

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 3561
OFFERED BY M . _____**

Strike all after the enacting clause and insert the following:

1 SECTION 1. SHORT TITLE.

2 This Act may be cited as the “Promoting Access to
3 Treatments and Increasing Extremely Needed Trans-
4 parency Act of 2023” or the “PATIENT Act of 2023”.

**5 TITLE I—INCREASING PRICE
6 TRANSPARENCY TO LOWER
7 COSTS**

8 SEC. 101. PRICE TRANSPARENCY REQUIREMENTS.

9 (a) IN GENERAL.—Section 2718(e) of the Public
10 Health Service Act (42 U.S.C. 300gg–18(e)) is amend-
11 ed—

12 (1) by striking “Each hospital” and inserting
13 the following:

14 “(1) IN GENERAL.—Each hospital”;

15 (2) by inserting “, without subscription and
16 free of charge, in a single machine-readable file,”
17 after “a list”;

1 (3) by inserting “all” after “of the hospital’s
2 standard charges for”;

3 (4) by inserting “and a list, in plain language
4 and without subscription and free of charge, in a
5 consumer-friendly format, of the hospital’s standard
6 charges for as many of the Centers for Medicare &
7 Medicaid Services-specified shoppable services that
8 are provided by the hospital, and as many additional
9 hospital-selected shoppable services (or all such addi-
10 tional services, if such hospital provides fewer than
11 300 shoppable services) as may be necessary for a
12 combined total of at least 300 shoppable services”
13 after “Social Security Act”; and

14 (5) by adding at the end the following: “Begin-
15 ning January 1, 2025, each hospital shall include in
16 its lists of standard charges, along with such addi-
17 tional information as the Secretary may require with
18 respect to such charges for purposes of promoting
19 public awareness of hospital pricing in advance of
20 receiving a hospital item or service, the following:

21 “(A) A plain language description of each
22 item or service included on such list, including,
23 as applicable, the Healthcare Common Proce-
24 dure Coding System (HCPCS) code, the Diag-
25 nosis Related Group (DRG), the National Drug

1 Code (NDC), or other payer identifier used or
2 approved by the Centers for Medicare & Med-
3 icaid Services for such item or service.

4 “(B) The gross charge, expressed as a dol-
5 lar amount, for each such item or service, when
6 provided in, as applicable, the hospital inpatient
7 setting and outpatient department setting.

8 “(C) Any current payer-specific negotiated
9 charges, clearly associated with the name of the
10 third party payer and plan and expressed as a
11 dollar amount, that applies to each such item or
12 service when provided in, as applicable, the hos-
13 pital inpatient setting and outpatient depart-
14 ment setting.

15 “(D) The de-identified maximum and min-
16 imum negotiated charges for each such item or
17 service.

18 “(E) The discounted cash price, expressed
19 as a dollar amount, for each such item or serv-
20 ice when provided in, as applicable, the hospital
21 inpatient setting and outpatient department
22 setting. If the discounted cash price is a per-
23 centage of another value provided, the cal-
24 culated value must be entered as a dollar
25 amount. If the discounted cash price equates to

1 the gross charge, the gross charge shall be re-
2 entered to indicate that no cash discount is
3 available.

4 “(2) DEEMED COMPLIANCE WITH SHOPPABLE
5 SERVICES REQUIREMENT FOR CERTAIN YEARS.—
6 With respect to a year before 2025, a hospital shall
7 be deemed to meet the requirement of paragraph (1)
8 that such hospital make available a list of standard
9 charges for shoppable services if the hospital main-
10 tains an internet-based price estimator tool that
11 meets the following requirements:

12 “(A) The tool provides estimates for as
13 many of the Centers for Medicare & Medicaid
14 Services specified shoppable services that are
15 provided by the hospital, and as many addi-
16 tional hospital-selected shoppable services (or
17 all such additional services, if such hospital pro-
18 vides fewer than 300 shoppable services) as
19 may be necessary for a combined total of at
20 least 300 shoppable services.

21 “(B) The tool allows health care con-
22 sumers to, at the time they use the tool, obtain
23 an estimate of the amount they will be obligated
24 to pay the hospital for the shoppable service.

1 “(C) The tool is prominently displayed on
2 the hospital’s website and easily accessible to
3 the public, without subscription, fee, or having
4 to submit personal identifying information, and
5 searchable by service description, billing code,
6 and payer.

7 The Secretary may not deem the establishment of an
8 internet-based price estimator tool that meets the re-
9 quirements of this paragraph to constitute compli-
10 ance with the requirement of paragraph (1) that
11 such hospital make available a list of standard
12 charges for shoppable services for 2025 or a subse-
13 quent year.

14 “(3) UNIFORM METHOD AND FORMAT.—Not
15 later than January 1, 2025, the Secretary shall im-
16 plement a standard, uniform method and format for
17 hospitals to use in order to satisfy the requirements
18 of this subsection for disclosing directly to the public
19 charge and price information. Such method and for-
20 mat may be similar to any template made available
21 by the Centers for Medicare & Medicaid Services as
22 of the date of the enactment of this paragraph for
23 reporting such information under this subsection
24 and shall meet such standards as determined appro-
25 priate by the Secretary.

1 “(4) MONITORING OF PRICING INFORMATION.—
2 The Secretary, in consultation with the Inspector
3 General of the Department of Health and Human
4 Services, shall, through notice and comment rule-
5 making, establish a process to regularly monitor the
6 accuracy of pricing information displayed by each
7 hospital pursuant to paragraph (1).

8 “(5) DEFINITIONS.—Notwithstanding any other
9 provision of law, for the purpose of paragraphs (1)
10 and (2):

11 “(A) DE-IDENTIFIED MAXIMUM NEGOTIATED CHARGE.—The term ‘de-identified maximum negotiated charge’ means the highest charge that a hospital has negotiated with all third party payers for an item or service.

12 “(B) DE-IDENTIFIED MINIMUM NEGOTIATED CHARGE.—The term ‘de-identified minimum negotiated charge’ means the lowest charge that a hospital has negotiated with all third party payers for an item or service.

13 “(C) DISCOUNTED CASH PRICE.—The
14 term ‘discounted cash price’ means the charge
15 that applies to an individual who pays cash, or
16 cash equivalent, for a hospital item or service.
17 Hospitals that do not offer self-pay discounts

1 may display the hospital’s undiscounted gross
2 charges as found in the hospital chargemaster.

3 “(D) GROSS CHARGE.—The term ‘gross
4 charge’ means the charge for an individual item
5 or service that is reflected on a hospital’s
6 chargemaster, absent any discounts.

7 “(E) PAYER-SPECIFIC NEGOTIATED
8 CHARGE.—The term ‘payer-specific negotiated
9 charge’ means the charge that a hospital has
10 negotiated with a third party payer for an item
11 or service.

12 “(F) SHOPPABLE SERVICE.—The term
13 ‘shoppable service’ means a service that can be
14 scheduled by a health care consumer in ad-
15 vance.

16 “(G) THIRD PARTY PAYER.—The term
17 ‘third party payer’ means an entity that is, by
18 statute, contract, or agreement, legally respon-
19 sible for payment of a claim for a health care
20 item or service.

21 “(6) ENFORCEMENT.—

22 “(A) IN GENERAL.—In the case of a hos-
23 pital that fails to comply with this subsection—

24 “(i) the Secretary shall notify such
25 hospital of such failure not later than 30

1 days after the date on which the Secretary
2 determines such failure exists; and

3 “(ii) not later than 45 days after the
4 date of such notification, the hospital shall
5 complete a corrective action plan to comply
6 with such requirements.

7 “(B) CIVIL MONETARY PENALTY.—

8 “(i) IN GENERAL.—In addition to any
9 other enforcement actions or penalties that
10 may apply under subsection (b)(3) or an-
11 other provision of law, a hospital that has
12 received a notification under subparagraph
13 (A)(i) and fails to satisfy the requirement
14 under subparagraph (A)(ii) or otherwise
15 comply with the requirements of this sub-
16 section by the date that is 90 days after
17 such notification shall be subject to a civil
18 monetary penalty of an amount—

19 “(I) in the case of a hospital with
20 not more than 30 beds (as determined
21 under section 180.90(c)(2)(ii)(D) of
22 title 45, Code of Federal Regulations,
23 as in effect on the date of the enact-
24 ment of this paragraph), not to exceed
25 \$300 per day that the violation is on-

1 going as determined by the Secretary;
2 and

3 “(II) in the case of a hospital
4 with more than 30 beds (as so deter-
5 mined), equal to—

6 “(aa) subject to item (bb),
7 \$10 per bed per day that the vio-
8 lation is ongoing as determined
9 by the Secretary, but for viola-
10 tions occurring before January 1,
11 2024, not to exceed \$5,500 per
12 each such day; or

13 “(bb) in the case such hos-
14 pital has failed to satisfy the re-
15 quirement under subparagraph
16 (A)(ii) or otherwise comply with
17 the requirements of this sub-
18 section for any 1-year period (as
19 determined by the Secretary) be-
20 ginning on or after January 1,
21 2024, and the amount otherwise
22 imposed under item (aa) for such
23 failure for such period would be
24 less than \$5,000,000, an amount
25 not less than \$5,000,000.

1 “(ii) INCREASE AUTHORITY.—In ap-
2 plying this subparagraph with respect to
3 violations occurring in 2025 or a subse-
4 quent year, the Secretary may through no-
5 tice and comment rulemaking increase any
6 dollar amount applied under this subpara-
7 graph by an amount specified by the Sec-
8 retary.

9 “(iii) APPLICATION OF CERTAIN PRO-
10 VISIONS.—The provisions of section 1128A
11 of the Social Security Act (other than sub-
12 sections (a) and (b) of such section) shall
13 apply to a civil monetary penalty imposed
14 under clause (i) in the same manner as
15 such provisions apply to a civil monetary
16 penalty imposed under subsection (a) of
17 such section.”.

18 (b) PUBLICATION OF LIST OF HOSPITALS.—

19 (1) LIST OF HOSPITALS.—Beginning not later
20 than 90 days after the date of enactment of this
21 Act, the Secretary of Health and Human Services
22 (referred to in this section as the “Secretary”) shall
23 establish and maintain a publicly available list on
24 the website of the Centers for Medicare & Medicaid
25 Services of each hospital that the Secretary has

1 found to be noncompliant with the provisions of sec-
2 tion 2718(e) of the Public Health Service Act (42
3 U.S.C. 300gg-18(e)). Such list shall include, with
4 respect to each such hospital, a specification as to
5 whether such hospital—

6 (A) has been issued a civil monetary pen-
7 alty;

8 (B) has received a warning notice; or

9 (C) has submitted a corrective action plan.

10 (2) ADDITIONS AND UPDATES.—In the case of
11 a hospital not included on the list described in para-
12 graph (1) as of the date of the establishment of such
13 list and that is subject to a review of such hospital's
14 compliance with the provisions described in such
15 paragraph after such date, the Secretary shall add
16 such hospital to such list, along with the specifica-
17 tions described in such paragraph, not later than 1
18 business day after such review occurs. The Secretary
19 shall update such specifications with respect to any
20 hospital included on such list—

21 (A) not later than 1 business day after any
22 subsequent review of such hospital's compliance
23 with such provisions; and

1 (B) not later than 1 business day after any
2 penalty, notice, or request described in para-
3 graph (1) is made with respect to such hospital.

4 (3) FOIA REQUESTS.—Any penalty, notice, or
5 request described in paragraph (1) shall be subject
6 to public disclosure, in full and without redaction,
7 under section 552 of title 21, United States Code,
8 notwithstanding any exemptions or exclusions other-
9 wise available under such section 552.

10 (4) REPORTS TO CONGRESS.—Not later than 1
11 year after the date of enactment of this Act and
12 each year thereafter, the Secretary of Health and
13 Human Services shall submit to Congress, and make
14 publicly available, a report that contains information
15 regarding complaints of alleged violations of law and
16 enforcement activities by the Secretary under the
17 hospital price transparency rule implementing sec-
18 tion 2718(e) of the Public Health Service Act (42
19 U.S.C. 300gg–18(e)). Such report shall be made
20 available to the public on the website of the Centers
21 for Medicare & Medicaid Services. Each such report
22 shall include, with respect to the year involved—

23 (A) the number of compliance and enforce-
24 ment inquiries opened by the Secretary pursu-
25 ant to such section;

1 (B) the number of notices of noncompli-
2 ance issued by the Secretary based on such in-
3 quiries;

4 (C) the identity of each hospital entity that
5 received a notice of noncompliance and the na-
6 ture of the failure giving rise to the Secretary's
7 determination of noncompliance;

8 (D) the amount of civil monetary penalty
9 assessed against the hospital entity;

10 (E) whether the hospital entity subse-
11 quently corrected the noncompliance; and

12 (F) an analysis of factors contributing to
13 increasing health care costs.

14 (5) GAO REPORT.—Not later than 1 year after
15 the date of enactment of this Act, the Comptroller
16 General of the United States shall submit to the
17 Committee on Energy and Commerce of the House
18 of Representatives and the Committee on Health,
19 Education, Labor, and Pensions of the Senate a re-
20 port on the compliance and enforcement with the
21 hospital price transparency rule implementing sec-
22 tion 2718(e) of the Public Health Service Act (42
23 U.S.C. 300gg–18(e)). The report shall include rec-
24 ommendations related to—

1 (A) improving price transparency to pa-
2 tients, employers, and the public; and

3 (B) increased civil monetary penalty
4 amounts to ensure compliance.

5 (6) REQUEST FOR INFORMATION.—Not later
6 than January 1, 2025, the Secretary of Health and
7 Human Services shall issue a public request for in-
8 formation as to the best method through which hos-
9 pitals may be required to publish quality data (such
10 as data required to be reported under the Medicare
11 Hospital Compare program) alongside data required
12 to be reported under section 2718(e) of the Public
13 Health Service Act (42 U.S.C. 300gg–18(e)).

14 (c) ENSURING ACCESSIBILITY THROUGH IMPLEMEN-
15 TATION.—In implementing the amendments made by this
16 section, the Secretary of Health and Human Services shall
17 through rulemaking ensure that a hospital submitting
18 charges and information pursuant to such amendments
19 takes reasonable steps (as specified by the Secretary) to
20 ensure the accessibility of such charges and information
21 to individuals with limited English proficiency. Such steps
22 may include the hospital’s provision of interpretation serv-
23 ices or the hospital’s provision of translations of charges
24 and information.

