution
19 process shall be initiated by a party pursuant to
20 the previous sentence by submission to the
21 other party and to the Secretary of a notifica-
22 tion (containing such information as specified
23 by the Secretary) and for purposes of this sub-
24 section, the date of initiation of such process
25 shall be the date of such submission or such

1 other date specified by the Secretary pursuant
2 to regulations that is not later than the date of
3 receipt of such notification by both the other
4 party and the Secretary.

5 “(2) INDEPENDENT DISPUTE RESOLUTION
6 PROCESS AVAILABLE IN CASE OF FAILED OPEN NE-
7 GOTIATIONS.—

8 “(A) ESTABLISHMENT.—Not later than 1
9 year after the date of the enactment of this
10 subsection, the Secretary, jointly with the Sec-
11 retary of Health and Human Services and the
12 Secretary of Labor, shall establish by regulation
13 one independent dispute resolution process (re-
14 ferred to in this subsection as the ‘IDR proc-
15 ess’) under which, in the case of air ambulance
16 services with respect to which a provider or
17 group health plan submits a notification under
18 paragraph (1)(B) (in this subsection referred to
19 as a ‘qualified IDR air ambulance services’), a
20 certified IDR entity under paragraph (4) deter-
21 mines, subject to subparagraph (B) and in ac-
22 cordance with the succeeding provisions of this
23 subsection, the amount of payment under the
24 plan for such services furnished by such pro-
25 vider.

1 “(B) AUTHORITY TO CONTINUE NEGOTIA-
2 TIONS.—Under the independent dispute resolu-
3 tion process, in the case that the parties to a
4 determination for qualified IDR air ambulance
5 services agree on a payment amount for such
6 services during such process but before the date
7 on which the entity selected with respect to
8 such determination under paragraph (4) makes
9 such determination under paragraph (5), such
10 amount shall be treated for purposes of section
11 9816(a)(3)(K)(ii) as the amount agreed to by
12 such parties for such services. In the case of an
13 agreement described in the previous sentence,
14 the independent dispute resolution process shall
15 provide for a method to determine how to allo-
16 cate between the parties to such determination
17 the payment of the compensation of the entity
18 selected with respect to such determination.

19 “(C) CLARIFICATION.—A nonparticipating
20 provider may not, with respect to an item or
21 service furnished by such provider, submit a no-
22 tification under paragraph (1)(B) if such pro-
23 vider is exempt from the requirement under
24 subsection (a) of section 2799B–2 of the Public
25 Health Service Act with respect to such item or

1 service pursuant to subsection (b) of such sec-
2 tion.

3 “(3) TREATMENT OF BATCHING OF SERV-
4 ICES.—The provisions of section 9816(c)(3) shall
5 apply with respect to a notification submitted under
6 this subsection with respect to air ambulance serv-
7 ices in the same manner and to the same extent
8 such provisions apply with respect to a notification
9 submitted under section 9816(c) with respect to
10 items and services described in such section.

11 “(4) IDR ENTITIES.—

12 “(A) ELIGIBILITY.—An IDR entity cer-
13 tified under this subsection is an IDR entity
14 certified under section 9816(c)(4).

15 “(B) SELECTION OF CERTIFIED IDR ENTI-
16 TY.—The provisions of subparagraph (F) of
17 section 9816(c)(4) shall apply with respect to
18 selecting an IDR entity certified pursuant to
19 subparagraph (A) with respect to the deter-
20 mination of the amount of payment under this
21 subsection of air ambulance services in the
22 same manner as such provisions apply with re-
23 spect to selecting an IDR entity certified under
24 such section with respect to the determination
25 of the amount of payment under section

1 9816(c) of an item or service. An entity selected
2 pursuant to the previous sentence to make a de-
3 termination described in such sentence shall be
4 referred to in this subsection as the ‘certified
5 IDR entity’ with respect to such determination.

6 “(5) PAYMENT DETERMINATION.—

7 “(A) IN GENERAL.—Not later than 30
8 days after the date of selection of the certified
9 IDR entity with respect to a determination for
10 qualified IDR ambulance services, the certified
11 IDR entity shall—

12 “(i) taking into account the consider-
13 ations specified in subparagraph (C), select
14 one of the offers submitted under subpara-
15 graph (B) to be the amount of payment for
16 such services determined under this sub-
17 section for purposes of subsection (a)(3);
18 and

19 “(ii) notify the provider or facility and
20 the group health plan party to such deter-
21 mination of the offer selected under clause
22 (i).

23 “(B) SUBMISSION OF OFFERS.—Not later
24 than 10 days after the date of selection of the
25 certified IDR entity with respect to a deter-

1 mination for qualified IDR air ambulance serv-
2 ices, the provider and the group health plan
3 party to such determination—

4 “(i) shall each submit to the certified
5 IDR entity with respect to such determina-
6 tion—

7 “(I) an offer for a payment
8 amount for such services furnished by
9 such provider; and

10 “(II) such information as re-
11 quested by the certified IDR entity re-
12 lating to such offer; and

13 “(ii) may each submit to the certified
14 IDR entity with respect to such determina-
15 tion any information relating to such offer
16 submitted by either party, including infor-
17 mation relating to any circumstance de-
18 scribed in subparagraph (C)(ii).

19 “(C) CONSIDERATIONS IN DETERMINA-
20 TION.—

21 “(i) IN GENERAL.—In determining
22 which offer is the payment to be applied
23 pursuant to this paragraph, the certified
24 IDR entity, with respect to the determina-

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1 tion for a qualified IDR air ambulance
2 service shall consider—

3 “(I) the qualifying payment
4 amounts (as defined in section
5 9816(a)(3)(E)) for the applicable year
6 for items or services that are com-
7 parable to the qualified IDR air am-
8 bulance service and that are furnished
9 in the same geographic region (as de-
10 fined by the Secretary for purposes of
11 such subsection) as such qualified
12 IDR air ambulance service; and

13 “(II) subject to clause (iii), infor-
14 mation on any circumstance described
15 in clause (ii), such information as re-
16 quested in subparagraph (B)(i)(II),
17 and any additional information pro-
18 vided in subparagraph (B)(ii).

19 “(ii) ADDITIONAL CIRCUMSTANCES.—
20 For purposes of clause (i)(II), the cir-
21 cumstances described in this clause are,
22 with respect to air ambulance services in-
23 cluded in the notification submitted under
24 paragraph (1)(B) of a nonparticipating

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1 provider, or group health plan the fol-
2 lowing:

3 “(I) The quality and outcomes
4 measurements of the provider that
5 furnished such services.

6 “(II) The acuity of the individual
7 receiving such services or the com-
8 plexity of furnishing such services to
9 such individual.

10 “(III) The training, experience,
11 and quality of the medical personnel
12 that furnished such services.

13 “(IV) Ambulance vehicle type, in-
14 cluding the clinical capability level of
15 such vehicle.

16 “(V) Population density of the
17 pick up location (such as urban, sub-
18 urban, rural, or frontier).

19 “(VI) Demonstrations of good
20 faith efforts (or lack of good faith ef-
21 forts) made by the nonparticipating
22 provider or nonparticipating facility or
23 the plan to enter into network agree-
24 ments and, if applicable, contracted

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1 rates between the provider and the
2 plan during the previous 4 plan years.

3 “(iii) PROHIBITION ON CONSIDER-
4 ATION OF CERTAIN FACTORS.—In deter-
5 mining which offer is the payment amount
6 to be applied with respect to qualified IDR
7 air ambulance services furnished by a pro-
8 vider, the certified IDR entity with respect
9 to such determination shall not consider
10 usual and customary charges, the amount
11 that would have been billed by such pro-
12 vider with respect to such services had the
13 provisions of section 2799B–5 of the Pub-
14 lic Health Service Act not applied, or the
15 payment or reimbursement rate for such
16 services furnished by such provider payable
17 by a public payor, including under the
18 Medicare program under title XVIII of the
19 Social Security Act, under the Medicaid
20 program under title XIX of such Act,
21 under the Children’s Health Insurance
22 Program under title XXI of such Act,
23 under the TRICARE program under chap-
24 ter 55 of title 10, United States Code, or

1 under chapter 17 of title 38, United States
2 Code.

3 “(D) EFFECTS OF DETERMINATION.—The
4 provisions of section 9816(c)(5)(E)) shall apply
5 with respect to a determination of a certified
6 IDR entity under subparagraph (A), the notifi-
7 cation submitted with respect to such deter-
8 mination, the services with respect to such noti-
9 fication, and the parties to such notification in
10 the same manner as such provisions apply with
11 respect to a determination of a certified IDR
12 entity under section 9816(c)(5)(E), the notifica-
13 tion submitted with respect to such determina-
14 tion, the items and services with respect to such
15 notification, and the parties to such notifica-
16 tion.

17 “(E) COSTS OF INDEPENDENT DISPUTE
18 RESOLUTION PROCESS.—The provisions of sec-
19 tion 9816(c)(5)(F) shall apply to a notification
20 made under this subsection, the parties to such
21 notification, and a determination under sub-
22 paragraph (A) in the same manner and to the
23 same extent such provisions apply to a notifica-
24 tion under section 9816(c), the parties to such

1 notification and a determination made under
2 section 9816(e)(5)(A).

3 “(6) TIMING OF PAYMENT.—The total plan
4 payment required pursuant to subsection (a)(3),
5 with respect to qualified IDR air ambulance services
6 for which a determination is made under paragraph
7 (5)(A) or with respect to air ambulance services for
8 which a payment amount is determined under open
9 negotiations under paragraph (1), shall be made di-
10 rectly to the nonparticipating provider not later than
11 30 days after the date on which such determination
12 is made.

13 “(7) PUBLICATION OF INFORMATION RELATING
14 TO THE IDR PROCESS.—

15 “(A) IN GENERAL.—For each calendar
16 quarter in 2022 and each calendar quarter in a
17 subsequent year, the Secretary shall publish on
18 the public website of the Department of the
19 Treasury—

20 “(i) the number of notifications sub-
21 mitted under the IDR process during such
22 calendar quarter;

23 “(ii) the number of such notifications
24 with respect to which a final determination
25 was made under paragraph (5)(A);

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1 “(iii) the information described in
2 subparagraph (B) with respect to each no-
3 tification with respect to which such a de-
4 termination was so made.

5 “(iv) the number of times the pay-
6 ment amount determined (or agreed to)
7 under this subsection exceeds the quali-
8 fying payment amount;

9 “(v) the amount of expenditures made
10 by the Secretary during such calendar
11 quarter to carry out the IDR process;

12 “(vi) the total amount of fees paid
13 under paragraph (8) during such calendar
14 quarter; and

15 “(vii) the total amount of compensa-
16 tion paid to certified IDR entities under
17 paragraph (5)(E) during such calendar
18 quarter.

19 “(B) INFORMATION WITH RESPECT TO RE-
20 QUESTS.—For purposes of subparagraph (A),
21 the information described in this subparagraph
22 is, with respect to a notification under the IDR
23 process of a nonparticipating provider, or group
24 health plan—

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1 “(i) a description of each air ambu-
2 lance service included in such notification;

3 “(ii) the geography in which the serv-
4 ices included in such notification were pro-
5 vided;

6 “(iii) the amount of the offer sub-
7 mitted under paragraph (2) by the group
8 health plan and by the nonparticipating
9 provider expressed as a percentage of the
10 qualifying payment amount;

11 “(iv) whether the offer selected by the
12 certified IDR entity under paragraph (5)
13 to be the payment applied was the offer
14 submitted by such plan or issuer (as appli-
15 cable) or by such provider and the amount
16 of such offer so selected expressed as a
17 percentage of the qualifying payment
18 amount;

19 “(v) ambulance vehicle type, including
20 the clinical capability level of such vehicle;

21 “(vi) the identity of the group health
22 plan or health insurance issuer or air am-
23 bulance provider with respect to such noti-
24 fication;

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1 “(vii) the length of time in making
2 each determination;

3 “(viii) the compensation paid to the
4 certified IDR entity with respect to the
5 settlement or determination; and

6 “(ix) any other information specified
7 by the Secretary.

8 “(C) IDR ENTITY REQUIREMENTS.—For
9 2022 and each subsequent year, an IDR entity,
10 as a condition of certification as an IDR entity,
11 shall submit to the Secretary such information
12 as the Secretary determines necessary for the
13 Secretary to carry out the provisions of this
14 paragraph.

15 “(D) CLARIFICATION.—The Secretary
16 shall ensure the public reporting under this
17 paragraph does not contain information that
18 would disclose privileged or confidential infor-
19 mation of a group health plan or health insur-
20 ance issuer offering group or individual health
21 insurance coverage or of a provider or facility.

22 “(8) ADMINISTRATIVE FEE.—

23 “(A) IN GENERAL.—Each party to a deter-
24 mination under paragraph (5) to which an enti-
25 ty is selected under paragraph (4) in a year

1 shall pay to the Secretary, at such time and in
2 such manner as specified by the Secretary, a
3 fee for participating in the IDR process with re-
4 spect to such determination in an amount de-
5 scribed in subparagraph (B) for such year.

6 “(B) AMOUNT OF FEE.—The amount de-
7 scribed in this subparagraph for a year is an
8 amount established by the Secretary in a man-
9 ner such that the total amount of fees paid
10 under this paragraph for such year is estimated
11 to be equal to the amount of expenditures esti-
12 mated to be made by the Secretary for such
13 year in carrying out the IDR process.

14 “(9) WAIVER AUTHORITY.—The Secretary may
15 modify any deadline or other timing requirement
16 specified under this subsection (other than the es-
17 tablishment date for the IDR process under para-
18 graph (2)(A) and other than under paragraph (6))
19 in cases of extenuating circumstances, as specified
20 by the Secretary, or to ensure that all claims that
21 occur during a 90-day period applied through para-
22 graph (5)(D), but with respect to which a notifica-
23 tion is not permitted by reason of such paragraph to
24 be submitted under paragraph (1)(B) during such
25 period, are eligible for the IDR process.

1 “(c) DEFINITIONS.—For purposes of this section:

2 “(1) AIR AMBULANCE SERVICES.—The term
3 ‘air ambulance service’ means medical transport by
4 helicopter or airplane for patients.

5 “(2) QUALIFYING PAYMENT AMOUNT.—The
6 term ‘qualifying payment amount’ has the meaning
7 given such term in section 9816(a)(3).

8 “(3) NONPARTICIPATING PROVIDER.—The term
9 ‘nonparticipating provider’ has the meaning given
10 such term in section 9816(a)(3).”.

11 (B) CLERICAL AMENDMENT.—The table of
12 sections for subchapter B of chapter 100 of the
13 Internal Revenue Code of 1986, as amended by
14 section 102(c)(3), is further amended by insert-
15 ing after the item relating to section 9816 the
16 following new item:

“Sec. 9817. Ending surprise air ambulance bills.”.

17 (4) EFFECTIVE DATE.—The amendments made
18 by this subsection shall apply with respect to plan
19 years beginning on or after January 1, 2022.

20 (b) AIR AMBULANCE PROVIDER BALANCE BILL-
21 ING.—Part E of title XXVII of the Public Health Service
22 Act, as added and amended by section 104, is further
23 amended by adding at the end the following new section:

1 **“SEC. 2799B-5. AIR AMBULANCE SERVICES.**

2 “In the case of a participant, beneficiary, or enrollee
3 with benefits under a group health plan or group or indi-
4 vidual health insurance coverage offered by a health insur-
5 ance issuer and who is furnished in a plan year beginning
6 on or after January 1, 2022, air ambulance services (for
7 which benefits are available under such plan or coverage)
8 from a nonparticipating provider (as defined in section
9 2799A-1(a)(3)(G)) with respect to such plan or coverage,
10 such provider shall not bill, and shall not hold liable, such
11 participant, beneficiary, or enrollee for a payment amount
12 for such service furnished by such provider that is more
13 than the cost-sharing amount for such service (as deter-
14 mined in accordance with paragraphs (1) and (2) of sec-
15 tion 2799A-2(a), section 717(a) of the Employee Retire-
16 ment Income Security Act of 1974, or section 9817(a) of
17 the Internal Revenue Code of 1986, as applicable).”.

18 **SEC. 106. REPORTING REQUIREMENTS REGARDING AIR AM-**
19 **BULANCE SERVICES.**

20 (a) REPORTING REQUIREMENTS FOR PROVIDERS OF
21 AIR AMBULANCE SERVICES.—

22 (1) IN GENERAL.—A provider of air ambulance
23 services shall submit to the Secretary of Health and
24 Human Services and the Secretary of Transpor-
25 tation—

1 (A) not later than the date that is 90 days
2 after the last day of the first calendar year be-
3 ginning on or after the date on which a final
4 rule is promulgated pursuant to the rulemaking
5 described in subsection (d), the information de-
6 scribed in paragraph (2) with respect to such
7 plan year; and

8 (B) not later than the date that is 90 days
9 after the last day of the plan year immediately
10 succeeding the plan year described in subpara-
11 graph (A), such information with respect to
12 such immediately succeeding plan year.

13 (2) INFORMATION DESCRIBED.—For purposes
14 of paragraph (1), information described in this para-
15 graph, with respect to a provider of air ambulance
16 services, is each of the following:

17 (A) Cost data, as determined appropriate
18 by the Secretary of Health and Human Serv-
19 ices, in consultation with the Secretary of
20 Transportation, for air ambulance services fur-
21 nished by such provider, separated to the max-
22 imum extent possible by air transportation costs
23 associated with furnishing such air ambulance
24 services and costs of medical services and sup-

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1 plies associated with furnishing such air ambu-
2 lance services.

3 (B) The number and location of all air am-
4 bulance bases operated by such provider.

5 (C) The number and type of aircraft oper-
6 ated by such provider.

7 (D) The number of air ambulance trans-
8 ports, disaggregated by payor mix, including—

9 (i)(I) group health plans;

10 (II) health insurance issuers; and

11 (III) State and Federal Government
12 payors; and

13 (ii) uninsured individuals.

14 (E) The number of claims of such provider
15 that have been denied payment by a group
16 health plan or health insurance issuer and the
17 reasons for any such denials.

18 (F) The number of emergency and non-
19 emergency air ambulance transports,
20 disaggregated by air ambulance base and type
21 of aircraft.

22 (G) Such other information regarding air
23 ambulance services as the Secretary of Health
24 and Human Services may specify.

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1 (b) REPORTING REQUIREMENTS FOR GROUP
2 HEALTH PLANS AND HEALTH INSURANCE ISSUERS.—

3 (1) PHSA.—Part D of title XXVII of the Pub-
4 lic Health Service Act, as added by section
5 102(a)(1), is amended by adding after section
6 2799A–7, as added by section 102(a)(2)(A) of this
7 Act, the following new section:

8 **“SEC. 2799A–8. AIR AMBULANCE REPORT REQUIREMENTS.**

9 “(a) IN GENERAL.—Each group health plan and
10 health insurance issuer offering group or individual health
11 insurance coverage shall submit to the Secretary, jointly
12 with the Secretary of Labor and the Secretary of the
13 Treasury—

14 “(1) not later than the date that is 90 days
15 after the last day of the first calendar year begin-
16 ning on or after the date on which a final rule is
17 promulgated pursuant to the rulemaking described
18 in section 106(d) of the No Surprises Act, the infor-
19 mation described in subsection (b) with respect to
20 such plan year; and

21 “(2) not later than the date that is 90 days
22 after the last day of the calendar year immediately
23 succeeding the plan year described in paragraph (1),
24 such information with respect to such immediately
25 succeeding plan year.

1 “(b) INFORMATION DESCRIBED.—For purposes of
2 subsection (a), information described in this subsection,
3 with respect to a group health plan or a health insurance
4 issuer offering group or individual health insurance cov-
5 erage, is each of the following:

6 “(1) Claims data for air ambulance services
7 furnished by providers of such services,
8 disaggregated by each of the following factors:

9 “(A) Whether such services were furnished
10 on an emergent or nonemergent basis.

11 “(B) Whether the provider of such services
12 is part of a hospital-owned or sponsored pro-
13 gram, municipality-sponsored program, hospital
14 independent partnership (hybrid) program,
15 independent program, or tribally operated pro-
16 gram in Alaska.

17 “(C) Whether the transport in which the
18 services were furnished originated in a rural or
19 urban area.

20 “(D) The type of aircraft (such as rotor
21 transport or fixed wing transport) used to fur-
22 nish such services.

23 “(E) Whether the provider of such services
24 has a contract with the plan or issuer, as appli-

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1 cable, to furnish such services under the plan or
2 coverage, respectively.

3 “(2) Such other information regarding pro-
4 viders of air ambulance services as the Secretary
5 may specify.”.

6 (2) ERISA.—

7 (A) IN GENERAL.—Subpart B of part 7 of
8 title I of the Employee Retirement Income Se-
9 curity Act of 1974 (29 U.S.C. 1185 et seq.) is
10 amended by adding after section 722, as added
11 by section 102(b)(2)(A) of this Act, the fol-
12 lowing new section:

13 **“SEC. 723. AIR AMBULANCE REPORT REQUIREMENTS.**

14 “(a) IN GENERAL.—Each group health plan and
15 health insurance issuer offering group health insurance
16 coverage shall submit to the Secretary, jointly with the
17 Secretary of Health and Human Services and the Sec-
18 retary of the Treasury—

19 “(1) not later than the date that is 90 days
20 after the last day of the first calendar year begin-
21 ning on or after the date on which a final rule is
22 promulgated pursuant to the rulemaking described
23 in section 106(d) of the No Surprises Act, the infor-
24 mation described in subsection (b) with respect to
25 such plan year; and

1 “(2) not later than the date that is 90 days
2 after the last day of the plan year immediately suc-
3 ceeding the calendar year described in paragraph
4 (1), such information with respect to such imme-
5 diately succeeding plan year.

6 “(b) INFORMATION DESCRIBED.—For purposes of
7 subsection (a), information described in this subsection,
8 with respect to a group health plan or a health insurance
9 issuer offering group health insurance coverage, is each
10 of the following:

11 “(1) Claims data for air ambulance services
12 furnished by providers of such services,
13 disaggregated by each of the following factors:

14 “(A) Whether such services were furnished
15 on an emergent or nonemergent basis.

16 “(B) Whether the provider of such services
17 is part of a hospital-owned or sponsored pro-
18 gram, municipality-sponsored program, hospital
19 independent partnership (hybrid) program,
20 independent program, or tribally operated pro-
21 gram in Alaska.

22 “(C) Whether the transport in which the
23 services were furnished originated in a rural or
24 urban area.

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1 “(D) The type of aircraft (such as rotor
2 transport or fixed wing transport) used to fur-
3 nish such services.

4 “(E) Whether the provider of such services
5 has a contract with the plan or issuer, as appli-
6 cable, to furnish such services under the plan or
7 coverage, respectively.

8 “(2) Such other information regarding pro-
9 viders of air ambulance services as the Secretary
10 may specify.”.

11 (B) CLERICAL AMENDMENT.—The table of
12 contents of the Employee Retirement Income
13 Security Act of 1974 is amended by adding
14 after the item relating to section 722, as added
15 by section 102(b) the following:

“Sec. 723. Air ambulance report requirements.”.

16 (3) IRC.—

17 (A) IN GENERAL.—Subchapter B of chap-
18 ter 100 of the Internal Revenue Code of 1986
19 is amended by adding after section 9822, as
20 added by section 102(c)(2)(A) of this Act, the
21 following new section:

22 **“SEC. 9823. AIR AMBULANCE REPORT REQUIREMENTS.**

23 “(a) IN GENERAL.—Each group health plan shall
24 submit to the Secretary, jointly with the Secretary of
25 Labor and the Secretary of Health and Human Services—

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1 “(1) not later than the date that is 90 days
2 after the last day of the first calendar year begin-
3 ning on or after the date on which a final rule is
4 promulgated pursuant to the rulemaking described
5 in section 106(d) of the No Surprises Act, the infor-
6 mation described in subsection (b) with respect to
7 such plan year; and

8 “(2) not later than the date that is 90 days
9 after the last day of the calendar year immediately
10 succeeding the plan year described in paragraph (1),
11 such information with respect to such immediately
12 succeeding plan year.

13 “(b) INFORMATION DESCRIBED.—For purposes of
14 subsection (a), information described in this subsection,
15 with respect to a group health plan is each of the fol-
16 lowing:

17 “(1) Claims data for air ambulance services
18 furnished by providers of such services,
19 disaggregated by each of the following factors:

20 “(A) Whether such services were furnished
21 on an emergent or nonemergent basis.

22 “(B) Whether the provider of such services
23 is part of a hospital-owned or sponsored pro-
24 gram, municipality-sponsored program, hospital
25 independent partnership (hybrid) program,

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1 independent program, or tribally operated pro-
2 gram in Alaska.

3 “(C) Whether the transport in which the
4 services were furnished originated in a rural or
5 urban area.

6 “(D) The type of aircraft (such as rotor
7 transport or fixed wing transport) used to fur-
8 nish such services.

9 “(E) Whether the provider of such services
10 has a contract with the plan or issuer, as appli-
11 cable, to furnish such services under the plan or
12 coverage, respectively.

13 “(2) Such other information regarding pro-
14 viders of air ambulance services as the Secretary
15 may specify.”.

16 (B) CLERICAL AMENDMENT.—The table of
17 sections for subchapter B of chapter 100 of the
18 Internal Revenue Code of 1986 is amended by
19 adding after the item relating to section 9822,
20 as added by section 102(c), the following new
21 item:

“Sec. 9823. Air ambulance report requirements.”.

22 (c) PUBLICATION OF COMPREHENSIVE REPORT.—

23 (1) IN GENERAL.—Not later than the date that
24 is one year after the date described in subsection
25 (a)(2) of section 2799A–8 of the Public Health

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1 Service Act, of section 723 of the Employee Retirement
2 ment Income Security Act of 1974, and of section
3 9823 of the Internal Revenue Code of 1986, as such
4 sections are added by subsection (b), the Secretary
5 of Health and Human Services, in consultation with
6 the Secretary of Transportation (referred to in this
7 section as the “Secretaries”), shall develop, and
8 make publicly available (subject to paragraph (3)), a
9 comprehensive report summarizing the information
10 submitted under subsection (a) and the amendments
11 made by subsection (b) and including each of the
12 following:

13 (A) The percentage of providers of air am-
14 bulance services that are part of a hospital-
15 owned or sponsored program, municipality-
16 sponsored program, hospital-independent part-
17 nership (hybrid) program, or independent pro-
18 gram.

19 (B) An assessment of the extent of com-
20 petition among providers of air ambulance serv-
21 ices on the basis of price and services offered,
22 and any changes in such competition over time.

23 (C) An assessment of the average charges
24 for air ambulance services, amounts paid by
25 group health plans and health insurance issuers

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1 offering group or individual health insurance
2 coverage to providers of air ambulance services
3 for furnishing such services, and amounts paid
4 out-of-pocket by consumers, and any changes in
5 such amounts paid over time.

6 (D) An assessment of the presence of air
7 ambulance bases in, or with the capability to
8 serve, rural areas, and the relative growth in air
9 ambulance bases in rural and urban areas over
10 time.

11 (E) Any evidence of gaps in rural access to
12 providers of air ambulance services.

13 (F) The percentage of providers of air am-
14 bulance services that have contracts with group
15 health plans or health insurance issuers offering
16 group or individual health insurance coverage to
17 furnish such services under such plans or cov-
18 erage, respectively.

19 (G) An assessment of whether there are in-
20 stances of unfair, deceptive, or predatory prac-
21 tices by providers of air ambulance services in
22 collecting payments from patients to whom such
23 services are furnished, such as referral of such
24 patients to collections, lawsuits, and liens or
25 wage garnishment actions.

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1 (H) An assessment of whether there are,
2 within the air ambulance industry, instances of
3 unreasonable industry concentration, excessive
4 market domination, or other conditions that
5 would allow at least one provider of air ambu-
6 lance services to unreasonably increase prices or
7 exclude competition in air ambulance services in
8 a given geographic region.

9 (I) An assessment of the frequency of pa-
10 tient balance billing, patient referrals to collec-
11 tions, lawsuits to collect balance bills, and liens
12 or wage garnishment actions by providers of air
13 ambulance services as part of a collections proc-
14 ess across hospital-owned or sponsored pro-
15 grams, municipality-sponsored programs, hos-
16 pital-independent partnership (hybrid) pro-
17 grams, tribally operated programs in Alaska, or
18 independent programs, providers of air ambu-
19 lance services operated by public agencies (such
20 as a State or county health department), and
21 other independent providers of air ambulance
22 services.

23 (J) An assessment of the frequency of
24 claims appeals made by providers of air ambu-
25 lance services to group health plans or health

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1 insurance issuers offering group or individual
2 health insurance coverage with respect to air
3 ambulance services furnished to enrollees of
4 such plans or coverage, respectively.

5 (K) Any other cost, quality, or other data
6 relating to air ambulance services or the air
7 ambulance industry, as determined necessary
8 and appropriate by the Secretaries.

9 (2) OTHER SOURCES OF INFORMATION.—The
10 Secretaries may incorporate information from inde-
11 pendent experts or third-party sources in developing
12 the comprehensive report required under paragraph
13 (1).

14 (3) PROTECTION OF PROPRIETARY INFORMA-
15 TION.—The Secretaries may not make publicly avail-
16 able under this subsection any proprietary informa-
17 tion.

18 (d) RULEMAKING.—Not later than the date that is
19 one year after the date of the enactment of this Act, the
20 Secretary of Health and Human Services, in consultation
21 with the Secretary of Transportation, shall, through notice
22 and comment rulemaking, specify the form and manner
23 in which reports described in subsection (a) and in the
24 amendments made by subsection (b) shall be submitted
25 to such Secretaries, taking into consideration (as applica-

1 ble and to the extent feasible) any recommendations in-
2 cluded in the report submitted by the Advisory Committee
3 on Air Ambulance and Patient Billing under section
4 418(e) of the FAA Reauthorization Act of 2018 (Public
5 Law 115–254; 49 U.S.C. 42301 note prec.).

6 (e) CIVIL MONEY PENALTIES.—

7 (1) IN GENERAL.—Subject to paragraph (2), a
8 provider of air ambulance services who fails to sub-
9 mit all information required under subsection (a)(2)
10 by the date described in subparagraph (A) or (B) of
11 subsection (a)(1), as applicable, shall be subject to
12 a civil money penalty of not more than \$10,000.

13 (2) EXCEPTION.—In the case of a provider of
14 air ambulance services that submits only some of the
15 information required under subsection (a)(2) by the
16 date described in subparagraph (A) or (B) of sub-
17 section (a)(1), as applicable, the Secretary of Health
18 and Human Services may waive the civil money pen-
19 alty imposed under paragraph (1) if such provider
20 demonstrates a good faith effort (as defined by the
21 Secretary pursuant to regulation) in working with
22 the Secretary to submit the remaining information
23 required under subsection (a)(2).

24 (3) PROCEDURE.—The provisions of section
25 1128A of the Social Security Act (42 U.S.C. 1320a–

1 7a), other than subsections (a) and (b) and the first
2 sentence of subsection (c)(1), shall apply to civil
3 money penalties under this subsection in the same
4 manner as such provisions apply to a penalty or pro-
5 ceeding under such section.

6 (f) UNFAIR AND DECEPTIVE PRACTICES AND UN-
7 FAIR METHODS OF COMPETITION.—The Secretary of
8 Transportation may use any information submitted under
9 subsection (a) in determining whether a provider of air
10 ambulance services has violated section 41712(a) of title
11 49, United States Code.

12 (g) ADVISORY COMMITTEE ON AIR AMBULANCE
13 QUALITY AND PATIENT SAFETY.—

14 (1) ESTABLISHMENT.—Not later than the date
15 that is 60 days after the date of the enactment of
16 this Act, the Secretary of Health and Human Serv-
17 ices and the Secretary of Transportation, shall es-
18 tablish an Advisory Committee on Air Ambulance
19 Quality and Patient Safety (referred to in this sub-
20 section as the “Committee”) for the purpose of re-
21 viewing options to establish quality, patient safety,
22 and clinical capability standards for each clinical ca-
23 pability level of air ambulances.

24 (2) MEMBERSHIP.—The Committee shall be
25 composed of the following members:

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1 (A) The Secretary of Health and Human
2 Services, or a designee of the Secretary, who
3 shall serve as the Chair of the Committee.

4 (B) The Secretary of Transportation, or a
5 designee of the Secretary.

6 (C) One representative, to be appointed by
7 the Secretary of Health and Human Services,
8 of each of the following:

9 (i) State health insurance regulators.

10 (ii) Health care providers.

11 (iii) Group health plans and health in-
12 surance issuers offering group or indi-
13 vidual health insurance coverage.

