

**AMENDMENT TO
RULES COMMITTEE PRINT 117-51
OFFERED BY M. _____**

Amend section 263 to read as follows:

1 **SEC. 263. REQUIRING PRESCRIBERS OF CONTROLLED SUB-**
2 **STANCES TO COMPLETE TRAINING.**

3 Section 303 of the Controlled Substances Act (21
4 U.S.C. 823) is amended by adding at the end the fol-
5 lowing:

6 “(1) REQUIRED TRAINING FOR PRESCRIBERS.—

7 “(1) TRAINING REQUIRED.—As a condition on
8 registration under this section to dispense controlled
9 substances in schedule II, III, IV, or V, the Attorney
10 General shall require any qualified practitioner, be-
11 ginning with the first applicable registration for the
12 practitioner, to meet the following:

13 “(A) If the practitioner is a physician (as
14 defined under section 1861(r) of the Social Se-
15 curity Act), the practitioner meets one or more
16 of the following conditions:

17 “(i) The physician holds a board cer-
18 tification in addiction psychiatry or addic-

1 tion medicine from the American Board of
2 Medical Specialties.

3 “(ii) The physician holds a board cer-
4 tification from the American Board of Ad-
5 diction Medicine.

6 “(iii) The physician holds a board cer-
7 tification in addiction medicine from the
8 American Osteopathic Association.

9 “(iv) The physician has, with respect
10 to the treatment and management of pa-
11 tients with opioid or other substance use
12 disorders, or the safe pharmacological
13 management of dental pain and screening,
14 brief intervention, and referral for appro-
15 priate treatment of patients with or at risk
16 of developing opioid or other substance use
17 disorders, completed not less than 8 hours
18 of training (through classroom situations,
19 seminars at professional society meetings,
20 electronic communications, or otherwise)
21 that is provided by—

22 “(I) the American Society of Ad-
23 diction Medicine, the American Acad-
24 emy of Addiction Psychiatry, the
25 American Medical Association, the

1 American Osteopathic Association, the
2 American Dental Association, the
3 American Association of Oral and
4 Maxillofacial Surgeons, the American
5 Psychiatric Association, or any other
6 organization accredited by the Accred-
7 itation Council for Continuing Medical
8 Education (commonly known as the
9 ‘ACCME’) or the Commission on
10 Dental Accreditation;

11 “(II) any organization accredited
12 by a State medical society accreditor
13 that is recognized by the ACCME or
14 the Commission on Dental Accredita-
15 tion;

16 “(III) any organization accred-
17 ited by the American Osteopathic As-
18 sociation to provide continuing med-
19 ical education; or

20 “(IV) any organization approved
21 by the Assistant Secretary for Mental
22 Health and Substance Abuse, the
23 ACCME, or the Commission on Den-
24 tal Accreditation.

1 “(v) The physician graduated in good
2 standing from an accredited school of
3 allopathic medicine, osteopathic medicine,
4 dental surgery, or dental medicine in the
5 United States during the 5-year period im-
6 mediately preceding the date on which the
7 physician first registers or renews under
8 this section and has successfully completed
9 a comprehensive allopathic or osteopathic
10 medicine curriculum or accredited medical
11 residency or dental surgery or dental medi-
12 cine curriculum that included not less than
13 8 hours of training on—

14 “(I) treating and managing pa-
15 tients with opioid and other substance
16 use disorders, including the appro-
17 priate clinical use of all drugs ap-
18 proved by the Food and Drug Admin-
19 istration for the treatment of a sub-
20 stance use disorder; or

21 “(II) the safe pharmacological
22 management of dental pain and
23 screening, brief intervention, and re-
24 ferral for appropriate treatment of pa-
25 tients with or at risk of developing

1 opioid and other substance use dis-
2 orders.

3 “(B) If the practitioner is not a physician
4 (as defined under section 1861(r) of the Social
5 Security Act), the practitioner meets one or
6 more of the following conditions:

7 “(i) The practitioner has completed
8 not fewer than 8 hours of training with re-
9 spect to the treatment and management of
10 patients with opioid or other substance use
11 disorders (through classroom situations,
12 seminars at professional society meetings,
13 electronic communications, or otherwise)
14 provided by the American Society of Addic-
15 tion Medicine, the American Academy of
16 Addiction Psychiatry, the American Med-
17 ical Association, the American Osteopathic
18 Association, the American Nurses
19 Credentialing Center, the American Psy-
20 chiatric Association, the American Associa-
21 tion of Nurse Practitioners, the American
22 Academy of Physician Associates, or any
23 other organization approved or accredited
24 by the Assistant Secretary for Mental
25 Health and Substance Abuse or the Ac-

1 creditation Council for Continuing Medical
2 Education.