1 **SEC. 102. STRENGTHENING HEALTH INSURER TRANS-**
2 **PARENCY REQUIREMENTS.**

3 (a) **TRANSPARENCY IN COVERAGE.**—Section
4 1311(e)(3)(C) of the Patient Protection and Affordable
5 Care Act (42 U.S.C. 18031(e)(3)(C)) is amended—

6 (1) by striking “The Exchange” and inserting
7 the following:

8 “(i) **IN GENERAL.**—The Exchange”;

9 (2) in clause (i), as inserted by paragraph (1)—

10 (A) by striking “participating provider”
11 and inserting “provider”;

12 (B) by inserting “shall include the infor-
13 mation specified in clause (ii) and” after “such
14 information”;

15 (C) by striking “an Internet website” and
16 inserting “a self-service tool that meets the re-
17 quirements of clause (iii)”; and

18 (D) by striking “and such other” and all
19 that follows through the period and inserting
20 “or, at the option such individual, through a
21 paper or phone disclosure (as selected by such
22 individual and provided at no cost to such indi-
23 vidual) that meets such requirements as the
24 Secretary may specify.”; and

25 (3) by adding at the end the following new
26 clauses:

1 “(ii) SPECIFIED INFORMATION.—For
2 purposes of clause (i), the information
3 specified in this clause is, with respect to
4 an item or service for which benefits are
5 available under a health plan furnished by
6 a health care provider, the following:

7 “(I) If such provider is a partici-
8 pating provider with respect to such
9 item or service, the in-network rate
10 (as defined in subparagraph (F)) for
11 such item or service.

12 “(II) If such provider is not de-
13 scribed in subclause (I), the maximum
14 allowed amount for such item or serv-
15 ice.

16 “(III) The amount of cost shar-
17 ing (including deductibles, copay-
18 ments, and coinsurance) that the indi-
19 vidual will incur for such item or serv-
20 ice (which, in the case such item or
21 service is to be furnished by a pro-
22 vider described in subclause (II), shall
23 be calculated using the maximum
24 amount described in such subclause).

1 “(IV) The amount the individual
2 has already accumulated with respect
3 to any deductible or out of pocket
4 maximum under the plan (broken
5 down, in the case separate deductibles
6 or maximums apply to separate indi-
7 viduals enrolled in the plan, by such
8 separate deductibles or maximums, in
9 addition to any cumulative deductible
10 or maximum).

11 “(V) In the case such plan im-
12 poses any frequency or volume limita-
13 tions with respect to such item or
14 service (excluding medical necessity
15 determinations), the amount that such
16 individual has accrued towards such
17 limitation with respect to such item or
18 service.

19 “(VI) Any prior authorization,
20 concurrent review, step therapy, fail
21 first, or similar requirements applica-
22 ble to coverage of such item or service
23 under such plan.

24 “(iii) SELF-SERVICE TOOL.—For pur-
25 poses of clause (i), a self-service tool estab-

1 lished by a health plan meets the require-
2 ments of this clause if such tool—

3 “(I) is based on an Internet
4 website;

5 “(II) provides for real-time re-
6 sponses to requests described in such
7 clause;

8 “(III) is updated in a manner
9 such that information provided
10 through such tool is timely and accu-
11 rate;

12 “(IV) allows such a request to be
13 made with respect to an item or serv-
14 ice furnished by—

15 “(aa) a specific provider
16 that is a participating provider
17 with respect to such item or serv-
18 ice;

19 “(bb) all providers that are
20 participating providers with re-
21 spect to such plan and such item
22 or service; or

23 “(cc) a provider that is not
24 described in item (bb); and

1 “(V) provides that such a request
2 may be made with respect to an item
3 or service through use of the billing
4 code for such item or service or
5 through use of a descriptive term for
6 such item or service.

7 The Secretary may require such tool, as a
8 condition of complying with subclause (V),
9 to link multiple billing codes to a single de-
10 scriptive term if the Secretary determines
11 that the billing codes to be so linked cor-
12 respond to items and services.”.

13 (b) DISCLOSURE OF ADDITIONAL INFORMATION.—
14 Section 1311(e)(3) of the Patient Protection and Afford-
15 able Care Act (42 U.S.C. 18031(e)(3)) is amended by add-
16 ing at the end the following new subparagraphs:

17 “(E) RATE AND PAYMENT INFORMA-
18 TION.—

19 “(i) IN GENERAL.—Not later than
20 January 1, 2025, and every 3 months
21 thereafter, each health plan shall submit to
22 the Secretary (or otherwise make available
23 to the Secretary through an Internet link
24 provided to the Secretary), and make avail-
25 able to the public, the rate and payment

1 information described in clause (ii) in ac-
2 cordance with clause (iii).

3 “(ii) RATE AND PAYMENT INFORMA-
4 TION DESCRIBED.—For purposes of clause
5 (i), the rate and payment information de-
6 scribed in this clause is, with respect to a
7 health plan, the following:

8 “(I) With respect to each item or
9 service for which benefits are available
10 under such plan, the in-network rate
11 in effect as of the date of the submis-
12 sion of such information with each
13 provider (identified by national pro-
14 vider identifier) that is a participating
15 provider with respect to such item or
16 service, other than such a rate in ef-
17 fect with a provider that, during the
18 1-year period ending on such date, did
19 not submit any claim for such item or
20 service to such plan.

21 “(II) With respect to each drug
22 (identified by national drug code) for
23 which benefits are available under
24 such plan, the average amount paid
25 by such plan (net of rebates, dis-

1 counts, and price concessions) for
2 such drug dispensed or administered
3 during the 90-day period beginning
4 180 days before such date of submis-
5 sion to each provider that was a par-
6 ticipating provider with respect to
7 such drug, broken down by each such
8 provider (identified by national pro-
9 vider identifier), other than such an
10 amount paid to a provider that, dur-
11 ing such period, submitted fewer than
12 20 claims for such drug to such plan.

13 “(III) With respect to each item
14 or service for which benefits are avail-
15 able under such plan, the amount
16 billed, and the amount allowed by the
17 plan, for each such item or service
18 furnished during the 90-day period
19 specified in subclause (II) by a pro-
20 vider that was not a participating pro-
21 vider with respect to such item or
22 service, broken down by each such
23 provider (identified by national pro-
24 vider identifier), other than items and
25 services with respect to which fewer

1 than 20 claims for such item or serv-
2 ice were submitted to such plan dur-
3 ing such period.

4 “(iii) MANNER OF SUBMISSION.—Rate
5 and payment information required to be
6 submitted and made available under this
7 subparagraph shall be so submitted and so
8 made available in dollar amounts through
9 3 separate machine-readable files cor-
10 responding to the information described in
11 each of subclauses (I) through (III) of
12 clause (ii) that meet such requirements as
13 specified by the Secretary through rule-
14 making. Such requirements shall ensure
15 that such files are limited to an appro-
16 priate size, are made available in a widely-
17 available format that allows for informa-
18 tion contained in such files to be compared
19 across health plans, and are accessible to
20 individuals at no cost and without the need
21 to establish a user account or provide other
22 credentials.

23 “(iv) USER GUIDE.—Each health plan
24 shall make available to the public instruc-
25 tions written in plain language explaining

1 how individuals may search for information
2 described in clause (ii) in files submitted in
3 accordance with clause (iii).

4 “(F) DEFINITIONS.—In this paragraph:

5 “(i) PARTICIPATING PROVIDER.—The
6 term ‘participating provider’ has the mean-
7 ing given such term in section 2799A–1 of
8 the Public Health Service Act.

9 “(ii) IN-NETWORK RATE.—The term
10 ‘in-network rate’ means, with respect to a
11 health plan and an item or service fur-
12 nished by a provider that is a participating
13 provider with respect to such plan and
14 item or service, the contracted rate in ef-
15 fect between such plan and such provider
16 for such item or service.”.

17 (c) REPORTS.—

18 (1) COMPLIANCE.—Not later than January 1,
19 2025, the Comptroller General of the United States
20 shall submit to Congress a report containing—

21 (A) an analysis of health plan compliance
22 with the amendments made by this section;

23 (B) an analysis of enforcement of such
24 amendments by the Secretaries of Health and
25 Human Services, Labor, and the Treasury;

1 (C) recommendations relating to improving
2 such enforcement; and

3 (D) recommendations relating to improving
4 public disclosure, and public awareness, of in-
5 formation required to be made available by such
6 plans pursuant to such amendments.

7 (2) PRICES.—Not later than January 1, 2028,
8 the Comptroller General of the United States shall
9 submit to Congress a report containing an assess-
10 ment of differences in negotiated prices (and any
11 trends in such prices) in the private market be-
12 tween—

13 (A) rural and urban areas;

14 (B) the individual, small group, and large
15 group markets;

16 (C) consolidated and nonconsolidated
17 health care provider areas (as specified by the
18 Secretary);

19 (D) nonprofit and for-profit hospitals;

20 (E) nonprofit and for-profit insurers; and

21 (F) insurers serving local or regional areas
22 and insurers serving multistate or national
23 areas.

24 (d) ENSURING ACCESSIBILITY THROUGH IMPLEMEN-
25 TATION.—In implementing the amendments made by this

1 section, the Secretary shall through rulemaking ensure
2 that any entity making available information pursuant to
3 such amendments takes reasonable steps (as specified by
4 the Secretary) to ensure the accessibility of such to indi-
5 viduals with limited English proficiency. Such steps may
6 include the entity's provision of interpretation services or
7 of translations of such information.

8 (e) GAO REPORT.—Not later than January 1, 2025,
9 the Comptroller General of the United States shall submit
10 to the Committee on Energy and Commerce of the House
11 of Representatives and the Committee on Health, Edu-
12 cation, Labor, and Pensions of the Senate a report con-
13 taining—

14 (1) an analysis of existing efforts amongst am-
15 bulatory surgical centers to make pricing informa-
16 tion available to patients, employers, and the public;
17 and

18 (2) recommendations, if any—

19 (A) to improve ambulatory surgical center
20 price transparency to help patients, employers,
21 and the public better understand pricing infor-
22 mation and make more informed care decisions
23 using existing authorities under current law;

24 (B) to improve current law to promote am-
25 bulatory surgical center price transparency for

1 the purposes described in subparagraph (A);
2 and

3 (C) to ensure that efforts to improve am-
4 bulatory surgical center price transparency have
5 a positive impact without significantly increas-
6 ing administrative costs and potentially contrib-
7 uting to increased consolidation.

8 (f) EFFECTIVE DATE.—

9 (1) IN GENERAL.—The amendments made by
10 subsection (a) shall apply beginning January 1,
11 2025.

12 (2) CONTINUED APPLICABILITY OF RULES FOR
13 PREVIOUS YEARS.—Nothing in the amendments
14 made by this section may be construed as affecting
15 the applicability of the rule entitled “Transparency
16 in Coverage” published by the Department of the
17 Treasury, the Department of Labor, and the De-
18 partment of Health and Human Services on Novem-
19 ber 12, 2020 (85 Fed. Reg. 72158) before January
20 1, 2025.

1 **SEC. 103. REQUIRING A SEPARATE IDENTIFICATION NUM-**
2 **BER AND AN ATTESTATION FOR EACH OFF-**
3 **CAMPUS OUTPATIENT DEPARTMENT OF A**
4 **PROVIDER.**

5 Section 1833(t) of the Social Security Act (42 U.S.C.
6 1395l(t)) is amended by adding at the end the following
7 new paragraph:

8 “(23) USE OF UNIQUE HEALTH IDENTIFIERS;
9 ATTESTATION.—

10 “(A) IN GENERAL.—No payment may be
11 made under this subsection (or under an appli-
12 cable payment system pursuant to paragraph
13 (21)) for items and services furnished on or
14 after January 1, 2026, by an off-campus out-
15 patient department of a provider (as defined in
16 subparagraph (C)) unless—

17 “(i) such department has obtained,
18 and such items and services are billed
19 under, a standard unique health identifier
20 for health care providers (as described in
21 section 1173(b)) that is separate from
22 such identifier for such provider; and

23 “(ii) such provider has submitted to
24 the Secretary, during the 2-year period
25 ending on the date such items and services
26 are so furnished, an attestation that such

1 department is compliant with the require-
2 ments described in section 413.65 of title
3 42, Code of Federal Regulations (or a suc-
4 cessor regulation).

5 “(B) PROCESS FOR SUBMISSION AND RE-
6 VIEW.—Not later than 1 year after the date of
7 enactment of this paragraph, the Secretary
8 shall, through notice and comment rulemaking,
9 establish a process for each provider with an
10 off-campus outpatient department of a provider
11 to submit an attestation pursuant to subpara-
12 graph (A)(ii), and for the Secretary to review
13 each such attestation and determine, through
14 site visits, remote audits, or other means (as
15 determined appropriate by the Secretary),
16 whether such department is compliant with the
17 requirements described in such subparagraph.

18 “(C) OFF-CAMPUS OUTPATIENT DEPART-
19 MENT OF A PROVIDER DEFINED.—For purposes
20 of this paragraph, the term ‘off-campus out-
21 patient department of a provider’ means a de-
22 partment of a provider (as defined in section
23 413.65 of title 42, Code of Federal Regulations,
24 or any successor regulation) that is not lo-
25 cated—

1 “(i) on the campus (as defined in such
2 section) of such provider; or

3 “(ii) within the distance (described in
4 such definition of campus) from a remote
5 location of a hospital facility (as defined in
6 such section).”.

7 **SEC. 104. MANDATORY REPORTING WITH RESPECT TO CER-**
8 **TAIN HEALTH-RELATED OWNERSHIP INFOR-**
9 **MATION.**

10 Part A of title XI of the Social Security Act (42
11 U.S.C. 1301 et seq.) is amended by adding at the end
12 the following new section:

13 **“SEC. 1150D. MANDATORY REPORTING WITH RESPECT TO**
14 **CERTAIN HEALTH-RELATED OWNERSHIP IN-**
15 **FORMATION.**

16 “(a) MANDATORY REPORTING WITH RESPECT CER-
17 TAIN HEALTH-RELATED OWNERSHIP INFORMATION.—

18 “(1) INITIAL REPORT.—Not later than January
19 1, 2025 (or in the case of a specified entity formed
20 after January 1, 2025, within 60 days of becoming
21 a specified entity), each specified entity (as defined
22 in subsection (g)(5)) shall submit to the Secretary,
23 in a form and manner specified by the Secretary, a
24 report containing the following information:

1 “(A) The business structure of the speci-
2 fied entity, including the business type and the
3 tax status of such entity.

4 “(B) Data on mergers, acquisitions, and
5 changes in ownership with respect to such spec-
6 ified entity for the previous 1-year period.

7 “(C) In the case that a specified entity is,
8 or includes, a hospital, the additional informa-
9 tion described in subsection (b).

10 “(D) As applicable, the name, address, and
11 business structure of the parent company of
12 such specified entity (including the tax status of
13 such parent company), and the name, address,
14 and business structure of any beneficial owners
15 of the parent company of such specified entity
16 (including the tax status of such beneficial
17 owner) who control (or own a controlling inter-
18 est in) the parent company, as of the date of
19 the submission of this report.

20 “(E) Any other information with respect to
21 ownership of a specified entity, as determined
22 by the Secretary.