14 (iv) Patient advocacy groups.

15 (v) Accrediting bodies with experience
16 in quality measures.

17 (D) Three representatives of the air ambu-
18 lance industry, to be appointed by the Secretary
19 of Transportation.

20 (E) Additional three representatives not
21 covered under subparagraphs (A) through (D),
22 as determined necessary and appropriate by the
23 Secretary of Health and Human Services and
24 Secretary of Transportation.

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1 (3) FIRST MEETING.—Not later than the date
2 that is 90 days after the date of the enactment of
3 this Act, the Committee shall hold its first meeting.

4 (4) DUTIES.—The Committee shall study and
5 make recommendations, as appropriate, to Congress
6 regarding each of the following with respect to air
7 ambulance services:

8 (A) Qualifications of different clinical ca-
9 pability levels and tiering of such levels.

10 (B) Patient safety and quality standards.

11 (C) Options for improving service reli-
12 ability during poor weather, night conditions, or
13 other adverse conditions.

14 (D) Differences between air ambulance ve-
15 hicle types, services, and technologies, and other
16 flight capability standards, and the impact of
17 such differences on patient safety.

18 (E) Clinical triage criteria for air ambu-
19 lances.

20 (5) REPORT.—Not later than the date that is
21 180 days after the date of the first meeting of the
22 Committee, the Committee, in consultation with rel-
23 evant experts and stakeholders, as appropriate, shall
24 develop and make publicly available a report on any
25 recommendations submitted to Congress under para-

1 graph (4). The Committee may update such report,
2 as determined appropriate by the Committee.

3 (h) DEFINITIONS.—In this section, the terms “group
4 health plan”, “health insurance coverage”, “individual
5 health insurance coverage”, “group health insurance cov-
6 erage”, and “health insurance issuer” have the meanings
7 given such terms in section 2791 of the Public Health
8 Service Act (42 U.S.C. 300gg–91).

9 **SEC. 107. TRANSPARENCY REGARDING IN-NETWORK AND**
10 **OUT-OF-NETWORK DEDUCTIBLES AND OUT-**
11 **OF-POCKET LIMITATIONS.**

12 (a) PHSA.—Section 2799A–1 of the Public Health
13 Service Act, as added by section 102(a) and amended by
14 section 103, is further amended by adding at the end the
15 following new subsection:

16 “(e) TRANSPARENCY REGARDING IN-NETWORK AND
17 OUT-OF-NETWORK DEDUCTIBLES AND OUT-OF-POCKET
18 LIMITATIONS.—A group health plan or a health insurance
19 issuer offering group or individual health insurance cov-
20 erage and providing or covering any benefit with respect
21 to items or services shall include, in clear writing, on any
22 physical or electronic plan or insurance identification card
23 issued to the participants, beneficiaries, or enrollees in the
24 plan or coverage the following:

1 “(1) Any deductible applicable to such plan or
2 coverage.

3 “(2) Any out-of-pocket maximum limitation ap-
4 plicable to such plan or coverage.

5 “(3) A telephone number and Internet website
6 address through which such individual may seek con-
7 sumer assistance information, such as information
8 related to hospitals and urgent care facilities that
9 have in effect a contractual relationship with such
10 plan or coverage for furnishing items and services
11 under such plan or coverage”.

12 (b) ERISA.—Section 716 of the Employee Retirement
13 Income Security Act of 1974, as added by section 102(b)
14 and amended by section 103, is further amended by add-
15 ing at the end the following new subsection:

16 “(e) TRANSPARENCY REGARDING IN-NETWORK AND
17 OUT-OF-NETWORK DEDUCTIBLES AND OUT-OF-POCKET
18 LIMITATIONS.—A group health plan or a health insurance
19 issuer offering group health insurance coverage and pro-
20 viding or covering any benefit with respect to items or
21 services shall include, in clear writing, on any physical or
22 electronic plan or insurance identification card issued to
23 the participants or beneficiaries in the plan or coverage
24 the following:

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1 “(1) Any deductible applicable to such plan or
2 coverage.

3 “(2) Any out-of-pocket maximum limitation ap-
4 plicable to such plan or coverage.

5 “(3) A telephone number and Internet website
6 address through which such individual may seek con-
7 sumer assistance information, such as information
8 related to hospitals and urgent care facilities that
9 have in effect a contractual relationship with such
10 plan or coverage for furnishing items and services
11 under such plan or coverage”.

12 (c) IRC.—Section 9816 of the Internal Revenue Code
13 of 1986, as added by section 102(c) and amended by sec-
14 tion 103, is further amended by adding at the end the
15 following new subsection:

16 “(e) TRANSPARENCY REGARDING IN-NETWORK AND
17 OUT-OF-NETWORK DEDUCTIBLES AND OUT-OF-POCKET
18 LIMITATIONS.—A group health plan providing or covering
19 any benefit with respect to items or services shall include,
20 in clear writing, on any physical or electronic plan or in-
21 surance identification card issued to the participants or
22 beneficiaries in the plan the following:

23 “(1) Any deductible applicable to such plan.

24 “(2) Any out-of-pocket maximum limitation ap-
25 plicable to such plan.

1 “(3) A telephone number and Internet website
2 address through which such individual may seek con-
3 sumer assistance information, such as information
4 related to hospitals and urgent care facilities that
5 have in effect a contractual relationship with such
6 plan for furnishing items and services under such
7 plan.”.

8 (d) **EFFECTIVE DATE.**—The amendments made by
9 this subsection shall apply with respect to plan years be-
10 ginning on or after January 1, 2022.

11 **SEC. 108. IMPLEMENTING PROTECTIONS AGAINST PRO-**
12 **VIDER DISCRIMINATION.**

13 Not later than January 1, 2022, the Secretary of
14 Health and Human Services, the Secretary of Labor, and
15 the Secretary of the Treasury shall issue a proposed rule
16 implementing the protections of section 2706(a) of the
17 Public Health Service Act (42 U.S.C. 300gg-5(a)). The
18 Secretaries shall accept and consider public comments on
19 any proposed rule issued pursuant to this subsection for
20 a period of 60 days after the date of such issuance. Not
21 later than 6 months after the date of the conclusion of
22 the comment period, the Secretaries shall issue a final rule
23 implementing the protections of section 2706(a) of the
24 Public Health Service Act (42 U.S.C. 300gg-5(a)).

1 **SEC. 109. REPORTS.**

2 (a) REPORTS IN CONSULTATION WITH FTC AND
3 AG.—Not later than January 1, 2023, and annually
4 thereafter for each of the following 4 years, the Secretary
5 of Health and Human Services, in consultation with the
6 Federal Trade Commission and the Attorney General,
7 shall—

8 (1) conduct a study on the effects of the provi-
9 sions of, including amendments made by, this Act
10 on—

11 (A) any patterns of vertical or horizontal
12 integration of health care facilities, providers,
13 group health plans, or health insurance issuers
14 offering group or individual health insurance
15 coverage;

16 (B) overall health care costs; and

17 (C) access to health care items and serv-
18 ices, including specialty services, in rural areas
19 and health professional shortage areas, as de-
20 fined in section 332 of the Public Health Serv-
21 ice Act (42 U.S.C. 254e);

22 (2) for purposes of the reports under paragraph
23 (3), in consultation with the Secretary of Labor and
24 the Secretary of the Treasury, make recommenda-
25 tions for the effective enforcement of subsections
26 (a)(1)(C)(iv) and (b)(1)(C) of section 2799A–1 of

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1 the Public Health Service Act, subsections
2 (a)(1)(C)(iv) and (b)(1)(C) of section 716 of the
3 Employee Retirement Income Security Act of 1974,
4 and subsections (a)(1)(C)(iv) and (b)(1)(C) of sec-
5 tion 9816 of the Internal Revenue Code of 1986, in-
6 cluding with respect to potential challenges to ad-
7 dressing anti-competitive consolidation of health care
8 facilities, providers, group health plans, or health in-
9 surance issuers offering group or individual health
10 insurance coverage; and

11 (3) submit a report on such study and including
12 such recommendations to the Committees on Energy
13 and Commerce; on Education and Labor; on Ways
14 and Means; and on the Judiciary of the House of
15 Representatives and the Committees on Health,
16 Education, Labor, and Pensions; on Commerce,
17 Science, and Transportation; on Finance; and on the
18 Judiciary of the Senate.

19 (b) GAO REPORT ON IMPACT OF SURPRISE BILLING
20 PROVISIONS.—Not later than January 1, 2025, the Comp-
21 troller General of the United States shall submit to Con-
22 gress a report summarizing the effects of the provisions
23 of this Act, including the amendments made by such provi-
24 sions, on changes during the period since the date on the
25 enactment of this Act in health care provider networks of

1 group health plans and group and individual health insur-
2 ance coverage offered by a health insurance issuer, in fee
3 schedules and amounts for health care services, and to
4 contracted rates under such plans or coverage. Such re-
5 port shall—

6 (1) to the extent practicable, sample a statis-
7 tically significant group of national health care pro-
8 viders;

9 (2) examine—

10 (A) provider network participation, includ-
11 ing nonparticipating providers furnishing items
12 and services at participating facilities;

13 (B) health care provider group network
14 participation, including specialty, size, and own-
15 ership;

16 (C) the impact of State surprise billing
17 laws and network adequacy standards on par-
18 ticipation of health care providers and facilities
19 in provider networks of group health plans and
20 of group and individual health insurance cov-
21 erage offered by health insurance issuers; and

22 (D) access to providers, including in rural
23 and medically underserved communities and
24 health professional shortage areas (as defined
25 in section 332 of the Public Health Service

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1 Act), and the extent of provider shortages in
2 such communities and areas;

3 (3) to the extent practicable, sample a statis-
4 tically significant group of national health insurance
5 plans and issuers and examine—

6 (A) the effects of the provisions of, includ-
7 ing amendments made by, this Act on pre-
8 miums and out-of-pocket costs with respect to
9 group health plans or group or individual health
10 insurance coverage;

11 (B) the adequacy of provider networks
12 with respect to such plans or coverage; and

13 (C) categories of providers of ancillary
14 services, as defined in section 2799B–2(b)(2) of
15 the Public Health Service Act, for which such
16 plans have no or a limited number of in-net-
17 work providers; and

18 (4) such other relevant effects of such provi-
19 sions and amendments.

20 (c) GAO REPORT ON ADEQUACY OF PROVIDER NET-
21 WORKS.—Not later than January 1, 2023, the Comp-
22 troller General of the United States shall submit to Con-
23 gress, and make publicly available, a report on the ade-
24 quacy of provider networks in group health plans and
25 group and individual health insurance coverage, including

1 legislative recommendations to improve the adequacy of
2 such networks.

3 (d) GAO REPORT ON IDR PROCESS AND POTENTIAL
4 FINANCIAL RELATIONSHIPS.—Not later than December
5 31, 2023, the Comptroller General of the United States
6 shall conduct a study and submit to Congress a report
7 on the IDR process established under this section. Such
8 study and report shall include an analysis of potential fi-
9 nancial relationships between providers and facilities that
10 utilize the IDR process established by the amendments
11 made by this Act and private equity investment firms.

12 **SEC. 110. CONSUMER PROTECTIONS THROUGH APPLICA-**
13 **TION OF HEALTH PLAN EXTERNAL REVIEW**
14 **IN CASES OF CERTAIN SURPRISE MEDICAL**
15 **BILLS.**

16 (a) IN GENERAL.—In applying the provisions of sec-
17 tion 2719(b) of the Public Health Service Act (42 U.S.C.
18 300gg–19(b)) to group health plans and health insurance
19 issuers offering group or individual health insurance cov-
20 erage, the Secretary of Health and Human Services, Sec-
21 retary of Labor, and Secretary of the Treasury, shall re-
22 quire, beginning not later than January 1, 2022, the ex-
23 ternal review process described in paragraph (1) of such
24 section to apply with respect to any adverse determination
25 by such a plan or issuer under section 2799A-1 or 2799A-

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1 2, section 716 or 717 of the Employee Retirement Income
2 Security Act of 1974, or section 9816 or 9817 of the In-
3 ternal Revenue Code of 1986, including with respect to
4 whether an item or service that is the subject to such a
5 determination is an item or service to which such respec-
6 tive section applies.

7 (b) DEFINITIONS.—The terms “group health plan”;
8 “health insurance issuer”; “group health insurance cov-
9 erage”, and “individual health insurance coverage” have
10 the meanings given such terms in section 2791 of the Pub-
11 lic Health Service Act (42 U.S.C. 300gg–91), section 733
12 of the Employee Retirement Income Security Act (29
13 U.S.C. 1191b), and section 9832 of the Internal Revenue
14 Code, as applicable.

15 **SEC. 111. CONSUMER PROTECTIONS THROUGH HEALTH**
16 **PLAN REQUIREMENT FOR FAIR AND HONEST**
17 **ADVANCE COST ESTIMATE.**

18 (a) PHSA AMENDMENT.—Section 2799A–1 of the
19 Public Health Service Act (42 U.S.C. 300gg–19a), as
20 added by section 102 and as further amended by the pre-
21 vious provisions of this title, is further amended by adding
22 at the end the following new subsection:

23 “(f) ADVANCED EXPLANATION OF BENEFITS.—

24 “(1) IN GENERAL.—For plan years beginning
25 on or after January 1, 2022, each group health

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1 plan, or a health insurance issuer offering group or
2 individual health insurance coverage shall, with re-
3 spect to a notification submitted under section
4 2799B–6 by a health care provider or health care fa-
5 cility to the plan or issuer for a participant, bene-
6 ficiary, or enrollee under plan or coverage scheduled
7 to receive an item or service from the provider or fa-
8 cility (or authorized representative of such partici-
9 pant, beneficiary, or enrollee), not later than 1 busi-
10 ness day (or, in the case such item or service was
11 so scheduled at least 10 business days before such
12 item or service is to be furnished (or in the case of
13 a request made to such plan or coverage by such
14 participant, beneficiary, or enrollee), 3 business
15 days) after the date on which the plan or coverage
16 receives such notification (or such request), provide
17 to the participant, beneficiary, or enrollee (through
18 mail or electronic means, as requested by the partici-
19 pant, beneficiary, or enrollee) a notification (in clear
20 and understandable language) including the fol-
21 lowing:

22 “(A) Whether or not the provider or facil-
23 ity is a participating provider or a participating
24 facility with respect to the plan or coverage

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1 with respect to the furnishing of such item or
2 service and—

3 “(i) in the case the provider or facility
4 is a participating provider or facility with
5 respect to the plan or coverage with re-
6 spect to the furnishing of such item or
7 service, the contracted rate under such
8 plan or coverage for such item or service
9 (based on the billing and diagnostic codes
10 provided by such provider or facility); and

11 “(ii) in the case the provider or facil-
12 ity is a nonparticipating provider or facility
13 with respect to such plan or coverage, a
14 description of how such individual may ob-
15 tain information on providers and facilities
16 that, with respect to such plan or coverage,
17 are participating providers and facilities, if
18 any.

19 “(B) The good faith estimate included in
20 the notification received from the provider or
21 facility (if applicable) based on such codes.

22 “(C) A good faith estimate of the amount
23 the plan or coverage is responsible for paying
24 for items and services included in the estimate
25 described in subparagraph (B).

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1 “(D) A good faith estimate of the amount
2 of any cost-sharing for which the participant,
3 beneficiary, or enrollee would be responsible for
4 such item or service (as of the date of such no-
5 tification).

6 “(E) A good faith estimate of the amount
7 that the participant, beneficiary, or enrollee has
8 incurred toward meeting the limit of the finan-
9 cial responsibility (including with respect to
10 deductibles and out-of-pocket maximums) under
11 the plan or coverage (as of the date of such no-
12 tification).

13 “(F) In the case such item or service is
14 subject to a medical management technique (in-
15 cluding concurrent review, prior authorization,
16 and step-therapy or fail-first protocols) for cov-
17 erage under the plan or coverage, a disclaimer
18 that coverage for such item or service is subject
19 to such medical management technique.

20 “(G) A disclaimer that the information
21 provided in the notification is only an estimate
22 based on the items and services reasonably ex-
23 pected, at the time of scheduling (or requesting)
24 the item or service, to be furnished and is sub-
25 ject to change.

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1 “(H) Any other information or disclaimer
2 the plan or coverage determines appropriate
3 that is consistent with information and dis-
4 claimers required under this section.

5 “(2) AUTHORITY TO MODIFY TIMING REQUIRE-
6 MENTS IN THE CASE OF SPECIFIED ITEMS AND
7 SERVICES.—

8 “(A) IN GENERAL.—In the case of a par-
9 ticipant, beneficiary, or enrollee scheduled to re-
10 ceive an item or service that is a specified item
11 or service (as defined in subparagraph (B)), the
12 Secretary may modify any timing requirements
13 relating to the provision of the notification de-
14 scribed in paragraph (1) to such participant,
15 beneficiary, or enrollee with respect to such
16 item or service. Any modification made by the
17 Secretary pursuant to the previous sentence
18 may not result in the provision of such notifica-
19 tion after such participant, beneficiary, or en-
20 rollee has been furnished such item or service.

21 “(B) SPECIFIED ITEM OR SERVICE DE-
22 FINED.—For purposes of subparagraph (A), the
23 term ‘specified item or service’ means an item
24 or service that has low utilization or significant
25 variation in costs (such as when furnished as

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1 part of a complex treatment), as specified by
2 the Secretary.”.

3 (b) IRC AMENDMENTS.—Section 9816 of the Inter-
4 nal Revenue Code of 1986, as added by section 102 and
5 further amended by the previous provisions of this title,
6 is further amended by inserting after subsection (e) the
7 following new subsection:

8 “(f) ADVANCED EXPLANATION OF BENEFITS.—

9 “(1) IN GENERAL.—For plan years beginning
10 on or after January 1, 2022, each group health plan
11 shall, with respect to a notification submitted under
12 section 2799B–6 of the Public Health Service Act by
13 a health care provider or health care facility to the
14 plan for a participant or beneficiary under plan
15 scheduled to receive an item or service from the pro-
16 vider or facility (or authorized representative of such
17 participant or beneficiary), not later than 1 business
18 day (or, in the case such item or service was so
19 scheduled at least 10 business days before such item
20 or service is to be furnished (or in the case of a re-
21 quest made to such plan or coverage by such partici-
22 pant or beneficiary), 3 business days) after the date
23 on which the plan receives such notification (or such
24 request), provide to the participant or beneficiary
25 (through mail or electronic means, as requested by

1 the participant or beneficiary) a notification (in clear
2 and understandable language) including the fol-
3 lowing:

4 “(A) Whether or not the provider or facil-
5 ity is a participating provider or a participating
6 facility with respect to the plan with respect to
7 the furnishing of such item or service and—

8 “(i) in the case the provider or facility
9 is a participating provider or facility with
10 respect to the plan or coverage with re-
11 spect to the furnishing of such item or
12 service, the contracted rate under such
13 plan for such item or service (based on the
14 billing and diagnostic codes provided by
15 such provider or facility); and

16 “(ii) in the case the provider or facil-
17 ity is a nonparticipating provider or facility
18 with respect to such plan, a description of
19 how such individual may obtain informa-
20 tion on providers and facilities that, with
21 respect to such plan, are participating pro-
22 viders and facilities, if any.

23 “(B) The good faith estimate included in
24 the notification received from the provider or
25 facility (if applicable) based on such codes.

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1 “(C) A good faith estimate of the amount
2 the plan is responsible for paying for items and
3 services included in the estimate described in
4 subparagraph (B).

5 “(D) A good faith estimate of the amount
6 of any cost-sharing for which the participant or
7 beneficiary would be responsible for such item
8 or service (as of the date of such notification).

9 “(E) A good faith estimate of the amount
10 that the participant or beneficiary has incurred
11 toward meeting the limit of the financial re-
12 sponsibility (including with respect to
13 deductibles and out-of-pocket maximums) under
14 the plan (as of the date of such notification).

15 “(F) In the case such item or service is
16 subject to a medical management technique (in-
17 cluding concurrent review, prior authorization,
18 and step-therapy or fail-first protocols) for cov-
19 erage under the plan, a disclaimer that coverage
20 for such item or service is subject to such med-
21 ical management technique.

22 “(G) A disclaimer that the information
23 provided in the notification is only an estimate
24 based on the items and services reasonably ex-
25 pected, at the time of scheduling (or requesting)

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1 the item or service, to be furnished and is sub-
2 ject to change.

3 “(H) Any other information or disclaimer
4 the plan determines appropriate that is con-
5 sistent with information and disclaimers re-
6 quired under this section.

7 “(2) AUTHORITY TO MODIFY TIMING REQUIRE-
8 MENTS IN THE CASE OF SPECIFIED ITEMS AND
9 SERVICES.—

10 “(A) IN GENERAL.—In the case of a par-
11 ticipant or beneficiary scheduled to receive an
12 item or service that is a specified item or serv-
13 ice (as defined in subparagraph (B)), the Sec-
14 retary may modify any timing requirements re-
15 lating to the provision of the notification de-
16 scribed in paragraph (1) to such participant or
17 beneficiary with respect to such item or service.
18 Any modification made by the Secretary pursu-
19 ant to the previous sentence may not result in
20 the provision of such notification after such
21 participant or beneficiary has been furnished
22 such item or service.

23 “(B) SPECIFIED ITEM OR SERVICE DE-
24 FINED.—For purposes of subparagraph (A), the
25 term ‘specified item or service’ means an item

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1 or service that has low utilization or significant
2 variation in costs (such as when furnished as
3 part of a complex treatment), as specified by
4 the Secretary.”.

5 (c) ERISA AMENDMENTS.—Section 716 of the Em-
6 ployee Retirement Income Security Act of 1974, as added
7 by section 102 and further amended by the previous
8 amendments of this title, is further amended by adding
9 at the end the following new subsection:

10 “(f) ADVANCED EXPLANATION OF BENEFITS.—

11 “(1) IN GENERAL.—For plan years beginning
12 on or after January 1, 2022, each group health
13 plan, or a health insurance issuer offering group
14 health insurance coverage shall, with respect to a no-
15 tification submitted under section 2799B–6 of the
16 Public Health Service Act by a health care provider
17 or health care facility to the plan or issuer for a par-
18 ticipant or beneficiary under plan or coverage sched-
19 uled to receive an item or service from the provider
20 or facility (or authorized representative of such par-
21 ticipant or beneficiary), not later than 1 business
22 day (or, in the case such item or service was so
23 scheduled at least 10 business days before such item
24 or service is to be furnished (or in the case of a re-
25 quest made to such plan or coverage by such partici-

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1 pant or beneficiary), 3 business days) after the date
2 on which the plan or coverage receives such notifica-
3 tion (or such request), provide to the participant or
4 beneficiary (through mail or electronic means, as re-
5 quested by the participant or beneficiary) a notifica-
6 tion (in clear and understandable language) includ-
7 ing the following:

8 “(A) Whether or not the provider or facil-
9 ity is a participating provider or a participating
10 facility with respect to the plan or coverage
11 with respect to the furnishing of such item or
12 service and—

13 “(i) in the case the provider or facility
14 is a participating provider or facility with
15 respect to the plan or coverage with re-
16 spect to the furnishing of such item or
17 service, the contracted rate under such
18 plan for such item or service (based on the
19 billing and diagnostic codes provided by
20 such provider or facility); and

21 “(ii) in the case the provider or facil-
22 ity is a nonparticipating provider or facility
23 with respect to such plan or coverage, a
24 description of how such individual may ob-
25 tain information on providers and facilities

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1 that, with respect to such plan or coverage,
2 are participating providers and facilities, if
3 any.

4 “(B) The good faith estimate included in
5 the notification received from the provider or
6 facility (if applicable) based on such codes.

7 “(C) A good faith estimate of the amount
8 the health plan is responsible for paying for
9 items and services included in the estimate de-
10 scribed in subparagraph (B).

11 “(D) A good faith estimate of the amount
12 of any cost-sharing for which the participant or
13 beneficiary would be responsible for such item
14 or service (as of the date of such notification).

15 “(E) A good faith estimate of the amount
16 that the participant or beneficiary has incurred
17 toward meeting the limit of the financial re-
18 sponsibility (including with respect to
19 deductibles and out-of-pocket maximums) under
20 the plan or coverage (as of the date of such no-
21 tification).

22 “(F) In the case such item or service is
23 subject to a medical management technique (in-
24 cluding concurrent review, prior authorization,
25 and step-therapy or fail-first protocols) for cov-

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1 erage under the plan or coverage, a disclaimer
2 that coverage for such item or service is subject
3 to such medical management technique.

4 “(G) A disclaimer that the information
5 provided in the notification is only an estimate
6 based on the items and services reasonably ex-
7 pected, at the time of scheduling (or requesting)
8 the item or service, to be furnished and is sub-
9 ject to change.

10 “(H) Any other information or disclaimer
11 the plan or coverage determines appropriate
12 that is consistent with information and dis-
13 claimers required under this section.

14 “(2) AUTHORITY TO MODIFY TIMING REQUIRE-
15 MENTS IN THE CASE OF SPECIFIED ITEMS AND
16 SERVICES.—

17 “(A) IN GENERAL.—In the case of a par-
18 ticipant or beneficiary scheduled to receive an
19 item or service that is a specified item or serv-
20 ice (as defined in subparagraph (B)), the Sec-
21 retary may modify any timing requirements re-
22 lating to the provision of the notification de-
23 scribed in paragraph (1) to such participant or
24 beneficiary with respect to such item or service.
25 Any modification made by the Secretary pursu-

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1 ant to the previous sentence may not result in
2 the provision of such notification after such
3 participant or beneficiary has been furnished
4 such item or service.

5 “(B) SPECIFIED ITEM OR SERVICE DE-
6 FINED.—For purposes of subparagraph (A), the
7 term ‘specified item or service’ means an item
8 or service that has low utilization or significant
9 variation in costs (such as when furnished as
10 part of a complex treatment), as specified by
11 the Secretary.”.

12 **SEC. 112. PATIENT PROTECTIONS THROUGH TRANS-**
13 **PARENCY AND PATIENT-PROVIDER DISPUTE**
14 **RESOLUTION.**

15 Part E of title XXVII of the Public Health Service
16 Act (42 U.S.C. 300gg et seq.), as added by section 104
17 and further amended by the previous provisions of this
18 title, is further amended by adding at the end the fol-
19 lowing new sections:

20 **“SEC. 2799B-6. PROVISION OF INFORMATION UPON RE-**
21 **QUEST AND FOR SCHEDULED APPOINT-**
22 **MENTS.**

23 “Each health care provider and health care facility
24 shall, beginning January 1, 2022, in the case of an indi-
25 vidual who schedules an item or service to be furnished

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1 to such individual by such provider or facility at least 3
2 business days before the date such item or service is to
3 be so furnished, not later than 1 business day after the
4 date of such scheduling (or, in the case of such an item
5 or service scheduled at least 10 business days before the
6 date such item or service is to be so furnished (or if re-
7 quested by the individual), not later than 3 business days
8 after the date of such scheduling or such request)—

9 “(1) inquire if such individual is enrolled in a
10 group health plan, group or individual health insur-
11 ance coverage offered by a health insurance issuer,
12 or a Federal health care program (and if is so en-
13 rolled in such plan or coverage, seeking to have a
14 claim for such item or service submitted to such
15 plan or coverage); and

16 “(2) provide a notification (in clear and under-
17 standable language) of the good faith estimate of the
18 expected charges for furnishing such item or service
19 (including any item or service that is reasonably ex-
20 pected to be provided in conjunction with such
21 scheduled item or service and such an item or serv-
22 ice reasonably expected to be so provided by another
23 health care provider or health care facility), with the
24 expected billing and diagnostic codes for any such
25 item or service, to—

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1 “(A) in the case the individual is enrolled
2 in such a plan or such coverage (and is seeking
3 to have a claim for such item or service sub-
4 mitted to such plan or coverage), such plan or
5 issuer of such coverage; and

6 “(B) in the case the individual is not de-
7 scribed in subparagraph (A) and not enrolled in
8 a Federal health care program, the individual.

9 **“SEC. 2799B-7. PATIENT-PROVIDER DISPUTE RESOLUTION.**

10 “(a) IN GENERAL.—Not later than January 1, 2022,
11 the Secretary shall establish a process (in this subsection
12 referred to as the ‘patient-provider dispute resolution
13 process’) under which an uninsured individual, with re-
14 spect to an item or service, who received, pursuant to sec-
15 tion 2799B-6, from a health care provider or health care
16 facility a good-faith estimate of the expected charges for
17 furnishing such item or service to such individual and who
18 after being furnished such item or service by such provider
19 or facility is billed by such provider or facility for such
20 item or service for charges that are substantially in excess
21 of such estimate, may seek a determination from a se-
22 lected dispute resolution entity for the charges to be paid
23 by such individual (in lieu of such amount so billed) to
24 such provider or facility for such item or service. For pur-
25 poses of this subsection, the term ‘uninsured individual’

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1 means, with respect to an item or service, an individual
2 who does not have benefits for such item or service under
3 a group health plan, group or individual health insurance
4 coverage offered by a health insurance issuer, Federal
5 health care program (as defined in section 1128B(f) of
6 the Social Security Act), or a health benefits plan under
7 chapter 89 of title 5, United States Code (or an individual
8 who has benefits for such item or service under a group
9 health plan or individual or group health insurance cov-
10 erage offered by a health insurance issuer, but who does
11 not seek to have a claim for such item or service submitted
12 to such plan or coverage).

13 “(b) SELECTION OF ENTITIES.—Under the patient-
14 provider dispute resolution process, the Secretary shall,
15 with respect to a determination sought by an individual
16 under subsection (a), with respect to charges to be paid
17 by such individual to a health care provider or health care
18 facility described in such paragraph for an item or service
19 furnished to such individual by such provider or facility,
20 provide for—

21 “(1) a method to select to make such deter-
22 mination an entity certified under subsection (d)
23 that—

24 “(A) is not a party to such determination
25 or an employee or agent of such party;

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1 “(B) does not have a material familial, fi-
2 nancial, or professional relationship with such a
3 party; and

4 “(C) does not otherwise have a conflict of
5 interest with such a party (as determined by
6 the Secretary); and

7 “(2) the provision of a notification of such se-
8 lection to the individual and the provider or facility
9 (as applicable) party to such determination.

10 An entity selected pursuant to the previous sentence to
11 make a determination described in such sentence shall be
12 referred to in this subsection as the ‘selected dispute reso-
13 lution entity’ with respect to such determination.

14 “(c) ADMINISTRATIVE FEE.—The Secretary shall es-
15 tablish a fee to participate in the patient-provider dispute
16 resolution process in such a manner as to not create a
17 barrier to an uninsured individual’s access to such process.

18 “(d) CERTIFICATION.—The Secretary shall establish
19 or recognize a process to certify entities under this sub-
20 paragraph. Such process shall ensure that an entity so cer-
21 tified satisfies at least the criteria specified in section
22 2799A–1(c).”.

23 **SEC. 113. ENSURING CONTINUITY OF CARE.**

24 (a) PUBLIC HEALTH SERVICE ACT.—Title XXVII of
25 the Public Health Service Act (42 U.S.C. 300gg et seq.)

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1 is amended, in the part D, as added and amended by sec-
2 tion 102(a) and further amended by the previous provi-
3 sions of this title, by inserting after section 2799A–2 the
4 following new section:

5 **“SEC. 2799A-3. CONTINUITY OF CARE.**

6 “(a) ENSURING CONTINUITY OF CARE WITH RE-
7 SPECT TO TERMINATIONS OF CERTAIN CONTRACTUAL
8 RELATIONSHIPS RESULTING IN CHANGES IN PROVIDER
9 NETWORK STATUS.—

10 “(1) IN GENERAL.—In the case of an individual
11 with benefits under a group health plan or group or
12 individual health insurance coverage offered by a
13 health insurance issuer and with respect to a health
14 care provider or facility that has a contractual rela-
15 tionship with such plan or such issuer (as applica-
16 ble) for furnishing items and services under such
17 plan or such coverage, if, while such individual is a
18 continuing care patient (as defined in subsection (b))
19 with respect to such provider or facility—

20 “(A) such contractual relationship is termi-
21 nated (as defined in subsection (b));

22 “(B) benefits provided under such plan or
23 such health insurance coverage with respect to
24 such provider or facility are terminated because
25 of a change in the terms of the participation of

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1 such provider or facility in such plan or cov-
2 erage; or

3 “(C) a contract between such group health
4 plan and a health insurance issuer offering
5 health insurance coverage in connection with
6 such plan is terminated, resulting in a loss of
7 benefits provided under such plan with respect
8 to such provider or facility;

9 the plan or issuer, respectively, shall meet the re-
10 quirements of paragraph (2) with respect to such in-
11 dividual.