3 “(ii) The practitioner has graduated
4 in good standing from an accredited physi-
5 cian assistant school or accredited school
6 of advanced practice nursing in the United
7 States during the 5-year period imme-
8 diately preceding the date on which the
9 practitioner first registers or renews under
10 this section and has successfully completed
11 a comprehensive physician assistant or ad-
12 vanced practice nursing curriculum that
13 included not fewer than 8 hours of training
14 on treating and managing patients with
15 opioid and other substance use disorders,
16 including the appropriate clinical use of all
17 drugs approved by the Food and Drug Ad-
18 ministration for the treatment of a sub-
19 stance use disorder.

20 “(2) ONE-TIME TRAINING.—

21 “(A) IN GENERAL.—The Attorney General
22 shall not require any qualified practitioner to
23 complete the training described in clause (iv) or
24 (v) of paragraph (1)(A) or clause (i) or (ii) of
25 paragraph (1)(B) more than once.

1 “(B) NOTIFICATION.—Not later than 90
2 days after the date of the enactment of the Re-
3 storing Hope for Mental Health and Well-Being
4 Act of 2022, the Attorney General shall provide
5 to qualified practitioners a single written, elec-
6 tronic notification of the training described in
7 clauses (iv) and (v) of paragraph (1)(A) or
8 clauses (i) and (ii) of paragraph (1)(B).

9 “(3) RULE OF CONSTRUCTION.—Nothing in
10 this subsection shall be construed to preclude the
11 use, by a qualified practitioner, of training received
12 pursuant to this subsection to satisfy registration re-
13 quirements of a State or for some other lawful pur-
14 pose.

15 “(4) DEFINITIONS.—In this section:

16 “(A) FIRST APPLICABLE REGISTRATION.—
17 The term ‘first applicable registration’ means
18 the first registration or renewal of registration
19 by a qualified practitioner under this section
20 that occurs on or after the date that is 180
21 days after the date of enactment of the Restor-
22 ing Hope for Mental Health and Well-Being
23 Act of 2022.

1 “(B) QUALIFIED PRACTITIONER.—In this
2 subsection, the term ‘qualified practitioner’
3 means a practitioner who—

4 “(i) is licensed under State law to pre-
5 scribe controlled substances; and

6 “(ii) is not solely a veterinarian.”.

Page 150, after line 5, insert the following:

7 **SEC. 312. REAUTHORIZATION OF MINORITY FELLOWSHIP**
8 **PROGRAM.**

9 Section 597(c) of the Public Health Service Act (42
10 U.S.C. 2901(c)) is amended by striking “\$12,669,000 for
11 each of fiscal years 2018 through 2022” and inserting
12 “\$25,000,000 for each of fiscal years 2023 through
13 2027”.

At the end of title IV, add the following new sub-
title:

14 **Subtitle D—Social Media and**
15 **Adolescent Mental Health**

16 **SEC. 431. STUDY ON THE EFFECTS OF SMARTPHONE AND**
17 **SOCIAL MEDIA USE ON ADOLESCENTS.**

18 (a) IN GENERAL.—Not later than 1 year after the
19 date of enactment of this Act, the Secretary of Health and
20 Human Services shall conduct or support research on—

1 (1) smartphone and social media use by adoles-
2 cents; and

3 (2) the effects of such use on—

4 (A) emotional, behavioral, and physical
5 health and development; and

6 (B) any disparities in the mental health
7 outcomes of rural, minority, and other under-
8 served populations.

9 (b) REPORT.—Not later than 5 years after the date
10 of enactment of this Act, the Secretary of Health and
11 Human Services shall submit to the Congress, and make
12 publicly available, a report on the findings of research
13 under this section.