23 “(2) SUBSEQUENT REPORTS.—Not later than 1
24 year after submitting the report under paragraph
25 (1), and annually thereafter, each specified entity

1 shall submit to the Secretary an updated report, in-
2 cluding—

3 “(A)(i) data on mergers, acquisitions, and
4 changes in ownership with respect to such enti-
5 ties for the previous 1-year period; and

6 “(ii) any other information with re-
7 spect to ownership of a specified entity, as
8 determined by the Secretary; and

9 “(B) in the case that a specified entity is,
10 or includes, a hospital, the additional informa-
11 tion described in subsection (b).

12 “(b) ADDITIONAL INFORMATION SUBMITTED BY
13 CERTAIN SPECIFIED ENTITIES.—For purposes of para-
14 graphs (1)(C) and (2)(B) of subsection (a), with respect
15 to a specified entity that is, or includes, a hospital, the
16 information described in this subsection is the following
17 information with respect to the previous 1-year period:

18 “(1) The average debt-to-earnings ratio of the
19 specified entity.

20 “(2) The average amount of debt incurred—

21 “(A) by the hospital; and

22 “(B) by the entire specified entity.

23 “(3) Information with respect to real estate
24 leases and purchases for property used, or intended

1 to be used, to furnish or otherwise support the provi-
2 sion of health care services.

3 “(4) In the case of a non-profit hospital, a sub-
4 sidiary of a non-profit hospital, or a 501(c)(3) entity
5 that shares common ownership with a non-profit
6 hospital, capital gains investments (disaggregated by
7 the type of investment) and any taxes paid on such
8 gains from such investments.

9 “(5) As applicable, information with respect to
10 the parent company of such specified entity.

11 “(c) PUBLIC REPORTING.—

12 “(1) Not later than January 1, 2027, and an-
13 nually thereafter, the Secretary shall post on a pub-
14 licly available website of the Department of Health
15 and Human Services a report with respect to the
16 previous 1-year period, including—

17 “(A) the number of specified entities re-
18 porting for such year, disaggregated by the
19 business structure of each specified entity in ac-
20 cordance with paragraph (2);

21 “(B) the number of owners of each speci-
22 fied entity;

23 “(C) any change in ownership for each
24 specified entity;

1 “(D) any change in the tax status of a
2 specified entity;

3 “(E) an analysis of trends in horizontal
4 and vertical consolidation, disaggregated by
5 business structure and provider type; and

6 “(F) as applicable, the name, address, and
7 business structure of the parent company of
8 such specified entity (including the business
9 type and the tax status of such parent com-
10 pany).

11 “(2) In disaggregating the business structure of
12 a specified entity under paragraph (1)(A), or a par-
13 ent company under subparagraph (F) of such para-
14 graph, the Secretary shall use the following business
15 structures, if applicable, and identify such structures
16 as privately held or publicly traded:

17 “(A) Hospitals.

18 “(B) Health plans.

19 “(C) Private equity companies.

20 “(D) Venture capital funds.

21 “(E) Unincorporated business entities.

22 “(F) S-corporations.

23 “(G) Real estate investment trusts.

24 “(H) Hedge funds.

25 “(I) Exchange-traded funds.

1 “(J) Sovereign wealth funds.

2 “(K) Public pension fund direct ownership
3 investments.

4 “(L) Physician-owned practices with non-
5 physician minority owners.

6 “(M) Other business structures as identi-
7 fied by the Secretary.

8 “(d) AUDITS.—The Secretary shall conduct an an-
9 nual audit consisting of a random sample of specified enti-
10 ties to verify compliance with the requirements of this sec-
11 tion and the accuracy of information submitted pursuant
12 to this section.

13 “(e) PENALTY FOR FAILURE TO REPORT.—If a spec-
14 ified entity fails to provide a complete report under sub-
15 section (a), or submits a report containing false informa-
16 tion, such entity shall be subject to a civil monetary pen-
17 alty of—

18 “(1) in the case of a specified entity that is a
19 hospital with more than 30 beds, not more than
20 \$5,000,000 for each such report not provided or
21 containing false information; and

22 “(2) in the case of all other specified entities,
23 not more than \$2,000,000 for each such report not
24 provided or containing false information.

1 Such penalties shall be imposed and collected in the same
2 manner as civil money penalties under subsection (a) of
3 section 1128A are imposed and collected under that sec-
4 tion.

5 “(f) INAPPLICABILITY OF PAPERWORK REDUCTION
6 ACT.—Chapter 35 of title 44, United States Code, shall
7 not apply to collections of information made under this
8 section.

9 “(g) DEFINITIONS.—In this section:

10 “(1) HEALTH PLAN.—The term ‘health plan’
11 has the meaning given such term in section
12 1128C(c).

13 “(2) HOSPITAL.—The term ‘hospital’ has the
14 meaning given such term in section 1861(e).

15 “(3) INDEPENDENT FREESTANDING EMER-
16 GENCY DEPARTMENT.—The term ‘independent free-
17 standing emergency department’ has the meaning
18 given such term in section 2799A–1(a)(3)(D) of the
19 Public Health Service Act.

20 “(4) PRIVATE EQUITY COMPANY.—The term
21 ‘private equity company’ means a publicly-traded or
22 non-publicly traded company that collects capital in-
23 vestments from individuals or entities and purchases
24 an ownership share of a provider of services.

1 “(5) SPECIFIED ENTITY.—The term ‘specified
2 entity’ means—

3 “(A) a hospital;

4 “(B) a physician-owned physician practice
5 with more than 25 physicians for a year;

6 “(C) a physician practice owned by a hos-
7 pital, a health plan, a private equity company,
8 or a venture capital firm;

9 “(D) an ambulatory surgical center meet-
10 ing the standards specified under section
11 1832(a)(2)(F)(i); or

12 “(E) an independent freestanding emer-
13 gency department.

14 “(6) VENTURE CAPITAL FUND.—The term ‘ven-
15 ture capital fund’ has the meaning given such term
16 in section 275.203(l)–1of title 17, Code of Federal
17 Regulations.”.

18 **SEC. 105. INCREASING PRICE TRANSPARENCY OF CLINICAL**
19 **DIAGNOSTIC LABORATORY TESTS UNDER**
20 **THE MEDICARE PROGRAM.**

21 Section 1846 of the Social Security Act (42 U.S.C.
22 1395w–2) is amended—

23 (1) in the header, by inserting “**AND ADDI-**
24 **TIONAL REQUIREMENTS**” after “**SANCTIONS**”;

25 and

1 (2) by adding at the end the following new sub-
2 section:

3 “(c) PRICE TRANSPARENCY REQUIREMENT.—

4 “(1) IN GENERAL.—Beginning January 1,
5 2025, any applicable laboratory that is available to
6 furnish any specified clinical diagnostic laboratory
7 test under this title shall—

8 “(A) make publicly available on an Inter-
9 net website the information described in para-
10 graph (2) with respect to each such specified
11 clinical diagnostic laboratory test that such lab-
12 oratory is so available to furnish; and

13 “(B) ensure that such information is up-
14 dated not less frequently than annually.

15 “(2) INFORMATION DESCRIBED.—For purposes
16 of paragraph (1), the information described in this
17 paragraph is, with respect to an applicable labora-
18 tory and a specified clinical diagnostic laboratory
19 test, the following:

20 “(A) The discounted cash price for such
21 test (or, if no such price exists, the gross
22 charge for such test).

23 “(B) The deidentified minimum negotiated
24 rate in effect between such laboratory and any

1 group health plan or group or individual health
2 insurance coverage for such test.

3 “(C) The deidentified maximum negotiated
4 rate in effect between such laboratory and any
5 such plan or coverage for such test.

6 “(3) INCLUSION OF ANCILLARY SERVICES.—
7 Any price or rate for a specified clinical diagnostic
8 laboratory test available to be furnished by an appli-
9 cable laboratory made publicly available in accord-
10 ance with paragraph (1) shall include the price or
11 rate (as applicable) for any ancillary item or service
12 (such as specimen collection services) that would
13 normally be furnished by such laboratory as part of
14 such test, as specified by the Secretary.

15 “(4) ENFORCEMENT.—

16 “(A) IN GENERAL.—In the case that the
17 Secretary determines that an applicable labora-
18 tory is not in compliance with paragraph (1)—

19 “(i) not later than 30 days after such
20 determination, the Secretary shall notify
21 such laboratory of such determination; and

22 “(ii) if such laboratory continues to
23 fail to comply with such paragraph after
24 the date that is 90 days after such notifi-
25 cation is sent, the Secretary may impose a

1 civil monetary penalty in an amount not to
2 exceed \$300 for each day (beginning with
3 the date that is 91 days after such notifi-
4 cation was sent) during which such failure
5 is ongoing.

6 “(B) APPLICATION OF CERTAIN PROVI-
7 SIONS.—The provisions of section 1128A (other
8 than subsections (a) and (b) of such section)
9 shall apply to a civil monetary penalty imposed
10 under this paragraph in the same manner as
11 such provisions apply to a civil monetary pen-
12 alty imposed under subsection (a) of such sec-
13 tion.

14 “(5) DEFINITIONS.—In this subsection:

15 “(A) APPLICABLE LABORATORY.—The
16 term ‘applicable laboratory’ has the meaning
17 given such term in section 414.502, of title 42,
18 Code of Federal Regulations.

19 “(B) GROUP HEALTH PLAN; GROUP
20 HEALTH INSURANCE COVERAGE; INDIVIDUAL
21 HEALTH INSURANCE COVERAGE.—The terms
22 ‘group health plan’, ‘group health insurance
23 coverage’, and ‘individual health insurance cov-
24 erage’ have the meaning given such terms in
25 section 2791 of the Public Health Service Act.

1 “(C) SPECIFIED CLINICAL DIAGNOSTIC
2 LABORATORY TEST.—the term ‘specified clinical
3 diagnostic laboratory test’ means a clinical di-
4 agnostic laboratory test that is included on the
5 list of shoppable services specified by the Cen-
6 ters for Medicare & Medicaid Services (as de-
7 scribed in section 2718(e)(1) of the Public
8 Health Service Act), other than such a test that
9 is only available to be furnished by a single pro-
10 vider of services or supplier.”.

11 **SEC. 106. PROMOTING TRANSPARENCY OF COMMON OWN-**
12 **ERSHIP INTERESTS UNDER PARTS C AND D**
13 **OF THE MEDICARE PROGRAM.**

14 (a) **MEDICARE ADVANTAGE.**—Section 1857(e) of the
15 Social Security Act (42 U.S.C. 1395w–27(e)) is amended
16 by adding at the end the following new paragraph:

17 “(6) **REQUIRED DISCLOSURE OF CERTAIN IN-**
18 **FORMATION RELATING TO HEALTH CARE PROVIDER**
19 **OWNERSHIP.**—

20 “(A) **IN GENERAL.**—For plan years begin-
21 ning on or after January 1, 2026, a contract
22 under this section with an MA organization
23 that is an applicable MA organization (as de-
24 fined in subparagraph (C)) with respect to such
25 plan year shall require the organization to re-

1 port to the Secretary, not later than 18 months
2 after the last day of such plan year, the infor-
3 mation described in subparagraph (B) with re-
4 spect to such plan year.

5 “(B) INFORMATION DESCRIBED.—For pur-
6 poses of subparagraph (A), the information de-
7 scribed in this subparagraph is, with respect to
8 an MA organization and a plan year, the fol-
9 lowing:

10 “(i) The number of items and services
11 furnished during such plan year by each
12 specified provider (as defined in subpara-
13 graph (C)) for which payment was made
14 by such organization.

15 “(ii) The number of items and serv-
16 ices furnished during such plan year by
17 providers of services or suppliers not de-
18 scribed in clause (i) for which payment was
19 made by such organization.

20 “(iii) The average per-enrollee number
21 of qualifying diagnoses (as defined in sub-
22 paragraph (C)) made during such plan
23 year by specified providers (including
24 through chart reviews and health risk as-
25 sements) with respect to individuals en-

1 rolled under an MA plan offered by such
2 organization, broken down by site of serv-
3 ice of such providers, as specified by the
4 Secretary.

5 “(iv) The average per-enrollee number
6 of qualifying diagnoses made during such
7 plan year by providers of services and sup-
8 pliers not described in clause (iii) (includ-
9 ing through such reviews and assessments)
10 with respect to such individuals, broken
11 down by site of service of such providers.

12 “(v) The average risk score (as cal-
13 culated under the methodology described in
14 subparagraph (C)(iii)) for such an indi-
15 vidual for such plan year who received
16 items and services from a specified pro-
17 vider during such plan year.

18 “(vi) The average risk score for such
19 an individual for such plan year who did
20 not receive items and services from a speci-
21 fied provider during such plan year.

22 “(vii) The average risk score for such
23 an individual for such plan year who re-
24 ceived a health risk assessment from an

1 assessment entity that was a specified as-
2 sessment entity during such plan year.

3 “(viii) The average risk score for such
4 an individual for such plan year who re-
5 ceived a health risk assessment from an
6 assessment entity that was not a specified
7 assessment entity during such plan year.

8 “(ix) The number of prior authoriza-
9 tion requests for an item or service sub-
10 mitted to such organization during such
11 plan year, the number of such requests
12 that were approved by such organization,
13 the number of such requests that were de-
14 nied by such organization, and the number
15 of such denied requests that were subse-
16 quently appealed and then approved at any
17 level of appeal, broken down by whether
18 the entity proposing to furnish such item
19 or service was a specified provider or not
20 a specified provider.

21 “(x) The total amount of incentive-
22 based payments made to, and the total
23 amount of shared losses recoupments col-
24 lected from, specified providers during
25 such plan year.

1 “(xi) The total amount of incentive-
2 based payments made to, and the total
3 amount of shared losses recoupments col-
4 lected from, providers of services and sup-
5 pliers not described in clause (x) during
6 such plan year.

7 “(xii) The allowed amount, and the
8 amount of cost sharing imposed, with re-
9 spect to each item and service furnished
10 during such plan year by specified pro-
11 viders paid by such organization.

12 “(xiii) The allowed amount, and the
13 amount of cost sharing imposed, with re-
14 spect to each item and service furnished
15 during such plan year by providers of serv-
16 ices and suppliers not described in clause
17 (xii) paid by such organization.

18 “(xiv) The taxpayer identification
19 number of each provider of services and
20 supplier that furnished an item or service
21 during such plan year for which payment
22 was made by such organization.

23 “(xv) For each MA plan offered by
24 such organization during such plan year—

1 “(I) the total amount of pay-
2 ments made under section 1853(a)(1)
3 to such organization for coverage of
4 individuals under such plan, and the
5 total amount of payments made by
6 such individuals to such organization
7 for coverage under such plan (includ-
8 ing any premiums, deductibles, coin-
9 surance, and copayments);

10 “(II) the total amount expended
11 under such plan as payment for items
12 and services furnished by each speci-
13 fied provider during such plan year;

14 “(III) the total amount expended
15 under such plan as payment for items
16 and services furnished by providers of
17 services or suppliers not described in
18 subclause (II) during such plan year;

19 “(IV) the medical loss ratio
20 under such plan with respect to indi-
21 viduals furnished an item or service
22 from a specified provider during such
23 plan year; and

24 “(V) the medical loss ratio under
25 such plan with respect to individuals

1 not described in subclause (IV) during
2 such plan year.