12 “(2) REQUIREMENTS.—The requirements of
13 this paragraph are that the plan or issuer—

14 “(A) notify each individual enrolled under
15 such plan or coverage who is a continuing care
16 patient with respect to a provider or facility at
17 the time of a termination described in para-
18 graph (1) affecting such provider or facility on
19 a timely basis of such termination and such in-
20 dividual’s right to elect continued transitional
21 care from such provider or facility under this
22 section;

23 “(B) provide such individual with an op-
24 portunity to notify the plan or issuer of the in-
25 dividual’s need for transitional care; and

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1 “(C) permit the patient to elect to continue
2 to have benefits provided under such plan or
3 such coverage, under the same terms and condi-
4 tions as would have applied and with respect to
5 such items and services as would have been cov-
6 ered under such plan or coverage had such ter-
7 mination not occurred, with respect to the
8 course of treatment furnished by such provider
9 or facility relating to such individual’s status as
10 a continuing care patient during the period be-
11 ginning on the date on which the notice under
12 subparagraph (A) is provided and ending on the
13 earlier of—

14 “(i) the 90-day period beginning on
15 such date; or

16 “(ii) the date on which such individual
17 is no longer a continuing care patient with
18 respect to such provider or facility.

19 “(b) DEFINITIONS.—In this section:

20 “(1) CONTINUING CARE PATIENT.—The term
21 ‘continuing care patient’ means an individual who,
22 with respect to a provider or facility—

23 “(A) is undergoing a course of treatment
24 for a serious and complex condition from the
25 provider or facility;

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1 “(B) is undergoing a course of institu-
2 tional or inpatient care from the provider or fa-
3 cility;

4 “(C) is scheduled to undergo nonelective
5 surgery from the provider, including receipt of
6 postoperative care from such provider or facility
7 with respect to such a surgery;

8 “(D) is pregnant and undergoing a course
9 of treatment for the pregnancy from the pro-
10 vider or facility; or

11 “(E) is or was determined to be terminally
12 ill (as determined under section 1861(dd)(3)(A)
13 of the Social Security Act) and is receiving
14 treatment for such illness from such provider or
15 facility.

16 “(2) SERIOUS AND COMPLEX CONDITION.—The
17 term ‘serious and complex condition’ means, with re-
18 spect to a participant, beneficiary, or enrollee under
19 a group health plan or group or individual health in-
20 surance coverage—

21 “(A) in the case of an acute illness, a con-
22 dition that is serious enough to require special-
23 ized medical treatment to avoid the reasonable
24 possibility of death or permanent harm; or

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1 “(B) in the case of a chronic illness or con-
2 dition, a condition that is—

3 “(i) is life-threatening, degenerative,
4 potentially disabling, or congenital; and

5 “(ii) requires specialized medical care
6 over a prolonged period of time.

7 “(3) TERMINATED.—The term ‘terminated’ in-
8 cludes, with respect to a contract, the expiration or
9 nonrenewal of the contract, but does not include a
10 termination of the contract for failure to meet appli-
11 cable quality standards or for fraud.”.

12 (b) INTERNAL REVENUE CODE.—

13 (1) IN GENERAL.—Subchapter B of chapter
14 100 of the Internal Revenue Code of 1986, as
15 amended by sections 102(c) and 105(a)(3), is fur-
16 ther amended by inserting after section 9817 the fol-
17 lowing new section:

18 **“SEC. 9818. CONTINUITY OF CARE.**

19 “(a) ENSURING CONTINUITY OF CARE WITH RE-
20 SPECT TO TERMINATIONS OF CERTAIN CONTRACTUAL
21 RELATIONSHIPS RESULTING IN CHANGES IN PROVIDER
22 NETWORK STATUS.—

23 “(1) IN GENERAL.—In the case of an individual
24 with benefits under a group health plan and with re-
25 spect to a health care provider or facility that has

1 a contractual relationship with such plan for fur-
2 nishing items and services under such plan, if, while
3 such individual is a continuing care patient (as de-
4 fined in subsection (b)) with respect to such provider
5 or facility—

6 “(A) such contractual relationship is termi-
7 nated (as defined in paragraph (b));

8 “(B) benefits provided under such plan
9 with respect to such provider or facility are ter-
10 minated because of a change in the terms of the
11 participation of such provider or facility in such
12 plan; or

13 “(C) a contract between such group health
14 plan and a health insurance issuer offering
15 health insurance coverage in connection with
16 such plan is terminated, resulting in a loss of
17 benefits provided under such plan with respect
18 to such provider or facility;

19 the plan shall meet the requirements of paragraph
20 (2) with respect to such individual.

21 “(2) REQUIREMENTS.—The requirements of
22 this paragraph are that the plan—

23 “(A) notify each individual enrolled under
24 such plan who is a continuing care patient with
25 respect to a provider or facility at the time of

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1 a termination described in paragraph (1) affect-
2 ing such provider on a timely basis of such ter-
3 mination and such individual's right to elect
4 continued transitional care from such provider
5 or facility under this section;

6 “(B) provide such individual with an op-
7 portunity to notify the plan of the individual's
8 need for transitional care; and

9 “(C) permit the patient to elect to continue
10 to have benefits provided under such plan,
11 under the same terms and conditions as would
12 have applied and with respect to such items and
13 services as would have been covered under such
14 plan had such termination not occurred, with
15 respect to the course of treatment furnished by
16 such provider or facility relating to such indi-
17 vidual's status as a continuing care patient dur-
18 ing the period beginning on the date on which
19 the notice under subparagraph (A) is provided
20 and ending on the earlier of—

21 “(i) the 90-day period beginning on
22 such date; or

23 “(ii) the date on which such individual
24 is no longer a continuing care patient with
25 respect to such provider or facility.

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1 “(b) DEFINITIONS.—In this section:

2 “(1) CONTINUING CARE PATIENT.—The term
3 ‘continuing care patient’ means an individual who,
4 with respect to a provider or facility—

5 “(A) is undergoing a course of treatment
6 for a serious and complex condition from the
7 provider or facility;

8 “(B) is undergoing a course of institu-
9 tional or inpatient care from the provider or fa-
10 cility;

11 “(C) is scheduled to undergo nonelective
12 surgery from the provider or facility, including
13 receipt of postoperative care from such provider
14 or facility with respect to such a surgery;

15 “(D) is pregnant and undergoing a course
16 of treatment for the pregnancy from the pro-
17 vider or facility; or

18 “(E) is or was determined to be terminally
19 ill (as determined under section 1861(dd)(3)(A)
20 of the Social Security Act) and is receiving
21 treatment for such illness from such provider or
22 facility.

23 “(2) SERIOUS AND COMPLEX CONDITION.—The
24 term ‘serious and complex condition’ means, with re-

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1 spect to a participant or beneficiary under a group
2 health plan—

3 “(A) in the case of an acute illness, a con-
4 dition that is serious enough to require special-
5 ized medical treatment to avoid the reasonable
6 possibility of death or permanent harm; or

7 “(B) in the case of a chronic illness or con-
8 dition, a condition that—

9 “(i) is life-threatening, degenerative,
10 potentially disabling, or congenital; and

11 “(ii) requires specialized medical care
12 over a prolonged period of time.

13 “(3) TERMINATED.—The term ‘terminated’ in-
14 cludes, with respect to a contract, the expiration or
15 nonrenewal of the contract, but does not include a
16 termination of the contract for failure to meet appli-
17 cable quality standards or for fraud.”.

18 (2) CLERICAL AMENDMENT.—The table of sec-
19 tions for such subchapter, as amended by the pre-
20 vious sections, is further amended by inserting after
21 the item relating to section 9817 the following new
22 item:

“Sec. 9818. Continuity of care.”.

23 (c) EMPLOYEE RETIREMENT INCOME SECURITY
24 ACT.—

1947

1 (1) IN GENERAL.—Subpart B of part 7 of sub-
2 title B of title I of the Employee Retirement Income
3 Security Act of 1974 (29 U.S.C. 1185 et seq.), as
4 amended by section 102(e) and further amended by
5 the previous provisions of this title, is further
6 amended by inserting after section 717 the following
7 new section:

8 **“SEC. 718. CONTINUITY OF CARE.**

9 “(a) ENSURING CONTINUITY OF CARE WITH RE-
10 SPECT TO TERMINATIONS OF CERTAIN CONTRACTUAL
11 RELATIONSHIPS RESULTING IN CHANGES IN PROVIDER
12 NETWORK STATUS.—

13 “(1) IN GENERAL.—In the case of an individual
14 with benefits under a group health plan or group
15 health insurance coverage offered by a health insur-
16 ance issuer and with respect to a health care pro-
17 vider or facility that has a contractual relationship
18 with such plan or such issuer (as applicable) for fur-
19 nishing items and services under such plan or such
20 coverage, if, while such individual is a continuing
21 care patient (as defined in subsection (b)) with re-
22 spect to such provider or facility—

23 “(A) such contractual relationship is termi-
24 nated (as defined in paragraph (b));

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1 “(B) benefits provided under such plan or
2 such health insurance coverage with respect to
3 such provider or facility are terminated because
4 of a change in the terms of the participation of
5 the provider or facility in such plan or coverage;
6 or

7 “(C) a contract between such group health
8 plan and a health insurance issuer offering
9 health insurance coverage in connection with
10 such plan is terminated, resulting in a loss of
11 benefits provided under such plan with respect
12 to such provider or facility;
13 the plan or issuer, respectively, shall meet the re-
14 quirements of paragraph (2) with respect to such in-
15 dividual.

16 “(2) REQUIREMENTS.—The requirements of
17 this paragraph are that the plan or issuer—

18 “(A) notify each individual enrolled under
19 such plan or coverage who is a continuing care
20 patient with respect to a provider or facility at
21 the time of a termination described in para-
22 graph (1) affecting such provider or facility on
23 a timely basis of such termination and such in-
24 dividual’s right to elect continued transitional

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1 care from such provider or facility under this
2 section;

3 “(B) provide such individual with an op-
4 portunity to notify the plan or issuer of the in-
5 dividual’s need for transitional care; and

6 “(C) permit the patient to elect to continue
7 to have benefits provided under such plan or
8 such coverage, under the same terms and condi-
9 tions as would have applied and with respect to
10 such items and services as would have been cov-
11 ered under such plan or coverage had such ter-
12 mination not occurred, with respect to the
13 course of treatment furnished by such provider
14 or facility relating to such individual’s status as
15 a continuing care patient during the period be-
16 ginning on the date on which the notice under
17 subparagraph (A) is provided and ending on the
18 earlier of—

19 “(i) the 90-day period beginning on
20 such date; or

21 “(ii) the date on which such individual
22 is no longer a continuing care patient with
23 respect to such provider or facility.

24 “(b) DEFINITIONS.—In this section:

1950

1 “(1) CONTINUING CARE PATIENT.—The term
2 ‘continuing care patient’ means an individual who,
3 with respect to a provider or facility—

4 “(A) is undergoing a course of treatment
5 for a serious and complex condition from the
6 provider or facility;

7 “(B) is undergoing a course of institu-
8 tional or inpatient care from the provider or fa-
9 cility;

10 “(C) is scheduled to undergo nonelective
11 surgery from the provide or facility, including
12 receipt of postoperative care from such provider
13 or facility with respect to such a surgery;

14 “(D) is pregnant and undergoing a course
15 of treatment for the pregnancy from the pro-
16 vider or facility; or

17 “(E) is or was determined to be terminally
18 ill (as determined under section 1861(dd)(3)(A)
19 of the Social Security Act) and is receiving
20 treatment for such illness from such provider or
21 facility.

22 “(2) SERIOUS AND COMPLEX CONDITION.—The
23 term ‘serious and complex condition’ means, with re-
24 spect to a participant or beneficiary under a group
25 health plan or group health insurance coverage—

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1 “(A) in the case of an acute illness, a con-
2 dition that is serious enough to require special-
3 ized medical treatment to avoid the reasonable
4 possibility of death or permanent harm; or

5 “(B) in the case of a chronic illness or con-
6 dition, a condition that—

7 “(i) is life-threatening, degenerative,
8 potentially disabling, or congenital; and

9 “(ii) requires specialized medical care
10 over a prolonged period of time.

11 “(3) TERMINATED.—The term ‘terminated’ in-
12 cludes, with respect to a contract, the expiration or
13 nonrenewal of the contract, but does not include a
14 termination of the contract for failure to meet appli-
15 cable quality standards or for fraud.”.

16 (2) CLERICAL AMENDMENT.—The table of con-
17 tents in section 1 of the Employee Retirement In-
18 come Security Act of 1974 is amended by inserting
19 after the item relating to section 716 the following
20 new item:

 “Sec. 718. Continuity of care.”.

21 (d) PROVIDER REQUIREMENT.—Part E of title
22 XXVII of the Public Health Service Act (42 U.S.C. 300gg
23 et seq.), as added by section 104 and further amended
24 by the previous provisions of this title, is further amended
25 by adding at the end the following new section:

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1 “SEC. 2799B-8. CONTINUITY OF CARE.

2 “A health care provider or health care facility shall,
3 in the case of an individual furnished items and services
4 by such provider or facility for which coverage is provided
5 under a group health plan or group or individual health
6 insurance coverage pursuant to section 2799A-3, section
7 9818 of the Internal Revenue Code of 1986, or section
8 718 of the Employee Retirement Income Security Act of
9 1974—

10 “(1) accept payment from such plan or such
11 issuer (as applicable) (and cost-sharing from such
12 individual, if applicable, in accordance with sub-
13 section (a)(2)(C) of such section 2799A-3, 9818, or
14 718) for such items and services as payment in full
15 for such items and services; and

16 “(2) continue to adhere to all policies, proce-
17 dures, and quality standards imposed by such plan
18 or issuer with respect to such individual and such
19 items and services in the same manner as if such
20 termination had not occurred.”.

21 (e) EFFECTIVE DATE.—The amendments made by
22 subsections (a), (b), and (c) shall apply with respect to
23 plan years beginning on or after January 1, 2022.

24 SEC. 114. MAINTENANCE OF PRICE COMPARISON TOOL.

25 (a) PUBLIC HEALTH SERVICE ACT.—Title XXVII of
26 the Public Health Service Act (42 U.S.C. 300gg et seq.)

1 is amended, in part D, as added and amended by section
2 102 and further amended by the previous provisions of
3 this title, by inserting after section 2799A–3 the following
4 new section:

5 **“SEC. 2799A–4. MAINTENANCE OF PRICE COMPARISON**
6 **TOOL.**

7 “A group health plan or a health insurance issuer of-
8 fering group or individual health insurance coverage shall
9 offer price comparison guidance by telephone and make
10 available on the Internet website of the plan or issuer a
11 price comparison tool that (to the extent practicable) al-
12 lows an individual enrolled under such plan or coverage,
13 with respect to such plan year, such geographic region,
14 and participating providers with respect to such plan or
15 coverage, to compare the amount of cost-sharing that the
16 individual would be responsible for paying under such plan
17 or coverage with respect to the furnishing of a specific
18 item or service by any such provider.”.

19 (b) INTERNAL REVENUE CODE.—

20 (1) IN GENERAL.—Subchapter B of chapter
21 100 of the Internal Revenue Code of 1986, as
22 amended by sections 102, 105, and 113, is further
23 amended by inserting after section 9818 the fol-
24 lowing new section:

1 **“SEC. 9819. MAINTENANCE OF PRICE COMPARISON TOOL.**

2 “A group health plan shall offer price comparison
3 guidance by telephone and make available on the Internet
4 website of the plan or issuer a price comparison tool that
5 (to the extent practicable) allows an individual enrolled
6 under such plan, with respect to such plan year, such geo-
7 graphic region, and participating providers with respect
8 to such plan or coverage, to compare the amount of cost-
9 sharing that the individual would be responsible for paying
10 under such plan with respect to the furnishing of a specific
11 item or service by any such provider.”.

12 (2) CLERICAL AMENDMENT.—The table of sec-
13 tions for such subchapter, as amended by the pre-
14 vious sections, is further amended by inserting after
15 the item relating to section 9818 the following new
16 item:

“Sec. 9819. Maintenance of price comparison tool.”.

17 (c) EMPLOYEE RETIREMENT INCOME SECURITY
18 ACT.—

19 (1) IN GENERAL.—Subpart B of part 7 of sub-
20 title B of title I of the Employee Retirement Income
21 Security Act of 1974 (29 U.S.C. 1185 et seq.), as
22 amended by sections 102, 105, and 113, is further
23 amended by inserting after section 718 the following
24 new section:

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1 **“SEC. 719. MAINTENANCE OF PRICE COMPARISON TOOL.**

2 “A group health plan or a health insurance issuer of-
3 fering group health insurance coverage shall offer price
4 comparison guidance by telephone and make available on
5 the Internet website of the plan or issuer a price compari-
6 son tool that (to the extent practicable) allows an indi-
7 vidual enrolled under such plan or coverage, with respect
8 to such plan year, such geographic region, and partici-
9 pating providers with respect to such plan or coverage, to
10 compare the amount of cost-sharing that the individual
11 would be responsible for paying under such plan or cov-
12 erage with respect to the furnishing of a specific item or
13 service by any such provider.”.

14 (2) CLERICAL AMENDMENT.—The table of con-
15 tents in section 1 of the Employee Retirement In-
16 come Security Act of 1974, as amended by the pre-
17 vious provisions of this title, is further amended by
18 inserting after the item relating to section 716 the
19 following new item:

“Sec. 719. Maintenance of price comparison tool.”.

20 (d) EFFECTIVE DATE.—The amendments made by
21 this section shall apply with respect to plan years begin-
22 ning on or after January 1, 2022.

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1 **SEC. 115. STATE ALL PAYER CLAIMS DATABASES.**

2 (a) GRANTS TO STATES.—Part B of title III of the
3 Public Health Service Act (42 U.S.C. 243 et seq.) is
4 amended by adding at the end the following:

5 **“SEC. 320B. STATE ALL PAYER CLAIMS DATABASES.**

6 “(a) IN GENERAL.—The Secretary shall make one-
7 time grants to eligible States for the purposes described
8 in subsection (b).

9 “(b) USES.—A State may use a grant received under
10 subsection (a) for one of the following purposes:

11 “(1) To establish a State All Payer Claims
12 Database.

13 “(2) To improve an existing State All Payer
14 Claims Databases.

15 “(c) ELIGIBILITY.—To be eligible to receive a grant
16 under subsection (a), a State shall submit to the Secretary
17 an application at such time, in such manner, and con-
18 taining such information as the Secretary specifies, includ-
19 ing, with respect to a State All Payer Claims Database,
20 at least specifics on how the State will ensure uniform
21 data collection and the privacy and security of such data.

22 “(d) GRANT PERIOD AND AMOUNT.—Grants award-
23 ed under this section shall be for a period of 3-years, and
24 in an amount of \$2,500,000, of which \$1,000,000 shall
25 be made available to the State for each of the first 2 years

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1 of the grant period, and \$500,000 shall be made available
2 to the State for the third year of the grant period.

3 “(e) AUTHORIZED USERS.—

4 “(1) APPLICATION.—An entity desiring author-
5 ization for access to a State All Payer Claims Data-
6 base that has received a grant under this section
7 shall submit to the State All Payer Claims Database
8 an application for such access, which shall include—

9 “(A) in the case of an entity requesting ac-
10 cess for research purposes—

11 “(i) a description of the uses and
12 methodologies for evaluating health system
13 performance using such data; and

14 “(ii) documentation of approval of the
15 research by an institutional review board,
16 if applicable for a particular plan of re-
17 search; or

18 “(B) in the case of an entity such as an
19 employer, health insurance issuer, third-party
20 administrator, or health care provider, request-
21 ing access for the purpose of quality improve-
22 ment or cost-containment, a description of the
23 intended uses for such data.

24 “(2) REQUIREMENTS.—

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1 “(A) ACCESS FOR RESEARCH PURPOSES.—

2 Upon approval of an application for research
3 purposes under paragraph (1)(A), the author-
4 ized user shall enter into a data use and con-
5 fidentiality agreement with the State All Payer
6 Claims Database that has received a grant
7 under this subsection, which shall include a pro-
8 hibition on attempts to reidentify and disclose
9 individually identifiable health information and
10 proprietary financial information.

11 “(B) CUSTOMIZED REPORTS.—Employers
12 and employer organizations may request cus-
13 tomized reports from a State All Payer Claims
14 Database that has received a grant under this
15 section, at cost, subject to the requirements of
16 this section with respect to privacy, security,
17 and proprietary financial information.

18 “(C) NON-CUSTOMIZED REPORTS.—A
19 State All Payer Claims Database that has re-
20 ceived a grant under this section shall make
21 available to all authorized users aggregate data
22 sets available through the State All Payer
23 Claims Database, free of charge.

24 “(3) WAIVERS.—The Secretary may waive the
25 requirements of this subsection of a State All Payer

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1 Claims Database to provide access of entities to such
2 database if such State All Payer Claims Database is
3 substantially in compliance with this subsection.

4 “(f) EXPANDED ACCESS.—

5 “(1) MULTI-STATE APPLICATIONS.—The Sec-
6 retary may prioritize applications submitted by a
7 State whose application demonstrates that the State
8 will work with other State All Payer Claims Data-
9 bases to establish a single application for access to
10 data by authorized users across multiple States.

11 “(2) EXPANSION OF DATA SETS.—The Sec-
12 retary may prioritize applications submitted by a
13 State whose application demonstrates that the State
14 will implement the reporting format for self-insured
15 group health plans described in section 735 of the
16 Employee Retirement Income Security Act of 1974.

17 “(g) DEFINITIONS.—In this section—

18 “(1) the term ‘individually identifiable health
19 information’ has the meaning given such term in
20 section 1171(6) of the Social Security Act;

21 “(2) the term ‘proprietary financial informa-
22 tion’ means data that would disclose the terms of a
23 specific contract between an individual health care
24 provider or facility and a specific group health plan,
25 managed care entity (as defined in section

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1 1932(a)(1)(B) of the Social Security Act) or other
2 managed care organization, or health insurance
3 issuer offering group or individual health insurance
4 coverage; and

5 “(3) the term ‘State All Payer Claims Data-
6 base’ means, with respect to a State, a database that
7 may include medical claims, pharmacy claims, dental
8 claims, and eligibility and provider files, which are
9 collected from private and public payers.

10 “(h) AUTHORIZATION OF APPROPRIATIONS.—To
11 carry out this section, there is authorized to be appro-
12 priated \$50,000,000 for each of fiscal years 2022 and
13 2023, and \$25,000,000 for fiscal year 2024, to remain
14 available until expended.”

15 (b) STANDARDIZED REPORTING FORMAT.—

16 Subpart C of part 7 of subtitle B of title I of
17 the Employee Retirement Income Security Act of
18 1974 (29 U.S.C. 1191 et seq.) is amended by adding
19 at the end the following:

20 **“SEC. 735. STANDARDIZED REPORTING FORMAT.**

21 “(a) IN GENERAL.—Not later than 1 year after the
22 date of enactment of this section, the Secretary shall es-
23 tablish (and periodically update) a standardized reporting
24 format for the voluntary reporting, by group health plans
25 to State All Payer Claims Databases, of medical claims,

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1 pharmacy claims, dental claims, and eligibility and pro-
2 vider files that are collected from private and public pay-
3 ers, and shall provide guidance to States on the process
4 by which States may collect such data from such plans
5 in the standardized reporting format.

6 “(b) CONSULTATION.—

7 “(1) ADVISORY COMMITTEE.—Not later than
8 90 days after the date of enactment of this section,
9 the Secretary shall convene an Advisory Committee
10 (referred to in this section as the ‘Committee’), con-
11 sisting of 15 members to advise the Secretary re-
12 garding the format and guidance described in para-
13 graph (1).

14 “(2) MEMBERSHIP.—

15 “(A) APPOINTMENT.—In accordance with
16 subparagraph (B), not later than 90 days after
17 the date of enactment this section, the Sec-
18 retary, in coordination with the Secretary of
19 Health and Human Services, shall appoint
20 under subparagraph (B)(iii), and the Comp-
21 troller General of the United States shall ap-
22 point under subparagraph (B)(iv), members
23 who have distinguished themselves in the fields
24 of health services research, health economics,
25 health informatics, data privacy and security, or

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1 the governance of State All Payer Claims Data-
2 bases, or who represent organizations likely to
3 submit data to or use the database, including
4 patients, employers, or employee organizations
5 that sponsor group health plans, health care
6 providers, health insurance issuers, or third-
7 party administrators of group health plans.
8 Such members shall serve 3-year terms on a
9 staggered basis. Vacancies on the Committee
10 shall be filled by appointment consistent with
11 this paragraph not later than 3 months after
12 the vacancy arises.

13 “(B) COMPOSITION.—The Committee shall
14 be comprised of—

15 “(i) the Assistant Secretary of Em-
16 ployee Benefits and Security Administra-
17 tion of the Department of Labor, or a des-
18 ignee of such Assistant Secretary;

19 “(ii) the Assistant Secretary for Plan-
20 ning and Evaluation of the Department of
21 Health and Human Services, or a designee
22 of such Assistant Secretary;

23 “(iii) members appointed by the Sec-
24 retary, in coordination with the Secretary

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1 of Health and Human Services, includ-
2 ing—

3 “(I) 1 member to serve as the
4 chair of the Committee;

5 “(II) 1 representative of the Cen-
6 ters for Medicare & Medicaid Services;

7 “(III) 1 representative of the
8 Agency for Healthcare Research and
9 Quality;

10 “(IV) 1 representative of the Of-
11 fice for Civil Rights of the Depart-
12 ment of Health and Human Services
13 with expertise in data privacy and se-
14 curity;

15 “(V) 1 representative of the Na-
16 tional Center for Health Statistics;

17 “(VI) 1 representative of the Of-
18 fice of the National Coordinator for
19 Health Information Technology; and

20 “(VII) 1 representative of a
21 State All-Payer Claims Database;

22 “(iv) members appointed by the
23 Comptroller General of the United States,
24 including—

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1 “(I) 1 representative of an em-
2 ployer that sponsors a group health
3 plan;

4 “(II) 1 representative of an em-
5 ployee organization that sponsors a
6 group health plan;

7 “(III) 1 academic researcher with
8 expertise in health economics or
9 health services research;

10 “(IV) 1 consumer advocate; and

11 “(V) 2 additional members.

12 “(3) REPORT.—Not later than 180 days after
13 the date of enactment of this section, the Committee
14 shall report to the Secretary, the Committee on
15 Health, Education, Labor, and Pensions of the Sen-
16 ate, and the Committee on Energy and Commerce
17 and the Committee on Education and Labor of the
18 House of Representatives. Such report shall include
19 recommendations on the establishment of the format
20 and guidance described in subsection (a).

21 “(c) STATE ALL PAYER CLAIMS DATABASE.—In this
22 section, the term ‘State All Payer Claims Database’
23 means, with respect to a State, a database that may in-
24 clude medical claims, pharmacy claims, dental claims, and

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1 eligibility and provider files, which are collected from pri-
2 vate and public payers.

3 “(d) AUTHORIZATION OF APPROPRIATIONS.—To
4 carry out this section, there are authorized to be appro-
5 priated \$5,000,000 for fiscal year 2021, to remain avail-
6 able until expended or, if sooner, until the date described
7 in subsection (e).

8 “(e) SUNSET.—Beginning on the date on which the
9 report is submitted under subsection (b)(3), subsection (b)
10 shall have no force or effect.”.

11 **SEC. 116. PROTECTING PATIENTS AND IMPROVING THE AC-**
12 **CURACY OF PROVIDER DIRECTORY INFOR-**
13 **MATION.**

14 (a) PHSA.—Part D of title XXVII of the Public
15 Health Service Act (42 U.S.C. 300gg et seq.), as added
16 and amended by section 102 and further amended by the
17 previous provisions of this title, is further amended by in-
18 serting after section 2799A–4 the following:

19 **“SEC. 2799A–5. PROTECTING PATIENTS AND IMPROVING**
20 **THE ACCURACY OF PROVIDER DIRECTORY**
21 **INFORMATION.**

22 “(a) PROVIDER DIRECTORY INFORMATION REQUIRE-
23 MENTS.—

24 “(1) IN GENERAL.—For plan years beginning
25 on or after January 1, 2022, each group health plan

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1 and health insurance issuer offering group or indi-
2 vidual health insurance coverage shall—

3 “(A) establish the verification process de-
4 scribed in paragraph (2);

5 “(B) establish the response protocol de-
6 scribed in paragraph (3);

7 “(C) establish the database described in
8 paragraph (4); and

9 “(D) include in any directory (other than
10 the database described in subparagraph (C))
11 containing provider directory information with
12 respect to such plan or such coverage the infor-
13 mation described in paragraph (5).

14 “(2) VERIFICATION PROCESS.—The verification
15 process described in this paragraph is, with respect
16 to a group health plan or a health insurance issuer
17 offering group or individual health insurance cov-
18 erage, a process—

19 “(A) under which, not less frequently than
20 once every 90 days, such plan or such issuer (as
21 applicable) verifies and updates the provider di-
22 rectory information included on the database
23 described in paragraph (4) of such plan or
24 issuer of each health care provider and health
25 care facility included in such database;

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1 “(B) that establishes a procedure for the
2 removal of such a provider or facility with re-
3 spect to which such plan or issuer has been un-
4 able to verify such information during a period
5 specified by the plan or issuer; and

6 “(C) that provides for the update of such
7 database within 2 business days of such plan or
8 issuer receiving from such a provider or facility
9 information pursuant to section 2799B-9.

10 “(3) RESPONSE PROTOCOL.—The response pro-
11 tocol described in this paragraph is, in the case of
12 an individual enrolled under a group health plan or
13 group or individual health insurance coverage of-
14 fered by a health insurance issuer who requests in-
15 formation through a telephone call or electronic,
16 web-based, or Internet-based means on whether a
17 health care provider or health care facility has a
18 contractual relationship to furnish items and services
19 under such plan or such coverage, a protocol under
20 which such plan or such issuer (as applicable), in the
21 case such request is made through a telephone call—

22 “(A) responds to such individual as soon
23 as practicable and in no case later than 1 busi-
24 ness day after such call is received, through a

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1 written electronic or print (as requested by such
2 individual) communication; and

3 “(B) retains such communication in such
4 individual’s file for at least 2 years following
5 such response.

6 “(4) DATABASE.—The database described in
7 this paragraph is, with respect to a group health
8 plan or health insurance issuer offering group or in-
9 dividual health insurance coverage, a database on
10 the public website of such plan or issuer that con-
11 tains—

12 “(A) a list of each health care provider and
13 health care facility with which such plan or
14 such issuer has a direct or indirect contractual
15 relationship for furnishing items and services
16 under such plan or such coverage; and

17 “(B) provider directory information with
18 respect to each such provider and facility.

19 “(5) INFORMATION.—The information de-
20 scribed in this paragraph is, with respect to a print
21 directory containing provider directory information
22 with respect to a group health plan or individual or
23 group health insurance coverage offered by a health
24 insurance issuer, a notification that such informa-
25 tion contained in such directory was accurate as of

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1 the date of publication of such directory and that an
2 individual enrolled under such plan or such coverage
3 should consult the database described in paragraph
4 (4) with respect to such plan or such coverage or
5 contact such plan or the issuer of such coverage to
6 obtain the most current provider directory informa-
7 tion with respect to such plan or such coverage.

8 “(6) DEFINITION.—For purposes of this sub-
9 section, the term ‘provider directory information’ in-
10 cludes, with respect to a group health plan and a
11 health insurance issuer offering group or individual
12 health insurance coverage, the name, address, spe-
13 cialty, telephone number, and digital contact infor-
14 mation of each health care provider or health care
15 facility with which such plan or such issuer has a
16 contractual relationship for furnishing items and
17 services under such plan or such coverage.

18 “(7) RULE OF CONSTRUCTION.—Nothing in
19 this section shall be construed to preempt any provi-
20 sion of State law relating to health care provider di-
21 rectories.

22 “(b) COST-SHARING FOR SERVICES PROVIDED
23 BASED ON RELIANCE ON INCORRECT PROVIDER NET-
24 WORK INFORMATION.—

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1 “(1) IN GENERAL.—For plan years beginning
2 on or after January 1, 2022, in the case of an item
3 or service furnished to a participant, beneficiary, or
4 enrollee of a group health plan or group or indi-
5 vidual health insurance coverage offered by a health
6 insurance issuer by a nonparticipating provider or a
7 nonparticipating facility, if such item or service
8 would otherwise be covered under such plan or cov-
9 erage if furnished by a participating provider or par-
10 ticipating facility and if either of the criteria de-
11 scribed in paragraph (2) applies with respect to such
12 participant, beneficiary, or enrollee and item or serv-
13 ice, the plan or coverage—

14 “(A) shall not impose on such participant,
15 beneficiary, or enrollee a cost-sharing amount
16 for such item or service so furnished that is
17 greater than the cost-sharing amount that
18 would apply under such plan or coverage had
19 such item or service been furnished by a partici-
20 pating provider; and

21 “(B) shall apply the deductible or out-of-
22 pocket maximum, if any, that would apply if
23 such services were furnished by a participating
24 provider or a participating facility.