At the end of the bill, add the following new titles:

14 **TITLE V—MEDICAID AND CHIP**

15 **SEC. 501. MEDICAID AND CHIP REQUIREMENTS FOR**
16 **HEALTH SCREENINGS AND REFERRALS FOR**
17 **ELIGIBLE JUVENILES IN PUBLIC INSTITU-**
18 **TIONS.**

19 (a) MEDICAID STATE PLAN REQUIREMENT.—Section
20 1902 of the Social Security Act (42 U.S.C. 1396a) is
21 amended—

22 (1) in subsection (a)(84)—

23 (A) in subparagraph (A), by inserting “,
24 subject to subparagraph (D),” after “but”;

1 (B) in subparagraph (B), by striking
2 “and” at the end;

3 (C) in subparagraph (C), by adding “and”
4 at the end; and

5 (D) by adding at the end the following new
6 subparagraph:

7 “(D) beginning on the first day of the first
8 calendar quarter that begins two years after the
9 date of enactment of this subparagraph, in the
10 case of individuals who are eligible juveniles de-
11 scribed in subsection (nn)(2), are within 30
12 days of the date on which such eligible juvenile
13 is scheduled to be released from a public insti-
14 tution following adjudication, the State shall
15 have in place a plan to ensure, and in accord-
16 ance with such plan, provide—

17 “(i) for, in the 30 days prior to the
18 release of such an eligible juvenile from
19 such public institution (or not later than
20 one week after release from the public in-
21 stitution), and in coordination with such
22 institution—

23 “(I) any screening or diagnostic
24 service which meets reasonable stand-
25 ards of medical and dental practice,

1 as determined by the State, or as in-
2 dicated as medically necessary, in ac-
3 cordance with paragraphs (1)(A) and
4 (5) of section 1905(r); and

5 “(II) a mental health or other be-
6 havioral health screening that is a
7 screening service described under sec-
8 tion 1905(r)(1), or a diagnostic serv-
9 ice described under paragraph (5) of
10 such section, if such screening or di-
11 agnostic service was not otherwise
12 conducted pursuant to this clause;

13 “(ii) for, not later than one week after
14 release from the public institution, refer-
15 rals for such eligible juvenile to the appro-
16 priate care and services available under the
17 State plan (or waiver of such plan) in the
18 geographic region of the home or residence
19 of such eligible juvenile, based on such
20 screenings; and

21 “(iii) for, following the release of such
22 eligible juvenile from such institution, not
23 less than 30 days of targeted case manage-
24 ment services furnished by a provider in

1 the geographic region of the home or resi-
2 dence of such eligible juvenile.”; and

3 (2) in subsection (m)(3), by striking “(30)”
4 and inserting “(31)”.

5 (b) AUTHORIZATION OF FEDERAL FINANCIAL PAR-
6 TICIPATION.—The subdivision (A) of section 1905(a) of
7 the Social Security Act (42 U.S.C. 1396d(a)) following
8 paragraph (31) of such section is amended by inserting
9 “, or in the case of an eligible juvenile described in section
10 1902(a)(84)(D) with respect to the screenings, diagnostic
11 services, referrals, and case management required under
12 such subparagraph (D)” after “(except as a patient in a
13 medical institution”.

14 (c) CHIP CONFORMING AMENDMENTS.—Section
15 2110(b) of the Social Security Act (42 U.S.C. 13977jj(b))
16 is amended—

17 (1) in paragraph (2)(A), by inserting “except as
18 provided in paragraph (7),” before “a child who is
19 an inmate of a public institution”; and

20 (2) by adding at the end the following new
21 paragraph:

22 “(7) EXCEPTION TO EXCLUSION OF CHILDREN
23 WHO ARE INMATES OF A PUBLIC INSTITUTION.—A
24 child shall not be considered to be described in para-
25 graph (2)(A) if such child is an eligible juvenile (as

1 described in section 1902(a)(84)(D)) with respect to
2 the screenings, diagnostic services, referrals, and
3 case management otherwise covered under the State
4 child health plan (or waiver of such plan).”.

5 **SEC. 502. GUIDANCE ON REDUCING ADMINISTRATIVE BAR-**
6 **RIERS TO PROVIDING HEALTH CARE SERV-**
7 **ICES IN SCHOOLS.**

8 (a) IN GENERAL.—Not later than 12 months after
9 the date of enactment of this Act, the Secretary of Health
10 and Human Services shall issue guidance to State Med-
11 icaid agencies, elementary and secondary schools, and
12 school-based health centers on reducing administrative
13 barriers to such schools and centers furnishing medical as-
14 sistance and obtaining payment for such assistance under
15 titles XIX and XXI of the Social Security Act (42 U.S.C.
16 1396 et seq., 1397aa et seq.).

17 (b) CONTENTS OF GUIDANCE.—The guidance issued
18 pursuant to subsection (a) shall—

19 (1) include revisions to the May 2003 Medicaid
20 School-Based Administrative Claiming Guide, the
21 1997 Medicaid and Schools Technical Assistance
22 Guide, and other relevant guidance in effect on the
23 date of enactment of this Act;

24 (2) provide information on payment under titles
25 XIX and XXI of the Social Security Act (42 U.S.C.