3 In calculating average per-enrollee numbers of qualifying
4 diagnoses and average risk scores under clauses (iii)
5 through (viii), a plan shall not take into account qualifying
6 diagnoses made with respect to individuals diagnosed with
7 end-stage renal disease or risk scores for such individuals.

8 “(C) DEFINITIONS.—In this paragraph:

9 “(i) APPLICABLE MA ORGANIZA-
10 TION.—The term ‘applicable MA organiza-
11 tion’ means, with respect to a plan year,
12 an MA organization with at least 25,000
13 individual enrolled under Medicare Advan-
14 tage plans offered by such organization
15 during such plan year.

16 “(ii) ASSESSMENT ENTITY.—The
17 term ‘assessment entity’ means an entity
18 with a focus on furnishing in-home health
19 risk assessments, as specified by the Sec-
20 retary.

21 “(iii) QUALIFYING DIAGNOSIS.—The
22 term ‘qualifying diagnosis’ means, with re-
23 spect to an individual, a diagnosis that is
24 taken into account in calculating a risk
25 score for such individual under the risk ad-

1 justment methodology established by the
2 Secretary pursuant to section 1853(a)(3).

3 “(iv) SPECIFIED ASSESSMENT ENTI-
4 TY.—The term ‘specified assessment enti-
5 ty’ means, with respect to an MA organiza-
6 tion and a plan year, an assessment entity
7 with respect to which such organization (or
8 any person with an ownership or control
9 interest (as defined in section 1124(a)(3))
10 in such organization) is a person with an
11 ownership or control interest (as so de-
12 fined).

13 “(v) SPECIFIED PROVIDER.—The
14 term ‘specified provider’ means, with re-
15 spect to an MA organization and a plan
16 year, a provider of services or supplier with
17 respect to which such organization (or any
18 person with an ownership or control inter-
19 est (as defined in section 1124(a)(3)) in
20 such organization) is a person with an
21 ownership or control interest (as so de-
22 fined).

23 “(D) NONAPPLICATION OF PAPERWORK
24 REDUCTION ACT.—Chapter 35 of title 44,

1 United States Code, shall not apply to informa-
2 tion collected under this paragraph.”.

3 (b) PHARMACY BENEFIT MANAGER AND PHARMACY
4 INFORMATION.—Section 1860D–12(b) of the Social Secu-
5 rity Act (42 U.S.C. 1395w–112(b)) is amended by adding
6 at the end the following new paragraphs:

7 “(9) PROVISION OF INFORMATION RELATING TO
8 PHARMACY OWNERSHIP.—

9 “(A) IN GENERAL.—For plan years begin-
10 ning on or after January 1, 2026, a contract
11 entered into under this part with a PDP spon-
12 sor that is an applicable PDP sponsor (as de-
13 fined in subparagraph (C)) with respect to such
14 plan year shall require the sponsor to report to
15 the Secretary, not later than 1 year after the
16 last day of such plan year, the information de-
17 scribed in subparagraph (B) with respect to
18 such plan year.

19 “(B) INFORMATION DESCRIBED.—For pur-
20 poses of subparagraph (A), the information de-
21 scribed in this subparagraph is, for each pre-
22 scription drug plan offered by a PDP sponsor
23 for a plan year, the following:

24 “(i) The average negotiated price for
25 each covered part D drug for which bene-

1 fits are available under such plan for each
2 network pharmacy during such plan year
3 (including an identification of whether
4 each such pharmacy is a specified phar-
5 macy).

6 “(ii) The average per-drug amount of
7 direct and indirect remuneration paid by
8 specified pharmacies for such covered part
9 D drugs dispensed during such plan year
10 under such plan.

11 “(iii) The average per-drug amount of
12 direct and indirect remuneration paid by
13 pharmacies not described in clause (ii) for
14 such covered part D drugs dispensed dur-
15 ing such plan year under such plan.

16 “(C) DEFINITIONS.—In this paragraph:

17 “(i) APPLICABLE PDP SPONSOR.—The
18 term ‘applicable PDP sponsor’ means, with
19 respect to a plan year, a PDP sponsor with
20 at least 25,000 individual enrolled under
21 prescription drug plans offered by such
22 sponsor during such plan year.

23 “(ii) DIRECT AND INDIRECT REMU-
24 NERATION.—The term ‘direct and indirect
25 remuneration’ has the meaning given such

1 term in section 423.308 of title 42, Code
2 of Federal Regulations (or any successor
3 regulation).

4 “(iii) NETWORK PHARMACY.—The
5 term ‘network pharmacy’ has the meaning
6 given such term in section 423.100 of title
7 42, Code of Federal Regulations (or any
8 successor regulation).

9 “(iv) NEGOTIATED PRICE.—The ‘ne-
10 gotiated price’ for a covered part D drug
11 shall take into account all negotiated price
12 concessions, such as discounts, direct or in-
13 direct subsidies, rebates, and direct or indi-
14 rect remunerations, for such drug, and in-
15 clude any dispensing fee for such drug.

16 “(v) SPECIFIED PHARMACY.—The
17 term ‘specified pharmacy’ means, with re-
18 spect to an PDP sponsor and a plan year,
19 a pharmacy with respect to which such
20 sponsor (or any person with an ownership
21 or control interest (as defined in section
22 1124(a)(3)) in such sponsor) is a person
23 with an ownership or control interest (as
24 so defined).

1 “(D) NONAPPLICATION OF PAPERWORK
2 REDUCTION ACT.—Chapter 35 of title 44,
3 United States Code, shall not apply to informa-
4 tion collected under this paragraph.

5 “(10) PROVISION OF INFORMATION BY PHAR-
6 MACY BENEFIT MANAGERS.—

7 “(A) IN GENERAL.—For plan years begin-
8 ning on or after January 1, 2026, a contract
9 entered into under this part with a PDP spon-
10 sor shall prohibit such sponsor from entering
11 into a contract with a specified pharmacy ben-
12 efit manager for purposes of performing any
13 service with respect to covered part D drugs
14 dispensed under any prescription drug plan of-
15 fered by such sponsor for such plan year unless
16 such manager agrees to report to the Secretary,
17 not later than 1 year after the last day of such
18 plan year, the information described in subpara-
19 graph (B) with respect to each prescription
20 drug plan for which such manager is providing
21 any such service during such plan year, regard-
22 less of the sponsor of such plan.

23 “(B) INFORMATION DESCRIBED.—For pur-
24 poses of subparagraph (A), the information de-
25 scribed in this subparagraph is, with respect to

1 a pharmacy benefit manager performing serv-
2 ices under a prescription drug plan for a plan
3 year, the following:

4 “(i) With respect to the total amount
5 of direct and indirect remuneration (as de-
6 fined in subparagraph (C)) collected by
7 such manager (or collected on behalf of
8 such plan by any other entity with a con-
9 tract in effect with such manager for such
10 collection) for all covered part D drugs dis-
11 pensed under such plan during such plan
12 year—

13 “(I) the total amount of such re-
14 munerations passed through to the
15 PDP sponsor of such plan; and

16 “(II) the total amount of such re-
17 munerations retained by such manager
18 or such other entities.

19 “(ii) The total amount paid by such
20 manager to pharmacies for drugs dis-
21 pensed under such plan during such plan
22 year.

23 “(iii) The total amount of payments
24 made by such sponsor to such manager as

1 reimbursement for such manager’s pay-
2 ments described in clause (ii).

3 “(iv) The total amount of payments
4 made by such sponsor to such manager as
5 fees for services furnished by such man-
6 ager with respect to such plan for such
7 plan year (not including payments de-
8 scribed in clause (iii)).

9 “(v) The total amount of administra-
10 tive costs incurred by such manager for
11 furnishing such services under such plan
12 for such plan year.

13 “(vi) A specification as to whether
14 such manager is a specified pharmacy ben-
15 efit manager with respect to the PDP
16 sponsor of such plan.

17 “(C) DEFINITION.—In this paragraph:

18 “(i) DIRECT AND INDIRECT REMU-
19 NERATION.—The term ‘direct and indirect
20 remuneration’ has the meaning given such
21 term in section 423.308 of title 42, Code
22 of Federal Regulations (or any successor
23 regulation).

24 “(ii) SPECIFIED PHARMACY BENEFIT
25 MANAGER.—the term ‘specified pharmacy

1 benefit manager’ means, with respect to an
2 PDP sponsor and a plan year, a pharmacy
3 benefit manager with respect to which such
4 sponsor (or any person with an ownership
5 or control interest (as defined in section
6 1124(a)(3)) in such sponsor) is a person
7 with an ownership or control interest (as
8 so defined).

9 “(D) NONAPPLICATION OF PAPERWORD
10 REDUCTION ACT.—Chapter 35 of title 44,
11 United States Code, shall not apply to informa-
12 tion collected under this paragraph.”.

13 (c) ENCOUNTER DATA.—Section 1859 of the Social
14 Security Act (42 U.S.C. 1395w–28) is amended by adding
15 at the end the following new subsection:

16 “(j) INCLUSION OF CERTAIN INFORMATION IN EN-
17 COUNTER DATA.—

18 “(1) IN GENERAL.—In the case of any encoun-
19 ter data submitted by a Medicare Advantage plan
20 with respect to an item or service furnished to an in-
21 dividual under such plan during a plan year begin-
22 ning on or after January 1, 2026, the Secretary
23 shall require that such data include—

24 “(A) the allowed amount for such item or
25 service;

1 “(B) the amount of cost sharing (including
2 deductibles, copayments, and coinsurance) im-
3 posed for such item or service;

4 “(C) in the case such individual was fur-
5 nished, during such plan year before such item
6 or service was so furnished, an at-home health
7 risk assessment from a specified assessment en-
8 tity, an indicator that such individual was so
9 furnished such an assessment by such an entity;
10 and

11 “(D) in the case such individual was fur-
12 nished, during such plan year before such item
13 or service was so furnished, an at-home health
14 risk assessment from an assessment entity not
15 described in subparagraph (C), an indicator
16 (distinct from the indicator described in such
17 subparagraph) that such individual was so fur-
18 nished such an assessment by such an entity.

19 “(2) DEFINITIONS.—For purposes of this sub-
20 section, the terms ‘assessment entity’ and ‘specified
21 assessment entity’ have the meaning given such
22 terms in section 1857(e)(6).”.

23 (d) MEDPAC REPORT.—

24 (1) IN GENERAL.—Not later than June 15,
25 2029, the Medicare Payment Advisory Commission

1 shall submit to Congress a report describing the
2 state of vertical integration in the health care sector
3 with respect to entities participating in the Medicare
4 program in 2025. Such report shall include an ex-
5 amination of entities such as health care providers,
6 pharmacies, PDP sponsors, MA organizations, and
7 pharmacy benefit managers.

8 (2) REPORT ON CHANGES.—Not later than
9 June 15, 2032, and again not later than June 15,
10 2035, the Medicare Payment Advisory Commission
11 shall submit to Congress a report describing the ef-
12 fects of any changes in the vertical integration in the
13 health care sector on the Medicare program that oc-
14 curred during the preceding 3 years, with a par-
15 ticular focus on such changes with respect to health
16 care providers, pharmacies, PDP sponsors, MA or-
17 ganizations, and pharmacy benefit managers that
18 were under separate ownership and that, as of the
19 date of the submission of such report, are under
20 common ownership.

21 (e) PUBLICATION.—Not later than January 1, 2027,
22 the Secretary of Health and Human Services shall estab-
23 lish a process under which information submitted to the
24 Secretary pursuant to the amendments made by sub-
25 sections (a) and (b) is publicly disclosed. Such process

1 shall ensure that any information so disclosed does not
2 identify a specific drug manufacturer, provider of services
3 or supplier, pharmacy, pharmacy benefit manager, or any
4 price charged with respect to a particular drug.

5 **SEC. 107. OVERSIGHT OF PHARMACY BENEFITS MANAGER**
6 **SERVICES.**

7 (a) PHSA.—Title XXVII of the Public Health Serv-
8 ice Act (42 U.S.C. 300gg et seq.) is amended—

9 (1) in part D (42 U.S.C. 300gg–111 et seq.),
10 by adding at the end the following new section:

11 **“SEC. 2799A–11. OVERSIGHT OF PHARMACY BENEFITS MAN-**
12 **AGER SERVICES.**

13 “(a) IN GENERAL.—For plan years beginning on or
14 after January 1, 2025, a group health plan or health in-
15 surance issuer offering group health insurance coverage
16 or an entity or subsidiary providing pharmacy benefits
17 management services on behalf of such a plan or issuer
18 shall not enter into a contract with a drug manufacturer,
19 distributor, wholesaler, subcontractor, rebate aggregator,
20 or any associated third party that limits the disclosure of
21 information to plan sponsors in such a manner that pre-
22 vents the plan or issuer, or an entity or subsidiary pro-
23 viding pharmacy benefits management services on behalf
24 of a plan or issuer, from making the reports described in
25 subsection (b).