1971

1 “(2) CRITERIA DESCRIBED.—For purposes of
2 paragraph (1), the criteria described in this para-
3 graph, with respect to an item or service furnished
4 to a participant, beneficiary, or enrollee of a group
5 health plan or group or individual health insurance
6 coverage offered by a health insurance issuer by a
7 nonparticipating provider or a nonparticipating facil-
8 ity, are the following:

9 “(A) The participant, beneficiary, or en-
10 rollee received through a database, provider di-
11 rectory, or response protocol described in sub-
12 section (a) information with respect to such
13 item and service to be furnished and such infor-
14 mation provided that the provider was a partici-
15 pating provider or facility was a participating
16 facility, with respect to the plan for furnishing
17 such item or service.

18 “(B) The information was not provided, in
19 accordance with subsection (a), to the partici-
20 pant, beneficiary, or enrollee and the partici-
21 pant, beneficiary, or enrollee requested through
22 the response protocol described in subsection
23 (a)(3) of the plan or coverage information on
24 whether the provider was a participating pro-
25 vider or facility was a participating facility with

1972

1 respect to the plan for furnishing such item or
2 service and was informed through such protocol
3 that the provider was such a participating pro-
4 vider or facility was such a participating facil-
5 ity.

6 “(c) DISCLOSURE ON PATIENT PROTECTIONS
7 AGAINST BALANCE BILLING.—For plan years beginning
8 on or after January 1, 2022, each group health plan and
9 health insurance issuer offering group or individual health
10 insurance coverage shall make publicly available, post on
11 a public website of such plan or issuer, and include on
12 each explanation of benefits for an item or service with
13 respect to which the requirements under section 2799A–
14 1 applies—

15 “(1) information in plain language on—

16 “(A) the requirements and prohibitions ap-
17 plied under sections 2799B–1 and 2799B–2
18 (relating to prohibitions on balance billing in
19 certain circumstances);

20 “(B) if provided for under applicable State
21 law, any other requirements on providers and
22 facilities regarding the amounts such providers
23 and facilities may, with respect to an item or
24 service, charge a participant, beneficiary, or en-
25 rollee of such plan or coverage with respect to

1973

1 which such a provider or facility does not have
2 a contractual relationship for furnishing such
3 item or service under the plan or coverage after
4 receiving payment from the plan or coverage for
5 such item or service and any applicable cost
6 sharing payment from such participant, bene-
7 ficiary, or enrollee; and

8 “(C) the requirements applied under sec-
9 tion 2799A-1; and

10 “(2) information on contacting appropriate
11 State and Federal agencies in the case that an indi-
12 vidual believes that such a provider or facility has
13 violated any requirement described in paragraph (1)
14 with respect to such individual.”.

15 (b) ERISA.—Subpart B of part 7 of subtitle B of
16 title I of the Employee Retirement Income Security Act
17 of 1974 (29 U.S.C. 1185 et seq.), as amended by sections
18 102, 105, 113, and 114, is further amended by inserting
19 after section 719 the following:

20 **“SEC. 720. PROTECTING PATIENTS AND IMPROVING THE**
21 **ACCURACY OF PROVIDER DIRECTORY INFOR-**
22 **MATION.**

23 “(a) PROVIDER DIRECTORY INFORMATION REQUIRE-
24 MENTS.—

1974

1 “(1) IN GENERAL.—For plan years beginning
2 on or after January 1, 2022, each group health plan
3 and health insurance issuer offering group health in-
4 surance coverage shall—

5 “(A) establish the verification process de-
6 scribed in paragraph (2);

7 “(B) establish the response protocol de-
8 scribed in paragraph (3);

9 “(C) establish the database described in
10 paragraph (4); and

11 “(D) include in any directory (other than
12 the database described in subparagraph (C))
13 containing provider directory information with
14 respect to such plan or such coverage the infor-
15 mation described in paragraph (5).

16 “(2) VERIFICATION PROCESS.—The verification
17 process described in this paragraph is, with respect
18 to a group health plan or a health insurance issuer
19 offering group health insurance coverage, a proc-
20 ess—

21 “(A) under which, not less frequently than
22 once every 90 days, such plan or such issuer (as
23 applicable) verifies and updates the provider di-
24 rectory information included on the database
25 described in paragraph (4) of such plan or

1975

1 issuer of each health care provider and health
2 care facility included in such database;

3 “(B) that establishes a procedure for the
4 removal of such a provider or facility with re-
5 spect to which such plan or issuer has been un-
6 able to verify such information during a period
7 specified by the plan or issuer; and

8 “(C) that provides for the update of such
9 database within 2 business days of such plan or
10 issuer receiving from such a provider or facility
11 information pursuant to section 2799B-9 of the
12 Public Health Service Act.

13 “(3) RESPONSE PROTOCOL.—The response pro-
14 tocol described in this paragraph is, in the case of
15 an individual enrolled under a group health plan or
16 group health insurance coverage offered by a health
17 insurance issuer who requests information through a
18 telephone call or electronic, web-based, or Internet-
19 based means on whether a health care provider or
20 health care facility has a contractual relationship to
21 furnish items and services under such plan or such
22 coverage, a protocol under which such plan or such
23 issuer (as applicable), in the case such request is
24 made through a telephone call—

1976

1 “(A) responds to such individual as soon
2 as practicable and in no case later than 1 busi-
3 ness day after such call is received, through a
4 written electronic or print (as requested by such
5 individual) communication; and

6 “(B) retains such communication in such
7 individual’s file for at least 2 years following
8 such response.

9 “(4) DATABASE.—The database described in
10 this paragraph is, with respect to a group health
11 plan or health insurance issuer offering group health
12 insurance coverage, a database on the public website
13 of such plan or issuer that contains—

14 “(A) a list of each health care provider and
15 health care facility with which such plan or
16 such issuer has a direct or indirect contractual
17 relationship for furnishing items and services
18 under such plan or such coverage; and

19 “(B) provider directory information with
20 respect to each such provider and facility.

21 “(5) INFORMATION.—The information de-
22 scribed in this paragraph is, with respect to a print
23 directory containing provider directory information
24 with respect to a group health plan or group health
25 insurance coverage offered by a health insurance

1977

1 issuer, a notification that such information con-
2 tained in such directory was accurate as of the date
3 of publication of such directory and that an indi-
4 vidual enrolled under such plan or such coverage
5 should consult the database described in paragraph
6 (4) with respect to such plan or such coverage or
7 contact such plan or the issuer of such coverage to
8 obtain the most current provider directory informa-
9 tion with respect to such plan or such coverage.

10 “(6) DEFINITION.—For purposes of this sub-
11 section, the term ‘provider directory information’ in-
12 cludes, with respect to a group health plan and a
13 health insurance issuer offering group health insur-
14 ance coverage, the name, address, specialty, tele-
15 phone number, and digital contact information of
16 each health care provider or health care facility with
17 which such plan or such issuer has a contractual re-
18 lationship for furnishing items and services under
19 such plan or such coverage.

20 “(7) RULE OF CONSTRUCTION.—Nothing in
21 this section shall be construed to preempt any provi-
22 sion of State law relating to health care provider di-
23 rectories, to the extent such State law applies to
24 such plan, coverage, or issuer, subject to section
25 514.

1978

1 “(b) COST-SHARING FOR SERVICES PROVIDED
2 BASED ON RELIANCE ON INCORRECT PROVIDER NET-
3 WORK INFORMATION.—

4 “(1) IN GENERAL.—For plan years beginning
5 on or after January 1, 2022, in the case of an item
6 or service furnished to a participant or beneficiary of
7 a group health plan or group health insurance cov-
8 erage offered by a health insurance issuer by a non-
9 participating provider or a nonparticipating facility,
10 if such item or service would otherwise be covered
11 under such plan or coverage if furnished by a par-
12 ticipating provider or participating facility and if ei-
13 ther of the criteria described in paragraph (2) ap-
14 plies with respect to such participant or beneficiary
15 and item or service, the plan or coverage—

16 “(A) shall not impose on such participant
17 or beneficiary a cost-sharing amount for such
18 item or service so furnished that is greater than
19 the cost-sharing amount that would apply under
20 such plan or coverage had such item or service
21 been furnished by a participating provider; and

22 “(B) shall apply the deductible or out-of-
23 pocket maximum, if any, that would apply if
24 such services were furnished by a participating
25 provider or a participating facility.

1979

1 “(2) CRITERIA DESCRIBED.—For purposes of
2 paragraph (1), the criteria described in this para-
3 graph, with respect to an item or service furnished
4 to a participant or beneficiary of a group health plan
5 or group health insurance coverage offered by a
6 health insurance issuer by a nonparticipating pro-
7 vider or a nonparticipating facility, are the following:

8 “(A) The participant or beneficiary re-
9 ceived through a database, provider directory,
10 or response protocol described in subsection (a)
11 information with respect to such item and serv-
12 ice to be furnished and such information pro-
13 vided that the provider was a participating pro-
14 vider or facility was a participating facility,
15 with respect to the plan for furnishing such
16 item or service.

17 “(B) The information was not provided, in
18 accordance with subsection (a), to the partici-
19 pant or beneficiary and the participant or bene-
20 ficiary requested through the response protocol
21 described in subsection (a)(3) of the plan or
22 coverage information on whether the provider
23 was a participating provider or facility was a
24 participating facility with respect to the plan
25 for furnishing such item or service and was in-

1980

1 formed through such protocol that the provider
2 was such a participating provider or facility was
3 such a participating facility.

4 “(c) DISCLOSURE ON PATIENT PROTECTIONS
5 AGAINST BALANCE BILLING.—For plan years beginning
6 on or after January 1, 2022, each group health plan and
7 health insurance issuer offering group health insurance
8 coverage shall make publicly available, post on a public
9 website of such plan or issuer, and include on each expla-
10 nation of benefits for an item or service with respect to
11 which the requirements under section 716 applies—

12 “(1) information in plain language on—

13 “(A) the requirements and prohibitions ap-
14 plied under sections 2799B–1 and 2799B–2 of
15 the Public Health Service Act (relating to pro-
16 hibitions on balance billing in certain cir-
17 cumstances);

18 “(B) if provided for under applicable State
19 law, any other requirements on providers and
20 facilities regarding the amounts such providers
21 and facilities may, with respect to an item or
22 service, charge a participant or beneficiary of
23 such plan or coverage with respect to which
24 such a provider or facility does not have a con-
25 tractual relationship for furnishing such item or

1981

1 service under the plan or coverage after receiv-
2 ing payment from the plan or coverage for such
3 item or service and any applicable cost sharing
4 payment from such participant or beneficiary;
5 and

6 “(C) the requirements applied under sec-
7 tion 716; and

8 “(2) information on contacting appropriate
9 State and Federal agencies in the case that an indi-
10 vidual believes that such a provider or facility has
11 violated any requirement described in paragraph (1)
12 with respect to such individual.”.

13 (c) IRC.—Subchapter B of chapter 100 of the Inter-
14 nal Revenue Code of 1986, as amended by sections 102,
15 105, 113, and 114, is further amended by inserting after
16 section 9819 the following:

17 **“SEC. 9820. PROTECTING PATIENTS AND IMPROVING THE**
18 **ACCURACY OF PROVIDER DIRECTORY INFOR-**
19 **MATION.**

20 “(a) PROVIDER DIRECTORY INFORMATION REQUIRE-
21 MENTS.—

22 “(1) IN GENERAL.—For plan years beginning
23 on or after January 1, 2022, each group health plan
24 shall—

1982

1 “(A) establish the verification process de-
2 scribed in paragraph (2);

3 “(B) establish the response protocol de-
4 scribed in paragraph (3);

5 “(C) establish the database described in
6 paragraph (4); and

7 “(D) include in any directory (other than
8 the database described in subparagraph (C))
9 containing provider directory information with
10 respect to such plan the information described
11 in paragraph (5).

12 “(2) VERIFICATION PROCESS.—The verification
13 process described in this paragraph is, with respect
14 to a group health plan, a process—

15 “(A) under which, not less frequently than
16 once every 90 days, such plan verifies and up-
17 dates the provider directory information in-
18 cluded on the database described in paragraph
19 (4) of such plan or issuer of each health care
20 provider and health care facility included in
21 such database;

22 “(B) that establishes a procedure for the
23 removal of such a provider or facility with re-
24 spect to which such plan or issuer has been un-

1983

1 able to verify such information during a period
2 specified by the plan or issuer; and

3 “(C) that provides for the update of such
4 database within 2 business days of such plan or
5 issuer receiving from such a provider or facility
6 information pursuant to section 2799B–9 of the
7 Public Health Service Act.

8 “(3) RESPONSE PROTOCOL.—The response pro-
9 tocol described in this paragraph is, in the case of
10 an individual enrolled under a group health plan who
11 requests information through a telephone call or
12 electronic, web-based, or Internet-based means on
13 whether a health care provider or health care facility
14 has a contractual relationship to furnish items and
15 services under such plan, a protocol under which
16 such plan or such issuer (as applicable), in the case
17 such request is made through a telephone call—

18 “(A) responds to such individual as soon
19 as practicable and in no case later than 1 busi-
20 ness day after such call is received, through a
21 written electronic or print (as requested by such
22 individual) communication; and

23 “(B) retains such communication in such
24 individual’s file for at least 2 years following
25 such response.

1984

1 “(4) DATABASE.—The database described in
2 this paragraph is, with respect to a group health
3 plan, a database on the public website of such plan
4 or issuer that contains—

5 “(A) a list of each health care provider and
6 health care facility with which such plan or
7 such issuer has a direct or indirect contractual
8 relationship for furnishing items and services
9 under such plan; and

10 “(B) provider directory information with
11 respect to each such provider and facility.

12 “(5) INFORMATION.—The information de-
13 scribed in this paragraph is, with respect to a print
14 directory containing provider directory information
15 with respect to a group health plan, a notification
16 that such information contained in such directory
17 was accurate as of the date of publication of such
18 directory and that an individual enrolled under such
19 plan should consult the database described in para-
20 graph (4) with respect to such plan or contact such
21 plan to obtain the most current provider directory
22 information with respect to such plan.

23 “(6) DEFINITION.—For purposes of this sub-
24 section, the term ‘provider directory information’ in-
25 cludes, with respect to a group health plan, the

1985

1 name, address, specialty, telephone number, and dig-
2 ital contact information of each health care provider
3 or health care facility with which such plan has a
4 contractual relationship for furnishing items and
5 services under such plan.

6 “(7) RULE OF CONSTRUCTION.—Nothing in
7 this section shall be construed to preempt any provi-
8 sion of State law relating to health care provider di-
9 rectories.

10 “(b) COST-SHARING FOR SERVICES PROVIDED
11 BASED ON RELIANCE ON INCORRECT PROVIDER NET-
12 WORK INFORMATION.—

13 “(1) IN GENERAL.—For plan years beginning
14 on or after January 1, 2022, in the case of an item
15 or service furnished to a participant or beneficiary of
16 a group health plan by a nonparticipating provider
17 or a nonparticipating facility, if such item or service
18 would otherwise be covered under such plan if fur-
19 nished by a participating provider or participating
20 facility and if either of the criteria described in para-
21 graph (2) applies with respect to such participant or
22 beneficiary and item or service, the plan—

23 “(A) shall not impose on such participant
24 or beneficiary a cost-sharing amount for such
25 item or service so furnished that is greater than

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1 the cost-sharing amount that would apply under
2 such plan had such item or service been fur-
3 nished by a participating provider; and

4 “(B) shall apply the deductible or out-of-
5 pocket maximum, if any, that would apply if
6 such services were furnished by a participating
7 provider or a participating facility.

8 “(2) CRITERIA DESCRIBED.—For purposes of
9 paragraph (1), the criteria described in this para-
10 graph, with respect to an item or service furnished
11 to a participant or beneficiary of a group health plan
12 by a nonparticipating provider or a nonparticipating
13 facility, are the following:

14 “(A) The participant or beneficiary re-
15 ceived through a database, provider directory,
16 or response protocol described in subsection (a)
17 information with respect to such item and serv-
18 ice to be furnished and such information pro-
19 vided that the provider was a participating pro-
20 vider or facility was a participating facility,
21 with respect to the plan for furnishing such
22 item or service.

23 “(B) The information was not provided, in
24 accordance with subsection (a), to the partici-
25 pant or beneficiary and the participant or bene-

1987

1 ficiary requested through the response protocol
2 described in subsection (a)(3) of the plan infor-
3 mation on whether the provider was a partici-
4 pating provider or facility was a participating
5 facility with respect to the plan for furnishing
6 such item or service and was informed through
7 such protocol that the provider was such a par-
8 ticipating provider or facility was such a par-
9 ticipating facility.

10 “(c) DISCLOSURE ON PATIENT PROTECTIONS
11 AGAINST BALANCE BILLING.—For plan years beginning
12 on or after January 1, 2022, each group health plan shall
13 make publicly available, post on a public website of such
14 plan or issuer, and include on each explanation of benefits
15 for an item or service with respect to which the require-
16 ments under section 9816 applies—

17 “(1) information in plain language on—

18 “(A) the requirements and prohibitions ap-
19 plied under sections 2799B–1 and 2799B–2 of
20 the Public Health Service Act(relating to prohi-
21 bitions on balance billing in certain cir-
22 cumstances);

23 “(B) if provided for under applicable State
24 law, any other requirements on providers and
25 facilities regarding the amounts such providers

1988

1 and facilities may, with respect to an item or
2 service, charge a participant or beneficiary of
3 such plan with respect to which such a provider
4 or facility does not have a contractual relation-
5 ship for furnishing such item or service under
6 the plan after receiving payment from the plan
7 for such item or service and any applicable cost
8 sharing payment from such participant or bene-
9 ficiary; and

10 “(C) the requirements applied under sec-
11 tion 9816; and

12 “(2) information on contacting appropriate
13 State and Federal agencies in the case that an indi-
14 vidual believes that such a provider or facility has
15 violated any requirement described in paragraph (1)
16 with respect to such individual.”.

17 (d) CLERICAL AMENDMENTS.—

18 (1) ERISA.—The table of contents in section 1
19 of the Employee Retirement Income Security Act of
20 1974 (29 U.S.C. 1001 et seq.), as amended by the
21 previous provisions of this title, is further amended
22 by inserting after the item relating to section 719
23 the following new item:

“720. Protecting patients and improving the accuracy of provider directory in-
formation.”.

1989

1 (2) IRC.—The table of sections for subchapter
2 B of chapter 100 of the Internal Revenue Code of
3 1986, as amended by the previous provisions of this
4 title, is further amended by inserting after the item
5 relating to section 9819 the following new item:

“9820. Protecting patients and improving the accuracy of provider directory in-
formation.”.

6 (e) PROVIDER REQUIREMENTS.—Part E of title
7 XXVII of the Public Health Service Act (42 U.S.C. 300gg
8 et seq.), as added by section 104 and as further amended
9 by the previous provisions of this title, is further amended
10 by adding at the end the following:

11 **“SEC. 2799B-9. PROVIDER REQUIREMENTS TO PROTECT PA-**
12 **TIENTS AND IMPROVE THE ACCURACY OF**
13 **PROVIDER DIRECTORY INFORMATION.**

14 “(a) PROVIDER BUSINESS PROCESSES.—Beginning
15 not later than January 1, 2022, each health care provider
16 and each health care facility shall have in place business
17 processes to ensure the timely provision of provider direc-
18 tory information to a group health plan or a health insur-
19 ance issuer offering group or individual health insurance
20 coverage to support compliance by such plans or issuers
21 with section 2799A-5(a)(1), section 720(a)(1) of the Em-
22 ployee Retirement Income Security Act of 1974, or section
23 9820(a)(1) of the Internal Revenue Code of 1986, as ap-

1990

1 plicable. Such providers shall submit provider directory in-
2 formation to a plan or issuers, at a minimum—

3 “(1) when the provider or facility begins a net-
4 work agreement with a plan or with an issuer with
5 respect to certain coverage;

6 “(2) when the provider or facility terminates a
7 network agreement with a plan or with an issuer
8 with respect to certain coverage;

9 “(3) when there are material changes to the
10 content of provider directory information of the pro-
11 vider or facility described in section 2799A–5(a)(1),
12 section 720(a)(1) of the Employee Retirement In-
13 come Security Act of 1974, or section 9820(a)(1) of
14 the Internal Revenue Code of 1986, as applicable;
15 and

16 “(4) at any other time (including upon the re-
17 quest of such issuer or plan) determined appropriate
18 by the provider, facility, or the Secretary.

19 “(b) REFUNDS TO ENROLLEES.—If a health care
20 provider submits a bill to an enrollee based on cost-sharing
21 for treatment or services provided by the health care pro-
22 vider that is in excess of the normal cost-sharing applied
23 for such treatment or services provided in-network, as pro-
24 hibited under section 2799A–5(b), section 720(b) of the
25 Employee Retirement Income Security Act of 1974, or

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1 section 9820(b) of the Internal Revenue Code of 1986,
2 as applicable, and the enrollee pays such bill, the provider
3 shall reimburse the enrollee for the full amount paid by
4 the enrollee in excess of the in-network cost-sharing
5 amount for the treatment or services involved, plus inter-
6 est, at an interest rate determined by the Secretary.

7 “(c) LIMITATION.—Nothing in this section shall pro-
8 hibit a provider from requiring in the terms of a contract,
9 or contract termination, with a group health plan or health
10 insurance issuer—

11 “(1) that the plan or issuer remove, at the time
12 of termination of such contract, the provider from a
13 directory of the plan or issuer described in section
14 2799A–5(a), section 720(a) of the Employee Retirement
15 Income Security Act of 1974, or section
16 9820(a) of the Internal Revenue Code of 1986, as
17 applicable; or

18 “(2) that the plan or issuer bear financial re-
19 sponsibility, including under section 2799A–5(b),
20 section 720(b) of the Employee Retirement Income
21 Security Act of 1974, or section 9820(b) of the In-
22 ternal Revenue Code of 1986, as applicable, for pro-
23 viding inaccurate network status information to an
24 enrollee.

1992

1 “(d) DEFINITION.—For purposes of this section, the
2 term ‘provider directory information’ includes the names,
3 addresses, specialty, telephone numbers, and digital con-
4 tact information of individual health care providers, and
5 the names, addresses, telephone numbers, and digital con-
6 tact information of each medical group, clinic, or facility
7 contracted to participate in any of the networks of the
8 group health plan or health insurance coverage involved.

9 “(e) RULE OF CONSTRUCTION.—Nothing in this sec-
10 tion shall be construed to preempt any provision of State
11 law relating to health care provider directories.”

12 **SEC. 117. ADVISORY COMMITTEE ON GROUND AMBULANCE**
13 **AND PATIENT BILLING.**

14 (a) IN GENERAL.—Not later than 90 days after the
15 date of enactment of this Act, the Secretary of Labor, Sec-
16 retary of Health and Human Services, and the Secretary
17 of the Treasury (the Secretaries) shall jointly establish an
18 advisory committee for the purpose of reviewing options
19 to improve the disclosure of charges and fees for ground
20 ambulance services, better inform consumers of insurance
21 options for such services, and protect consumers from bal-
22 ance billing.

23 (b) COMPOSITION OF THE ADVISORY COMMITTEE.—
24 The advisory committee shall be composed of the following
25 members:

1993

1 (1) The Secretary of Labor, or the Secretary's
2 designee.

3 (2) The Secretary of Health and Human Serv-
4 ices, or the Secretary's designee.

5 (3) The Secretary of the Treasury, or the Sec-
6 retary's designee.

7 (4) One representative, to be appointed jointly
8 by the Secretaries, for each of the following:

9 (A) Each relevant Federal agency, as de-
10 termined by the Secretaries.

11 (B) State insurance regulators.

12 (C) Health insurance providers.

13 (D) Patient advocacy groups.

14 (E) Consumer advocacy groups.

15 (F) State and local governments.

16 (G) Physician specializing in emergency,
17 trauma, cardiac, or stroke.

18 (H) State Emergency Medical Services Of-
19 ficials.

20 (I) Emergency medical technicians, para-
21 medics, and other emergency medical services
22 personnel.

23 (5) Three representatives, to be appointed joint-
24 ly by the Secretaries, to represent the various seg-
25 ments of the ground ambulance industry.

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1 (6) Up to an additional 2 representatives other-
2 wise not described in paragraphs (1) through (5), as
3 determined necessary and appropriate by the Secre-
4 taries.

5 (c) CONSULTATION.—The advisory committee shall,
6 as appropriate, consult with relevant experts and stake-
7 holders, including those not otherwise included under sub-
8 section (b), while conducting the review described in sub-
9 section (a).

10 (d) RECOMMENDATIONS.—The advisory committee
11 shall make recommendations with respect to disclosure of
12 charges and fees for ground ambulance services and insur-
13 ance coverage, consumer protection and enforcement au-
14 thorities of the Departments of Labor, Health and Human
15 Services, and the Treasury and State authorities, and the
16 prevention of balance billing to consumers. The rec-
17 ommendations shall address, at a minimum—

18 (1) options, best practices, and identified stand-
19 ards to prevent instances of balance billing;

20 (2) steps that can be taken by State legisla-
21 tures, State insurance regulators, State attorneys
22 general, and other State officials as appropriate,
23 consistent with current legal authorities regarding
24 consumer protection; and

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1 (3) legislative options for Congress to prevent
2 balance billing.

3 (e) REPORT.—Not later than 180 days after the date
4 of the first meeting of the advisory committee, the advi-
5 sory committee shall submit to the Secretaries, and the
6 Committees on Education and Labor, Energy and Com-
7 merce, and Ways and Means of the House of Representa-
8 tives and the Committees on Finance and Health, Edu-
9 cation, Labor, and Pensions a report containing the rec-
10 ommendations made under subsection (d).

11 **SEC. 118. IMPLEMENTATION FUNDING.**

12 (a) IN GENERAL.—For the purposes described in
13 subsection (b), there are appropriated, out of amounts in
14 the Treasury not otherwise appropriated, to the Secretary
15 of Health and Human Services, the Secretary of Labor,
16 and the Secretary of the Treasury, \$500,000,000 for fiscal
17 year 2021, to remain available until expended through
18 2024.

19 (b) PERMITTED PURPOSES.—The purposes described
20 in this subsection are limited to the following purposes,
21 insofar as such purposes are to carry out the provisions
22 of, including the amendments made by, this title and title
23 II:

24 (1) Preparing, drafting, and issuing proposed
25 and final regulations or interim regulations.

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1 (2) Preparing, drafting, and issuing guidance
2 and public information.

3 (3) Preparing and holding public meetings.

4 (4) Preparing, drafting, and publishing reports.

5 (5) Enforcement of such provisions.

6 (6) Reporting, collection, and analysis of data.

7 (7) Establishment and initial implementation of
8 the processes for independent dispute resolution and
9 implementation of patient-provider dispute resolution
10 under such provisions.

11 (8) Conducting audits.

12 (9) Other administrative duties necessary for
13 implementation of such provisions.

14 (c) **TRANSPARENCY OF IMPLEMENTATION FUNDS.**—
15 Each Secretary described in subsection (a) shall annually
16 submit to the Committees on Energy and Commerce, on
17 Ways and Means, on Education and Labor, and on Appro-
18 priations of the House of Representatives and on the Com-
19 mittees on Health, Education, Labor, and Pensions and
20 on Appropriations of the Senate a report on funds ex-
21 pended pursuant to funds appropriated under this section.

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1 TITLE II—TRANSPARENCY**2 SEC. 201. INCREASING TRANSPARENCY BY REMOVING GAG**
3 CLAUSES ON PRICE AND QUALITY INFORMA-
4 TION.

5 (a) PHSA.—Part D of title XXVII of the Public
6 Health Service Act (42 U.S.C. 300gg et seq.), as added
7 and amended by title I, is further amended by adding at
8 the end the following:

9 “SEC. 2799A-9. INCREASING TRANSPARENCY BY REMOVING
10 GAG CLAUSES ON PRICE AND QUALITY IN-
11 FORMATION.

12 “(a) INCREASING PRICE AND QUALITY TRANS-
13 PARENCY FOR PLAN SPONSORS AND GROUP AND INDI-
14 VIDUAL MARKET CONSUMERS.—

15 “(1) GROUP HEALTH PLANS.—A group health
16 plan or health insurance issuer offering group health
17 insurance coverage may not enter into an agreement
18 with a health care provider, network or association
19 of providers, third-party administrator, or other
20 service provider offering access to a network of pro-
21 viders that would directly or indirectly restrict a
22 group health plan or health insurance issuer offering
23 such coverage from—

24 “(A) providing provider-specific cost or
25 quality of care information or data, through a

1998

1 consumer engagement tool or any other means,
2 to referring providers, the plan sponsor, enroll-
3 ees, or individuals eligible to become enrollees of
4 the plan or coverage;

5 “(B) electronically accessing de-identified
6 claims and encounter information or data for
7 each enrollee in the plan or coverage, upon re-
8 quest and consistent with the privacy regula-
9 tions promulgated pursuant to section 264(c) of
10 the Health Insurance Portability and Account-
11 ability Act of 1996, the amendments made by
12 the Genetic Information Nondiscrimination Act
13 of 2008, and the Americans with Disabilities
14 Act of 1990, including, on a per claim basis—

15 “(i) financial information, such as the
16 allowed amount, or any other claim-related
17 financial obligations included in the pro-
18 vider contract;

19 “(ii) provider information, including
20 name and clinical designation;

21 “(iii) service codes; or

22 “(iv) any other data element included
23 in claim or encounter transactions; or

24 “(C) sharing information or data described
25 in subparagraph (A) or (B), or directing that

1999

1 such data be shared, with a business associate
2 as defined in section 160.103 of title 45, Code
3 of Federal Regulations (or successor regula-
4 tions), consistent with the privacy regulations
5 promulgated pursuant to section 264(c) of the
6 Health Insurance Portability and Accountability
7 Act of 1996, the amendments made by the Ge-
8 netic Information Nondiscrimination Act of
9 2008, and the Americans with Disabilities Act
10 of 1990.

11 “(2) INDIVIDUAL HEALTH INSURANCE COV-
12 ERAGE.—A health insurance issuer offering indi-
13 vidual health insurance coverage may not enter into
14 an agreement with a health care provider, network
15 or association of providers, or other service provider
16 offering access to a network of providers that would
17 directly or indirectly restrict the health insurance
18 issuer from—

19 “(A) providing provider-specific price or
20 quality of care information, through a consumer
21 engagement tool or any other means, to refer-
22 ring providers, enrollees, or individuals eligible
23 to become enrollees of the plan or coverage; or

24 “(B) sharing, for plan design, plan admin-
25 istration, and plan, financial, legal, and quality

2000

1 improvement activities, data described in sub-
2 paragraph (A) with a business associate as de-
3 fined in section 160.103 of title 45, Code of
4 Federal Regulations (or successor regulations),
5 consistent with the privacy regulations promul-
6 gated pursuant to section 264(c) of the Health
7 Insurance Portability and Accountability Act of
8 1996, the amendments made by the Genetic In-
9 formation Nondiscrimination Act of 2008, and
10 the Americans with Disabilities Act of 1990.

11 “(3) CLARIFICATION REGARDING PUBLIC DIS-
12 CLOSURE OF INFORMATION.—Nothing in paragraph
13 (1)(A) or (2)(A) prevents a health care provider,
14 network or association of providers, or other service
15 provider from placing reasonable restrictions on the
16 public disclosure of the information described in
17 such paragraphs (1) and (2).

18 “(4) ATTESTATION.—A group health plan or a
19 health insurance issuer offering group or individual
20 health insurance coverage shall annually submit to
21 the Secretary an attestation that such plan or issuer
22 of such coverage is in compliance with the require-
23 ments of this subsection.

24 “(5) RULES OF CONSTRUCTION.—Nothing in
25 this section shall be construed to modify or eliminate

2001

1 existing privacy protections and standards under
2 State and Federal law. Nothing in this subsection
3 shall be construed to otherwise limit access by a
4 group health plan, plan sponsor, or health insurance
5 issuer to data as permitted under the privacy regula-
6 tions promulgated pursuant to section 264(c) of the
7 Health Insurance Portability and Accountability Act
8 of 1996, the amendments made by the Genetic In-
9 formation Nondiscrimination Act of 2008, and the
10 Americans with Disabilities Act of 1990.”.