1 1396 et seq., 1397aa et seq.) for the provision of
2 medical assistance, including such assistance pro-
3 vided in accordance with an individualized education
4 program or under the policy described in the State
5 Medicaid Director letter on payment for services
6 issued on December 15, 2014 (#14-006);

7 (3) take into account reasons why small and
8 rural local education agencies may not provide med-
9 ical assistance and provide information on best prac-
10 tices to encourage such agencies to provide such as-
11 sistance; and

12 (4) include best practices and examples of
13 methods that State Medicaid agencies and local edu-
14 cation agencies have used to pay for, and increase
15 the availability of, medical assistance.

16 (c) DEFINITIONS.—In this Act:

17 (1) INDIVIDUALIZED EDUCATION PROGRAM.—
18 The term “individualized education program” has
19 the meaning given such term in section 602(14) of
20 the Individuals with Disabilities Education Act (20
21 U.S.C. 1401(14)).

22 (2) SCHOOL-BASED HEALTH CENTER.—The
23 term “school-based health center” has the meaning
24 given such term in section 2110(c)(9) of the Social
25 Security Act (42 U.S.C. 1397jj(c)(9)), and includes

1 an entity that provides Medicaid-covered services in
2 school-based settings for which Federal financial
3 participation is permitted.

4 **SEC. 503. GUIDANCE TO STATES ON SUPPORTING PEDI-**
5 **ATRIC BEHAVIORAL HEALTH SERVICES**
6 **UNDER MEDICAID AND CHIP.**

7 Not later than 18 months after the date of enactment
8 of this Act, the Secretary of Health and Human Services
9 shall issue guidance to States on how to expand the provi-
10 sion of, and access to, behavioral health services, including
11 mental health services, for children covered under State
12 plans (or waivers of such plans) under title XIX of the
13 Social Security Act (42 U.S.C. 1396 et seq.), or State
14 child health plans (or waivers of such plans) under title
15 XXI of such Act (42 U.S.C. 1397aa et seq.), including
16 a description of best practices for—

- 17 (1) expanding access to such services;
- 18 (2) expanding access to such services in under-
19 served communities;
- 20 (3) flexibilities that States may offer for pedi-
21 atric hospitals and other pediatric behavioral health
22 providers to expand access to services; and
- 23 (4) recruitment and retention of providers of
24 such services.

1 **SEC. 504. ENSURING CHILDREN RECEIVE TIMELY ACCESS**
2 **TO CARE.**

3 (a) GUIDANCE TO STATES ON FLEXIBILITIES TO EN-
4 SURE PROVIDER CAPACITY TO PROVIDE PEDIATRIC BE-
5 HAVIORAL HEALTH, INCLUDING MENTAL HEALTH, CRI-
6 SIS CARE.—Not later than 18 months after the date of
7 enactment of this Act, the Secretary of Health and
8 Human Services shall provide guidance to States on exist-
9 ing flexibilities under State plans (or waivers of such
10 plans) under title XIX of the Social Security Act (42
11 U.S.C. 1396 et seq.), or State child health plans under
12 title XXI of such Act (42 U.S.C. 1397aa et seq.), to sup-
13 port children experiencing a behavioral health crisis or in
14 need of intensive behavioral health, including mental
15 health, services.

16 (b) ENSURING CONSISTENT REVIEW AND STATE IM-
17 PLEMENTATION OF EARLY AND PERIODIC SCREENING,
18 DIAGNOSTIC, AND TREATMENT SERVICES.—Section
19 1905(r) of the Social Security Act (42 U.S.C. 1396d(r))
20 is amended by adding at the end the following: “Not later
21 than January 1, 2025, and every 5 years thereafter, the
22 Secretary shall review implementation of the requirements
23 of this subsection by States, including such requirements
24 relating to services provided by managed care organiza-
25 tions, prepaid inpatient health plans, prepaid ambulatory
26 health plans, and primary care case managers, to identify

1 and disseminate best practices for ensuring comprehensive
2 coverage of services, to identify gaps and deficiencies in
3 meeting Federal requirements, and to provide guidance to
4 States on addressing identified gaps and disparities and
5 meeting Federal coverage requirements in order to ensure
6 children have access to health services.”.