1 “(b) REPORTS.—

2 “(1) IN GENERAL.—For plan years beginning
3 on or after January 1, 2025, not less frequently
4 than annually, a health insurance issuer offering
5 group health insurance coverage or an entity pro-
6 viding pharmacy benefits management services on
7 behalf of a group health plan or an issuer providing
8 group health insurance coverage shall submit to the
9 plan sponsor (as defined in section 3(16)(B) of the
10 Employee Retirement Income Security Act of 1974)
11 of such group health plan or health insurance cov-
12 erage a report in accordance with this subsection
13 and make such report available to the plan sponsor
14 in a machine-readable format. Each such report
15 shall include, with respect to the applicable group
16 health plan or health insurance coverage—

17 “(A) as applicable, information collected
18 from drug manufacturers by such issuer or en-
19 tity on the total amount of copayment assist-
20 ance dollars paid, or copayment cards applied,
21 that were funded by the drug manufacturer
22 with respect to the participants and bene-
23 ficiaries in such plan or coverage;

24 “(B) a list of each drug covered by such
25 plan, issuer, or entity providing pharmacy bene-

1 fits management services that was dispensed
2 during the reporting period, including, with re-
3 spect to each such drug during the reporting
4 period—

5 “(i) the brand name, chemical entity,
6 and National Drug Code;

7 “(ii) the number of participants and
8 beneficiaries for whom the drug was filled
9 during the plan year, the total number of
10 prescription fills for the drug (including
11 original prescriptions and refills), and the
12 total number of dosage units of the drug
13 dispensed across the plan year, including
14 whether the dispensing channel was by re-
15 tail, mail order, or specialty pharmacy;

16 “(iii) the wholesale acquisition cost,
17 listed as cost per days supply and cost per
18 pill, or in the case of a drug in another
19 form, per dose;

20 “(iv) the total out-of-pocket spending
21 by participants and beneficiaries on such
22 drug, including participant and beneficiary
23 spending through copayments, coinsurance,
24 and deductibles; and

1 “(v) for any drug for which gross
2 spending of the group health plan or
3 health insurance coverage exceeded
4 \$10,000 during the reporting period—

5 “(I) a list of all other drugs in
6 the same therapeutic category or
7 class, including brand name drugs
8 and biological products and generic
9 drugs or biosimilar biological products
10 that are in the same therapeutic cat-
11 egory or class as such drug; and

12 “(II) the rationale for preferred
13 formulary placement of such drug in
14 that therapeutic category or class, if
15 applicable;

16 “(C) a list of each therapeutic category or
17 class of drugs that were dispensed under the
18 health plan or health insurance coverage during
19 the reporting period, and, with respect to each
20 such therapeutic category or class of drugs,
21 during the reporting period—

22 “(i) total gross spending by the plan,
23 before manufacturer rebates, fees, or other
24 manufacturer remuneration;

1 “(ii) the number of participants and
2 beneficiaries who filled a prescription for a
3 drug in that category or class;

4 “(iii) if applicable to that category or
5 class, a description of the formulary tiers
6 and utilization mechanisms (such as prior
7 authorization or step therapy) employed
8 for drugs in that category or class;

9 “(iv) the total out-of-pocket spending
10 by participants and beneficiaries, including
11 participant and beneficiary spending
12 through copayments, coinsurance, and
13 deductibles; and

14 “(v) for each therapeutic category or
15 class under which 3 or more drugs are in-
16 cluded on the formulary of such plan or
17 coverage—

18 “(I) the amount received, or ex-
19 pected to be received, from drug man-
20 ufacturers in rebates, fees, alternative
21 discounts, or other remuneration—

22 “(aa) that has been paid, or
23 is to be paid, by drug manufac-
24 turers for claims incurred during
25 the reporting period; or

1 “(bb) that is related to utili-
2 zation of drugs, in such thera-
3 peutic category or class;

4 “(II) the total net spending, after
5 deducting rebates, price concessions,
6 alternative discounts or other remu-
7 neration from drug manufacturers, by
8 the health plan or health insurance
9 coverage on that category or class of
10 drugs; and

11 “(III) the net price per course of
12 treatment or single fill, such as a 30-
13 day supply or 90-day supply, incurred
14 by the health plan or health insurance
15 coverage and its participants and
16 beneficiaries, after manufacturer re-
17 bates, fees, and other remuneration
18 for drugs dispensed within such thera-
19 peutic category or class during the re-
20 porting period;

21 “(D) total gross spending on prescription
22 drugs by the plan or coverage during the re-
23 porting period, before rebates and other manu-
24 facturer fees or remuneration;

1 “(E) total amount received, or expected to
2 be received, by the health plan or health insur-
3 ance coverage in drug manufacturer rebates,
4 fees, alternative discounts, and all other remu-
5 neration received from the manufacturer or any
6 third party, other than the plan sponsor, re-
7 lated to utilization of drug or drug spending
8 under that health plan or health insurance cov-
9 erage during the reporting period;

10 “(F) the total net spending on prescription
11 drugs by the health plan or health insurance
12 coverage during the reporting period; and

13 “(G) amounts paid directly or indirectly in
14 rebates, fees, or any other type of remuneration
15 to brokers, consultants, advisors, or any other
16 individual or firm who referred the group health
17 plan’s or health insurance issuer’s business to
18 the pharmacy benefits manager.

19 “(2) PRIVACY REQUIREMENTS.—Health insur-
20 ance issuers offering group health insurance cov-
21 erage and entities providing pharmacy benefits man-
22 agement services on behalf of a group health plan
23 shall provide information under paragraph (1) in a
24 manner consistent with the privacy, security, and
25 breach notification regulations promulgated under

1 section 264(c) of the Health Insurance Portability
2 and Accountability Act of 1996, and shall restrict
3 the use and disclosure of such information according
4 to such privacy regulations.

5 “(3) DISCLOSURE AND REDISCLOSURE.—

6 “(A) LIMITATION TO BUSINESS ASSOCI-
7 ATES.—A group health plan receiving a report
8 under paragraph (1) may disclose such informa-
9 tion only to business associates of such plan as
10 defined in section 160.103 of title 45, Code of
11 Federal Regulations (or successor regulations).

12 “(B) CLARIFICATION REGARDING PUBLIC
13 DISCLOSURE OF INFORMATION.—Nothing in
14 this section prevents a health insurance issuer
15 offering group health insurance coverage or an
16 entity providing pharmacy benefits management
17 services on behalf of a group health plan from
18 placing reasonable restrictions on the public dis-
19 closure of the information contained in a report
20 described in paragraph (1), except that such
21 issuer or entity may not restrict disclosure of
22 such report to the Department of Health and
23 Human Services, the Department of Labor, the
24 Department of the Treasury, the Comptroller

1 General of the United States, or applicable
2 State agencies.

3 “(C) LIMITED FORM OF REPORT.—The
4 Secretary shall define through rulemaking a
5 limited form of the report under paragraph (1)
6 required of plan sponsors who are drug manu-
7 facturers, drug wholesalers, or other direct par-
8 ticipants in the drug supply chain, in order to
9 prevent anti-competitive behavior.

10 “(4) REPORT TO GAO.—A health insurance
11 issuer offering group health insurance coverage or
12 an entity providing pharmacy benefits management
13 services on behalf of a group health plan shall sub-
14 mit to the Comptroller General of the United States
15 each of the first 4 reports submitted to a plan spon-
16 sor under paragraph (1) with respect to such cov-
17 erage or plan, and other such reports as requested,
18 in accordance with the privacy requirements under
19 paragraph (2), the disclosure and redisclosure stand-
20 ards under paragraph (3), the standards specified
21 pursuant to paragraph (5), and such other informa-
22 tion that the Comptroller General determines nec-
23 essary to carry out the study under section 2(d) of
24 the Pharmacy Benefits Manager Accountability Act.

1 “(5) STANDARD FORMAT.—Not later than 6
2 months after the date of enactment of this section,
3 the Secretary shall specify through rulemaking
4 standards for health insurance issuers and entities
5 required to submit reports under paragraph (4) to
6 submit such reports in a standard format.

7 “(c) ENFORCEMENT.—

8 “(1) IN GENERAL.—The Secretary, in consulta-
9 tion with the Secretary of Labor and the Secretary
10 of the Treasury, shall enforce this section.

11 “(2) FAILURE TO PROVIDE TIMELY INFORMA-
12 TION.—A health insurance issuer or an entity pro-
13 viding pharmacy benefits management services that
14 violates subsection (a) or fails to provide information
15 required under subsection (b) shall be subject to a
16 civil monetary penalty in the amount of \$10,000 for
17 each day during which such violation continues or
18 such information is not disclosed or reported.

19 “(3) FALSE INFORMATION.—A health insurance
20 issuer or entity providing pharmacy benefits man-
21 agement services that knowingly provides false infor-
22 mation under this section shall be subject to a civil
23 money penalty in an amount not to exceed \$100,000
24 for each item of false information. Such civil money

1 penalty shall be in addition to other penalties as
2 may be prescribed by law.

3 “(4) PROCEDURE.—The provisions of section
4 1128A of the Social Security Act, other than sub-
5 section (a) and (b) and the first sentence of sub-
6 section (c)(1) of such section shall apply to civil
7 monetary penalties under this subsection in the
8 same manner as such provisions apply to a penalty
9 or proceeding under section 1128A of the Social Se-
10 curity Act.

11 “(5) WAIVERS.—The Secretary may waive pen-
12 alties under paragraph (2), or extend the period of
13 time for compliance with a requirement of this sec-
14 tion, for an entity in violation of this section that
15 has made a good-faith effort to comply with this sec-
16 tion.

17 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
18 tion shall be construed to permit a health insurance issuer,
19 group health plan, or other entity to restrict disclosure to,
20 or otherwise limit the access of, the Department of Health
21 and Human Services to a report described in subsection
22 (b)(1) or information related to compliance with sub-
23 section (a) by such issuer, plan, or entity.

1 “(e) DEFINITION.—In this section, the term ‘whole-
2 sale acquisition cost’ has the meaning given such term in
3 section 1847A(c)(6)(B) of the Social Security Act.”; and

4 (2) in section 2723 (42 U.S.C. 300gg-22)—

5 (A) in subsection (a)—

6 (i) in paragraph (1), by inserting
7 “(other than subsections (a) and (b) of
8 section 2799A-11)” after “part D”; and

9 (ii) in paragraph (2), by inserting
10 “(other than subsections (a) and (b) of
11 section 2799A-11)” after “part D”; and

12 (B) in subsection (b)—

13 (i) in paragraph (1), by inserting
14 “(other than subsections (a) and (b) of
15 section 2799A-11)” after “part D”;

16 (ii) in paragraph (2)(A), by inserting
17 “(other than subsections (a) and (b) of
18 section 2799A-11)” after “part D”; and

19 (iii) in paragraph (2)(C)(ii), by insert-
20 ing “(other than subsections (a) and (b) of
21 section 2799A-11)” after “part D”.

22 (b) ERISA.—

23 (1) IN GENERAL.—Subtitle B of title I of the
24 Employee Retirement Income Security Act of 1974
25 (29 U.S.C. 1021 et seq.) is amended—

1 (A) in subpart B of part 7 (29 U.S.C.
2 1185 et seq.), by adding at the end the fol-
3 lowing:

4 **“SEC. 726. OVERSIGHT OF PHARMACY BENEFITS MANAGER**
5 **SERVICES.**

6 “(a) IN GENERAL.—For plan years beginning on or
7 after January 1, 2025, a group health plan (or health in-
8 surance issuer offering group health insurance coverage
9 in connection with such a plan) or an entity or subsidiary
10 providing pharmacy benefits management services on be-
11 half of such a plan or issuer shall not enter into a contract
12 with a drug manufacturer, distributor, wholesaler, subcon-
13 tractor, rebate aggregator, or any associated third party
14 that limits the disclosure of information to plan sponsors
15 in such a manner that prevents the plan or issuer, or an
16 entity or subsidiary providing pharmacy benefits manage-
17 ment services on behalf of a plan or issuer, from making
18 the reports described in subsection (b).

19 “(b) REPORTS.—

20 “(1) IN GENERAL.—For plan years beginning
21 on or after January 1, 2025, not less frequently
22 than annually, a health insurance issuer offering
23 group health insurance coverage or an entity pro-
24 viding pharmacy benefits management services on
25 behalf of a group health plan or an issuer providing

1 group health insurance coverage shall submit to the
2 plan sponsor (as defined in section 3(16)(B)) of
3 such group health plan or group health insurance
4 coverage a report in accordance with this subsection
5 and make such report available to the plan sponsor
6 in a machine-readable format. Each such report
7 shall include, with respect to the applicable group
8 health plan or health insurance coverage—

9 “(A) as applicable, information collected
10 from drug manufacturers by such issuer or en-
11 tity on the total amount of copayment assist-
12 ance dollars paid, or copayment cards applied,
13 that were funded by the drug manufacturer
14 with respect to the participants and bene-
15 ficiaries in such plan or coverage;

16 “(B) a list of each drug covered by such
17 plan, issuer, or entity providing pharmacy bene-
18 fits management services that was dispensed
19 during the reporting period, including, with re-
20 spect to each such drug during the reporting
21 period—

22 “(i) the brand name, chemical entity,
23 and National Drug Code;

24 “(ii) the number of participants and
25 beneficiaries for whom the drug was filled

1 during the plan year, the total number of
2 prescription fills for the drug (including
3 original prescriptions and refills), and the
4 total number of dosage units of the drug
5 dispensed across the plan year, including
6 whether the dispensing channel was by re-
7 tail, mail order, or specialty pharmacy;

8 “(iii) the wholesale acquisition cost,
9 listed as cost per days supply and cost per
10 pill, or in the case of a drug in another
11 form, per dose;

12 “(iv) the total out-of-pocket spending
13 by participants and beneficiaries on such
14 drug, including participant and beneficiary
15 spending through copayments, coinsurance,
16 and deductibles; and

17 “(v) for any drug for which gross
18 spending of the group health plan or
19 health insurance coverage exceeded
20 \$10,000 during the reporting period—

21 “(I) a list of all other drugs in
22 the same therapeutic category or
23 class, including brand name drugs
24 and biological products and generic
25 drugs or biosimilar biological products

1 that are in the same therapeutic cat-
2 egory or class as such drug; and

3 “**(II)** the rationale for preferred
4 formulary placement of such drug in
5 that therapeutic category or class, if
6 applicable;

7 “**(C)** a list of each therapeutic category or
8 class of drugs that were dispensed under the
9 health plan or health insurance coverage during
10 the reporting period, and, with respect to each
11 such therapeutic category or class of drugs,
12 during the reporting period—

13 “(i) total gross spending by the plan,
14 before manufacturer rebates, fees, or other
15 manufacturer remuneration;

16 “(ii) the number of participants and
17 beneficiaries who filled a prescription for a
18 drug in that category or class;

19 “(iii) if applicable to that category or
20 class, a description of the formulary tiers
21 and utilization mechanisms (such as prior
22 authorization or step therapy) employed
23 for drugs in that category or class;

24 “(iv) the total out-of-pocket spending
25 by participants and beneficiaries, including

1 participant and beneficiary spending
2 through copayments, coinsurance, and
3 deductibles; and

4 “(v) for each therapeutic category or
5 class under which 3 or more drugs are in-
6 cluded on the formulary of such plan or
7 coverage—

8 “(I) the amount received, or ex-
9 pected to be received, from drug man-
10 ufacturers in rebates, fees, alternative
11 discounts, or other remuneration—

12 “(aa) that has been paid, or
13 is to be paid, by drug manufac-
14 turers for claims incurred during
15 the reporting period; or

16 “(bb) that is related to utili-
17 zation of drugs, in such thera-
18 peutic category or class;

19 “(II) the total net spending, after
20 deducting rebates, price concessions,
21 alternative discounts or other remu-
22 neration from drug manufacturers, by
23 the health plan or health insurance
24 coverage on that category or class of
25 drugs; and

1 “(III) the net price per course of
2 treatment or single fill, such as a 30-
3 day supply or 90-day supply, incurred
4 by the health plan or health insurance
5 coverage and its participants and
6 beneficiaries, after manufacturer re-
7 bates, fees, and other remuneration
8 for drugs dispensed within such thera-
9 peutic category or class during the re-
10 porting period;

11 “(D) total gross spending on prescription
12 drugs by the plan or coverage during the re-
13 porting period, before rebates and other manu-
14 facturer fees or remuneration;

15 “(E) total amount received, or expected to
16 be received, by the health plan or health insur-
17 ance coverage in drug manufacturer rebates,
18 fees, alternative discounts, and all other remu-
19 neration received from the manufacturer or any
20 third party, other than the plan sponsor, re-
21 lated to utilization of drug or drug spending
22 under that health plan or health insurance cov-
23 erage during the reporting period;

1 “(F) the total net spending on prescription
2 drugs by the health plan or health insurance
3 coverage during the reporting period; and

4 “(G) amounts paid directly or indirectly in
5 rebates, fees, or any other type of remuneration
6 to brokers, consultants, advisors, or any other
7 individual or firm who referred the group health
8 plan’s or health insurance issuer’s business to
9 the pharmacy benefits manager.