11 (b) ERISA.—Subpart B of part 7 of subtitle B of
12 title I of the Employee Retirement Income Security Act
13 of 1974 (29 U.S.C. 1185 et seq.), as amended by title
14 I, is further amended by adding at the end the following:

15 **“SEC. 724. INCREASING TRANSPARENCY BY REMOVING GAG**
16 **CLAUSES ON PRICE AND QUALITY INFORMA-**
17 **TION.**

18 “(a) INCREASING PRICE AND QUALITY TRANS-
19 PARENCY FOR PLAN SPONSORS AND CONSUMERS.—

20 “(1) IN GENERAL.—A group health plan (or an
21 issuer of health insurance coverage offered in con-
22 nection with such a plan) may not enter into an
23 agreement with a health care provider, network or
24 association of providers, third-party administrator,
25 or other service provider offering access to a network

2002

1 of providers that would directly or indirectly restrict
2 a group health plan or health insurance issuer offer-
3 ing such coverage from—

4 “(A) providing provider-specific cost or
5 quality of care information or data, through a
6 consumer engagement tool or any other means,
7 to referring providers, the plan sponsor, partici-
8 pants or beneficiaries, or individuals eligible to
9 become participants or beneficiaries of the plan
10 or coverage;

11 “(B) electronically accessing de-identified
12 claims and encounter information or data for
13 each participant or beneficiary in the plan or
14 coverage, upon request and consistent with the
15 privacy regulations promulgated pursuant to
16 section 264(c) of the Health Insurance Port-
17 ability and Accountability Act of 1996, the
18 amendments made by the Genetic Information
19 Nondiscrimination Act of 2008, and the Ameri-
20 cans with Disabilities Act of 1990, including, on
21 a per claim basis—

22 “(i) financial information, such as the
23 allowed amount, or any other claim-related
24 financial obligations included in the pro-
25 vider contract;

2003

1 “(ii) provider information, including
2 name and clinical designation;

3 “(iii) service codes; or

4 “(iv) any other data element included
5 in claim or encounter transactions; or

6 “(C) sharing information or data described
7 in subparagraph (A) or (B), or directing that
8 such data be shared, with a business associate
9 as defined in section 160.103 of title 45, Code
10 of Federal Regulations (or successor regula-
11 tions), consistent with the privacy regulations
12 promulgated pursuant to section 264(c) of the
13 Health Insurance Portability and Accountability
14 Act of 1996, the amendments made by the Ge-
15 netic Information Nondiscrimination Act of
16 2008, and the Americans with Disabilities Act
17 of 1990.

18 “(2) CLARIFICATION REGARDING PUBLIC DIS-
19 CLOSURE OF INFORMATION.—Nothing in paragraph
20 (1)(A) prevents a health care provider, network or
21 association of providers, or other service provider
22 from placing reasonable restrictions on the public
23 disclosure of the information described in such para-
24 graph (1).

2004

1 “(3) ATTESTATION.—A group health plan (or
2 health insurance coverage offered in connection with
3 such a plan) shall annually submit to the Secretary
4 an attestation that such plan or issuer of such cov-
5 erage is in compliance with the requirements of this
6 subsection.

7 “(4) RULES OF CONSTRUCTION.—Nothing in
8 this section shall be construed to modify or eliminate
9 existing privacy protections and standards under
10 State and Federal law. Nothing in this subsection
11 shall be construed to otherwise limit access by a
12 group health plan, plan sponsor, or health insurance
13 issuer to data as permitted under the privacy regula-
14 tions promulgated pursuant to section 264(c) of the
15 Health Insurance Portability and Accountability Act
16 of 1996, the amendments made by the Genetic In-
17 formation Nondiscrimination Act of 2008, and the
18 Americans with Disabilities Act of 1990.”.

19 (c) IRC.—Subchapter B of chapter 100 of the Inter-
20 nal Revenue Code of 1986, as amended by title I, is fur-
21 ther amended by adding at the end the following:

2005

1 **“SEC. 9824. INCREASING TRANSPARENCY BY REMOVING**
2 **GAG CLAUSES ON PRICE AND QUALITY IN-**
3 **FORMATION.**

4 “(a) INCREASING PRICE AND QUALITY TRANS-
5 PARENCY FOR PLAN SPONSORS AND CONSUMERS.—

6 “(1) IN GENERAL.—A group health plan may
7 not enter into an agreement with a health care pro-
8 vider, network or association of providers, third-
9 party administrator, or other service provider offer-
10 ing access to a network of providers that would di-
11 rectly or indirectly restrict a group health plan
12 from—

13 “(A) providing provider-specific cost or
14 quality of care information or data, through a
15 consumer engagement tool or any other means,
16 to referring providers, the plan sponsor, partici-
17 pants or beneficiaries, or individuals eligible to
18 become participants or beneficiaries of the plan;

19 “(B) electronically accessing de-identified
20 claims and encounter information or data for
21 each participant or beneficiary in the plan,
22 upon request and consistent with the privacy
23 regulations promulgated pursuant to section
24 264(c) of the Health Insurance Portability and
25 Accountability Act of 1996, the amendments
26 made by the Genetic Information Non-

2006

1 discrimination Act of 2008, and the Americans
2 with Disabilities Act of 1990, including, on a
3 per claim basis—

4 “(i) financial information, such as the
5 allowed amount, or any other claim-related
6 financial obligations included in the pro-
7 vider contract;

8 “(ii) provider information, including
9 name and clinical designation;

10 “(iii) service codes; or

11 “(iv) any other data element included
12 in claim or encounter transactions; or

13 “(C) sharing information or data described
14 in subparagraph (A) or (B), or directing that
15 such data be shared, with a business associate
16 as defined in section 160.103 of title 45, Code
17 of Federal Regulations (or successor regula-
18 tions), consistent with the privacy regulations
19 promulgated pursuant to section 264(c) of the
20 Health Insurance Portability and Accountability
21 Act of 1996, the amendments made by the Ge-
22 netic Information Nondiscrimination Act of
23 2008, and the Americans with Disabilities Act
24 of 1990.

2007

1 “(2) CLARIFICATION REGARDING PUBLIC DIS-
2 CLOSURE OF INFORMATION.—Nothing in paragraph
3 (1)(A) prevents a health care provider, network or
4 association of providers, or other service provider
5 from placing reasonable restrictions on the public
6 disclosure of the information described in such para-
7 graph (1).

8 “(3) ATTESTATION.—A group health plan shall
9 annually submit to the Secretary an attestation that
10 such plan is in compliance with the requirements of
11 this subsection.

12 “(4) RULES OF CONSTRUCTION.—Nothing in
13 this section shall be construed to modify or eliminate
14 existing privacy protections and standards under
15 State and Federal law. Nothing in this subsection
16 shall be construed to otherwise limit access by a
17 group health plan or plan sponsor to data as per-
18 mitted under the privacy regulations promulgated
19 pursuant to section 264(c) of the Health Insurance
20 Portability and Accountability Act of 1996, the
21 amendments made by the Genetic Information Non-
22 discrimination Act of 2008, and the Americans with
23 Disabilities Act of 1990.”.

24 (d) CLERICAL AMENDMENTS.—

2008

1 (1) ERISA.—The table of contents in section 1
2 of the Employee Retirement Income Security Act of
3 1974 (29 U.S.C. 1001 et seq.), as amended by title
4 I, is further amended by inserting after the item re-
5 lating to section 723 the following new item:

“Sec. 724. Increasing transparency by removing gag clauses on price and qual-
ity information.”.

6 (2) IRC.—The table of sections for subchapter
7 B of chapter 100 of the Internal Revenue Code of
8 1986, as amended by title I, is further amended by
9 adding at the end the following new item:

“Sec. 9824. Increasing transparency by removing gag clauses on price and
quality information.”.

10 **SEC. 202. DISCLOSURE OF DIRECT AND INDIRECT COM-**
11 **PENSATION FOR BROKERS AND CONSULT-**
12 **ANTS TO EMPLOYER-SPONSORED HEALTH**
13 **PLANS AND ENROLLEES IN PLANS ON THE IN-**
14 **DIVIDUAL MARKET.**

15 (a) GROUP HEALTH PLANS.—Section 408(b)(2) of
16 the Employee Retirement Income Security Act of 1974
17 (29 U.S.C. 1108(b)(2)) is amended—

18 (1) by striking “(2) Contracting or making”
19 and inserting “(2)(A) Contracting or making”; and
20 (2) by adding at the end the following:

21 “(B)(i) No contract or arrangement for services
22 between a covered plan and a covered service pro-
23 vider, and no extension or renewal of such a contract

2009

1 or arrangement, is reasonable within the meaning of
2 this paragraph unless the requirements of this
3 clause are met.

4 “(ii)(I) For purposes of this subparagraph:

5 “(aa) The term ‘covered plan’ means a
6 group health plan as defined section 733(a).

7 “(bb) The term ‘covered service provider’
8 means a service provider that enters into a con-
9 tract or arrangement with the covered plan and
10 reasonably expects \$1,000 (or such amount as
11 the Secretary may establish in regulations to
12 account for inflation since the date of enact-
13 ment of the Consolidated Appropriations Act,
14 2021, as appropriate) or more in compensation,
15 direct or indirect, to be received in connection
16 with providing one or more of the following
17 services, pursuant to the contract or arrange-
18 ment, regardless of whether such services will
19 be performed, or such compensation received,
20 by the covered service provider, an affiliate, or
21 a subcontractor:

22 “(AA) Brokerage services, for which
23 the covered service provider, an affiliate, or
24 a subcontractor reasonably expects to re-
25 ceive indirect compensation or direct com-

2010

1 pensation described in item (dd), provided
2 to a covered plan with respect to selection
3 of insurance products (including vision and
4 dental), recordkeeping services, medical
5 management vendor, benefits administra-
6 tion (including vision and dental), stop-loss
7 insurance, pharmacy benefit management
8 services, wellness services, transparency
9 tools and vendors, group purchasing orga-
10 nization preferred vendor panels, disease
11 management vendors and products, compli-
12 ance services, employee assistance pro-
13 grams, or third party administration serv-
14 ices.

15 “(BB) Consulting, for which the cov-
16 ered service provider, an affiliate, or a sub-
17 contractor reasonably expects to receive in-
18 direct compensation or direct compensation
19 described in item (dd), related to the devel-
20 opment or implementation of plan design,
21 insurance or insurance product selection
22 (including vision and dental), record-
23 keeping, medical management, benefits ad-
24 ministration selection (including vision and
25 dental), stop-loss insurance, pharmacy ben-

2011

1 efit management services, wellness design
2 and management services, transparency
3 tools, group purchasing organization agree-
4 ments and services, participation in and
5 services from preferred vendor panels, dis-
6 ease management, compliance services, em-
7 ployee assistance programs, or third party
8 administration services.

9 “(cc) The term ‘affiliate’, with respect to a
10 covered service provider, means an entity that
11 directly or indirectly (through one or more
12 intermediaries) controls, is controlled by, or is
13 under common control with, such provider, or is
14 an officer, director, or employee of, or partner
15 in, such provider.

16 “(dd)(AA) The term ‘compensation’ means
17 anything of monetary value, but does not in-
18 clude non-monetary compensation valued at
19 \$250 (or such amount as the Secretary may es-
20 tablish in regulations to account for inflation
21 since the date of enactment of the Consolidated
22 Appropriations Act, 2021, as appropriate) or
23 less, in the aggregate, during the term of the
24 contract or arrangement.

2012

1 “(BB) The term ‘direct compensation’
2 means compensation received directly from a
3 covered plan.

4 “(CC) The term ‘indirect compensation’
5 means compensation received from any source
6 other than the covered plan, the plan sponsor,
7 the covered service provider, or an affiliate.
8 Compensation received from a subcontractor is
9 indirect compensation, unless it is received in
10 connection with services performed under a con-
11 tract or arrangement with a subcontractor.

12 “(ee) The term ‘responsible plan fiduciary’
13 means a fiduciary with authority to cause the
14 covered plan to enter into, or extend or renew,
15 the contract or arrangement.

16 “(ff) The term ‘subcontractor’ means any
17 person or entity (or an affiliate of such person
18 or entity) that is not an affiliate of the covered
19 service provider and that, pursuant to a con-
20 tract or arrangement with the covered service
21 provider or an affiliate, reasonably expects to
22 receive \$1,000 (or such amount as the Sec-
23 retary may establish in regulations to account
24 for inflation since the date of enactment of the
25 Consolidated Appropriations Act, 2021, as ap-

2013

1 appropriate) or more in compensation for per-
2 forming one or more services described in item
3 (bb) under a contract or arrangement with the
4 covered plan.

5 “(II) For purposes of this subparagraph, a de-
6 scription of compensation or cost may be expressed
7 as a monetary amount, formula, or a per capita
8 charge for each enrollee or, if the compensation or
9 cost cannot reasonably be expressed in such terms,
10 by any other reasonable method, including a disclo-
11 sure that additional compensation may be earned
12 but may not be calculated at the time of contract if
13 such a disclosure includes a description of the cir-
14 cumstances under which the additional compensation
15 may be earned and a reasonable and good faith esti-
16 mate if the covered service provider cannot otherwise
17 readily describe compensation or cost and explains
18 the methodology and assumptions used to prepare
19 such estimate. Any such description shall contain
20 sufficient information to permit evaluation of the
21 reasonableness of the compensation or cost.

22 “(III) No person or entity is a ‘covered service
23 provider’ within the meaning of subclause (I)(bb)
24 solely on the basis of providing services as an affil-
25 iate or a subcontractor that is performing one or

2014

1 more of the services described in subitem (AA) or
2 (BB) of such subclause under the contract or ar-
3 rangement with the covered plan.

4 “(iii) A covered service provider shall disclose to
5 a responsible plan fiduciary, in writing, the fol-
6 lowing:

7 “(I) A description of the services to be pro-
8 vided to the covered plan pursuant to the con-
9 tract or arrangement.

10 “(II) If applicable, a statement that the
11 covered service provider, an affiliate, or a sub-
12 contractor will provide, or reasonably expects to
13 provide, services pursuant to the contract or ar-
14 rangement directly to the covered plan as a fi-
15 duciary (within the meaning of section 3(21)).

16 “(III) A description of all direct compensa-
17 tion, either in the aggregate or by service, that
18 the covered service provider, an affiliate, or a
19 subcontractor reasonably expects to receive in
20 connection with the services described in sub-
21 clause (I).

22 “(IV)(aa) A description of all indirect com-
23 pensation that the covered service provider, an
24 affiliate, or a subcontractor reasonably expects

2015

1 to receive in connection with the services de-
2 scribed in subclause (I)—

3 “(AA) including compensation from a
4 vendor to a brokerage firm based on a
5 structure of incentives not solely related to
6 the contract with the covered plan; and

7 “(BB) not including compensation re-
8 ceived by an employee from an employer
9 on account of work performed by the em-
10 ployee.

11 “(bb) A description of the arrangement be-
12 tween the payer and the covered service pro-
13 vider, an affiliate, or a subcontractor, as appli-
14 cable, pursuant to which such indirect com-
15 pensation is paid.

16 “(cc) Identification of the services for
17 which the indirect compensation will be re-
18 ceived, if applicable.

19 “(dd) Identification of the payer of the in-
20 direct compensation.

21 “(V) A description of any compensation
22 that will be paid among the covered service pro-
23 vider, an affiliate, or a subcontractor, in con-
24 nection with the services described in subclause
25 (I) if such compensation is set on a transaction

2016

1 basis (such as commissions, finder's fees, or
2 other similar incentive compensation based on
3 business placed or retained), including identi-
4 fication of the services for which such com-
5 pensation will be paid and identification of the
6 payers and recipients of such compensation (in-
7 cluding the status of a payer or recipient as an
8 affiliate or a subcontractor), regardless of
9 whether such compensation also is disclosed
10 pursuant to subclause (III) or (IV).

11 “(VI) A description of any compensation
12 that the covered service provider, an affiliate, or
13 a subcontractor reasonably expects to receive in
14 connection with termination of the contract or
15 arrangement, and how any prepaid amounts
16 will be calculated and refunded upon such ter-
17 mination.

18 “(iv) A covered service provider shall disclose to
19 a responsible plan fiduciary, in writing a description
20 of the manner in which the compensation described
21 in clause (iii), as applicable, will be received.

22 “(v)(I) A covered service provider shall disclose
23 the information required under clauses (iii) and (iv)
24 to the responsible plan fiduciary not later than the
25 date that is reasonably in advance of the date on

2017

1 which the contract or arrangement is entered into,
2 and extended or renewed.

3 “(II) A covered service provider shall disclose
4 any change to the information required under clause
5 (iii) and (iv) as soon as practicable, but not later
6 than 60 days from the date on which the covered
7 service provider is informed of such change, unless
8 such disclosure is precluded due to extraordinary cir-
9 cumstances beyond the covered service provider’s
10 control, in which case the information shall be dis-
11 closed as soon as practicable.

12 “(vi)(I) Upon the written request of the respon-
13 sible plan fiduciary or covered plan administrator, a
14 covered service provider shall furnish any other in-
15 formation relating to the compensation received in
16 connection with the contract or arrangement that is
17 required for the covered plan to comply with the re-
18 porting and disclosure requirements under this Act.

19 “(II) The covered service provider shall disclose
20 the information required under clause (iii)(I) reason-
21 ably in advance of the date upon which such respon-
22 sible plan fiduciary or covered plan administrator
23 states that it is required to comply with the applica-
24 ble reporting or disclosure requirement, unless such
25 disclosure is precluded due to extraordinary cir-

2018

1 cumstances beyond the covered service provider’s
2 control, in which case the information shall be dis-
3 closed as soon as practicable.

4 “(vii) No contract or arrangement will fail to be
5 reasonable under this subparagraph solely because
6 the covered service provider, acting in good faith and
7 with reasonable diligence, makes an error or omis-
8 sion in disclosing the information required pursuant
9 to clause (iii) (or a change to such information dis-
10 closed pursuant to clause (v)(II)) or clause (vi), pro-
11 vided that the covered service provider discloses the
12 correct information to the responsible plan fiduciary
13 as soon as practicable, but not later than 30 days
14 from the date on which the covered service provider
15 knows of such error or omission.

16 “(viii)(I) Pursuant to subsection (a), subpara-
17 graphs (C) and (D) of section 406(a)(1) shall not
18 apply to a responsible plan fiduciary, notwith-
19 standing any failure by a covered service provider to
20 disclose information required under clause (iii), if
21 the following conditions are met:

22 “(aa) The responsible plan fiduciary did
23 not know that the covered service provider
24 failed or would fail to make required disclosures
25 and reasonably believed that the covered service

2019

1 provider disclosed the information required to
2 be disclosed.

3 “(bb) The responsible plan fiduciary, upon
4 discovering that the covered service provider
5 failed to disclose the required information, re-
6 quests in writing that the covered service pro-
7 vider furnish such information.

8 “(cc) If the covered service provider fails
9 to comply with a written request described in
10 subclause (II) within 90 days of the request,
11 the responsible plan fiduciary notifies the Sec-
12 retary of the covered service provider’s failure,
13 in accordance with subclauses (II) and (III).

14 “(II) A notice described in subclause (I)(cc)
15 shall contain—

16 “(aa) the name of the covered plan;

17 “(bb) the plan number used for the annual
18 report on the covered plan;

19 “(cc) the plan sponsor’s name, address,
20 and employer identification number;

21 “(dd) the name, address, and telephone
22 number of the responsible plan fiduciary;

23 “(ee) the name, address, phone number,
24 and, if known, employer identification number
25 of the covered service provider;

2020

1 “(ff) a description of the services provided
2 to the covered plan;

3 “(gg) a description of the information that
4 the covered service provider failed to disclose;

5 “(hh) the date on which such information
6 was requested in writing from the covered serv-
7 ice provider; and

8 “(ii) a statement as to whether the covered
9 service provider continues to provide services to
10 the plan.

11 “(III) A notice described in subclause (I)(cc)
12 shall be filed with the Department not later than 30
13 days following the earlier of—

14 “(aa) The covered service provider’s re-
15 fusals to furnish the information requested by
16 the written request described in subclause
17 (I)(bb); or

18 “(bb) 90 days after the written request re-
19 ferred to in subclause (I)(cc) is made.

20 “(IV) If the covered service provider fails to
21 comply with the written request under subclause
22 (I)(bb) within 90 days of such request, the respon-
23 sible plan fiduciary shall determine whether to ter-
24 minate or continue the contract or arrangement
25 under section 404. If the requested information re-

2021

1 lates to future services and is not disclosed promptly
2 after the end of the 90-day period, the responsible
3 plan fiduciary shall terminate the contract or ar-
4 rangement as expeditiously as possible, consistent
5 with such duty of prudence.

6 “(ix) Nothing in this subparagraph shall be
7 construed to supersede any provision of State law
8 that governs disclosures by parties that provide the
9 services described in this section, except to the ex-
10 tent that such law prevents the application of a re-
11 quirement of this section.”.

12 (b) **APPLICABILITY OF EXISTING REGULATIONS.**—
13 Nothing in the amendments made by subsection (a) shall
14 be construed to affect the applicability of section
15 2550.408b–2 of title 29, Code of Federal Regulations (or
16 any successor regulations), with respect to any applicable
17 entity other than a covered plan or a covered service pro-
18 vider (as defined in section 408(b)(2)(B)(ii) of the Em-
19 ployee Retirement Income Security Act of 1974, as
20 amended by subsection (a)).

21 (c) **INDIVIDUAL MARKET COVERAGE.**—Subpart 1 of
22 part B of title XXVII of the Public Health Service Act
23 (42 U.S.C. 300gg–41 et seq.) is amended by adding at
24 the end the following:

2022

1 **“SEC. 2746. DISCLOSURE TO ENROLLEES OF INDIVIDUAL**
2 **MARKET COVERAGE.**

3 “(a) IN GENERAL.—A health insurance issuer offer-
4 ing individual health insurance coverage or a health insur-
5 ance issuer offering short-term limited duration insurance
6 coverage shall make disclosures to enrollees in such cov-
7 erage, as described in subsection (b), and reports to the
8 Secretary, as described in subsection (c), regarding direct
9 or indirect compensation provided by the issuer to an
10 agent or broker associated with enrolling individuals in
11 such coverage.

12 “(b) DISCLOSURE.—A health insurance issuer de-
13 scribed in subsection (a) shall disclose to an enrollee the
14 amount of direct or indirect compensation provided to an
15 agent or broker for services provided by such agent or
16 broker associated with plan selection and enrollment. Such
17 disclosure shall be—

18 “(1) made prior to the individual finalizing plan
19 selection; and

20 “(2) included on any documentation confirming
21 the individual’s enrollment.

22 “(c) REPORTING.—A health insurance issuer de-
23 scribed in subsection (a) shall annually report to the Sec-
24 retary, prior to the beginning of open enrollment, any di-
25 rect or indirect compensation provided to an agent or

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1 broker associated with enrolling individuals in such cov-
2 erage.

3 “(d) RULEMAKING.—Not later than 1 year after the
4 date of enactment of the Consolidated Appropriations Act,
5 2021, the Secretary shall finalize, through notice-and-com-
6 ment rulemaking, the timing, form, and manner in which
7 issuers described in subsection (a) are required to make
8 the disclosures described in subsection (b) and the reports
9 described in subsection (c). Such rulemaking may also in-
10 clude adjustments to notice requirements to reflect the dif-
11 ferent processes for plan renewals, in order to provide en-
12 rollees with full, timely information.”.

13 (d) TRANSITION RULE.—No contract executed prior
14 to the effective date described in subsection (e) by a group
15 health plan subject to the requirements of section
16 408(b)(2)(B) of the Employee Retirement Income Secu-
17 rity Act of 1974 (as amended by subsection (a)) or by
18 a health insurance issuer subject to the requirements of
19 section 2746 of the Public Health Service Act (as added
20 by subsection (c)) shall be subject to the requirements of
21 such section 408(b)(2)(B) or such section 2746, as appli-
22 cable.

23 (e) APPLICATION.—The amendments made by sub-
24 sections (a) and (c) shall apply beginning 1 year after the
25 date of enactment of this Act.

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1 **SEC. 203. STRENGTHENING PARITY IN MENTAL HEALTH**
2 **AND SUBSTANCE USE DISORDER BENEFITS.**

3 (a) IN GENERAL.—

4 (1) PHSA.—Section 2726(a) of the Public
5 Health Service Act (42 U.S.C. 300gg–26(a)) is
6 amended by adding at the end the following:

7 “(8) COMPLIANCE REQUIREMENTS.—

8 “(A) NONQUANTITATIVE TREATMENT LIM-
9 ITATION (NQTL) REQUIREMENTS.—In the case
10 of a group health plan or a health insurance
11 issuer offering group or individual health insur-
12 ance coverage that provides both medical and
13 surgical benefits and mental health or sub-
14 stance use disorder benefits and that imposes
15 nonquantitative treatment limitations (referred
16 to in this section as ‘NQTLs’) on mental health
17 or substance use disorder benefits, such plan or
18 issuer shall perform and document comparative
19 analyses of the design and application of
20 NQTLs and, beginning 45 days after the date
21 of enactment of the Consolidated Appropria-
22 tions Act, 2021, make available to the applica-
23 ble State authority (or, as applicable, to the
24 Secretary of Labor or the Secretary of Health
25 and Human Services), upon request, the com-
26 parative analyses and the following information:

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1 “(i) The specific plan or coverage
2 terms or other relevant terms regarding
3 the NQTLs and a description of all mental
4 health or substance use disorder and med-
5 ical or surgical benefits to which each such
6 term applies in each respective benefits
7 classification.

8 “(ii) The factors used to determine
9 that the NQTLs will apply to mental
10 health or substance use disorder benefits
11 and medical or surgical benefits.

12 “(iii) The evidentiary standards used
13 for the factors identified in clause (ii),
14 when applicable, provided that every factor
15 shall be defined, and any other source or
16 evidence relied upon to design and apply
17 the NQTLs to mental health or substance
18 use disorder benefits and medical or sur-
19 gical benefits.

20 “(iv) The comparative analyses dem-
21 onstrating that the processes, strategies,
22 evidentiary standards, and other factors
23 used to apply the NQTLs to mental health
24 or substance use disorder benefits, as writ-
25 ten and in operation, are comparable to,

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1 and are applied no more stringently than,
2 the processes, strategies, evidentiary stand-
3 ards, and other factors used to apply the
4 NQTLs to medical or surgical benefits in
5 the benefits classification.

6 “(v) The specific findings and conclu-
7 sions reached by the group health plan or
8 health insurance issuer with respect to the
9 health insurance coverage, including any
10 results of the analyses described in this
11 subparagraph that indicate that the plan
12 or coverage is or is not in compliance with
13 this section.

14 “(B) SECRETARY REQUEST PROCESS.—

15 “(i) SUBMISSION UPON REQUEST.—
16 The Secretary shall request that a group
17 health plan or a health insurance issuer of-
18 fering group or individual health insurance
19 coverage submit the comparative analyses
20 described in subparagraph (A) for plans
21 that involve potential violations of this sec-
22 tion or complaints regarding noncompli-
23 ance with this section that concern NQTLs
24 and any other instances in which the Sec-
25 retary determines appropriate. The Sec-

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1 retary shall request not fewer than 20 such
2 analyses per year.

3 “(ii) ADDITIONAL INFORMATION.—In
4 instances in which the Secretary has con-
5 cluded that the group health plan or health
6 insurance issuer with respect to health in-
7 surance coverage has not submitted suffi-
8 cient information for the Secretary to re-
9 view the comparative analyses described in
10 subparagraph (A), as requested under
11 clause (i), the Secretary shall specify to the
12 plan or issuer the information the plan or
13 issuer must submit to be responsive to the
14 request under clause (i) for the Secretary
15 to review the comparative analyses de-
16 scribed in subparagraph (A) for compliance
17 with this section. Nothing in this para-
18 graph shall require the Secretary to con-
19 clude that a group health plan or health
20 insurance issuer is in compliance with this
21 section solely based upon the inspection of
22 the comparative analyses described in sub-
23 paragraph (A), as requested under clause
24 (i).

25 “(iii) REQUIRED ACTION.—

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1 “(I) IN GENERAL.—In instances
2 in which the Secretary has reviewed
3 the comparative analyses described in
4 subparagraph (A), as requested under
5 clause (i), and determined that the
6 group health plan or health insurance
7 issuer is not in compliance with this
8 section, the plan or issuer—

9 “(aa) shall specify to the
10 Secretary the actions the plan or
11 issuer will take to be in compli-
12 ance with this section and pro-
13 vide to the Secretary additional
14 comparative analyses described in
15 subparagraph (A) that dem-
16 onstrate compliance with this sec-
17 tion not later than 45 days after
18 the initial determination by the
19 Secretary that the plan or issuer
20 is not in compliance; and

21 “(bb) following the 45-day
22 corrective action period under
23 item (aa), if the Secretary makes
24 a final determination that the
25 plan or issuer still is not in com-

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1 pliance with this section, not
2 later than 7 days after such de-
3 termination, shall notify all indi-
4 viduals enrolled in the plan or
5 applicable health insurance cov-
6 erage offered by the issuer that
7 the plan or issuer, with respect to
8 such coverage, has been deter-
9 mined to be not in compliance
10 with this section.

11 “(II) EXEMPTION FROM DISCLO-
12 SURE.—Documents or communica-
13 tions produced in connection with the
14 Secretary’s recommendations to a
15 group health plan or health insurance
16 issuer shall not be subject to disclo-
17 sure pursuant to section 552 of title
18 5, United States Code.

19 “(iv) REPORT.—Not later than 1 year
20 after the date of enactment of this para-
21 graph, and not later than October 1 of
22 each year thereafter, the Secretary shall
23 submit to Congress, and make publicly
24 available, a report that contains—

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1 “(I) a summary of the compara-
2 tive analyses requested under clause
3 (i), including the identity of each
4 group health plan or health insurance
5 issuer, with respect to particular
6 health insurance coverage that is de-
7 termined to be not in compliance after
8 the final determination by the Sec-
9 retary described in clause (iii)(I)(bb);

10 “(II) the Secretary’s conclusions
11 as to whether each group health plan
12 or health insurance issuer submitted
13 sufficient information for the Sec-
14 retary to review the comparative anal-
15 yses requested under clause (i) for
16 compliance with this section;

17 “(III) for each group health plan
18 or health insurance issuer that did
19 submit sufficient information for the
20 Secretary to review the comparative
21 analyses requested under clause (i),
22 the Secretary’s conclusions as to
23 whether and why the plan or issuer is
24 in compliance with the requirements
25 under this section;

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1 “(IV) the Secretary’s specifica-
2 tions described in clause (ii) for each
3 group health plan or health insurance
4 issuer that the Secretary determined
5 did not submit sufficient information
6 for the Secretary to review the com-
7 parative analyses requested under
8 clause (i) for compliance with this sec-
9 tion; and

10 “(V) the Secretary’s specifica-
11 tions described in clause (iii) of the
12 actions each group health plan or
13 health insurance issuer that the Sec-
14 retary determined is not in compliance
15 with this section must take to be in
16 compliance with this section, including
17 the reason why the Secretary deter-
18 mined the plan or issuer is not in
19 compliance.

20 “(C) COMPLIANCE PROGRAM GUIDANCE
21 DOCUMENT UPDATE PROCESS.—

22 “(i) IN GENERAL.—The Secretary
23 shall include instances of noncompliance
24 that the Secretary discovers upon review-
25 ing the comparative analyses requested

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1 under subparagraph (B)(i) in the compli-
2 ance program guidance document de-
3 scribed in paragraph (6), as it is updated
4 every 2 years, except that such instances
5 shall not disclose any protected health in-
6 formation or individually identifiable infor-
7 mation.

8 “(ii) GUIDANCE AND REGULATIONS.—
9 Not later than 18 months after the date of
10 enactment of this paragraph, the Secretary
11 shall finalize any draft or interim guidance
12 and regulations relating to mental health
13 parity under this section. Such draft guid-
14 ance shall include guidance to clarify the
15 process and timeline for current and poten-
16 tial participants and beneficiaries (and au-
17 thorized representatives and health care
18 providers of such participants and bene-
19 ficiaries) with respect to plans to file com-
20 plaints of such plans or issuers being in
21 violation of this section, including guid-
22 ance, by plan type, on the relevant State,
23 regional, or national office with which such
24 complaints should be filed.

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1 “(iii) STATE.—The Secretary shall
2 share information on findings of compli-
3 ance and noncompliance discovered upon
4 reviewing the comparative analyses re-
5 quested under subparagraph (B)(i) shall be
6 shared with the State where the group
7 health plan is located or the State where
8 the health insurance issuer is licensed to
9 do business for coverage offered by a
10 health insurance issuer in the group mar-
11 ket, in accordance with paragraph
12 (6)(B)(iii)(II).”.