7 **SEC. 505. STRATEGIES TO INCREASE ACCESS TO TELE-**
8 **HEALTH UNDER MEDICAID AND CHIP.**

9 Not later than 1 year after the date of the enactment
10 of this Act, and in the event updates are available, once
11 every five years thereafter, the Secretary of Health and
12 Human Services shall update guidance issued by the Cen-
13 ters for Medicare & Medicaid Services to States, the State
14 Medicaid & CHIP Telehealth Toolkit, or any successor
15 guidance, to describe strategies States may use to over-
16 come existing barriers and increase access to telehealth
17 services under the Medicaid program under title XIX of
18 the Social Security Act (42 U.S.C. 1396 et seq.) and the
19 Children’s Health Insurance Program under title XXI of
20 such Act (42 U.S.C. 1397aa et seq.). Such updated guid-
21 ance shall include examples of and promising practices re-
22 garding—

23 (1) telehealth delivery of covered services;

1 (2) recommended voluntary billing codes, modi-
2 fiers, and place-of-service designations for telehealth
3 and other virtual health care services;

4 (3) strategies States can use for the simplifica-
5 tion or alignment of provider credentialing and en-
6 rollment protocols with respect to telehealth across
7 States, State Medicaid plans under title XIX, State
8 child health plans under title XXI, Medicaid man-
9 aged care organizations, prepaid inpatient health
10 plans, prepaid ambulatory health plans, and primary
11 care case managers, including during national public
12 health emergencies; and

13 (4) strategies States can use to integrate tele-
14 health and other virtual health care services into
15 value-based health care models.

16 **SEC. 506. REMOVAL OF LIMITATIONS ON FEDERAL FINAN-**
17 **CIAL PARTICIPATION FOR INMATES WHO ARE**
18 **ELIGIBLE JUVENILES PENDING DISPOSITION**
19 **OF CHARGES.**

20 (a) MEDICAID.—

21 (1) IN GENERAL.—The subdivision (A) of sec-
22 tion 1905(a) of the Social Security Act (42 U.S.C.
23 1396d(a)) following paragraph (31) of such section,
24 as amended by section 501(b), is further amended
25 by inserting “, or, at the option of the State, for an

1 individual who is an eligible juvenile (as defined in
2 section 1902(nn)(2)), while such individual is an in-
3 mate of a public institution (as defined in section
4 1902(nn)(3)) pending disposition of charges” after
5 “or in the case of an eligible juvenile described in
6 section 1902(a)(84)(D) with respect to the
7 screenings, diagnostic services, referrals, and case
8 management required under such subparagraph
9 (D)”.

10 (2) CONFORMING.—Section 1902(a)(84)(A) of
11 the Social Security Act (42 U.S.C. 1396a(a)(84)(A))
12 is amended by inserting “(or in the case of a State
13 electing the option described in the subdivision (A)
14 following paragraph (31) of section 1905(a), during
15 such period beginning after the disposition of
16 charges with respect to such individual)” after “is
17 such an inmate”.

18 (b) CHIP.—Section 2110(b)(7) of the Social Security
19 Act (42 U.S.C. 13977jj(b)(7)), as added by section
20 501(c)(2)(B), is further amended by inserting “or, at the
21 option of the State, for an individual who is a juvenile,
22 while such individual is an inmate of a public institution
23 pending disposition of charges” after “if such child is an
24 eligible juvenile (as described in section 1902(a)(84)(D))
25 with respect to screenings, diagnostic services, referrals,

1 and case management otherwise covered under the State
2 child health plan (or waiver of such plan)”.

3 (c) EFFECTIVE DATE.—The amendments made by
4 this section shall take effect on the first day of the first
5 calendar quarter that begins after the date that is 18
6 months after the date of enactment of this Act and shall
7 apply to items and services furnished for periods beginning
8 on or after such date.

9 **TITLE VI—MISCELLANEOUS**
10 **PROVISIONS**

11 **SEC. 601. DETERMINATION OF BUDGETARY EFFECTS.**

12 The budgetary effects of this Act, for the purpose of
13 complying with the Statutory Pay-As-You-Go Act of 2010,
14 shall be determined by reference to the latest statement
15 titled “Budgetary Effects of PAYGO Legislation” for this
16 Act, submitted for printing in the Congressional Record
17 by the Chairman of the House Budget Committee, pro-
18 vided that such statement has been submitted prior to the
19 vote on passage.