10 “(2) PRIVACY REQUIREMENTS.—Health insur-
11 ance issuers offering group health insurance cov-
12 erage and entities providing pharmacy benefits man-
13 agement services on behalf of a group health plan
14 shall provide information under paragraph (1) in a
15 manner consistent with the privacy, security, and
16 breach notification regulations promulgated under
17 section 264(c) of the Health Insurance Portability
18 and Accountability Act of 1996, and shall restrict
19 the use and disclosure of such information according
20 to such privacy regulations.

21 “(3) DISCLOSURE AND REDISCLOSURE.—

22 “(A) LIMITATION TO BUSINESS ASSOCI-
23 ATES.—A group health plan receiving a report
24 under paragraph (1) may disclose such informa-
25 tion only to business associates of such plan as

1 defined in section 160.103 of title 45, Code of
2 Federal Regulations (or successor regulations).

3 “(B) CLARIFICATION REGARDING PUBLIC
4 DISCLOSURE OF INFORMATION.—Nothing in
5 this section prevents a health insurance issuer
6 offering group health insurance coverage or an
7 entity providing pharmacy benefits management
8 services on behalf of a group health plan from
9 placing reasonable restrictions on the public dis-
10 closure of the information contained in a report
11 described in paragraph (1), except that such
12 issuer or entity may not restrict disclosure of
13 such report to the Department of Health and
14 Human Services, the Department of Labor, the
15 Department of the Treasury, the Comptroller
16 General of the United States, or applicable
17 State agencies.

18 “(C) LIMITED FORM OF REPORT.—The
19 Secretary shall define through rulemaking a
20 limited form of the report under paragraph (1)
21 required of plan sponsors who are drug manu-
22 facturers, drug wholesalers, or other direct par-
23 ticipants in the drug supply chain, in order to
24 prevent anti-competitive behavior.

1 “(4) REPORT TO GAO.—A health insurance
2 issuer offering group health insurance coverage or
3 an entity providing pharmacy benefits management
4 services on behalf of a group health plan shall sub-
5 mit to the Comptroller General of the United States
6 each of the first 4 reports submitted to a plan spon-
7 sor under paragraph (1) with respect to such cov-
8 erage or plan, and other such reports as requested,
9 in accordance with the privacy requirements under
10 paragraph (2), the disclosure and redisclosure stand-
11 ards under paragraph (3), the standards specified
12 pursuant to paragraph (5), and such other informa-
13 tion that the Comptroller General determines nec-
14 essary to carry out the study under section 2(d) of
15 the Pharmacy Benefits Manager Accountability Act.

16 “(5) STANDARD FORMAT.—Not later than 6
17 months after the date of enactment of this section,
18 the Secretary shall specify through rulemaking
19 standards for health insurance issuers and entities
20 required to submit reports under paragraph (4) to
21 submit such reports in a standard format.

22 “(c) RULE OF CONSTRUCTION.—Nothing in this sec-
23 tion shall be construed to permit a health insurance issuer,
24 group health plan, or other entity to restrict disclosure to,
25 or otherwise limit the access of, the Department of Labor

1 to a report described in subsection (b)(1) or information
2 related to compliance with subsection (a) by such issuer,
3 plan, or entity.

4 “(d) DEFINITION.—In this section, the term ‘whole-
5 sale acquisition cost’ has the meaning given such term in
6 section 1847A(c)(6)(B) of the Social Security Act.”; and

7 (B) in section 502 (29 U.S.C. 1132)—

8 (i) in subsection (a)—

9 (I) in paragraph (6), by striking
10 “or (9)” and inserting “(9), or (13)”;

11 (II) in paragraph (10), by strik-
12 ing at the end “or”;

13 (III) in paragraph (11), at the
14 end by striking the period and insert-
15 ing “; or”; and

16 (IV) by adding at the end the fol-
17 lowing new paragraph:

18 “(12) by the Secretary, in consultation with the
19 Secretary of Health and Human Services, and the
20 Secretary of the Treasury, to enforce section 726.”;

21 (ii) in subsection (b)(3), by inserting
22 “and subsections (a)(12) and (c)(13)” be-
23 fore “, the Secretary is not”; and

24 (iii) in subsection (c), by adding at
25 the end the following new paragraph:

1 “(13) SECRETARIAL ENFORCEMENT AUTHORITY
2 RELATING TO OVERSIGHT OF PHARMACY BENEFITS
3 MANAGER SERVICES.—

4 “(A) FAILURE TO PROVIDE TIMELY INFOR-
5 MATION.—The Secretary, in consultation with
6 the Secretary of Health and Human Services
7 and the Secretary of the Treasury, may impose
8 a penalty against any health insurance issuer or
9 entity providing pharmacy benefits management
10 services that violates section 726(a) or fails to
11 provide information required under section
12 726(b) in the amount of \$10,000 for each day
13 during which such violation continues or such
14 information is not disclosed or reported.

15 “(B) FALSE INFORMATION.—The Sec-
16 retary, in consultation with the Secretary of
17 Health and Human Services and the Secretary
18 of the Treasury, may impose a penalty against
19 a health insurance issuer or entity providing
20 pharmacy benefits management services that
21 knowingly provides false information under sec-
22 tion 726 in an amount not to exceed \$100,000
23 for each item of false information. Such penalty
24 shall be in addition to other penalties as may
25 be prescribed by law.

1 or an entity or subsidiary providing pharmacy benefits
2 management services on behalf of a plan, from making
3 the reports described in subsection (b).

4 “(b) REPORTS.—

5 “(1) IN GENERAL.—For plan years beginning
6 on or after January 1, 2025, not less frequently
7 than annually, an entity providing pharmacy benefits
8 management services on behalf of a group health
9 plan shall submit to the plan sponsor (as defined in
10 section 3(16)(B) of the Employee Retirement In-
11 come Security Act of 1974) of such group health
12 plan a report in accordance with this subsection and
13 make such report available to the plan sponsor in a
14 machine-readable format. Each such report shall in-
15 clude, with respect to the applicable group health
16 plan—

17 “(A) as applicable, information collected
18 from drug manufacturers by such entity on the
19 total amount of copayment assistance dollars
20 paid, or copayment cards applied, that were
21 funded by the drug manufacturer with respect
22 to the participants and beneficiaries in such
23 plan;

24 “(B) a list of each drug covered by such
25 plan or entity providing pharmacy benefits

1 management services that was dispensed during
2 the reporting period, including, with respect to
3 each such drug during the reporting period—

4 “(i) the brand name, chemical entity,
5 and National Drug Code;

6 “(ii) the number of participants and
7 beneficiaries for whom the drug was filled
8 during the plan year, the total number of
9 prescription fills for the drug (including
10 original prescriptions and refills), and the
11 total number of dosage units of the drug
12 dispensed across the plan year, including
13 whether the dispensing channel was by re-
14 tail, mail order, or specialty pharmacy;

15 “(iii) the wholesale acquisition cost,
16 listed as cost per days supply and cost per
17 pill, or in the case of a drug in another
18 form, per dose;

19 “(iv) the total out-of-pocket spending
20 by participants and beneficiaries on such
21 drug, including participant and beneficiary
22 spending through copayments, coinsurance,
23 and deductibles; and

1 “(v) for any drug for which gross
2 spending of the group health plan exceeded
3 \$10,000 during the reporting period—

4 “(I) a list of all other drugs in
5 the same therapeutic category or
6 class, including brand name drugs
7 and biological products and generic
8 drugs or biosimilar biological products
9 that are in the same therapeutic cat-
10 egory or class as such drug; and

11 “(II) the rationale for preferred
12 formulary placement of such drug in
13 that therapeutic category or class, if
14 applicable;

15 “(C) a list of each therapeutic category or
16 class of drugs that were dispensed under the
17 health plan during the reporting period, and,
18 with respect to each such therapeutic category
19 or class of drugs, during the reporting period—

20 “(i) total gross spending by the plan,
21 before manufacturer rebates, fees, or other
22 manufacturer remuneration;

23 “(ii) the number of participants and
24 beneficiaries who filled a prescription for a
25 drug in that category or class;

1 “(iii) if applicable to that category or
2 class, a description of the formulary tiers
3 and utilization mechanisms (such as prior
4 authorization or step therapy) employed
5 for drugs in that category or class;

6 “(iv) the total out-of-pocket spending
7 by participants and beneficiaries, including
8 participant and beneficiary spending
9 through copayments, coinsurance, and
10 deductibles; and

11 “(v) for each therapeutic category or
12 class under which 3 or more drugs are in-
13 cluded on the formulary of such plan—

14 “(I) the amount received, or ex-
15 pected to be received, from drug man-
16 ufacturers in rebates, fees, alternative
17 discounts, or other remuneration—

18 “(aa) that has been paid, or
19 is to be paid, by drug manufac-
20 turers for claims incurred during
21 the reporting period; or

22 “(bb) that is related to utili-
23 zation of drugs, in such thera-
24 peutic category or class;

1 “(II) the total net spending, after
2 deducting rebates, price concessions,
3 alternative discounts or other remun-
4 eration from drug manufacturers, by
5 the health plan on that category or
6 class of drugs; and

7 “(III) the net price per course of
8 treatment or single fill, such as a 30-
9 day supply or 90-day supply, incurred
10 by the health plan and its participants
11 and beneficiaries, after manufacturer
12 rebates, fees, and other remuneration
13 for drugs dispensed within such thera-
14 peutic category or class during the re-
15 porting period;

16 “(D) total gross spending on prescription
17 drugs by the plan during the reporting period,
18 before rebates and other manufacturer fees or
19 remuneration;

20 “(E) total amount received, or expected to
21 be received, by the health plan in drug manu-
22 facturer rebates, fees, alternative discounts, and
23 all other remuneration received from the manu-
24 facturer or any third party, other than the plan
25 sponsor, related to utilization of drug or drug

1 spending under that health plan during the re-
2 porting period;

3 “(F) the total net spending on prescription
4 drugs by the health plan during the reporting
5 period; and

6 “(G) amounts paid directly or indirectly in
7 rebates, fees, or any other type of remuneration
8 to brokers, consultants, advisors, or any other
9 individual or firm who referred the group health
10 plan’s business to the pharmacy benefits man-
11 ager.

12 “(2) PRIVACY REQUIREMENTS.—Entities pro-
13 viding pharmacy benefits management services on
14 behalf of a group health plan shall provide informa-
15 tion under paragraph (1) in a manner consistent
16 with the privacy, security, and breach notification
17 regulations promulgated under section 264(c) of the
18 Health Insurance Portability and Accountability Act
19 of 1996, and shall restrict the use and disclosure of
20 such information according to such privacy regula-
21 tions.

22 “(3) DISCLOSURE AND REDISCLOSURE.—

23 “(A) LIMITATION TO BUSINESS ASSOCI-
24 ATES.—A group health plan receiving a report
25 under paragraph (1) may disclose such informa-

1 tion only to business associates of such plan as
2 defined in section 160.103 of title 45, Code of
3 Federal Regulations (or successor regulations).

4 “(B) CLARIFICATION REGARDING PUBLIC
5 DISCLOSURE OF INFORMATION.—Nothing in
6 this section prevents an entity providing phar-
7 macy benefits management services on behalf of
8 a group health plan from placing reasonable re-
9 strictions on the public disclosure of the infor-
10 mation contained in a report described in para-
11 graph (1), except that such entity may not re-
12 strict disclosure of such report to the Depart-
13 ment of Health and Human Services, the De-
14 partment of Labor, the Department of the
15 Treasury, the Comptroller General of the
16 United States, or applicable State agencies.

17 “(C) LIMITED FORM OF REPORT.—The
18 Secretary shall define through rulemaking a
19 limited form of the report under paragraph (1)
20 required of plan sponsors who are drug manu-
21 facturers, drug wholesalers, or other direct par-
22 ticipants in the drug supply chain, in order to
23 prevent anti-competitive behavior.

24 “(4) REPORT TO GAO.—An entity providing
25 pharmacy benefits management services on behalf of

1 a group health plan shall submit to the Comptroller
2 General of the United States each of the first 4 re-
3 ports submitted to a plan sponsor under paragraph
4 (1) with respect to such plan, and other such reports
5 as requested, in accordance with the privacy require-
6 ments under paragraph (2), the disclosure and re-
7 disclosure standards under paragraph (3), the stand-
8 ards specified pursuant to paragraph (5), and such
9 other information that the Comptroller General de-
10 termines necessary to carry out the study under sec-
11 tion 2(d) of the Pharmacy Benefits Manager Ac-
12 countability Act.

13 “(5) STANDARD FORMAT.—Not later than 6
14 months after the date of enactment of this section,
15 the Secretary shall specify through rulemaking
16 standards for entities required to submit reports
17 under paragraph (4) to submit such reports in a
18 standard format.

19 “(c) ENFORCEMENT.—

20 “(1) IN GENERAL.—The Secretary, in consulta-
21 tion with the Secretary of Labor and the Secretary
22 of Health and Human Services, shall enforce this
23 section.

24 “(2) FAILURE TO PROVIDE TIMELY INFORMA-
25 TION.—An entity providing pharmacy benefits man-

1 agement services that violates subsection (a) or fails
2 to provide information required under subsection (b)
3 shall be subject to a civil monetary penalty in the
4 amount of \$10,000 for each day during which such
5 violation continues or such information is not dis-
6 closed or reported.

7 “(3) FALSE INFORMATION.—An entity pro-
8 viding pharmacy benefits management services that
9 knowingly provides false information under this sec-
10 tion shall be subject to a civil money penalty in an
11 amount not to exceed \$100,000 for each item of
12 false information. Such civil money penalty shall be
13 in addition to other penalties as may be prescribed
14 by law.

15 “(4) PROCEDURE.—The provisions of section
16 1128A of the Social Security Act, other than sub-
17 section (a) and (b) and the first sentence of sub-
18 section (c)(1) of such section shall apply to civil
19 monetary penalties under this subsection in the
20 same manner as such provisions apply to a penalty
21 or proceeding under section 1128A of the Social Se-
22 curity Act.

23 “(5) WAIVERS.—The Secretary may waive pen-
24 alties under paragraph (2), or extend the period of
25 time for compliance with a requirement of this sec-

1 tion, for an entity in violation of this section that
2 has made a good-faith effort to comply with this sec-
3 tion.

4 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
5 tion shall be construed to permit a group health plan or
6 other entity to restrict disclosure to, or otherwise limit the
7 access of, the Department of the Treasury to a report de-
8 scribed in subsection (b)(1) or information related to com-
9 pliance with subsection (a) by such plan or entity.