13 (2) ERISA.—Section 712(a) of the Employee
14 Retirement Income Security Act of 1974 (29 U.S.C.
15 1185a(a)) is amended by adding at the end the fol-
16 lowing:

17 “(6) COMPLIANCE PROGRAM GUIDANCE DOCU-
18 MENT.—

19 “(A) IN GENERAL.—The Secretary, the
20 Secretary of Health and Human Services, and
21 the Secretary of the Treasury, in consultation
22 with the Inspector General of the Department
23 of Health and Human Services, the Inspector
24 General of the Department of Labor, and the
25 Inspector General of the Department of the

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1 Treasury, shall issue a compliance program
2 guidance document to help improve compliance
3 with this section, section 2726 of the Public
4 Health Service Act, and section 9812 of the In-
5 ternal Revenue Code of 1986, as applicable. In
6 carrying out this paragraph, the Secretaries
7 may take into consideration the 2016 publica-
8 tion of the Department of Health and Human
9 Services and the Department of Labor, entitled
10 ‘Warning Signs - Plan or Policy Non-Quan-
11 titative Treatment Limitations (NQTLs) that
12 Require Additional Analysis to Determine Men-
13 tal Health Parity Compliance’.

14 “(B) EXAMPLES ILLUSTRATING COMPLI-
15 ANCE AND NONCOMPLIANCE.—

16 “(i) IN GENERAL.—The compliance
17 program guidance document required
18 under this paragraph shall provide illus-
19 trative, de-identified examples (that do not
20 disclose any protected health information
21 or individually identifiable information) of
22 previous findings of compliance and non-
23 compliance with this section, section 2726
24 of the Public Health Service Act, or sec-
25 tion 9812 of the Internal Revenue Code of

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1 1986, as applicable, based on investiga-
2 tions of violations of such sections, includ-
3 ing—

4 “(I) examples illustrating re-
5 quirements for information disclosures
6 and nonquantitative treatment limita-
7 tions; and

8 “(II) descriptions of the viola-
9 tions uncovered during the course of
10 such investigations.

11 “(ii) NONQUANTITATIVE TREATMENT
12 LIMITATIONS.—To the extent that any ex-
13 ample described in clause (i) involves a
14 finding of compliance or noncompliance
15 with regard to any requirement for non-
16 quantitative treatment limitations, the ex-
17 ample shall provide sufficient detail to fully
18 explain such finding, including a full de-
19 scription of the criteria involved for ap-
20 proving medical and surgical benefits and
21 the criteria involved for approving mental
22 health and substance use disorder benefits.

23 “(iii) ACCESS TO ADDITIONAL INFOR-
24 MATION REGARDING COMPLIANCE.—In de-
25 veloping and issuing the compliance pro-

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1 gram guidance document required under
2 this paragraph, the Secretaries specified in
3 subparagraph (A)—

4 “(I) shall enter into interagency
5 agreements with the Inspector Gen-
6 eral of the Department of Health and
7 Human Services, the Inspector Gen-
8 eral of the Department of Labor, and
9 the Inspector General of the Depart-
10 ment of the Treasury to share find-
11 ings of compliance and noncompliance
12 with this section, section 2726 of the
13 Public Health Service Act, or section
14 9812 of the Internal Revenue Code of
15 1986, as applicable; and

16 “(II) shall seek to enter into an
17 agreement with a State to share infor-
18 mation on findings of compliance and
19 noncompliance with this section, sec-
20 tion 2726 of the Public Health Serv-
21 ice Act, or section 9812 of the Inter-
22 nal Revenue Code of 1986, as applica-
23 ble.

24 “(C) RECOMMENDATIONS.—The compli-
25 ance program guidance document shall include

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1 recommendations to advance compliance with
2 this section, section 2726 of the Public Health
3 Service Act, or section 9812 of the Internal
4 Revenue Code of 1986, as applicable, and en-
5 courage the development and use of internal
6 controls to monitor adherence to applicable
7 statutes, regulations, and program require-
8 ments. Such internal controls may include illus-
9 trative examples of nonquantitative treatment
10 limitations on mental health and substance use
11 disorder benefits, which may fail to comply with
12 this section, section 2726 of the Public Health
13 Service Act, or section 9812 of the Internal
14 Revenue Code of 1986, as applicable, in relation
15 to nonquantitative treatment limitations on
16 medical and surgical benefits.

17 “(D) UPDATING THE COMPLIANCE PRO-
18 GRAM GUIDANCE DOCUMENT.—The Secretary,
19 the Secretary of Health and Human Services,
20 and the Secretary of the Treasury, in consulta-
21 tion with the Inspector General of the Depart-
22 ment of Health and Human Services, the In-
23 spector General of the Department of Labor,
24 and the Inspector General of the Department of
25 the Treasury, shall update the compliance pro-

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1 gram guidance document every 2 years to in-
2 clude illustrative, de-identified examples (that
3 do not disclose any protected health information
4 or individually identifiable information) of pre-
5 vious findings of compliance and noncompliance
6 with this section, section 2726 of the Public
7 Health Service Act, or section 9812 of the In-
8 ternal Revenue Code of 1986, as applicable.

9 “(7) ADDITIONAL GUIDANCE.—

10 “(A) IN GENERAL.—The Secretary, the
11 Secretary of Health and Human Services, and
12 the Secretary of the Treasury shall issue guid-
13 ance to group health plans and health insurance
14 issuers offering group health insurance coverage
15 to assist such plans and issuers in satisfying
16 the requirements of this section, section 2726 of
17 the Public Health Service Act, or section 9812
18 of the Internal Revenue Code of 1986, as appli-
19 cable.

20 “(B) DISCLOSURE.—

21 “(i) GUIDANCE FOR PLANS AND
22 ISSUERS.—The guidance issued under this
23 paragraph shall include clarifying informa-
24 tion and illustrative examples of methods
25 that group health plans and health insur-

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1 ance issuers offering group or individual
2 health insurance coverage may use for dis-
3 closing information to ensure compliance
4 with the requirements under this section,
5 section 2726 of the Public Health Service
6 Act, or section 9812 of the Internal Rev-
7 enue Code of 1986, as applicable, (and any
8 regulations promulgated pursuant to such
9 sections, as applicable).

10 “(ii) DOCUMENTS FOR PARTICIPANTS,
11 BENEFICIARIES, CONTRACTING PROVIDERS,
12 OR AUTHORIZED REPRESENTATIVES.—The
13 guidance issued under this paragraph shall
14 include clarifying information and illus-
15 trative examples of methods that group
16 health plans and health insurance issuers
17 offering group health insurance coverage
18 may use to provide any participant, bene-
19 ficiary, contracting provider, or authorized
20 representative, as applicable, with docu-
21 ments containing information that the
22 health plans or issuers are required to dis-
23 close to participants, beneficiaries, con-
24 tracting providers, or authorized represent-
25 atives to ensure compliance with this sec-

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1 tion, section 2726 of the Public Health
2 Service Act, or section 9812 of the Inter-
3 nal Revenue Code of 1986, as applicable,
4 compliance with any regulation issued pur-
5 suant to such respective section, or compli-
6 ance with any other applicable law or regu-
7 lation. Such guidance shall include infor-
8 mation that is comparative in nature with
9 respect to—

10 “(I) nonquantitative treatment
11 limitations for both medical and sur-
12 gical benefits and mental health and
13 substance use disorder benefits;

14 “(II) the processes, strategies,
15 evidentiary standards, and other fac-
16 tors used to apply the limitations de-
17 scribed in subclause (I); and

18 “(III) the application of the limi-
19 tations described in subclause (I) to
20 ensure that such limitations are ap-
21 plied in parity with respect to both
22 medical and surgical benefits and
23 mental health and substance use dis-
24 order benefits.

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1 “(C) NONQUANTITATIVE TREATMENT LIM-
2 ITATIONS.—The guidance issued under this
3 paragraph shall include clarifying information
4 and illustrative examples of methods, processes,
5 strategies, evidentiary standards, and other fac-
6 tors that group health plans and health insur-
7 ance issuers offering group health insurance
8 coverage may use regarding the development
9 and application of nonquantitative treatment
10 limitations to ensure compliance with this sec-
11 tion, section 2726 of the Public Health Service
12 Act, or section 9812 of the Internal Revenue
13 Code of 1986, as applicable, (and any regula-
14 tions promulgated pursuant to such respective
15 section), including—

16 “(i) examples of methods of deter-
17 mining appropriate types of nonquantita-
18 tive treatment limitations with respect to
19 both medical and surgical benefits and
20 mental health and substance use disorder
21 benefits, including nonquantitative treat-
22 ment limitations pertaining to—

23 “(I) medical management stand-
24 ards based on medical necessity or ap-

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1 appropriateness, or whether a treatment
2 is experimental or investigative;

3 “(II) limitations with respect to
4 prescription drug formulary design;
5 and

6 “(III) use of fail-first or step
7 therapy protocols;

8 “(ii) examples of methods of deter-
9 mining—

10 “(I) network admission standards
11 (such as credentialing); and

12 “(II) factors used in provider re-
13 imbursement methodologies (such as
14 service type, geographic market, de-
15 mand for services, and provider sup-
16 ply, practice size, training, experience,
17 and licensure) as such factors apply to
18 network adequacy;

19 “(iii) examples of sources of informa-
20 tion that may serve as evidentiary stand-
21 ards for the purposes of making deter-
22 minations regarding the development and
23 application of nonquantitative treatment
24 limitations;

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1 “(iv) examples of specific factors, and
2 the evidentiary standards used to evaluate
3 such factors, used by such plans or issuers
4 in performing a nonquantitative treatment
5 limitation analysis;

6 “(v) examples of how specific evi-
7 dentiary standards may be used to deter-
8 mine whether treatments are considered
9 experimental or investigative;

10 “(vi) examples of how specific evi-
11 dentiary standards may be applied to each
12 service category or classification of bene-
13 fits;

14 “(vii) examples of methods of reach-
15 ing appropriate coverage determinations
16 for new mental health or substance use
17 disorder treatments, such as evidence-
18 based early intervention programs for indi-
19 viduals with a serious mental illness and
20 types of medical management techniques;

21 “(viii) examples of methods of reach-
22 ing appropriate coverage determinations
23 for which there is an indirect relationship
24 between the covered mental health or sub-
25 stance use disorder benefit and a tradi-

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1 tional covered medical and surgical benefit,
2 such as residential treatment or hos-
3 pitalizations involving voluntary or involun-
4 tary commitment; and

5 “(ix) additional illustrative examples
6 of methods, processes, strategies, evi-
7 dentiary standards, and other factors for
8 which the Secretary determines that addi-
9 tional guidance is necessary to improve
10 compliance with this section, section 2726
11 of the Public Health Service Act, or sec-
12 tion 9812 of the Internal Revenue Code of
13 1986, as applicable.

14 “(D) PUBLIC COMMENT.—Prior to issuing
15 any final guidance under this paragraph, the
16 Secretary shall provide a public comment period
17 of not less than 60 days during which any
18 member of the public may provide comments on
19 a draft of the guidance.

20 “(8) COMPLIANCE REQUIREMENTS.—

21 “(A) NONQUANTITATIVE TREATMENT LIM-
22 ITATION (NQTL) REQUIREMENTS.—In the case
23 of a group health plan or a health insurance
24 issuer offering group health insurance coverage
25 that provides both medical and surgical benefits

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1 and mental health or substance use disorder
2 benefits and that imposes nonquantitative treat-
3 ment limitations (referred to in this section as
4 ‘NQTLs’) on mental health or substance use
5 disorder benefits, such plan or issuer shall per-
6 form and document comparative analyses of the
7 design and application of NQTLs and, begin-
8 ning 45 days after the date of enactment of the
9 Consolidated Appropriations Act, 2021, make
10 available to the Secretary, upon request, the
11 comparative analyses and the following informa-
12 tion:

13 “(i) The specific plan or coverage
14 terms or other relevant terms regarding
15 the NQTLs, that applies to such plan or
16 coverage, and a description of all mental
17 health or substance use disorder and med-
18 ical or surgical benefits to which each such
19 term applies in each respective benefits
20 classification.

21 “(ii) The factors used to determine
22 that the NQTLs will apply to mental
23 health or substance use disorder benefits
24 and medical or surgical benefits.

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1 “(iii) The evidentiary standards used
2 for the factors identified in clause (ii),
3 when applicable, provided that every factor
4 shall be defined, and any other source or
5 evidence relied upon to design and apply
6 the NQTLs to mental health or substance
7 use disorder benefits and medical or sur-
8 gical benefits.

9 “(iv) The comparative analyses dem-
10 onstrating that the processes, strategies,
11 evidentiary standards, and other factors
12 used to apply the NQTLs to mental health
13 or substance use disorder benefits, as writ-
14 ten and in operation, are comparable to,
15 and are applied no more stringently than,
16 the processes, strategies, evidentiary stand-
17 ards, and other factors used to apply the
18 NQTLs to medical or surgical benefits in
19 the benefits classification.

20 “(v) The specific findings and conclu-
21 sions reached by the group health plan or
22 health insurance issuer with respect to the
23 health insurance coverage, including any
24 results of the analyses described in this
25 subparagraph that indicate that the plan

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1 or coverage is or is not in compliance with
2 this section.

3 “(B) SECRETARY REQUEST PROCESS.—

4 “(i) SUBMISSION UPON REQUEST.—

5 The Secretary shall request that a group
6 health plan or a health insurance issuer of-
7 fering group health insurance coverage
8 submit the comparative analyses described
9 in subparagraph (A) for plans that involve
10 potential violations of this section or com-
11 plaints regarding noncompliance with this
12 section that concern NQTLs and any other
13 instances in which the Secretary deter-
14 mines appropriate. The Secretary shall re-
15 quest not fewer than 20 such analyses per
16 year.

17 “(ii) ADDITIONAL INFORMATION.—In
18 instances in which the Secretary has con-
19 cluded that the group health plan or health
20 insurance issuer with respect to group
21 health insurance coverage has not sub-
22 mitted sufficient information for the Sec-
23 retary to review the comparative analyses
24 described in subparagraph (A), as re-
25 quested under clause (i), the Secretary

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1 shall specify to the plan or issuer the infor-
2 mation the plan or issuer must submit to
3 be responsive to the request under clause
4 (i) for the Secretary to review the com-
5 parative analyses described in subpara-
6 graph (A) for compliance with this section.
7 Nothing in this paragraph shall require the
8 Secretary to conclude that a group health
9 plan or health insurance issuer is in com-
10 pliance with this section solely based upon
11 the inspection of the comparative analyses
12 described in subparagraph (A), as re-
13 quested under clause (i).

14 “(iii) REQUIRED ACTION.—

15 “(I) IN GENERAL.—In instances
16 in which the Secretary has reviewed
17 the comparative analyses described in
18 subparagraph (A), as requested under
19 clause (i), and determined that the
20 group health plan or health insurance
21 issuer is not in compliance with this
22 section, the plan or issuer—

23 “(aa) shall specify to the
24 Secretary the actions the plan or
25 issuer will take to be in compli-

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1 ance with this section and pro-
2 vide to the Secretary additional
3 comparative analyses described in
4 subparagraph (A) that dem-
5 onstrate compliance with this sec-
6 tion not later than 45 days after
7 the initial determination by the
8 Secretary that the plan or issuer
9 is not in compliance; and

10 “(bb) following the 45-day
11 corrective action period under
12 item (aa), if the Secretary makes
13 a final determination that the
14 plan or issuer still is not in com-
15 pliance with this section, not
16 later than 7 days after such de-
17 termination, shall notify all indi-
18 viduals enrolled in the plan or
19 applicable health insurance cov-
20 erage offered by the issuer that
21 the plan or issuer, with respect to
22 such coverage, has been deter-
23 mined to be not in compliance
24 with this section.

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1 “(II) EXEMPTION FROM DISCLO-
2 SURE.—Documents or communica-
3 tions produced in connection with the
4 Secretary’s recommendations to a
5 group health plan or health insurance
6 issuer shall not be subject to disclo-
7 sure pursuant to section 552 of title
8 5, United States Code.

9 “(iv) REPORT.—Not later than 1 year
10 after the date of enactment of this para-
11 graph, and not later than October 1 of
12 each year thereafter, the Secretary shall
13 submit to Congress, and make publicly
14 available, a report that contains—

15 “(I) a summary of the compara-
16 tive analyses requested under clause
17 (i), including the identity of each
18 group health plan or health insurance
19 issuer, with respect to certain health
20 insurance coverage that is determined
21 to be not in compliance after the final
22 determination by the Secretary de-
23 scribed in clause (iii)(I)(bb);

24 “(II) the Secretary’s conclusions
25 as to whether each group health plan

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1 or health insurance issuer submitted
2 sufficient information for the Sec-
3 retary to review the comparative anal-
4 yses requested under clause (i) for
5 compliance with this section;

6 “(III) for each group health plan
7 or health insurance issuer that did
8 submit sufficient information for the
9 Secretary to review the comparative
10 analyses requested under clause (i),
11 the Secretary’s conclusions as to
12 whether and why the plan or issuer is
13 in compliance with the disclosure re-
14 quirements under this section;

15 “(IV) the Secretary’s specifica-
16 tions described in clause (ii) for each
17 group health plan or health insurance
18 issuer that the Secretary determined
19 did not submit sufficient information
20 for the Secretary to review the com-
21 parative analyses requested under
22 clause (i) for compliance with this sec-
23 tion; and

24 “(V) the Secretary’s specifica-
25 tions described in clause (iii) of the

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1 actions each group health plan or
2 health insurance issuer that the Sec-
3 retary determined is not in compliance
4 with this section must take to be in
5 compliance with this section, including
6 the reason why the Secretary deter-
7 mined the plan or issuer is not in
8 compliance.

9 “(C) COMPLIANCE PROGRAM GUIDANCE
10 DOCUMENT UPDATE PROCESS.—

11 “(i) IN GENERAL.—The Secretary
12 shall include instances of noncompliance
13 that the Secretary discovers upon review-
14 ing the comparative analyses requested
15 under subparagraph (B)(i) in the compli-
16 ance program guidance document de-
17 scribed in paragraph (6), as it is updated
18 every 2 years, except that such instances
19 shall not disclose any protected health in-
20 formation or individually identifiable infor-
21 mation.

22 “(ii) GUIDANCE AND REGULATIONS.—
23 Not later than 18 months after the date of
24 enactment of this paragraph, the Secretary
25 shall finalize any draft or interim guidance

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1 and regulations relating to mental health
2 parity under this section. Such draft guid-
3 ance shall include guidance to clarify the
4 process and timeline for current and poten-
5 tial participants and beneficiaries (and au-
6 thorized representatives and health care
7 providers of such participants and bene-
8 ficiaries) with respect to plans to file com-
9 plaints of such plans or issuers being in
10 violation of this section, including guid-
11 ance, by plan type, on the relevant State,
12 regional, or national office with which such
13 complaints should be filed.

14 “(iii) STATE.—The Secretary shall
15 share information on findings of compli-
16 ance and noncompliance discovered upon
17 reviewing the comparative analyses re-
18 quested under subparagraph (B)(i) shall be
19 shared with the State where the group
20 health plan is located or the State where
21 the health insurance issuer is licensed to
22 do business for coverage offered by a
23 health insurance issuer in the group mar-
24 ket, in accordance with paragraph
25 (6)(B)(iii)(II).”.

1 (3) IRC.—Section 9812(a) of the Internal Rev-
2 enue Code of 1986 is amended by adding at the end
3 the following:

4 “(6) COMPLIANCE PROGRAM GUIDANCE DOCU-
5 MENT.—

6 “(A) IN GENERAL.—The Secretary, the
7 Secretary of Health and Human Services, and
8 the Secretary of Labor, in consultation with the
9 Inspector General of the Department of Health
10 and Human Services, the Inspector General of
11 the Department of Labor, and the Inspector
12 General of the Department of the Treasury,
13 shall issue a compliance program guidance doc-
14 ument to help improve compliance with this sec-
15 tion, section 2726 of the Public Health Service
16 Act, and section 712 of the Employee Retirement
17 Income Security Act of 1974, as applica-
18 ble. In carrying out this paragraph, the Secre-
19 taries may take into consideration the 2016
20 publication of the Department of Health and
21 Human Services and the Department of Labor,
22 entitled ‘Warning Signs - Plan or Policy Non-
23 Quantitative Treatment Limitations (NQTLs)
24 that Require Additional Analysis to Determine
25 Mental Health Parity Compliance’.

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1 “(B) EXAMPLES ILLUSTRATING COMPLI-
2 ANCE AND NONCOMPLIANCE.—

3 “(i) IN GENERAL.—The compliance
4 program guidance document required
5 under this paragraph shall provide illus-
6 trative, de-identified examples (that do not
7 disclose any protected health information
8 or individually identifiable information) of
9 previous findings of compliance and non-
10 compliance with this section, section 2726
11 of the Public Health Service Act, or sec-
12 tion 712 of the Employee Retirement In-
13 come Security Act of 1974, as applicable,
14 based on investigations of violations of
15 such sections, including—

16 “(I) examples illustrating re-
17 quirements for information disclosures
18 and nonquantitative treatment limita-
19 tions; and

20 “(II) descriptions of the viola-
21 tions uncovered during the course of
22 such investigations.

23 “(ii) NONQUANTITATIVE TREATMENT
24 LIMITATIONS.—To the extent that any ex-
25 ample described in clause (i) involves a

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1 finding of compliance or noncompliance
2 with regard to any requirement for non-
3 quantitative treatment limitations, the ex-
4 ample shall provide sufficient detail to fully
5 explain such finding, including a full de-
6 scription of the criteria involved for ap-
7 proving medical and surgical benefits and
8 the criteria involved for approving mental
9 health and substance use disorder benefits.

10 “(iii) ACCESS TO ADDITIONAL INFOR-
11 MATION REGARDING COMPLIANCE.—In de-
12 veloping and issuing the compliance pro-
13 gram guidance document required under
14 this paragraph, the Secretaries specified in
15 subparagraph (A)—

16 “(I) shall enter into interagency
17 agreements with the Inspector Gen-
18 eral of the Department of Health and
19 Human Services, the Inspector Gen-
20 eral of the Department of Labor, and
21 the Inspector General of the Depart-
22 ment of the Treasury to share find-
23 ings of compliance and noncompliance
24 with this section, section 2726 of the
25 Public Health Service Act, or section

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1 712 of the Employee Retirement In-
2 come Security Act of 1974, as appli-
3 cable; and

4 “(II) shall seek to enter into an
5 agreement with a State to share infor-
6 mation on findings of compliance and
7 noncompliance with this section, sec-
8 tion 2726 of the Public Health Serv-
9 ice Act, or section 712 of the Em-
10 ployee Retirement Income Security
11 Act of 1974, as applicable.

12 “(C) RECOMMENDATIONS.—The compli-
13 ance program guidance document shall include
14 recommendations to advance compliance with
15 this section, section 2726 of the Public Health
16 Service Act, or section 712 of the Employee Re-
17 tirement Income Security Act of 1974, as appli-
18 cable, and encourage the development and use
19 of internal controls to monitor adherence to ap-
20 plicable statutes, regulations, and program re-
21 quirements. Such internal controls may include
22 illustrative examples of nonquantitative treat-
23 ment limitations on mental health and sub-
24 stance use disorder benefits, which may fail to
25 comply with this section, section 2726 of the

1 Public Health Service Act, or section 712 of the
2 Employee Retirement Income Security Act of
3 1974, as applicable, in relation to nonquantita-
4 tive treatment limitations on medical and sur-
5 gical benefits.

6 “(D) UPDATING THE COMPLIANCE PRO-
7 GRAM GUIDANCE DOCUMENT.—The Secretary,
8 the Secretary of Health and Human Services,
9 and the Secretary of Labor, in consultation
10 with the Inspector General of the Department
11 of Health and Human Services, the Inspector
12 General of the Department of Labor, and the
13 Inspector General of the Department of the
14 Treasury, shall update the compliance program
15 guidance document every 2 years to include il-
16 lustrative, de-identified examples (that do not
17 disclose any protected health information or in-
18 dividually identifiable information) of previous
19 findings of compliance and noncompliance with
20 this section, section 2726 of the Public Health
21 Service Act, or section 712 of the Employee Re-
22 tirement Income Security Act of 1974, as appli-
23 cable.

24 “(7) ADDITIONAL GUIDANCE.—

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1 “(A) IN GENERAL.—The Secretary, the
2 Secretary of Health and Human Services, and
3 the Secretary of Labor shall issue guidance to
4 group health plans to assist such plans in satis-
5 fying the requirements of this section, section
6 2726 of the Public Health Service Act, or sec-
7 tion 712 of the Employee Retirement Income
8 Security Act of 1974, as applicable.

9 “(B) DISCLOSURE.—

10 “(i) GUIDANCE FOR PLANS.—The
11 guidance issued under this paragraph shall
12 include clarifying information and illus-
13 trative examples of methods that group
14 health plans may use for disclosing infor-
15 mation to ensure compliance with the re-
16 quirements under this section, section
17 2726 of the Public Health Service Act, or
18 section 712 of the Employee Retirement
19 Income Security Act of 1974, as applica-
20 ble, (and any regulations promulgated pur-
21 suant to such sections, as applicable).

22 “(ii) DOCUMENTS FOR PARTICIPANTS,
23 BENEFICIARIES, CONTRACTING PROVIDERS,
24 OR AUTHORIZED REPRESENTATIVES.—The
25 guidance issued under this paragraph shall

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1 include clarifying information and illus-
2 trative examples of methods that group
3 health plans may use to provide any partic-
4 ipant, beneficiary, contracting provider, or
5 authorized representative, as applicable,
6 with documents containing information
7 that the health plans are required to dis-
8 close to participants, beneficiaries, con-
9 tracting providers, or authorized represent-
10 atives to ensure compliance with this sec-
11 tion, section 2726 of the Public Health
12 Service Act, or section 712 of the Em-
13 ployee Retirement Income Security Act of
14 1974, as applicable, compliance with any
15 regulation issued pursuant to such respec-
16 tive section, or compliance with any other
17 applicable law or regulation. Such guidance
18 shall include information that is compara-
19 tive in nature with respect to—

20 “(I) nonquantitative treatment
21 limitations for both medical and sur-
22 gical benefits and mental health and
23 substance use disorder benefits;

24 “(II) the processes, strategies,
25 evidentiary standards, and other fac-

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1 tors used to apply the limitations de-
2 scribed in subclause (I); and

3 “**(III)** the application of the limi-
4 tations described in subclause (I) to
5 ensure that such limitations are ap-
6 plied in parity with respect to both
7 medical and surgical benefits and
8 mental health and substance use dis-
9 order benefits.

10 “**(C) NONQUANTITATIVE TREATMENT LIM-**
11 **ITATIONS.**—The guidance issued under this
12 paragraph shall include clarifying information
13 and illustrative examples of methods, processes,
14 strategies, evidentiary standards, and other fac-
15 tors that group health plans may use regarding
16 the development and application of non-
17 quantitative treatment limitations to ensure
18 compliance with this section, section 2726 of
19 the Public Health Service Act, or section 712 of
20 the Employee Retirement Income Security Act
21 of 1974, as applicable, (and any regulations
22 promulgated pursuant to such respective sec-
23 tion), including—

24 “**(i)** examples of methods of deter-
25 mining appropriate types of nonquantita-

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1 tive treatment limitations with respect to
2 both medical and surgical benefits and
3 mental health and substance use disorder
4 benefits, including nonquantitative treat-
5 ment limitations pertaining to—

6 “(I) medical management stand-
7 ards based on medical necessity or ap-
8 propriateness, or whether a treatment
9 is experimental or investigative;

10 “(II) limitations with respect to
11 prescription drug formulary design;
12 and

13 “(III) use of fail-first or step
14 therapy protocols;

15 “(ii) examples of methods of deter-
16 mining—

17 “(I) network admission standards
18 (such as credentialing); and

19 “(II) factors used in provider re-
20 imbursement methodologies (such as
21 service type, geographic market, de-
22 mand for services, and provider sup-
23 ply, practice size, training, experience,
24 and licensure) as such factors apply to
25 network adequacy;

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1 “(iii) examples of sources of informa-
2 tion that may serve as evidentiary stand-
3 ards for the purposes of making deter-
4 minations regarding the development and
5 application of nonquantitative treatment
6 limitations;

7 “(iv) examples of specific factors, and
8 the evidentiary standards used to evaluate
9 such factors, used by such plans in per-
10 forming a nonquantitative treatment limi-
11 tation analysis;

12 “(v) examples of how specific evi-
13 dentiary standards may be used to deter-
14 mine whether treatments are considered
15 experimental or investigative;

16 “(vi) examples of how specific evi-
17 dentiary standards may be applied to each
18 service category or classification of bene-
19 fits;

20 “(vii) examples of methods of reach-
21 ing appropriate coverage determinations
22 for new mental health or substance use
23 disorder treatments, such as evidence-
24 based early intervention programs for indi-

1 viduals with a serious mental illness and
2 types of medical management techniques;

3 “(viii) examples of methods of reach-
4 ing appropriate coverage determinations
5 for which there is an indirect relationship
6 between the covered mental health or sub-
7 stance use disorder benefit and a tradi-
8 tional covered medical and surgical benefit,
9 such as residential treatment or hos-
10 pitalizations involving voluntary or involun-
11 tary commitment; and

12 “(ix) additional illustrative examples
13 of methods, processes, strategies, evi-
14 dentiary standards, and other factors for
15 which the Secretary determines that addi-
16 tional guidance is necessary to improve
17 compliance with this section, section 2726
18 of the Public Health Service Act, or sec-
19 tion 712 of the Employee Retirement In-
20 come Security Act of 1974, as applicable.

21 “(D) PUBLIC COMMENT.—Prior to issuing
22 any final guidance under this paragraph, the
23 Secretary shall provide a public comment period
24 of not less than 60 days during which any

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1 member of the public may provide comments on
2 a draft of the guidance.

3 “(8) COMPLIANCE REQUIREMENTS.—

4 “(A) NONQUANTITATIVE TREATMENT LIM-
5 ITATION (NQTL) REQUIREMENTS.—In the case
6 of a group health plan that provides both med-
7 ical and surgical benefits and mental health or
8 substance use disorder benefits and that im-
9 poses nonquantitative treatment limitations (re-
10 ferred to in this section as ‘NQTLs’) on mental
11 health or substance use disorder benefits, such
12 plan shall perform and document comparative
13 analyses of the design and application of
14 NQTLs and, beginning 45 days after the date
15 of enactment of the Consolidated Appropria-
16 tions Act, 2021, make available to the Sec-
17 retary, upon request, the comparative analyses
18 and the following information:

19 “(i) The specific plan terms or other
20 relevant terms regarding the NQTLs and a
21 description of all mental health or sub-
22 stance use disorder and medical or surgical
23 benefits to which each such term applies in
24 each respective benefits classification.

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1 “(ii) The factors used to determine
2 that the NQTLs will apply to mental
3 health or substance use disorder benefits
4 and medical or surgical benefits.

5 “(iii) The evidentiary standards used
6 for the factors identified in clause (ii),
7 when applicable, provided that every factor
8 shall be defined, and any other source or
9 evidence relied upon to design and apply
10 the NQTLs to mental health or substance
11 use disorder benefits and medical or sur-
12 gical benefits.

13 “(iv) The comparative analyses dem-
14 onstrating that the processes, strategies,
15 evidentiary standards, and other factors
16 used to apply the NQTLs to mental health
17 or substance use disorder benefits, as writ-
18 ten and in operation, are comparable to,
19 and are applied no more stringently than,
20 the processes, strategies, evidentiary stand-
21 ards, and other factors used to apply the
22 NQTLs to medical or surgical benefits in
23 the benefits classification.

24 “(v) A disclosure of the specific find-
25 ings and conclusions reached by the group

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1 health plan, including any results of the
2 analyses described in this subparagraph
3 that indicate that the plan is or is not in
4 compliance with this section.

5 “(B) SECRETARY REQUEST PROCESS.—

6 “(i) SUBMISSION UPON REQUEST.—

7 The Secretary shall request that a group
8 health plan submit the comparative anal-
9 yses described in subparagraph (A) for
10 plans that involve potential violations of
11 this section or complaints regarding non-
12 compliance with this section that concern
13 NQTLs and any other instances in which
14 the Secretary determines appropriate. The
15 Secretary shall request not fewer than 20
16 such analyses per year.