20 **SEC. 602. OVERSIGHT OF PHARMACY BENEFIT MANAGER**
21 **SERVICES.**

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

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

1 **“SEC. 2799A–11. OVERSIGHT OF PHARMACY BENEFIT MAN-**
2 **AGER SERVICES.**

3 “(a) IN GENERAL.—For plan years beginning on or
4 after January 1, 2024, a group health plan or health in-
5 surance issuer offering group health insurance coverage
6 or an entity or subsidiary providing pharmacy benefits
7 management services on behalf of such a plan or issuer
8 shall not enter into a contract with a drug manufacturer,
9 distributor, wholesaler, subcontractor, rebate aggregator,
10 or any associated third party that limits the disclosure of
11 information to plan sponsors in such a manner that pre-
12 vents the plan or issuer, or an entity or subsidiary pro-
13 viding pharmacy benefits management services on behalf
14 of a plan or issuer, from making the reports described in
15 subsection (b).

16 “(b) REPORTS.—

17 “(1) IN GENERAL.—For plan years beginning
18 on or after January 1, 2024, not less frequently
19 than once every 6 months, a health insurance issuer
20 offering group health insurance coverage or an enti-
21 ty providing pharmacy benefits management services
22 on behalf of a group health plan or an issuer pro-
23 viding group health insurance coverage shall submit
24 to the plan sponsor (as defined in section 3(16)(B)
25 of the Employee Retirement Income Security Act of
26 1974) of such group health plan or health insurance

1 coverage a report in accordance with this subsection
2 and make such report available to the plan sponsor
3 in a machine-readable format. Each such report
4 shall include, with respect to the applicable group
5 health plan or health insurance coverage—

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

13 “(B) a list of each drug covered by such
14 plan, issuer, or entity providing pharmacy ben-
15 efit management services that was dispensed
16 during the reporting period, including, with re-
17 spect to each such drug during the reporting
18 period—

19 “(i) the brand name, chemical entity,
20 and National Drug Code;

21 “(ii) the number of participants and
22 beneficiaries for whom the drug was filled
23 during the plan year, the total number of
24 prescription fills for the drug (including
25 original prescriptions and refills), and the

1 total number of dosage units of the drug
2 dispensed across the plan year, including
3 whether the dispensing channel was by re-
4 tail, mail order, or specialty pharmacy;

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

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

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

18 “(I) a list of all other drugs in
19 the same therapeutic category or
20 class, including brand name drugs
21 and biological products and generic
22 drugs or biosimilar biological products
23 that are in the same therapeutic cat-
24 egory or class as such drug; and

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

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

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

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

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

22 “(iv) the total out-of-pocket spending
23 by participants and beneficiaries, including
24 participant and beneficiary spending

1 through copayments, coinsurance, and
2 deductibles; and

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

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

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

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

18 “(II) the total net spending, after
19 deducting rebates, price concessions,
20 alternative discounts or other remu-
21 nation from drug manufacturers, by
22 the health plan or health insurance
23 coverage on that category or class of
24 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 benefit 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, or applicable
16 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.—A health insurance
25 issuer offering group health insurance coverage or

1 an entity providing pharmacy benefits management
2 services on behalf of a group health plan shall sub-
3 mit to the Comptroller General of the United States
4 each of the first 4 reports submitted to a plan spon-
5 sor under paragraph (1) with respect to such cov-
6 erage or plan, and other such reports as requested,
7 in accordance with the privacy requirements under
8 paragraph (2), the disclosure and redisclosure stand-
9 ards under paragraph (3), the standards specified
10 pursuant to paragraph (5), and such other informa-
11 tion that the Comptroller General determines nec-
12 essary to carry out the study under section 602(d)
13 of the Restoring Hope for Mental Health and Well-
14 Being Act of 2022.

15 “(5) STANDARD FORMAT.—Not later than June
16 1, 2023, the Secretary shall specify through rule-
17 making standards for health insurance issuers and
18 entities required to submit reports under paragraph
19 (4) to submit such reports in a standard format.

20 “(c) ENFORCEMENT.—

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

24 “(2) FAILURE TO PROVIDE TIMELY INFORMA-
25 TION.—A health insurance issuer or an entity pro-

1 viding pharmacy benefit management services that
2 violates subsection (a) or fails to provide information
3 required under subsection (b), or a drug manufac-
4 turer that fails to provide information under sub-
5 section (b)(1)(A) in a timely manner, shall be sub-
6 ject to a civil monetary penalty in the amount of
7 \$10,000 for each day during which such violation
8 continues or such information is not disclosed or re-
9 ported.