10 “(e) DEFINITION.—In this section, the term ‘whole-
11 sale acquisition cost’ has the meaning given such term in
12 section 1847A(c)(6)(B) of the Social Security Act.”.

13 (2) CLERICAL AMENDMENT.—The table of sec-
14 tions for subchapter B of chapter 100 of the Inter-
15 nal Revenue Code of 1986 is amended by adding at
16 the end the following new item:

 “Sec. 9826. Oversight of pharmacy benefits manager services.”.

17 (d) GAO STUDY.—

18 (1) IN GENERAL.—Not later than 3 years after
19 the date of enactment of this Act, the Comptroller
20 General of the United States shall submit to Con-
21 gress a report on—

22 (A) pharmacy networks of group health
23 plans, health insurance issuers, and entities
24 providing pharmacy benefits management serv-
25 ices under such group health plan or group or

1 individual health insurance coverage, including
2 networks that have pharmacies that are under
3 common ownership (in whole or part) with
4 group health plans, health insurance issuers, or
5 entities providing pharmacy benefits manage-
6 ment services or pharmacy benefits administra-
7 tive services under group health plan or group
8 or individual health insurance coverage;

9 (B) as it relates to pharmacy networks
10 that include pharmacies under common owner-
11 ship described in subparagraph (A)—

12 (i) whether such networks are de-
13 signed to encourage enrollees of a plan or
14 coverage to use such pharmacies over other
15 network pharmacies for specific services or
16 drugs, and if so, the reasons the networks
17 give for encouraging use of such phar-
18 macies; and

19 (ii) whether such pharmacies are used
20 by enrollees disproportionately more in the
21 aggregate or for specific services or drugs
22 compared to other network pharmacies;

23 (C) whether group health plans and health
24 insurance issuers offering group or individual
25 health insurance coverage have options to elect

1 different network pricing arrangements in the
2 marketplace with entities that provide phar-
3 macy benefits management services, the preva-
4 lence of electing such different network pricing
5 arrangements;

6 (D) pharmacy network design parameters
7 that encourage enrollees in the plan or coverage
8 to fill prescriptions at mail order, specialty, or
9 retail pharmacies that are wholly or partially-
10 owned by that issuer or entity; and

11 (E) the degree to which mail order, spe-
12 cialty, or retail pharmacies that dispense pre-
13 scription drugs to an enrollee in a group health
14 plan or health insurance coverage that are
15 under common ownership (in whole or part)
16 with group health plans, health insurance
17 issuers, or entities providing pharmacy benefits
18 management services or pharmacy benefits ad-
19 ministrative services under group health plan or
20 group or individual health insurance coverage
21 receive reimbursement that is greater than the
22 median price charged to the group health plan
23 or health insurance issuer when the same drug
24 is dispensed to enrollees in the plan or coverage
25 by other pharmacies included in the pharmacy

1 network of that plan, issuer, or entity that are
2 not wholly or partially owned by the health in-
3 surance issuer or entity providing pharmacy
4 benefits management services.

5 (2) REQUIREMENT.—The Comptroller General
6 of the United States shall ensure that the report
7 under paragraph (1) does not contain information
8 that would allow a reader to identify a specific plan
9 or entity providing pharmacy benefits management
10 services or otherwise contain commercial or financial
11 information that is privileged or confidential.

12 (3) DEFINITIONS.—In this subsection, the
13 terms “group health plan”, “health insurance cov-
14 erage”, and “health insurance issuer” have the
15 meanings given such terms in section 2791 of the
16 Public Health Service Act (42 U.S.C. 300gg–91).

1 **TITLE II—SUPPORTING PA-**
2 **TIENTS, HEALTH CARE WORK-**
3 **ERS, COMMUNITY HEALTH**
4 **CENTERS, AND HOSPITALS**

5 **SEC. 201. EXTENSION FOR COMMUNITY HEALTH CENTERS,**
6 **THE NATIONAL HEALTH SERVICE CORPS,**
7 **AND TEACHING HEALTH CENTERS THAT OP-**
8 **ERATE GME PROGRAMS.**

9 (a) TEACHING HEALTH CENTERS THAT OPERATE
10 GRADUATE MEDICAL EDUCATION PROGRAMS.—

11 (1) ADDITION TO CAPPED AMOUNTS FOR FIS-
12 CAL YEARS 2024 AND 2025.—Paragraph (2) of section
13 340H(b) of the Public Health Service Act (42
14 U.S.C. 256h(b)) is amended by adding at the end
15 the following:

16 “(C) ADDITION.—For each of fiscal years
17 2024 and 2025, the Secretary may use the
18 amounts made available under subsection (f)
19 for payments described in such subparagraphs
20 (A) and (B) in addition to the total amount of
21 funds appropriated under subsection (g).”.

22 (3) RECONCILIATION.—Section 340H(f) of the
23 Public Health Service Act (42 U.S.C. 256h(f)) is
24 amended—

1 (A) by striking “The Secretary shall deter-
2 mine” and inserting the following:

3 “(1) DETERMINATION.—The Secretary shall de-
4 termine”.; and

5 (B) by adding at the end the following:

6 “(2) ANNUAL REPORT TO CONGRESS.—For
7 each fiscal year, the Secretary shall submit to the
8 Committee on Energy and Commerce of the House
9 of Representatives and the Committee on Health,
10 Education, Labor, and Pensions of the Senate a re-
11 port specifying—

12 “(A) the total amount of funds recouped
13 under paragraph (1);

14 “(B) the rationale for the funds being re-
15 couped; and

16 “(C) in the case of the reports for each of
17 fiscal years 2024 and 2025, the total amount of
18 funds recouped under paragraph (1) that were
19 used pursuant to subsection (b)(2)(C) to adjust
20 total payment amounts above the total amounts
21 appropriated under subsection (g).”.

22 (4) FUNDING.—Section 340H(g) of the Public
23 Health Service Act (42 U.S.C. 256h(g)) is amend-
24 ed—

1 (A) by amending paragraph (1) to read as
2 follows:

3 “(1) IN GENERAL.—To carry out this section,
4 there are appropriated such sums as may be nec-
5 essary, not to exceed—

6 “(A) \$230,000,000, for the period of fiscal
7 years 2011 through 2015;

8 “(B) \$60,000,000 for each of fiscal years
9 2016 and 2017;

10 “(C) \$126,500,000 for each of fiscal years
11 2018 through 2023;

12 “(D) \$175,000,000 for each of fiscal years
13 2024 and 2025;

14 “(E) \$225,000,000 for each of fiscal years
15 2026 and 2027; and

16 “(F) \$275,000,000 for each of fiscal years
17 2028 and 2029.”; and

18 (B) by adding at the end the following:

19 “(3) AVAILABILITY.—The amounts made avail-
20 able under paragraph (1) shall remain available until
21 expended.”.

22 (b) EXTENSION FOR COMMUNITY HEALTH CEN-
23 TERS.—Section 10503(b)(1)(F) of the Patient Protection
24 and Affordable Care Act (42 U.S.C. 254b–2(b)(1)(F)) is
25 amended—

1 (1) by striking “and” before “\$4,000,000,000”
2 and inserting a comma; and

3 (2) by inserting “, and \$4,200,000,000 for each
4 of fiscal years 2024 and 2025” before the semicolon.

5 (c) EXTENSION FOR THE NATIONAL HEALTH SERV-
6 ICE CORPS.—Section 10503(b)(2) of the Patient Protec-
7 tion and Affordable Care Act (42 U.S.C. 254b–2(b)(2))
8 is amended—

9 (1) in subparagraph (G), by striking “and” at
10 the end;

11 (2) in subparagraph (H), by striking the period
12 at the end and inserting “; and”; and

13 (3) by adding at the end the following:

14 “(I) \$350,000,000 for each of fiscal years
15 2024 and 2025.”.

16 (d) GOVERNMENT ACCOUNTABILITY OFFICE RE-
17 PORT.—

18 (1) IN GENERAL.—Not later than one year
19 after the date of enactment of this Act, the Comp-
20 troller General of the United States shall submit to
21 the Committee on Energy and Commerce of the
22 House of Representatives and the Committee on
23 Health, Education, Labor, and Pensions of the Sen-
24 ate a report assessing the effectiveness of the Na-

1 tional Health Service Corps at attracting health care
2 professionals to HPSAs, including by—

3 (A) assessing the metrics used by the
4 Health Resources and Services Administration
5 in evaluating the program;

6 (B) comparing the retention rates of
7 NHSC participants in the HPSAs where they
8 completed their period of obligated service to
9 the retention rate of non-NHSC participants in
10 the corresponding HPSAs;

11 (C) comparing the retention rates of
12 NHSC participants in the HPSAs where they
13 completed their period of obligated service to
14 the retention rates of NHSC participants in
15 HPSAs other than those where they completed
16 their period of obligated service;

17 (D) identifying factors that influence a
18 NHSC participant's decision to practice in a
19 HPSA other than the HPSA where they com-
20 pleted their period of obligated service;

21 (E) identifying factors other than partici-
22 pation in the National Health Service Corps
23 Scholarship and Loan Repayment Programs
24 that attract health care professionals to a
25 HPSA;

1 (F) assessing the impact the National
2 Health Service Corps has on wages for health
3 care professionals in a HPSA; and

4 (G) comparing the distribution of NHSC
5 participants across HPSAs, including a com-
6 parison of rural versus non-rural HPSAs.

7 (2) DEFINITION.—In this section:

8 (A) The term “HPSA” means a health
9 professional shortage area designated under
10 section 332 of the Public Health Service Act
11 (42 U.S.C. 254e).

12 (B) The term “NHSC participant” means
13 a National Health Service Corps member par-
14 ticipating in the National Health Service Corps
15 Scholarship or Loan Repayment Program.

16 (e) APPLICATION OF PROVISIONS.—Amounts appro-
17 priated pursuant to the amendments made by this section
18 shall be subject to the requirements contained in Public
19 Law 117–328 for funds for programs authorized under
20 sections 330 through 340 of the Public Health Service
21 Act.

22 (f) CONFORMING AMENDMENT.—Paragraph (4) of
23 section 3014(h) of title 18, United States Code, is amend-
24 ed by striking “and section 301(d) of division BB of the
25 Consolidated Appropriations Act, 2021.” and inserting

1 “section 301(d) of division BB of the Consolidated Appro-
2 priations Act, 2021, and section 201(e) of the PATIENT
3 Act of 2023”.

4 **SEC. 202. EXTENSION OF SPECIAL DIABETES PROGRAMS.**

5 (a) EXTENSION OF SPECIAL DIABETES PROGRAMS
6 FOR TYPE I DIABETES.—Section 330B(b)(2) of the Pub-
7 lic Health Service Act (42 U.S.C. 254c–2(b)(2)) is amend-
8 ed—

9 (1) in subparagraph (C), by striking “and” at
10 the end;

11 (2) in subparagraph (D), by striking the period
12 and inserting “; and”; and

13 (3) by adding at the end the following new sub-
14 paragraph:

15 “(E) \$170,000,000 for each of fiscal years
16 2024 and 2025, to remain available until ex-
17 pended.”.

18 (b) EXTENDING FUNDING FOR SPECIAL DIABETES
19 PROGRAMS FOR INDIANS.—Section 330C(c)(2) of the
20 Public Health Service Act (42 U.S.C. 254c–3(c)(2)) is
21 amended—

22 (1) in subparagraph (C), by striking “and” at
23 the end;

24 (2) in subparagraph (D), by striking the period
25 and inserting “; and”; and

1 (3) by adding at the end the following new sub-
2 paragraph:

3 “(E) \$170,000,000 for each of fiscal years
4 2024 and 2025, to remain available until ex-
5 pended.”.

6 **SEC. 203. DELAYING CERTAIN DISPROPORTIONATE SHARE**
7 **HOSPITAL PAYMENT REDUCTIONS UNDER**
8 **THE MEDICAID PROGRAM.**

9 Section 1923(f)(7)(A) of the Social Security Act (42
10 U.S.C.1396r-4(f)(7)(A)) is amended—

11 (1) in clause (i), in the matter preceding sub-
12 clause (I), by striking “2024” and inserting “2026”;
13 and

14 (2) in clause (ii), by striking “2024” and in-
15 serting “2026”.

16 **SEC. 204. MEDICAID IMPROVEMENT FUND.**

17 Section 1941(b)(3)(A) of the Social Security Act (42
18 U.S.C. 1396w-1(b)(3)(A)) is amended by striking
19 “\$7,000,000,000” and inserting “\$0”.

1 **TITLE III—REDUCING HEALTH**
2 **CARE COSTS**

3 **SEC. 301. INCREASING TRANSPARENCY IN GENERIC DRUG**
4 **APPLICATIONS.**

5 (a) IN GENERAL.—Section 505(j)(3) of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(3)) is
7 amended by adding at the end the following:

8 “(H)(i) Upon request (in controlled correspondence
9 or an analogous process) by a person that has submitted
10 or intends to submit an abbreviated application under this
11 subsection for a drug that is required by regulation to con-
12 tain one or more of the same inactive ingredients in the
13 same concentrations as the listed drug referred to, or for
14 which the Secretary determines there is a scientific jus-
15 tification for an approach that is in vitro in whole or in
16 part to be used to demonstrate bioequivalence for a drug
17 if such a drug contains one or more of the same inactive
18 ingredients in the same concentrations as the listed drug,
19 the Secretary shall inform the person whether such drug
20 is qualitatively and quantitatively the same as the listed
21 drug. The Secretary may also provide such information
22 to such a person on the Secretary’s own initiative during
23 the review of an abbreviated application under this sub-
24 section for such drug.

1 “(ii) Notwithstanding section 301(j), if the Secretary
2 determines that such drug is not qualitatively or quan-
3 titatively the same as the listed drug, the Secretary shall
4 identify and disclose to the person—

5 “(I) the ingredient or ingredients that cause
6 such drug not to be qualitatively or quantitatively
7 the same as the listed drug; and

8 “(II) for any ingredient for which there is an
9 identified quantitative deviation, whether the quan-
10 tity or proportion of any ingredient in such drug is
11 greater than or less than the quantity or proportion
12 of such ingredient in the listed drug.

13 “(iii) If the Secretary determines that such drug is
14 qualitatively and quantitatively the same as the listed
15 drug, the Secretary shall not change or rescind such deter-
16 mination after the submission of an abbreviated applica-
17 tion for such drug under this subsection unless—

18 “(I) the formulation of the listed drug has been
19 changed and the Secretary has determined that the
20 prior listed drug formulation was withdrawn for rea-
21 sons of safety or effectiveness; or

22 “(II) the Secretary makes a written determina-
23 tion that the prior determination must be changed
24 because an error has been identified.

1 “(iv) If the Secretary makes a written determination
2 described in clause (iii)(II), the Secretary shall provide no-
3 tice and a copy of the written determination to the person
4 making the request under clause (i).