17 “(ii) ADDITIONAL INFORMATION.—In
18 instances in which the Secretary has con-
19 cluded that the group health plan has not
20 submitted sufficient information for the
21 Secretary to review the comparative anal-
22 yses described in subparagraph (A), as re-
23 quested under clause (i), the Secretary
24 shall specify to the plan the information
25 the plan must submit to be responsive to

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1 the request under clause (i) for the Sec-
2 retary to review the comparative analyses
3 described in subparagraph (A) for compli-
4 ance with this section. Nothing in this
5 paragraph shall require the Secretary to
6 conclude that a group health plan is in
7 compliance with this section solely based
8 upon the inspection of the comparative
9 analyses described in subparagraph (A), as
10 requested under clause (i).

11 “(iii) REQUIRED ACTION.—

12 “(I) IN GENERAL.—In instances
13 in which the Secretary has reviewed
14 the comparative analyses described in
15 subparagraph (A), as requested under
16 clause (i), and determined that the
17 group health plan is not in compliance
18 with this section, the plan—

19 “(aa) shall specify to the
20 Secretary the actions the plan
21 will take to be in compliance with
22 this section and provide to the
23 Secretary additional comparative
24 analyses described in subpara-
25 graph (A) that demonstrate com-

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1 pliance with this section not later
2 than 45 days after the initial de-
3 termination by the Secretary that
4 the plan is not in compliance;
5 and

6 “*(bb)* following the 45-day
7 corrective action period under
8 item *(aa)*, if the Secretary makes
9 a final determination that the
10 plan still is not in compliance
11 with this section, not later than 7
12 days after such determination,
13 shall notify all individuals en-
14 rolled in the plan that the plan
15 has been determined to be not in
16 compliance with this section.

17 “(II) EXEMPTION FROM DISCLO-
18 SURE.—Documents or communica-
19 tions produced in connection with the
20 Secretary’s recommendations to a
21 group health plan shall not be subject
22 to disclosure pursuant to section 552
23 of title 5, United States Code.

24 “(iv) REPORT.—Not later than 1 year
25 after the date of enactment of this para-

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1 graph, and not later than October 1 of
2 each year thereafter, the Secretary shall
3 submit to Congress, and make publicly
4 available, a report that contains—

5 “(I) a summary of the compara-
6 tive analyses requested under clause
7 (i), including the identity of each
8 group plan that is determined to be
9 not in compliance after the final de-
10 termination by the Secretary de-
11 scribed in clause (iii)(I)(bb);

12 “(II) the Secretary’s conclusions
13 as to whether each group health plan
14 submitted sufficient information for
15 the Secretary to review the compara-
16 tive analyses requested under clause
17 (i) for compliance with this section;

18 “(III) for each group health plan
19 that did submit sufficient information
20 for the Secretary to review the com-
21 parative analyses requested under
22 clause (i), the Secretary’s conclusions
23 as to whether and why the plan is in
24 compliance with the disclosure re-
25 quirements under this section;

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1 “(IV) the Secretary’s specifica-
2 tions described in clause (ii) for each
3 group health plan that the Secretary
4 determined did not submit sufficient
5 information for the Secretary to re-
6 view the comparative analyses re-
7 quested under clause (i) for compli-
8 ance with this section; and

9 “(V) the Secretary’s specifica-
10 tions described in clause (iii) of the
11 actions each group health plan that
12 the Secretary determined is not in
13 compliance with this section must
14 take to be in compliance with this sec-
15 tion, including the reason why the
16 Secretary determined the plan is not
17 in compliance.

18 “(C) COMPLIANCE PROGRAM GUIDANCE
19 DOCUMENT UPDATE PROCESS.—

20 “(i) IN GENERAL.—The Secretary
21 shall include instances of noncompliance
22 that the Secretary discovers upon review-
23 ing the comparative analyses requested
24 under subparagraph (B)(i) in the compli-
25 ance program guidance document de-

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1 scribed in paragraph (6), as it is updated
2 every 2 years, except that such instances
3 shall not disclose any protected health in-
4 formation or individually identifiable infor-
5 mation.

6 “(ii) GUIDANCE AND REGULATIONS.—
7 Not later than 18 months after the date of
8 enactment of this paragraph, the Secretary
9 shall finalize any draft or interim guidance
10 and regulations relating to mental health
11 parity under this section. Such draft guid-
12 ance shall include guidance to clarify the
13 process and timeline for current and poten-
14 tial participants and beneficiaries (and au-
15 thorized representatives and health care
16 providers of such participants and bene-
17 ficiaries) with respect to plans to file com-
18 plaints of such plans being in violation of
19 this section, including guidance, by plan
20 type, on the relevant State, regional, or na-
21 tional office with which such complaints
22 should be filed.

23 “(iii) STATE.—The Secretary shall
24 share information on findings of compli-
25 ance and noncompliance discovered upon

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1 reviewing the comparative analyses re-
2 requested under subparagraph (B)(i) shall be
3 shared with the State where the group
4 health plan is located, in accordance with
5 paragraph (6)(B)(iii)(II).”.

6 (4) MEDICAID AND CHIP COMPLIANCE.—

7 (A) MEDICAID MANAGED CARE ORGANIZA-
8 TIONS.—Section 1932(b)(8) of the Social Secu-
9 rity Act (42 U.S.C. 1396u–2(b)(8)) is amended
10 by adding at the end the following new sen-
11 tence: “In applying the previous sentence with
12 respect to requirements under paragraph (8) of
13 section 2726(a) of the Public Health Service
14 Act, a Medicaid managed care organization (or
15 a prepaid inpatient health plan (as defined by
16 the Secretary) or prepaid ambulatory health
17 plan (as defined by the Secretary) that offers
18 services to enrollees of a Medicaid managed
19 care organization) shall be treated as in compli-
20 ance with such requirements if the Medicaid
21 managed care organization (or prepaid inpa-
22 tient health plan or prepaid ambulatory health
23 plan) is in compliance with subpart K of part
24 438 of title 42, Code of Federal Regulations,

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1 and section 438.3(n) of such title, or any suc-
2 cessor regulation.”.

3 (B) OTHER BENCHMARK BENEFIT PACK-
4 AGES OR BENCHMARK EQUIVALENT COV-
5 ERAGE.—Section 1937(b)(6)(A) of such Act (42
6 U.S.C. 1396u–7(b)(6)(A)) is amended—

7 (i) by striking “section 2705(a)” and
8 inserting “section 2726(a)”; and

9 (ii) by adding at the end the following
10 new sentence: “In applying the previous
11 sentence with respect to requirements
12 under paragraph (8) of section 2726(a) of
13 the Public Health Service Act, a bench-
14 mark benefit package or benchmark equiv-
15 alent coverage described in such sentence
16 shall be treated as in compliance with such
17 requirements if the State plan under this
18 title or the benchmark benefit package or
19 benefit equivalent coverage, as applicable,
20 is in compliance with subpart C of part
21 440 of title 42, Code of Federal Regula-
22 tions, or any successor regulation.”.

23 (C) STATE CHILD HEALTH PLANS.—Sec-
24 tion 2103(c)(7)(A) of the Social Security Act
25 (42 U.S.C. 1397cc(c)(7)(A)) is amended—

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1 (i) by striking “section 2705(a)” and
2 inserting “section 2726(a)”; and

3 (ii) by adding at the end the following
4 new sentence: “In applying the previous
5 sentence with respect to requirements
6 under paragraph (8) of section 2726(a) of
7 the Public Health Service Act, a State
8 child health plan described in such sen-
9 tence shall be treated as in compliance
10 with such requirements if the State child
11 health plan is in compliance with section
12 457.496 of title 42, Code of Federal Regu-
13 lations, or any successor regulation.”.

14 (b) GUIDANCE.—The Secretary of Health and
15 Human Services, jointly with the Secretary of Labor and
16 the Secretary of the Treasury, shall issue guidance to
17 carry out the amendments made by paragraphs (1), (2),
18 and (3) of subsection (a).

19 **SEC. 204. REPORTING ON PHARMACY BENEFITS AND DRUG**
20 **COSTS.**

21 (a) PHSA.—Part D of title XXVII of the Public
22 Health Service Act (42 U.S.C. 300gg et seq.), as amended
23 by section 201, is further amended by adding at the end
24 the following:

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1 **“SEC. 2799A-10. REPORTING ON PHARMACY BENEFITS AND**
2 **DRUG COSTS.**

3 “(a) IN GENERAL.—Not later than 1 year after the
4 date of enactment of the Consolidated Appropriations Act,
5 2021, and not later than June 1 of each year thereafter,
6 a group health plan or health insurance issuer offering
7 group or individual health insurance coverage (except for
8 a church plan) shall submit to the Secretary, the Secretary
9 of Labor, and the Secretary of the Treasury the following
10 information with respect to the health plan or coverage
11 in the previous plan year:

12 “(1) The beginning and end dates of the plan
13 year.

14 “(2) The number of enrollees.

15 “(3) Each State in which the plan or coverage
16 is offered.

17 “(4) The 50 brand prescription drugs most fre-
18 quently dispensed by pharmacies for claims paid by
19 the plan or coverage, and the total number of paid
20 claims for each such drug.

21 “(5) The 50 most costly prescription drugs with
22 respect to the plan or coverage by total annual
23 spending, and the annual amount spent by the plan
24 or coverage for each such drug.

25 “(6) The 50 prescription drugs with the great-
26 est increase in plan expenditures over the plan year

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1 preceding the plan year that is the subject of the re-
2 port, and, for each such drug, the change in
3 amounts expended by the plan or coverage in each
4 such plan year.

5 “(7) Total spending on health care services by
6 such group health plan or health insurance coverage,
7 broken down by—

8 “(A) the type of costs, including—

9 “(i) hospital costs;

10 “(ii) health care provider and clinical
11 service costs, for primary care and spe-
12 cialty care separately;

13 “(iii) costs for prescription drugs; and

14 “(iv) other medical costs, including
15 wellness services; and

16 “(B) spending on prescription drugs by—

17 “(i) the health plan or coverage; and

18 “(ii) the enrollees.

19 “(8) The average monthly premium—

20 “(A) paid by employers on behalf of enroll-
21 ees, as applicable; and

22 “(B) paid by enrollees.

23 “(9) Any impact on premiums by rebates, fees,
24 and any other remuneration paid by drug manufac-
25 turers to the plan or coverage or its administrators

1 or service providers, with respect to prescription
2 drugs prescribed to enrollees in the plan or coverage,
3 including—

4 “(A) the amounts so paid for each thera-
5 peutic class of drugs; and

6 “(B) the amounts so paid for each of the
7 25 drugs that yielded the highest amount of re-
8 bates and other remuneration under the plan or
9 coverage from drug manufacturers during the
10 plan year.

11 “(10) Any reduction in premiums and out-of-
12 pocket costs associated with rebates, fees, or other
13 remuneration described in paragraph (9).

14 “(b) REPORT.—Not later than 18 months after the
15 date on which the first report is required under subsection
16 (a) and biannually thereafter, the Secretary, acting
17 through the Assistant Secretary of Planning and Evalua-
18 tion and in coordination with the Inspector General of the
19 Department of Health and Human Services, shall make
20 available on the internet website of the Department of
21 Health and Human Services a report on prescription drug
22 reimbursements under group health plans and group and
23 individual health insurance coverage, prescription drug
24 pricing trends, and the role of prescription drug costs in
25 contributing to premium increases or decreases under such

1 plans or coverage, aggregated in such a way as no drug
2 or plan specific information will be made public.

3 “(c) PRIVACY PROTECTIONS.—No confidential or
4 trade secret information submitted to the Secretary under
5 subsection (a) shall be included in the report under sub-
6 section (b).”.

7 (b) ERISA.—Subpart B of part 7 of subtitle B of
8 title I of the Employee Retirement Income Security Act
9 of 1974 (29 U.S.C. 1185 et seq.), as amended by section
10 201, is further amended by adding at the end the fol-
11 lowing:

12 **“SEC. 725. REPORTING ON PHARMACY BENEFITS AND**
13 **DRUG COSTS.**

14 “(a) IN GENERAL.—Not later than 1 year after the
15 date of enactment of the Consolidated Appropriations Act,
16 2021, and not later than June 1 of each year thereafter,
17 a group health plan (or health insurance coverage offered
18 in connection with such a plan) shall submit to the Sec-
19 retary, the Secretary of Health and Human Services, and
20 the Secretary of the Treasury the following information
21 with respect to the health plan or coverage in the previous
22 plan year:

23 “(1) The beginning and end dates of the plan
24 year.

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1 “(2) The number of participants and bene-
2 ficiaries.

3 “(3) Each State in which the plan or coverage
4 is offered.

5 “(4) The 50 brand prescription drugs most fre-
6 quently dispensed by pharmacies for claims paid by
7 the plan or coverage, and the total number of paid
8 claims for each such drug.

9 “(5) The 50 most costly prescription drugs with
10 respect to the plan or coverage by total annual
11 spending, and the annual amount spent by the plan
12 or coverage for each such drug.

13 “(6) The 50 prescription drugs with the great-
14 est increase in plan expenditures over the plan year
15 preceding the plan year that is the subject of the re-
16 port, and, for each such drug, the change in
17 amounts expended by the plan or coverage in each
18 such plan year.

19 “(7) Total spending on health care services by
20 such group health plan or health insurance coverage,
21 broken down by—

22 “(A) the type of costs, including—

23 “(i) hospital costs;

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1 “(ii) health care provider and clinical
2 service costs, for primary care and spe-
3 cialty care separately;

4 “(iii) costs for prescription drugs; and
5 “(iv) other medical costs, including
6 wellness services; and

7 “(B) spending on prescription drugs by—

8 “(i) the health plan or coverage; and

9 “(ii) the participants and bene-
10 ficiaries.

11 “(8) The average monthly premium—

12 “(A) paid by employers on behalf of par-
13 ticipants and beneficiaries, as applicable; and

14 “(B) paid by participants and bene-
15 ficiaries.

16 “(9) Any impact on premiums by rebates, fees,
17 and any other remuneration paid by drug manufac-
18 turers to the plan or coverage or its administrators
19 or service providers, with respect to prescription
20 drugs prescribed to participants or beneficiaries in
21 the plan or coverage, including—

22 “(A) the amounts so paid for each thera-
23 peutic class of drugs; and

24 “(B) the amounts so paid for each of the
25 25 drugs that yielded the highest amount of re-

1 bates and other remuneration under the plan or
2 coverage from drug manufacturers during the
3 plan year.

4 “(10) Any reduction in premiums and out-of-
5 pocket costs associated with rebates, fees, or other
6 remuneration described in paragraph (9).

7 “(b) REPORT.—Not later than 18 months after the
8 date on which the first report is required under subsection
9 (a) and biannually thereafter, the Secretary, acting in co-
10 ordination with the Inspector General of the Department
11 of Labor, shall make available on the internet website of
12 the Department of Labor a report on prescription drug
13 reimbursements under group health plans (or health in-
14 surance coverage offered in connection with such a plan),
15 prescription drug pricing trends, and the role of prescrip-
16 tion drug costs in contributing to premium increases or
17 decreases under such plans or coverage, aggregated in
18 such a way as no drug or plan specific information will
19 be made public.

20 “(c) PRIVACY PROTECTIONS.—No confidential or
21 trade secret information submitted to the Secretary under
22 subsection (a) shall be included in the report under sub-
23 section (b).”.

1 (c) IRC.—Subchapter B of chapter 100 of the Inter-
2 nal Revenue Code of 1986, as amended by section 201,
3 is further amended by adding at the end the following:

4 **“SEC. 9825. REPORTING ON PHARMACY BENEFITS AND**
5 **DRUG COSTS.**

6 “(a) IN GENERAL.—Not later than 1 year after the
7 date of enactment of the Consolidated Appropriations Act,
8 2021, and not later than June 1 of each year thereafter,
9 a group health plan shall submit to the Secretary, the Sec-
10 retary of Health and Human Services, and the Secretary
11 of Labor the following information with respect to the
12 health plan in the previous plan year:

13 “(1) The beginning and end dates of the plan
14 year.

15 “(2) The number of participants and bene-
16 ficiaries.

17 “(3) Each State in which the plan is offered.

18 “(4) The 50 brand prescription drugs most fre-
19 quently dispensed by pharmacies for claims paid by
20 the plan, and the total number of paid claims for
21 each such drug.

22 “(5) The 50 most costly prescription drugs with
23 respect to the plan by total annual spending, and the
24 annual amount spent by the plan for each such
25 drug.

1 “(6) The 50 prescription drugs with the great-
2 est increase in plan expenditures over the plan year
3 preceding the plan year that is the subject of the re-
4 port, and, for each such drug, the change in
5 amounts expended by the plan in each such plan
6 year.

7 “(7) Total spending on health care services by
8 such group health plan, broken down by—

9 “(A) the type of costs, including—

10 “(i) hospital costs;

11 “(ii) health care provider and clinical
12 service costs, for primary care and spe-
13 cialty care separately;

14 “(iii) costs for prescription drugs; and

15 “(iv) other medical costs, including
16 wellness services; and

17 “(B) spending on prescription drugs by—

18 “(i) the health plan; and

19 “(ii) the participants and bene-
20 ficiaries.

21 “(8) The average monthly premium—

22 “(A) paid by employers on behalf of par-
23 ticipants and beneficiaries, as applicable; and

24 “(B) paid by participants and bene-
25 ficiaries.

1 “(9) Any impact on premiums by rebates, fees,
2 and any other remuneration paid by drug manufac-
3 turers to the plan or its administrators or service
4 providers, with respect to prescription drugs pre-
5 scribed to participants or beneficiaries in the plan,
6 including—

7 “(A) the amounts so paid for each thera-
8 peutic class of drugs; and

9 “(B) the amounts so paid for each of the
10 25 drugs that yielded the highest amount of re-
11 bates and other remuneration under the plan
12 from drug manufacturers during the plan year.

13 “(10) Any reduction in premiums and out-of-
14 pocket costs associated with rebates, fees, or other
15 remuneration described in paragraph (9).

16 “(b) REPORT.—Not later than 18 months after the
17 date on which the first report is required under subsection
18 (a) and biannually thereafter, the Secretary, acting in co-
19 ordination with the Inspector General of the Department
20 of the Treasury, shall make available on the internet
21 website of the Department of the Treasury a report on
22 prescription drug reimbursements under group health
23 plans, prescription drug pricing trends, and the role of
24 prescription drug costs in contributing to premium in-
25 creases or decreases under such plans, aggregated in such

1 a way as no drug or plan specific information will be made
2 public.

3 “(c) PRIVACY PROTECTIONS.—No confidential or
4 trade secret information submitted to the Secretary under
5 subsection (a) shall be included in the report under sub-
6 section (b).”.

7 (d) CLERICAL AMENDMENTS.—

8 (1) ERISA.—The table of contents in section 1
9 of the Employee Retirement Income Security Act of
10 1974 (29 U.S.C. 1001 et seq.), as amended by sec-
11 tion 201, is further amended by inserting after the
12 item relating to section 724 the following new item:

“Sec. 725. Reporting on pharmacy benefits and drug costs.”.

13 (2) IRC.—The table of sections for subchapter
14 B of chapter 100 of the Internal Revenue Code of
15 1986, as amended by section 201, is further amend-
16 ed by adding at the end the following new item:

“Sec. 9825. Reporting on pharmacy benefits and drug costs.”.

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1 **TITLE III—PUBLIC HEALTH**
2 **PROVISIONS**
3 **Subtitle A—Extenders Provisions**

4 **SEC. 301. EXTENSION FOR COMMUNITY HEALTH CENTERS,**
5 **THE NATIONAL HEALTH SERVICE CORPS,**
6 **AND TEACHING HEALTH CENTERS THAT OP-**
7 **ERATE GME PROGRAMS.**

8 (a) COMMUNITY HEALTH CENTERS.—Section
9 10503(b)(1)(F) of the Patient Protection and Affordable
10 Care Act (42 U.S.C. 254b–2(b)(1)(F)) is amended by
11 striking “, \$4,000,000,000 for fiscal year 2019,
12 \$4,000,000,000 for fiscal year 2020, and \$865,753,425
13 for the period beginning on October 1, 2020, and ending
14 on December 18, 2020” and inserting “and
15 \$4,000,000,000 for each of fiscal years 2019 through
16 2023”.

17 (b) NATIONAL HEALTH SERVICE CORPS.—Section
18 10503(b)(2)(H) of the Patient Protection and Affordable
19 Care Act (42 U.S.C. 254b–2(b)(2)(H)) is amended by
20 striking “ \$67,095,890 for the period beginning on Octo-
21 ber 1, 2020, and ending on December 18, 2020” and in-
22 serting “ \$310,000,000 for each of fiscal years 2021
23 through 2023”.

24 (c) TEACHING HEALTH CENTERS THAT OPERATE
25 GRADUATE MEDICAL EDUCATION PROGRAMS.—Section

1 340H(g)(1) of the Public Health Service Act (42 U.S.C.
2 256h(g)(1)) is amended—

3 (1) by inserting “and” after “2017,”; and

4 (2) by striking “fiscal year 2020, and
5 \$27,379,452 for the period beginning on October 1,
6 2020, and ending on December 18, 2020” and in-
7 serting “2023”.

8 (d) APPLICATION OF PROVISIONS.—Amounts appro-
9 priated pursuant to the amendments made by this section
10 for fiscal years 2021 through 2023 shall be subject to the
11 requirements contained in Public Law 116–94 for funds
12 for programs authorized under sections 330 through 340
13 of the Public Health Service Act.

14 (e) CONFORMING AMENDMENTS.—Paragraph (4) of
15 section 3014(h) of title 18, United States Code, as amend-
16 ed by section 1201(e) of the Further Continuing Appro-
17 priations Act, 2021, and Other Extensions Act, is amend-
18 ed by striking “and section 1201(d) of the Further Con-
19 tinuing Appropriations Act, 2021, and Other Extensions
20 Act” and inserting “, section 1201(d) of the Further Con-
21 tinuing Appropriations Act, 2021, and Other Extensions
22 Act, and section 301(d) of division BB of the Consolidated
23 Appropriations Act, 2021.”.

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1 **SEC. 302. DIABETES PROGRAMS.**

2 (a) TYPE I.—Section 330B(b)(2)(D) of the Public
3 Health Service Act (42 U.S.C. 254e–2(b)(2)(D)) is
4 amended by striking “2020, and \$32,465,753 for the pe-
5 riod beginning on October 1, 2020, and ending on Decem-
6 ber 18, 2020” and inserting “2023”.

7 (b) INDIANS.—Section 330C(c)(2)(D) of the Public
8 Health Service Act (42 U.S.C. 254e–3(c)(2)(D)) is
9 amended by striking “2020, and \$32,465,753 for the pe-
10 riod beginning on October 1, 2020, and ending on Decem-
11 ber 18, 2020” and inserting “2023”.

12 **Subtitle B—Strengthening Public**
13 **Health**

14 **SEC. 311. IMPROVING AWARENESS OF DISEASE PREVEN-**
15 **TION.**

16 (a) IN GENERAL.—The Public Health Service Act is
17 amended by striking section 313 of such Act (42 U.S.C.
18 245) and inserting the following:

19 **“SEC. 313. PUBLIC AWARENESS CAMPAIGN ON THE IMPOR-**
20 **TANCE OF VACCINATIONS.**

21 “(a) IN GENERAL.—The Secretary, acting through
22 the Director of the Centers for Disease Control and Pre-
23 vention and in coordination with other offices and agen-
24 cies, as appropriate, shall award competitive grants or
25 contracts to one or more public or private entities to carry
26 out a national, evidence-based campaign to increase

1 awareness and knowledge of the safety and effectiveness
2 of vaccines for the prevention and control of diseases, com-
3 bat misinformation about vaccines, and disseminate sci-
4 entific and evidence-based vaccine-related information,
5 with the goal of increasing rates of vaccination across all
6 ages, as applicable, particularly in communities with low
7 rates of vaccination, to reduce and eliminate vaccine-pre-
8 ventable diseases.

9 “(b) CONSULTATION.—In carrying out the campaign
10 under this section, the Secretary shall consult with appro-
11 priate public health and medical experts, including the Na-
12 tional Academy of Medicine and medical and public health
13 associations and nonprofit organizations, in the develop-
14 ment, implementation, and evaluation of the evidence-
15 based public awareness campaign.

16 “(c) REQUIREMENTS.—The campaign under this sec-
17 tion shall—

18 “(1) be a nationwide, evidence-based media and
19 public engagement initiative;

20 “(2) include the development of resources for
21 communities with low rates of vaccination, including
22 culturally and linguistically appropriate resources, as
23 applicable;

24 “(3) include the dissemination of vaccine infor-
25 mation and communication resources to public

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1 health departments, health care providers, and
2 health care facilities, including such providers and
3 facilities that provide prenatal and pediatric care;

4 “(4) be complementary to, and coordinated
5 with, any other Federal, State, local, or Tribal ef-
6 forts, as appropriate; and

7 “(5) assess the effectiveness of communication
8 strategies to increase rates of vaccination.

9 “(d) **ADDITIONAL ACTIVITIES.**—The campaign under
10 this section may—

11 “(1) include the use of television, radio, the
12 internet, and other media and telecommunications
13 technologies;

14 “(2) include the use of in-person activities;

15 “(3) be focused to address specific needs of
16 communities and populations with low rates of vac-
17 cination; and

18 “(4) include the dissemination of scientific and
19 evidence-based vaccine-related information, such
20 as—

21 “(A) advancements in evidence-based re-
22 search related to diseases that may be pre-
23 vented by vaccines and vaccine development;

24 “(B) information on vaccinations for indi-
25 viduals and communities, including individuals

1 for whom vaccines are not recommended by the
2 Advisory Committee for Immunization Prac-
3 tices, and the effects of low vaccination rates
4 within a community on such individuals;

5 “(C) information on diseases that may be
6 prevented by vaccines; and

7 “(D) information on vaccine safety and the
8 systems in place to monitor vaccine safety.

9 “(e) EVALUATION.—The Secretary shall—

10 “(1) establish benchmarks and metrics to quan-
11 titatively measure and evaluate the awareness cam-
12 paign under this section;

13 “(2) conduct qualitative assessments regarding
14 the awareness campaign under this section; and

15 “(3) prepare and submit to the Committee on
16 Health, Education, Labor, and Pensions of the Sen-
17 ate and Committee on Energy and Commerce of the
18 House of Representatives an evaluation of the
19 awareness campaign under this section.

20 “(f) SUPPLEMENT NOT SUPPLANT.—Funds appro-
21 priated under this section shall be used to supplement and
22 not supplant other Federal, State, and local public funds
23 provided for activities described in this section.

24 “(g) AUTHORIZATION OF APPROPRIATIONS.—There
25 are authorized to be appropriated to carry out this section

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1 and subsections (k) and (n) of section 317, \$15,000,000
2 for each of fiscal years 2021 through 2025.”.

3 (b) GRANTS TO ADDRESS VACCINE-PREVENTABLE
4 DISEASES.—Section 317 of the Public Health Service Act
5 (42 U.S.C. 247b) is amended—

6 (1) in subsection (k)(1)—

7 (A) in subparagraph (C), by striking “;
8 and” and inserting a semicolon;

9 (B) in subparagraph (D), by striking the
10 period and inserting a semicolon; and

11 (C) by adding at the end the following:

12 “(E) planning, implementation, and evaluation
13 of activities to address vaccine-preventable diseases,
14 including activities to—

15 “(i) identify communities at high risk of
16 outbreaks related to vaccine-preventable dis-
17 eases, including through improved data collec-
18 tion and analysis;

19 “(ii) pilot innovative approaches to improve
20 vaccination rates in communities and among
21 populations with low rates of vaccination;

22 “(iii) reduce barriers to accessing vaccines
23 and evidence-based information about the
24 health effects of vaccines;

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1 “(iv) partner with community organiza-
2 tions and health care providers to develop and
3 deliver evidence-based interventions, including
4 culturally and linguistically appropriate inter-
5 ventions, to increase vaccination rates;

6 “(v) improve delivery of evidence-based
7 vaccine-related information to parents and oth-
8 ers; and

9 “(vi) improve the ability of State, local,
10 Tribal, and territorial public health depart-
11 ments to engage communities at high risk for
12 outbreaks related to vaccine-preventable dis-
13 eases, including, as appropriate, with local edu-
14 cational agencies, as defined in section 8101 of
15 the Elementary and Secondary Education Act
16 of 1965; and

17 “(F) research related to strategies for improv-
18 ing awareness of scientific and evidence-based vac-
19 cine-related information, including for communities
20 with low rates of vaccination, in order to understand
21 barriers to vaccination, improve vaccination rates,
22 and assess the public health outcomes of such strate-
23 gies.”; and

24 (2) by adding at the end the following:

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1 “(n) VACCINATION DATA.—The Secretary, acting
2 through the Director of the Centers for Disease Control
3 and Prevention, shall expand and enhance, and, as appro-
4 priate, establish and improve, programs and conduct ac-
5 tivities to collect, monitor, and analyze vaccination cov-
6 erage data to assess levels of protection from vaccine-pre-
7 ventable diseases, including by assessing factors contrib-
8 uting to underutilization of vaccines and variations of such
9 factors, and identifying communities at high risk of out-
10 breaks associated with vaccine-preventable diseases.”.

11 (c) SUPPLEMENTAL GRANT FUNDS.—Section
12 330(d)(1) of the Public Health Service Act (42 U.S.C.
13 254b) is amended—

14 (1) in subparagraph (F), by striking “and” at
15 the end;

16 (2) in subparagraph (G), by striking the period
17 and inserting “; and”; and

18 (3) by adding at the end the following:

19 “(H) improving access to recommended
20 immunizations.”.

21 (d) UPDATE OF 2015 NVAC REPORT.—The National
22 Vaccine Advisory Committee established under section
23 2105 of the Public Health Service Act (42 U.S.C. 300aa-
24 5) shall, as appropriate, update the report entitled, “As-
25 sessing the State of Vaccine Confidence in the United

1 States: Recommendations from the National Vaccine Advi-
2 sory Committee”, approved by the National Vaccine Advi-
3 sory Committee on June 10, 2015, with respect to factors
4 affecting childhood vaccination.

5 **SEC. 312. GUIDE ON EVIDENCE-BASED STRATEGIES FOR**
6 **PUBLIC HEALTH DEPARTMENT OBESITY PRE-**
7 **VENTION PROGRAMS.**

8 (a) DEVELOPMENT AND DISSEMINATION OF AN EVI-
9 DENCE-BASED STRATEGIES GUIDE.—The Secretary of
10 Health and Human Services (referred to in this section
11 as the “Secretary”), acting through the Director of the
12 Centers for Disease Control and Prevention, not later than
13 2 years after the date of enactment of this Act, may—

14 (1) develop a guide on evidence-based strategies
15 for State, territorial, and local health departments to
16 use to build and maintain effective obesity preven-
17 tion and reduction programs, and, in consultation
18 with Indian Tribes, Tribal organizations, and urban
19 Indian organizations, a guide on such evidence-based
20 strategies with respect to Indian Tribes and Tribal
21 organizations for such Indian Tribes and Tribal or-
22 ganizations to use for such purpose, both of which
23 guides shall—

24 (A) describe an integrated program struc-
25 ture for implementing interventions proven to

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1 be effective in preventing and reducing the inci-
2 dence of obesity; and

3 (B) recommend—

4 (i) optimal resources, including staff-
5 ing and infrastructure, for promoting nu-
6 trition and obesity prevention and reduc-
7 tion; and

8 (ii) strategies for effective obesity pre-
9 vention programs for State, territorial, and
10 local health departments, Indian Tribes,
11 and Tribal organizations, including strate-
12 gies related to—

13 (I) the application of evidence-
14 based and evidence-informed practices
15 to prevent and reduce obesity rates;

16 (II) the development, implemen-
17 tation, and evaluation of obesity pre-
18 vention and reduction strategies for
19 specific communities and populations;

20 (III) demonstrated knowledge of
21 obesity prevention practices that re-
22 duce associated preventable diseases,
23 health conditions, death, and health
24 care costs;

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1 (IV) best practices for the coordi-
2 nation of efforts to prevent and re-
3 duce obesity and related chronic dis-
4 eases;

5 (V) addressing the underlying
6 risk factors and social determinants of
7 health that impact obesity rates; and

8 (VI) interdisciplinary coordina-
9 tion between relevant public health of-
10 ficials specializing in fields such as
11 nutrition, physical activity, epidemi-
12 ology, communications, and policy im-
13 plementation, and collaboration be-
14 tween public health officials, commu-
15 nity-based organizations, and others,
16 as appropriate; and

17 (2) disseminate the guides and current re-
18 search, evidence-based practices, tools, and edu-
19 cational materials related to obesity prevention, con-
20 sistent with the guides, to State, territorial, and
21 local health departments, Indian Tribes, and Tribal
22 organizations.