10 “(3) FALSE INFORMATION.—A health insurance
11 issuer, entity providing pharmacy benefit manage-
12 ment services, or drug manufacturer that knowingly
13 provides false information under this section shall be
14 subject to a civil money penalty in an amount not
15 to exceed \$100,000 for each item of false informa-
16 tion. Such civil money penalty shall be in addition to
17 other penalties as may be prescribed by law.

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

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

7 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
8 tion shall be construed to permit a health insurance issuer,
9 group health plan, or other entity to restrict disclosure to,
10 or otherwise limit the access of, the Department of Health
11 and Human Services to a report described in subsection
12 (b)(1) or information related to compliance with sub-
13 section (a) by such issuer, plan, or entity.

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

17 (2) in section 2723 (42 U.S.C. 300gg–22)—

18 (A) in subsection (a)—

19 (i) in paragraph (1), by inserting
20 “(other than subsections (a) and (b) of
21 section 2799A–11)” after “part D”; and

22 (ii) in paragraph (2), by inserting
23 “(other than subsections (a) and (b) of
24 section 2799A–11)” after “part D”; and

25 (B) in subsection (b)—

1 (i) in paragraph (1), by inserting
2 “(other than subsections (a) and (b) of
3 section 2799A–11)” after “part D”;

4 (ii) in paragraph (2)(A), by inserting
5 “(other than subsections (a) and (b) of
6 section 2799A–11)” after “part D”; and

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

10 (b) ERISA.—

11 (1) IN GENERAL.—Subtitle B of title I of the
12 Employee Retirement Income Security Act of 1974
13 (29 U.S.C. 1021 et seq.) is amended—

14 (A) in subpart B of part 7 (29 U.S.C.
15 1185 et seq.), by adding at the end the fol-
16 lowing:

17 **“SEC. 726. OVERSIGHT OF PHARMACY BENEFIT MANAGER**
18 **SERVICES.**

19 “(a) IN GENERAL.—For plan years beginning on or
20 after January 1, 2024, a group health plan (or health in-
21 surance issuer offering group health insurance coverage
22 in connection with such a plan) or an entity or subsidiary
23 providing pharmacy benefits management services on be-
24 half of such a plan or issuer shall not enter into a contract
25 with a drug manufacturer, distributor, wholesaler, subcon-

1 tractor, rebate aggregator, or any associated third party
2 that limits the disclosure of information to plan sponsors
3 in such a manner that prevents the plan or issuer, or an
4 entity or subsidiary providing pharmacy benefits manage-
5 ment services on behalf of a plan or issuer, from making
6 the reports described in subsection (b).

7 “(b) REPORTS.—

8 “(1) IN GENERAL.—For plan years beginning
9 on or after January 1, 2024, not less frequently
10 than once every 6 months, a health insurance issuer
11 offering group health insurance coverage or an enti-
12 ty providing pharmacy benefits management services
13 on behalf of a group health plan or an issuer pro-
14 viding group health insurance coverage shall submit
15 to the plan sponsor (as defined in section 3(16)(B))
16 of such group health plan or group health insurance
17 coverage a report in accordance with this subsection
18 and make such report available to the plan sponsor
19 in a machine-readable format. Each such report
20 shall include, with respect to the applicable group
21 health plan or health insurance coverage—

22 “(A) as applicable, information collected
23 from drug manufacturers by such issuer or en-
24 tity on the total amount of copayment assist-
25 ance dollars paid, or copayment cards applied,

1 that were funded by the drug manufacturer
2 with respect to the participants and bene-
3 ficiaries in such plan or coverage;

4 “(B) a list of each drug covered by such
5 plan, issuer, or entity providing pharmacy ben-
6 efit management services that was dispensed
7 during the reporting period, including, with re-
8 spect to each such drug during the reporting
9 period—

10 “(i) the brand name, chemical entity,
11 and National Drug Code;

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

21 “(iii) the wholesale acquisition cost,
22 listed as cost per days supply and cost per
23 pill, or in the case of a drug in another
24 form, per dose;

1 “(iv) the total out-of-pocket spending
2 by participants and beneficiaries on such
3 drug, including participant and beneficiary
4 spending through copayments, coinsurance,
5 and deductibles; and

6 “(v) for any drug for which gross
7 spending of the group health plan or
8 health insurance coverage exceeded
9 \$10,000 during the reporting period—

10 “(I) a list of all other drugs in
11 the same therapeutic category or
12 class, including brand name drugs
13 and biological products and generic
14 drugs or biosimilar biological products
15 that are in the same therapeutic cat-
16 egory or class as such drug; and