5 “(v) The disclosures required by this subparagraph
6 are disclosures authorized by law, including for purposes
7 of section 1905 of title 18, United States Code.”.

8 (b) GUIDANCE.—

9 (1) IN GENERAL.—Not later than one year
10 after the date of enactment of this Act, the Sec-
11 retary of Health and Human Services shall issue
12 draft guidance, or update guidance, describing how
13 the Secretary will determine whether a drug is quali-
14 tatively and quantitatively the same as the listed
15 drug (as such terms are used in section
16 505(j)(3)(H) of the Federal Food, Drug, and Cos-
17 metic Act, as added by subsection (a)), including
18 with respect to assessing pH adjusters.

19 (2) PROCESS.—In issuing guidance under this
20 subsection, the Secretary of Health and Human
21 Services shall—

22 (A) publish draft guidance;

23 (B) provide a period of at least 60 days for
24 comment on the draft guidance; and

1 (C) after considering any comments re-
2 ceived and not later than one year after the
3 close of the comment period on the draft guid-
4 ance, publish final guidance.

5 (c) APPLICABILITY.—Section 505(j)(3)(H) of the
6 Federal Food, Drug, and Cosmetic Act, as added by sub-
7 section (a), applies beginning on the date of enactment
8 of this Act, irrespective of the date on which the guidance
9 required by subsection (b) is finalized.

10 **SEC. 302. PARITY IN MEDICARE PAYMENTS FOR HOSPITAL**
11 **OUTPATIENT DEPARTMENT SERVICES FUR-**
12 **NISHED OFF-CAMPUS.**

13 (a) IN GENERAL.—Section 1833(t)(16) of the Social
14 Security Act (42 U.S.C. 1395l(t)(16)) is amended by add-
15 ing at the end the following new subparagraph:

16 “(H) PARITY IN FEE SCHEDULE AMOUNT
17 FOR CERTAIN SERVICES FURNISHED BY AN
18 OFF-CAMPUS OUTPATIENT DEPARTMENT OF A
19 PROVIDER.—

20 “(i) IN GENERAL.—Subject to clause
21 (iii), in the case of specified OPD services
22 (as defined in clause (iii)) that are fur-
23 nished during 2025 or a subsequent year
24 by an off-campus outpatient department of
25 a provider (as defined in clause (iv)), there

1 shall be substituted for the amount other-
2 wise determined under this subsection for
3 such service and year an amount equal to
4 the payment amount that would have been
5 payable under the applicable payment sys-
6 tem under this part (other than under this
7 subsection) had such services been fur-
8 nished by such a department subject to
9 such payment system pursuant to para-
10 graph (21)(C).

11 “(ii) NOT BUDGET NEUTRAL IMPLE-
12 MENTATION.—In making any budget neu-
13 trality adjustments under this subsection
14 for 2025 or a subsequent year, the Sec-
15 retary shall not take into account the re-
16 duced expenditures that result from the
17 application of this subparagraph.

18 “(iii) TRANSITION.—The Secretary
19 shall provide for a 4-year phase-in of the
20 application of clause (i), with clause (i)
21 being fully applicable for specified OPD
22 services beginning with 2028.

23 “(iv) DEFINITIONS.—For purposes of
24 this subparagraph:

1 “(I) DESIGNATED AMBULATORY
2 PAYMENT CLASSIFICATION GROUP.—

3 The term ‘designated ambulatory pay-
4 ment classification group’ means an
5 ambulatory payment classification
6 group for drug administration serv-
7 ices.

8 “(II) SPECIFIED OPD SERVICES
9 DEFINED.—The term ‘specified OPD
10 services’ means covered OPD services
11 assigned to a designated ambulatory
12 payment classification group.

13 “(III) OFF-CAMPUS OUTPATIENT
14 DEPARTMENT OF A PROVIDER DE-
15 FINED.—The term ‘off-campus out-
16 patient department of a provider’
17 means a department of a provider (as
18 defined in section 413.65(a)(2) of title
19 42, Code of Federal Regulations) that
20 is not located—

21 “(aa) on the campus (as
22 such term is defined in such sec-
23 tion 413.65(a)(2)) of such pro-
24 vider; or

1 “(bb) within the distance
2 (described in such definition of
3 campus) from a remote location
4 of a hospital facility (as defined
5 in such section 413.65(a)(2)).”.

6 (b) IMPLEMENTATION.—Section 1833(t)(12) of the
7 Social Security Act (42 U.S.C. 1395l(t)(12)) is amend-
8 ed—

9 (1) in subparagraph (D), by striking “and” at
10 the end;

11 (2) in subparagraph (E), by striking the period
12 at the end and inserting “; and”; and

13 (3) by adding at the end the following new sub-
14 paragraph:

15 “(F) the determination of any payment
16 amount under paragraph (16)(H), including the
17 transition under clause (iii) of such para-
18 graph.”.

19 **SEC. 303. IMPROVING TRANSPARENCY AND PREVENTING**
20 **THE USE OF ABUSIVE SPREAD PRICING AND**
21 **RELATED PRACTICES IN MEDICAID.**

22 (a) PHARMACY PRICE REIMBURSEMENT REQUIRE-
23 MENTS.—

1 (1) IN GENERAL.—Section 1927(e) of the So-
2 cial Security Act (42 U.S.C. 1396r–8(e)) is amended
3 by adding at the end the following:

4 “(6) PHARMACY PRICE REIMBURSEMENT RE-
5 QUIRED.—

6 “(A) IN GENERAL.—A contract between
7 the State and a pharmacy benefit manager (in
8 this paragraph referred to as a ‘PBM’), or a
9 contract between the State and a designated en-
10 tity (as defined in subparagraph (C)) that in-
11 cludes provisions making the entity responsible
12 for the administration of medical assistance
13 consisting of covered outpatient drugs for indi-
14 viduals enrolled with the entity, shall require
15 that payment for such drugs and related ad-
16 ministrative services (as applicable), including
17 payments made by a PBM on behalf of the
18 State or entity, is based on pharmacy price re-
19 imbursement model under which—

20 “(i) any payment made by the entity
21 or the PBM (as applicable) for such a
22 drug—

23 “(I) is limited to—

24 “(aa) ingredient cost; and

1 “(bb) a professional dis-
2 pensing fee that is not less than
3 the professional dispensing fee
4 that the State plan or waiver
5 would pay if the plan or waiver
6 was making the payment directly;

7 “(II) is passed through in its en-
8 tirety by the entity or PBM to the
9 pharmacy or provider that dispenses
10 the drug; and

11 “(III) is made in a manner that
12 is consistent with sections 447.502,
13 447.512, 447.514, and 447.518 of
14 title 42, Code of Federal Regulations
15 (or any successor regulation) as if
16 such requirements applied directly to
17 the entity or the PBM, except that
18 any payment by the entity or the
19 PBM for the ingredient cost of such a
20 drug furnished by a covered entity (as
21 defined in subsection (a)(5)(B)) may
22 exceed the acquisition cost for such
23 drug if—

1 “(aa) such drug was subject
2 to agreement under section 340B
3 of the Public Health Service Act;

4 “(bb) such payment for such
5 cost of such drug does not exceed
6 the maximum payment that
7 would have been made by the
8 designated entity or the PBM for
9 the ingredient cost of such drug
10 had such drug not been furnished
11 by such a covered entity; and

12 “(cc) such covered entity re-
13 ports to the Secretary, on an an-
14 nual basis and with respect to
15 payments for such costs of such
16 drugs so furnished by such entity
17 that are in excess of the acquisi-
18 tion costs for such drugs, the ag-
19 gregate amount of such excess;

20 “(ii) payment to the entity or the
21 PBM (as applicable) for administrative
22 services performed by the designated entity
23 or PBM is limited to an administrative fee
24 that reflects the fair market value of pro-
25 viding such services;

1 “(iii) the entity or the PBM (as appli-
2 cable) makes available to the State, and
3 the Secretary upon request, all costs and
4 payments related to covered outpatient
5 drugs and accompanying administrative
6 services incurred, received, or made by the
7 entity or the PBM, including ingredient
8 costs, professional dispensing fees, admin-
9 istrative fees, post-sale and post-invoice
10 fees, discounts, or related adjustments
11 such as direct and indirect remuneration
12 fees, and any and all other remuneration;
13 and

14 “(iv) any form of spread pricing
15 whereby any amount charged or claimed by
16 the entity or the PBM (as applicable) is in
17 excess of the amount paid to the phar-
18 macies on behalf of the entity, including
19 any post-sale or post-invoice fees, dis-
20 counts, or related adjustments such as di-
21 rect and indirect remuneration fees or as-
22 sessments (after allowing for a fair mar-
23 ket administrative fee as described in
24 clause (ii)), is not allowable for purposes of

1 claiming Federal matching payments under
2 this title.

3 “(B) MAKING CERTAIN INFORMATION
4 AVAILABLE.—The Secretary shall publish, not
5 less frequently than on an annual basis, infor-
6 mation received by the Secretary pursuant to
7 subparagraph (A)(i)(III)(cc). Such information
8 shall be so published in an electronic and
9 searchable format, such as through the 340B
10 Office of Pharmacy Affairs Information System
11 (or a successor system).

12 “(C) DEFINITIONS.—In this paragraph:

13 “(i) DESIGNATED ENTITY.—The term
14 ‘covered entity’ means a managed care en-
15 tity or a specified entity.

16 “(ii) MANAGED CARE ENTITY; SPECI-
17 FIED ENTITY.—The terms ‘managed care
18 entity’ and ‘specified entity’ have the
19 meaning given such terms in section
20 1903(m)(9)(D).”.

21 (2) CONFORMING AMENDMENTS.—Section
22 1903(m)(2)(A)(xiii) of such Act (42 U.S.C.
23 1396b(m)(2)(A)(xiii)) is amended—

24 (A) by striking “and (III)” and inserting
25 “(III)”;

1 (B) by inserting before the period at the
2 end the following: “, and (IV) the pharmacy
3 benefit provided by the entity (or pharmacy
4 benefit manager on behalf of the entity under
5 a contract), the other specified entity (as de-
6 fined in paragraph (9)(D)), or by another ar-
7 rangement between the entity and the phar-
8 macy benefit manager, shall comply with the re-
9 quirements of section 1927(e)(6)”;

10 (C) by moving the left margin 2 ems to the
11 left.

12 (3) EFFECTIVE DATE.—The amendments made
13 by this subsection apply to contracts between States
14 and pharmacy benefit managers and covered entities
15 (as defined in section 1927(e)(6) of the Social Secu-
16 rity Act, as added by paragraph (1) that have an ef-
17 fective date beginning on or after the date that is 18
18 months after the date of enactment of this Act.

19 (b) ENSURING ACCURATE PAYMENTS TO PHAR-
20 MACIES UNDER MEDICAID.—

21 (1) IN GENERAL.—Section 1927(f) of the Social
22 Security Act (42 U.S.C. 1396r–8(f)) is amended—

23 (A) by striking “and” after the semicolon
24 at the end of paragraph (1)(A)(i) and all that

1 precedes it through “(1)” and inserting the fol-
2 lowing:

3 “(1) DETERMINING PHARMACY ACTUAL ACQUI-
4 SITION COSTS.—The Secretary shall conduct a sur-
5 vey of retail community pharmacy drug prices to de-
6 termine the national average drug acquisition cost as
7 follows:

8 “(A) USE OF VENDOR.—The Secretary
9 may contract services for—

10 “(i) with respect to retail community
11 pharmacies, the determination of retail
12 survey prices of the national average drug
13 acquisition cost for covered outpatient
14 drugs based on a monthly survey of such
15 pharmacies; and”;

16 (B) by adding at the end of paragraph (1)
17 the following:

18 “(F) SURVEY REPORTING.—A State shall
19 require that any retail community pharmacy in
20 the State that receives any payment, reimburse-
21 ment, administrative fee, discount, or rebate re-
22 lated to the dispensing of covered outpatient
23 drugs to individuals receiving benefits under
24 this title, regardless of whether such payment,
25 reimbursement, administrative fee, discount, or

1 rebate is received from the State or a managed
2 care entity directly or from a pharmacy benefit
3 manager or other specified entity (as defined in
4 section 1903(m)(9)(D)) that has a contract
5 with the State or a managed care entity, shall
6 respond to surveys of retail prices conducted
7 under this subsection.

8 “(G) SURVEY INFORMATION.—Information
9 on national drug acquisition prices obtained
10 under this paragraph shall be made publicly
11 available in a timely manner following the col-
12 lection of such information and shall include at
13 least the following:

14 “(i) The monthly response rate to the
15 survey including a list of pharmacies not in
16 compliance with subparagraph (F).

17 “(ii) The sampling frame and number
18 of pharmacies sampled monthly.

19 “(iii) Information on price concessions
20 to the pharmacy, including discounts, re-
21 bates, and other price concessions, to the
22 extent that such information is available
23 during the survey period.

24 “(H) REPORT ON SPECIALTY PHAR-
25 MACIES.—Not later than 1 year after the date

1 that this subparagraph takes effect, the Sec-
2 retary shall submit to Congress a report exam-
3 ining specialty drug coverage and reimburse-
4 ment under this title, including—

5 “(i) a description of how State Med-
6 icaid programs define specialty drugs and
7 specialty pharmacies;

8 “(ii) the amount State Medicaid pro-
9 grams pay for specialty drugs;

10 “(iii) how States and managed care
11 entities determine payment for specialty
12 drugs;

13 “(iv) the settings in which specialty
14 drugs are dispensed to individuals receiv-
15 ing benefits under this title (such as retail
16 community pharmacies or specialty phar-
17 macies);

18 “(v) the extent to which speciality
19 drugs (as defined by the respective States)
20 are captured in the national average drug
21 acquisition cost survey (or through another
22 process);

23 “(vi) examples of specialty drug dis-
24 pensing fees to support the services associ-

1 ated with dispensing such specialty drugs;
2 and

3 “(vii) recommendations as to whether
4 specialty pharmacies should be included in
5 the survey of retail prices to ensure na-
6 tional average drug acquisition costs cap-
7 ture drugs sold at specialty pharmacies,
8 and how such specialty pharmacies should
9 be defined.

10 “(I) ENFORCEMENT.—At the discretion of
11 the Secretary, the Secretary may enforce non-
12 compliance with this paragraph by a pharmacy
13 through the establishment of penalties or the
14 suspension of payments under this title, in full
15 or in part, until compliance with this paragraph
16 has been completed.”; and

17 (C) in paragraph (2)—

18 (i) in subparagraph (A), by inserting
19 “(including payment rates under Medicaid
20 managed care plans)” after “under this
21 title”; and

22 (ii) in subparagraph (B), by inserting
23 “, and the basis for such dispensing fees”
24 before the semicolon at the end.

1 (2) EFFECTIVE DATE.—The amendments made
2 by this subsection take effect on the first day of the
3 first quarter that begins on or after the date that is
4 18 months after the date of enactment of this Act.