23 (b) TECHNICAL ASSISTANCE.—The Secretary, acting
24 through the Director of the Centers for Disease Control
25 and Prevention, shall provide technical assistance to State,

1 territorial, and local health departments, Indian Tribes,
2 and Tribal organizations to support such health depart-
3 ments in implementing the guide developed under sub-
4 section (a)(1).

5 (c) INDIAN TRIBES; TRIBAL ORGANIZATIONS; URBAN
6 INDIAN ORGANIZATIONS.—In this section—

7 (1) the terms “Indian Tribe” and “Tribal orga-
8 nization” have the meanings given the terms “In-
9 dian tribe” and “tribal organization”, respectively,
10 in section 4 of the Indian Self-Determination and
11 Education Assistance Act (25 U.S.C. 5304); and

12 (2) the term “urban Indian organization” has
13 the meaning given such term in section 4 of the In-
14 dian Health Care Improvement Act (25 U.S.C.
15 1603).

16 **SEC. 313. EXPANDING CAPACITY FOR HEALTH OUTCOMES.**

17 Title III of the Public Health Service Act is amended
18 by inserting after section 330M (42 U.S.C. 254c-19) the
19 following:

20 **“SEC. 330N. EXPANDING CAPACITY FOR HEALTH OUT-
21 COMES.**

22 “(a) DEFINITIONS.—In this section:

23 “(1) ELIGIBLE ENTITY.—The term ‘eligible en-
24 tity’ means an entity that provides, or supports the
25 provision of, health care services in rural areas, fron-

1 tier areas, health professional shortage areas, or
2 medically underserved areas, or to medically under-
3 served populations or Native Americans, including
4 Indian Tribes, Tribal organizations, and urban In-
5 dian organizations, and which may include entities
6 leading, or capable of leading, a technology-enabled
7 collaborative learning and capacity building model or
8 engaging in technology-enabled collaborative training
9 of participants in such model.

10 “(2) HEALTH PROFESSIONAL SHORTAGE
11 AREA.—The term ‘health professional shortage area’
12 means a health professional shortage area des-
13 ignated under section 332.

14 “(3) INDIAN TRIBE.—The terms ‘Indian Tribe’
15 and ‘Tribal organization’ have the meanings given
16 the terms ‘Indian tribe’ and ‘tribal organization’ in
17 section 4 of the Indian Self-Determination and Edu-
18 cation Assistance Act.

19 “(4) MEDICALLY UNDERSERVED POPU-
20 LATION.—The term ‘medically underserved popu-
21 lation’ has the meaning given the term in section
22 330(b)(3).

23 “(5) NATIVE AMERICANS.—The term ‘Native
24 Americans’ has the meaning given the term in sec-

1 tion 736 and includes Indian Tribes and Tribal or-
2 ganizations.

3 “(6) TECHNOLOGY-ENABLED COLLABORATIVE
4 LEARNING AND CAPACITY BUILDING MODEL.—The
5 term ‘technology-enabled collaborative learning and
6 capacity building model’ means a distance health
7 education model that connects health care profes-
8 sionals, and particularly specialists, with multiple
9 other health care professionals through simultaneous
10 interactive videoconferencing for the purpose of fa-
11 cilitating case-based learning, disseminating best
12 practices, and evaluating outcomes.

13 “(7) URBAN INDIAN ORGANIZATION.—The term
14 ‘urban Indian organization’ has the meaning given
15 the term in section 4 of the Indian Health Care Im-
16 provement Act.

17 “(b) PROGRAM ESTABLISHED.—The Secretary shall,
18 as appropriate, award grants to evaluate, develop, and, as
19 appropriate, expand the use of technology-enabled collabo-
20 rative learning and capacity building models, to improve
21 retention of health care providers and increase access to
22 health care services, such as those to address chronic dis-
23 eases and conditions, infectious diseases, mental health,
24 substance use disorders, prenatal and maternal health, pe-
25 diatric care, pain management, palliative care, and other

1 specialty care in rural areas, frontier areas, health profes-
2 sional shortage areas, or medically underserved areas and
3 for medically underserved populations or Native Ameri-
4 cans.

5 “(c) USE OF FUNDS.—

6 “(1) IN GENERAL.—Grants awarded under sub-
7 section (b) shall be used for—

8 “(A) the development and acquisition of
9 instructional programming, and the training of
10 health care providers and other professionals
11 that provide or assist in the provision of serv-
12 ices through models described in subsection (b),
13 such as training on best practices for data col-
14 lection and leading or participating in such
15 technology-enabled activities consistent with
16 technology-enabled collaborative learning and
17 capacity-building models;

18 “(B) information collection and evaluation
19 activities to study the impact of such models on
20 patient outcomes and health care providers, and
21 to identify best practices for the expansion and
22 use of such models; or

23 “(C) other activities consistent with achiev-
24 ing the objectives of the grants awarded under
25 this section, as determined by the Secretary.

1 “(2) OTHER USES.—In addition to any of the
2 uses under paragraph (1), grants awarded under
3 subsection (b) may be used for—

4 “(A) equipment to support the use and ex-
5 pansion of technology-enabled collaborative
6 learning and capacity building models, including
7 for hardware and software that enables distance
8 learning, health care provider support, and the
9 secure exchange of electronic health informa-
10 tion; or

11 “(B) support for health care providers and
12 other professionals that provide or assist in the
13 provision of services through such models.

14 “(d) LENGTH OF GRANTS.—Grants awarded under
15 subsection (b) shall be for a period of up to 5 years.

16 “(e) GRANT REQUIREMENTS.—The Secretary may
17 require entities awarded a grant under this section to col-
18 lect information on the effect of the use of technology-
19 enabled collaborative learning and capacity building mod-
20 els, such as on health outcomes, access to health care serv-
21 ices, quality of care, and provider retention in areas and
22 populations described in subsection (b). The Secretary
23 may award a grant or contract to assist in the coordina-
24 tion of such models, including to assess outcomes associ-
25 ated with the use of such models in grants awarded under

1 subsection (b), including for the purpose described in sub-
2 section (c)(1)(B).

3 “(f) APPLICATION.—An eligible entity that seeks to
4 receive a grant under subsection (b) shall submit to the
5 Secretary an application, at such time, in such manner,
6 and containing such information as the Secretary may re-
7 quire. Such application shall include plans to assess the
8 effect of technology-enabled collaborative learning and ca-
9 pacity building models on patient outcomes and health
10 care providers.

11 “(g) ACCESS TO BROADBAND.—In administering
12 grants under this section, the Secretary may coordinate
13 with other agencies to ensure that funding opportunities
14 are available to support access to reliable, high-speed
15 internet for grantees.

16 “(h) TECHNICAL ASSISTANCE.—The Secretary shall
17 provide (either directly through the Department of Health
18 and Human Services or by contract) technical assistance
19 to eligible entities, including recipients of grants under
20 subsection (b), on the development, use, and evaluation
21 of technology-enabled collaborative learning and capacity
22 building models in order to expand access to health care
23 services provided by such entities, including for medically
24 underserved areas and to medically underserved popu-
25 lations or Native Americans.

1 “(i) RESEARCH AND EVALUATION.—The Secretary,
2 in consultation with stakeholders with appropriate exper-
3 tise in such models, shall develop a strategic plan to re-
4 search and evaluate the evidence for such models. The
5 Secretary shall use such plan to inform the activities car-
6 ried out under this section.

7 “(j) REPORT BY SECRETARY.—Not later than 4
8 years after the date of enactment of this section, the Sec-
9 retary shall prepare and submit to the Committee on
10 Health, Education, Labor, and Pensions of the Senate and
11 the Committee on Energy and Commerce of the House
12 of Representatives, and post on the internet website of the
13 Department of Health and Human Services, a report in-
14 cluding, at minimum—

15 “(1) a description of any new and continuing
16 grants awarded to entities under subsection (b) and
17 the specific purpose and amounts of such grants;

18 “(2) an overview of—

19 “(A) the evaluations conducted under sub-
20 sections (b);

21 “(B) technical assistance provided under
22 subsection (h); and

23 “(C) activities conducted by entities award-
24 ed grants under subsection (b); and

1 respect to the interoperability and improvement
2 of such systems (including as it relates to pre-
3 paredness for, prevention and detection of, and
4 response to public health emergencies); and

5 “(B) award grants or cooperative agree-
6 ments to State, local, Tribal, or territorial pub-
7 lic health departments for the expansion and
8 modernization of public health data systems, to
9 assist public health departments and public
10 health laboratories in—

11 “(i) assessing current data infrastruc-
12 ture capabilities and gaps to—

13 “(I) improve and increase con-
14 sistency in data collection, storage,
15 and analysis; and

16 “(II) as appropriate, improve dis-
17 semination of public health-related in-
18 formation;

19 “(ii) improving secure public health
20 data collection, transmission, exchange,
21 maintenance, and analysis, including with
22 respect to demographic data, as appro-
23 priate;

24 “(iii) improving the secure exchange
25 of data between the Centers for Disease

1 Control and Prevention, State, local, Trib-
2 al, and territorial public health depart-
3 ments, public health laboratories, public
4 health organizations, and health care pro-
5 viders, including by public health officials
6 in multiple jurisdictions within such State,
7 as appropriate, and by simplifying and
8 supporting reporting by health care pro-
9 viders, as applicable, pursuant to State
10 law, including through the use of health in-
11 formation technology;

12 “(iv) enhancing the interoperability of
13 public health data systems (including sys-
14 tems created or accessed by public health
15 departments) with health information tech-
16 nology, including with health information
17 technology certified under section
18 3001(e)(5);

19 “(v) supporting and training data sys-
20 tems, data science, and informatics per-
21 sonnel;

22 “(vi) supporting earlier disease and
23 health condition detection, such as through
24 near real-time data monitoring, to support
25 rapid public health responses;

1 “(vii) supporting activities within the
2 applicable jurisdiction related to the expan-
3 sion and modernization of electronic case
4 reporting; and

5 “(viii) developing and disseminating
6 information related to the use and impor-
7 tance of public health data.

8 “(2) DATA STANDARDS.—In carrying out para-
9 graph (1), the Secretary, acting through the Direc-
10 tor of the Centers for Disease Control and Preven-
11 tion, shall, as appropriate and in consultation with
12 the Office of the National Coordinator for Health
13 Information Technology, designate data and tech-
14 nology standards (including standards for interoper-
15 ability) for public health data systems, with def-
16 erence given to standards published by consensus-
17 based standards development organizations with
18 public input and voluntary consensus-based stand-
19 ards bodies.

20 “(3) PUBLIC-PRIVATE PARTNERSHIPS.—The
21 Secretary may develop and utilize public-private
22 partnerships for technical assistance, training, and
23 related implementation support for State, local,
24 Tribal, and territorial public health departments,
25 and the Centers for Disease Control and Prevention,

1 on the expansion and modernization of electronic
2 case reporting and public health data systems, as
3 applicable.

4 “(b) REQUIREMENTS.—

5 “(1) HEALTH INFORMATION TECHNOLOGY
6 STANDARDS.—The Secretary may not award a grant
7 or cooperative agreement under subsection (a)(1)(B)
8 unless the applicant uses or agrees to use standards
9 endorsed by the National Coordinator for Health In-
10 formation Technology pursuant to section
11 3001(e)(1) or adopted by the Secretary under sec-
12 tion 3004.

13 “(2) WAIVER.—The Secretary may waive the
14 requirement under paragraph (1) with respect to an
15 applicant if the Secretary determines that the activi-
16 ties under subsection (a)(1)(B) cannot otherwise be
17 carried out within the applicable jurisdiction.

18 “(3) APPLICATION.—A State, local, Tribal, or
19 territorial health department applying for a grant or
20 cooperative agreement under this section shall sub-
21 mit an application to the Secretary at such time and
22 in such manner as the Secretary may require. Such
23 application shall include information describing—

24 “(A) the activities that will be supported
25 by the grant or cooperative agreement; and

1 “(B) how the modernization of the public
2 health data systems involved will support or im-
3 pact the public health infrastructure of the
4 health department, including a description of
5 remaining gaps, if any, and the actions needed
6 to address such gaps.

7 “(c) STRATEGY AND IMPLEMENTATION PLAN.—Not
8 later than 180 days after the date of enactment of this
9 section, the Secretary, acting through the Director of the
10 Centers for Disease Control and Prevention, shall submit
11 to the Committee on Health, Education, Labor, and Pen-
12 sions of the Senate and the Committee on Energy and
13 Commerce of the House of Representatives a coordinated
14 strategy and an accompanying implementation plan that
15 identifies and demonstrates the measures the Secretary
16 will utilize to—

17 “(1) update and improve applicable public
18 health data systems used by the Centers for Disease
19 Control and Prevention; and

20 “(2) carry out the activities described in this
21 section to support the improvement of State, local,
22 Tribal, and territorial public health data systems.

23 “(d) CONSULTATION.—The Secretary, acting
24 through the Director of the Centers for Disease Control
25 and Prevention, shall consult with State, local, Tribal, and

1 territorial health departments, professional medical and
2 public health associations, associations representing hos-
3 pitals or other health care entities, health information
4 technology experts, and other appropriate public or private
5 entities regarding the plan and grant program to mod-
6 ernize public health data systems pursuant to this section.
7 Activities under this subsection may include the provision
8 of technical assistance and training related to the ex-
9 change of information by such public health data systems
10 used by relevant health care and public health entities at
11 the local, State, Federal, Tribal, and territorial levels, and
12 the development and utilization of public-private partner-
13 ships for implementation support applicable to this sec-
14 tion.

15 “(e) REPORT TO CONGRESS.—Not later than 1 year
16 after the date of enactment of this section, the Secretary
17 shall submit a report to the Committee on Health, Edu-
18 cation, Labor, and Pensions of the Senate and the Com-
19 mittee on Energy and Commerce of the House of Rep-
20 resentatives that includes—

21 “(1) a description of any barriers to—

22 “(A) public health authorities imple-
23 menting interoperable public health data sys-
24 tems and electronic case reporting;

1 “(B) the exchange of information pursuant
2 to electronic case reporting;

3 “(C) reporting by health care providers
4 using such public health data systems, as ap-
5 propriate, and pursuant to State law; or

6 “(D) improving demographic data collec-
7 tion or analysis;

8 “(2) an assessment of the potential public
9 health impact of implementing electronic case re-
10 porting and interoperable public health data sys-
11 tems; and

12 “(3) a description of the activities carried out
13 pursuant to this section.

14 “(f) ELECTRONIC CASE REPORTING.—In this sec-
15 tion, the term ‘electronic case reporting’ means the auto-
16 mated identification, generation, and bilateral exchange of
17 reports of health events among electronic health record or
18 health information technology systems and public health
19 authorities.

20 “(g) AUTHORIZATION OF APPROPRIATIONS.—To
21 carry out this section, there are authorized to be appro-
22 priated \$100,000,000 for each of fiscal years 2021
23 through 2025.”.

1 **SEC. 315. NATIVE AMERICAN SUICIDE PREVENTION.**

2 Section 520E(b) of the Public Health Service Act (42
3 U.S.C. 290bb–36(b) is amended by inserting after para-
4 graph (3) the following:

5 “(4) CONSULTATION.—An entity described in
6 paragraph (1)(A) or (1)(B) that applies for a grant
7 or cooperative agreement under this section shall
8 agree to consult or confer with entities described in
9 paragraph (1)(C) and Native Hawaiian Health Care
10 Systems, as applicable, in the applicable State with
11 respect to the development and implementation of a
12 statewide early intervention strategy.”.

13 **SEC. 316. REAUTHORIZATION OF THE YOUNG WOMEN’S**
14 **BREAST HEALTH EDUCATION AND AWARE-**
15 **NESS REQUIRES LEARNING YOUNG ACT OF**
16 **2009.**

17 Section 399NN(h) of the Public Health Service Act
18 (42 U.S.C. 280m(h)) is amended by striking “ \$4,900,000
19 for each of fiscal years 2015 through 2019” and inserting
20 “ \$9,000,000 for each of fiscal years 2022 through 2026”.

21 **SEC. 317. REAUTHORIZATION OF SCHOOL-BASED HEALTH**
22 **CENTERS.**

23 Section 399Z–1(l) of the Public Health Service Act
24 (42 U.S.C. 280h–5(l)) is amended by striking “2010
25 through 2014” and inserting “2022 through 2026”.

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1 **Subtitle C—FDA Amendments**

2 **SEC. 321. RARE PEDIATRIC DISEASE PRIORITY REVIEW** 3 **VOUCHER EXTENSION.**

4 Section 529(b)(5) of the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 360ff(b)(5)) is amended—

6 (1) by striking “December 18, 2020” each
7 place it appears and inserting “September 30,
8 2024”; and

9 (2) in subparagraph (B), by striking “Decem-
10 ber 18, 2022” and inserting “September 30, 2026”.

11 **SEC. 322. CONDITIONS OF USE FOR BIOSIMILAR BIOLOGI-** 12 **CAL PRODUCTS.**

13 Section 351(k)(2)(A)(iii) of the Public Health Service
14 Act (42 U.S.C. 262(k)(2)(A)(iii)) is amended—

15 (1) in subclause (I), by striking “; and” and in-
16 serting a semicolon;

17 (2) in subclause (II), by striking the period and
18 inserting “; and”; and

19 (3) by adding at the end the following:

20 “(III) may include information to
21 show that the conditions of use pre-
22 scribed, recommended, or suggested in
23 the labeling proposed for the biological
24 product have been previously approved
25 for the reference product.”.

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1 **SEC. 323. ORPHAN DRUG CLARIFICATION.**

2 Section 527(c) of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 360cc(c)) is amended by adding at
4 the end the following:

5 “(3) **APPLICABILITY.**—This subsection applies
6 to any drug designated under section 526 for which
7 an application was approved under section 505 of
8 this Act or licensed under section 351 of the Public
9 Health Service Act after the date of enactment of
10 the FDA Reauthorization Act of 2017, regardless of
11 the date on which such drug was designated under
12 section 526.”.

13 **SEC. 324. MODERNIZING THE LABELING OF CERTAIN GE-**
14 **NERIC DRUGS.**

15 Chapter V of the Federal Food, Drug, and Cosmetic
16 Act (21 U.S.C. 351 et seq.) is amended by inserting after
17 section 503C the following:

18 **“SEC. 503D. PROCESS TO UPDATE LABELING FOR CERTAIN**
19 **GENERIC DRUGS.**

20 “(a) **DEFINITIONS.**—For purposes of this section:

21 “(1) The term ‘covered drug’ means a drug ap-
22 proved under section 505(c)—

23 “(A) for which there are no unexpired pat-
24 ents included in the list under section 505(j)(7)
25 and no unexpired period of exclusivity;

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1 “(B) for which the approval of the applica-
2 tion has been withdrawn for reasons other than
3 safety or effectiveness; and

4 “(C) for which—

5 “(i)(I) there is new scientific evidence
6 available pertaining to new or existing con-
7 ditions of use that is not reflected in the
8 approved labeling;

9 “(II) the approved labeling does not
10 reflect current legal and regulatory re-
11 quirements for content or format; or

12 “(III) there is a relevant accepted use
13 in clinical practice that is not reflected in
14 the approved labeling; and

15 “(ii) updating the approved labeling
16 would benefit the public health.

17 “(2) The term ‘period of exclusivity’, with re-
18 spect to a drug approved under section 505(e),
19 means any period of exclusivity under clause (ii),
20 (iii), or (iv) of section 505(e)(3)(E), clause (ii), (iii),
21 or (iv) of section 505(j)(5)(F), or section 505A,
22 505E, or 527.

23 “(3) The term ‘generic version’ means a drug
24 approved under section 505(j) whose reference listed
25 drug is a covered drug.

1 “(4) The term ‘relevant accepted use’ means a
2 use for a drug in clinical practice that is supported
3 by scientific evidence that appears to the Secretary
4 to meet the standards for approval under section
5 505.

6 “(5) The term ‘selected drug’ means a covered
7 drug for which the Secretary has determined
8 through the process under subsection (c) that the la-
9 beling should be changed.

10 “(b) IDENTIFICATION OF COVERED DRUGS.—The
11 Secretary may identify covered drugs for which labeling
12 updates would provide a public health benefit. To assist
13 in identifying covered drugs, the Secretary may do one or
14 both of the following:

15 “(1) Enter into cooperative agreements or con-
16 tracts with public or private entities to review the
17 available scientific evidence concerning such drugs.

18 “(2) Seek public input concerning such drugs,
19 including input on whether there is a relevant ac-
20 cepted use in clinical practice that is not reflected in
21 the approved labeling of such drugs or whether new
22 scientific evidence is available regarding the condi-
23 tions of use for such drug, by—

24 “(A) holding one or more public meetings;

1 “(B) opening a public docket for the sub-
2 mission of public comments; or

3 “(C) other means, as the Secretary deter-
4 mines appropriate.

5 “(c) SELECTION OF DRUGS FOR UPDATING.—If the
6 Secretary determines, with respect to a covered drug, that
7 the available scientific evidence meets the standards under
8 section 505 for adding or modifying information to the
9 labeling or providing supplemental information to the la-
10 beling regarding the use of the covered drug, the Secretary
11 may initiate the process under subsection (d).

12 “(d) INITIATION OF THE PROCESS OF UPDATING.—
13 If the Secretary determines that labeling changes are ap-
14 propriate for a selected drug pursuant to subsection (c),
15 the Secretary shall provide notice to the holders of ap-
16 proved applications for a generic version of such drug
17 that—

18 “(1) summarizes the findings supporting the
19 determination of the Secretary that the available sci-
20 entific evidence meets the standards under section
21 505 for adding or modifying information or pro-
22 viding supplemental information to the labeling of
23 the covered drug pursuant to subsection (c);

24 “(2) provides a clear statement regarding the
25 additional, modified, or supplemental information for

1 such labeling, according to the determination by the
2 Secretary (including, as applicable, modifications to
3 add the relevant accepted use to the labeling of the
4 drug as an additional indication for the drug); and

5 “(3) states whether the statement under para-
6 graph (2) applies to the selected drug as a class of
7 covered drugs or only to a specific drug product.

8 “(e) RESPONSE TO NOTIFICATION.—Within 30 days
9 of receipt of notification provided by the Secretary pursu-
10 ant to subsection (d), the holder of an approved applica-
11 tion for a generic version of the selected drug shall—

12 “(1) agree to change the approved labeling to
13 reflect the additional, modified, or supplemental in-
14 formation the Secretary has determined to be appro-
15 priate; or

16 “(2) notify the Secretary that the holder of the
17 approved application does not believe that the re-
18 quested labeling changes are warranted and submit
19 a statement detailing the reasons why such changes
20 are not warranted.

21 “(f) REVIEW OF APPLICATION HOLDER’S RE-
22 SPONSE.—

23 “(1) IN GENERAL.—Upon receipt of the appli-
24 cation holder’s response, the Secretary shall prompt-
25 ly review each statement received under subsection

1 (e)(2) and determine which labeling changes pursu-
2 ant to the Secretary's notice under subsection (d)
3 are appropriate, if any. If the Secretary disagrees
4 with the reasons why such labeling changes are not
5 warranted, the Secretary shall provide opportunity
6 for discussions with the application holders to reach
7 agreement on whether the labeling for the covered
8 drug should be updated to reflect available scientific
9 evidence, and if so, the content of such labeling
10 changes.

11 “(2) CHANGES TO LABELING.—After consid-
12 ering all responses from the holder of an approved
13 application under paragraph (1) or (2) of subsection
14 (e), and any discussion under paragraph (1), the
15 Secretary may order such holder to make the label-
16 ing changes the Secretary determines are appro-
17 priate. Such holder of an approved application
18 shall—

19 “(A) update its paper labeling for the drug
20 at the next printing of that labeling;

21 “(B) update any electronic labeling for the
22 drug within 30 days of such order; and

23 “(C) submit the revised labeling through
24 the form, ‘Supplement—Changes Being Ef-
25 fected’.

1 “(g) VIOLATION.—If the holder of an approved appli-
2 cation for the generic version of the selected drug does
3 not comply with the requirements of subsection (f)(2),
4 such generic version of the selected drug shall be deemed
5 to be misbranded under section 502.

6 “(h) LIMITATIONS; GENERIC DRUGS.—

7 “(1) IN GENERAL.—With respect to any label-
8 ing change required under this section, the generic
9 version shall be deemed to have the same conditions
10 of use and the same labeling as its reference listed
11 drug for purposes of clauses (i) and (v) of section
12 505(j)(2)(A). Any labeling change so required shall
13 not have any legal effect for the applicant that is
14 different than the legal effect that would have re-
15 sulted if a supplemental application had been sub-
16 mitted and approved to conform the labeling of the
17 generic version to a change in the labeling of the ref-
18 erence drug.

19 “(2) SUPPLEMENTAL APPLICATIONS.—Changes
20 to labeling made in accordance with this section
21 shall not be eligible for an exclusivity period under
22 this Act.

23 “(3) SELECTION OF DRUGS.—The Secretary
24 shall not identify a drug as a covered drug or select
25 a drug label for updating under subsection (b) or (c)

1 solely based on the availability of new safety infor-
2 mation. Upon identification of a drug as a covered
3 drug under subsection (b), the Secretary may then
4 consider the availability of new safety information
5 (as defined in section 505–1(b)) in determining
6 whether the drug is a selected drug and in deter-
7 mining what labeling changes are appropriate.

8 “(i) RULES OF CONSTRUCTION.—

9 “(1) APPROVAL STANDARDS.—This section
10 shall not be construed as altering the applicability of
11 the standards for approval of an application under
12 section 505. No order shall be issued under this sub-
13 section unless the scientific evidence supporting the
14 changed labeling meets the standards for approval
15 applicable to any change to labeling under section
16 505.

17 “(2) REMOVAL OF INFORMATION.—Nothing in
18 this section shall be construed to give the Secretary
19 additional authority to remove approved indications
20 for drugs, other than the authority described in this
21 section.

22 “(3) SECRETARY AUTHORITY.—Nothing in this
23 section shall be construed to limit the authority of
24 the Secretary to require labeling changes under sec-
25 tion 505(o).

1 “(4) MAINTENANCE OF LABELING.—Nothing in
2 this section shall be construed to affect the responsi-
3 bility of the holder of an approved application under
4 section 505(j) to maintain its labeling in accordance
5 with existing requirements, including subpart B of
6 part 201 and sections 314.70 and 314.97 of title 21,
7 Code of Federal Regulations (or any successor regu-
8 lations).

9 “(j) REPORTS.—Not later than 4 years after the date
10 of the enactment of this section, and every 4 years there-
11 after, the Secretary shall prepare and submit to the Com-
12 mittee on Energy and Commerce of the House of Rep-
13 resentatives and the Committee on Health, Education,
14 Labor, and Pensions of the Senate, a report that—

15 “(1) describes the actions of the Secretary
16 under this section, including—

17 “(A) the number of covered drugs and de-
18 scription of the types of drugs the Secretary
19 has selected for labeling changes and the ra-
20 tionale for such recommended changes; and

21 “(B) the number of times the Secretary
22 entered into discussions concerning a disagree-
23 ment with an application holder or holders and
24 a summary of the decision regarding a labeling
25 change, if any; and

1 “(2) includes any recommendations of the Sec-
2 retary for modifying the program under this sec-
3 tion.”.

4 **SEC. 325. BIOLOGICAL PRODUCT PATENT TRANSPARENCY.**

5 (a) IN GENERAL.—Section 351(k) of the Public
6 Health Service Act (42 U.S.C. 262(k)) is amended by add-
7 ing at the end the following:

8 “(9) PUBLIC LISTING.—

9 “(A) IN GENERAL.—

10 “(i) INITIAL PUBLICATION.—Not later
11 than 180 days after the date of enactment
12 of this paragraph, the Secretary shall pub-
13 lish and make available to the public in a
14 searchable, electronic format—

15 “(I) a list of each biological prod-
16 uct, by nonproprietary name (proper
17 name), for which, as of such date of
18 enactment, a biologics license under
19 subsection (a) or this subsection is in
20 effect, or that, as of such date of en-
21 actment, is deemed to be licensed
22 under this section pursuant to section
23 7002(e)(4) of the Biologics Price
24 Competition and Innovation Act of
25 2009;

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1 “(II) the date of licensure of the
2 marketing application and the applica-
3 tion number; and

4 “(III) with respect to each bio-
5 logical product described in subclause
6 (I), the licensure status, and, as avail-
7 able, the marketing status.

8 “(ii) REVISIONS.—Every 30 days
9 after the publication of the first list under
10 clause (i), the Secretary shall revise the list
11 to include each biological product which
12 has been licensed under subsection (a) or
13 this subsection during the 30-day period or
14 deemed licensed under this section pursu-
15 ant to section 7002(e)(4) of the Biologics
16 Price Competition and Innovation Act of
17 2009.

18 “(iii) PATENT INFORMATION.—Not
19 later than 30 days after a list of patents
20 under subsection (l)(3)(A), or a supple-
21 ment to such list under subsection (l)(7),
22 has been provided by the reference product
23 sponsor to the subsection (k) applicant re-
24 specting a biological product included on
25 the list published under this subparagraph,

1 the reference product sponsor shall provide
2 such list of patents (or supplement there-
3 to) and their corresponding expiry dates to
4 the Secretary, and the Secretary shall, in
5 revisions made under clause (ii), include
6 such information for such biological prod-
7 uct. Within 30 days of providing any sub-
8 sequent or supplemental list of patents to
9 any subsequent subsection (k) applicant
10 under subsection (l)(3)(A) or (l)(7), the
11 reference product sponsor shall update the
12 information provided to the Secretary
13 under this clause with any additional pat-
14 ents from such subsequent or supplemental
15 list and their corresponding expiry dates.

16 “(iv) LISTING OF EXCLUSIVITIES.—
17 For each biological product included on the
18 list published under this subparagraph, the
19 Secretary shall specify each exclusivity pe-
20 riod under paragraph (6) or paragraph (7)
21 for which the Secretary has determined
22 such biological product to be eligible and
23 that has not concluded.

24 “(B) REVOCATION OR SUSPENSION OF LI-
25 CENSE.—If the license of a biological product is

1 determined by the Secretary to have been re-
2 voked or suspended for safety, purity, or po-
3 tency reasons, it may not be published in the
4 list under subparagraph (A). If such revocation
5 or suspension occurred after inclusion of such
6 biological product in the list published under
7 subparagraph (A), the reference product spon-
8 sor shall notify the Secretary that—

9 “(i) the biological product shall be im-
10 mediately removed from such list for the
11 same period as the revocation or suspen-
12 sion; and

13 “(ii) a notice of the removal shall be
14 published in the Federal Register.”.

15 (b) REVIEW AND REPORT ON TYPES OF INFORMA-
16 TION TO BE LISTED.—Not later than 3 years after the
17 date of enactment of this Act, the Secretary of Health and
18 Human Services shall—

19 (1) solicit public comment regarding the type of
20 information, if any, that should be added to or re-
21 moved from the list required by paragraph (9) of
22 section 351(k) of the Public Health Service Act (42
23 U.S.C. 262(k)), as added by subsection (a); and

24 (2) transmit to Congress an evaluation of such
25 comments, including any recommendations about the

1 types of information that should be added to or re-
2 moved from the list.

3 **Subtitle D—Technical Corrections**

4 **SEC. 331. TECHNICAL CORRECTIONS.**

5 (a) EDUCATION AND TRAINING RELATING TO GERI-
6 ATRICS.—Section 753(a)(7)(B) of the Public Health Serv-
7 ice Act (42 U.S.C. 294c(a)(7)(B)) is amended, in the mat-
8 ter preceding clause (i), by striking “Title VII Health
9 Care Workforce Reauthorization Act of 2019” and insert-
10 ing “Coronavirus Aid, Relief, and Economic Security
11 Act”.

12 (b) NURSING.—Section 851(d)(3) of the Public
13 Health Service Act (42 U.S.C. 297t(d)(3)) is amended by
14 striking “Title VIII Nursing Reauthorization Act” and in-
15 serting “Coronavirus Aid, Relief, and Economic Security
16 Act”.

17 (c) CITATION.—Section 3404(a)(9) of the
18 Coronavirus Aid, Relief, and Economic Security Act (Pub-
19 lic Law 116–136) is amended by striking “section 846A
20 (42 U.S.C. 247n–1)” and inserting “section 846A (42
21 U.S.C. 297n–1)”.

22 (d) EFFECTIVE DATE.—The amendments made by
23 subsections (a), (b), and (c) shall take effect as if included
24 in the enactment of the Coronavirus Aid, Relief, and Eco-
25 nomic Security Act (Public Law 116–136).