17 “(II) the rationale for preferred
18 formulary placement of such drug in
19 that therapeutic category or class, if
20 applicable;

21 “(C) a list of each therapeutic category or
22 class of drugs that were dispensed under the
23 health plan or health insurance coverage during
24 the reporting period, and, with respect to each

1 such therapeutic category or class of drugs,
2 during the reporting period—

3 “(i) total gross spending by the plan,
4 before manufacturer rebates, fees, or other
5 manufacturer remuneration;

6 “(ii) the number of participants and
7 beneficiaries who filled a prescription for a
8 drug in that category or class;

9 “(iii) if applicable to that category or
10 class, a description of the formulary tiers
11 and utilization mechanisms (such as prior
12 authorization or step therapy) employed
13 for drugs in that category or class;

14 “(iv) the total out-of-pocket spending
15 by participants and beneficiaries, including
16 participant and beneficiary spending
17 through copayments, coinsurance, and
18 deductibles; and

19 “(v) for each therapeutic category or
20 class under which 3 or more drugs are in-
21 cluded on the formulary of such plan or
22 coverage—

23 “(I) the amount received, or ex-
24 pected to be received, from drug man-

1 manufacturers in rebates, fees, alternative
2 discounts, or other remuneration—

3 “(aa) that has been paid, or
4 is to be paid, by drug manufac-
5 turers for claims incurred during
6 the reporting period; or

7 “(bb) that is related to utili-
8 zation of drugs, in such thera-
9 peutic category or class;

10 “(II) the total net spending, after
11 deducting rebates, price concessions,
12 alternative discounts or other remu-
13 nation from drug manufacturers, by
14 the health plan or health insurance
15 coverage on that category or class of
16 drugs; and

17 “(III) the net price per course of
18 treatment or single fill, such as a 30-
19 day supply or 90-day supply, incurred
20 by the health plan or health insurance
21 coverage and its participants and
22 beneficiaries, after manufacturer re-
23 bates, fees, and other remuneration
24 for drugs dispensed within such thera-

1 peutic category or class during the re-
2 porting period;

3 “(D) total gross spending on prescription
4 drugs by the plan or coverage during the re-
5 porting period, before rebates and other manu-
6 facturer fees or remuneration;

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

16 “(F) the total net spending on prescription
17 drugs by the health plan or health insurance
18 coverage during the reporting period; and

19 “(G) amounts paid directly or indirectly in
20 rebates, fees, or any other type of remuneration
21 to brokers, consultants, advisors, or any other
22 individual or firm who referred the group health
23 plan’s or health insurance issuer’s business to
24 the pharmacy benefit manager.

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

12 “(3) DISCLOSURE AND REDISCLOSURE.—

13 “(A) LIMITATION TO BUSINESS ASSOCI-
14 ATES.—A group health plan receiving a report
15 under paragraph (1) may disclose such informa-
16 tion only to business associates of such plan as
17 defined in section 160.103 of title 45, Code of
18 Federal Regulations (or successor regulations).

19 “(B) CLARIFICATION REGARDING PUBLIC
20 DISCLOSURE OF INFORMATION.—Nothing in
21 this section prevents a health insurance issuer
22 offering group health insurance coverage or an
23 entity providing pharmacy benefits management
24 services on behalf of a group health plan from
25 placing reasonable restrictions on the public dis-

1 closure of the information contained in a report
2 described in paragraph (1), except that such
3 issuer or entity may not restrict disclosure of
4 such report to the Department of Health and
5 Human Services, the Department of Labor, the
6 Department of the Treasury, or applicable
7 State agencies.

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

15 “(4) REPORT TO GAO.—A health insurance
16 issuer offering group health insurance coverage or
17 an entity providing pharmacy benefits management
18 services on behalf of a group health plan shall sub-
19 mit to the Comptroller General of the United States
20 each of the first 4 reports submitted to a plan spon-
21 sor under paragraph (1) with respect to such cov-
22 erage or plan, and other such reports as requested,
23 in accordance with the privacy requirements under
24 paragraph (2), the disclosure and redisclosure stand-
25 ards under paragraph (3), the standards specified

1 pursuant to paragraph (5), and such other informa-
2 tion that the Comptroller General determines nec-
3 essary to carry out the study under section 602(d)
4 of the Restoring Hope for Mental Health and Well-
5 Being Act of 2022.

6 “(5) STANDARD FORMAT.—Not later than June
7 1, 2023, the Secretary shall specify through rule-
8 making standards for health insurance issuers and
9 entities required to submit reports under paragraph
10 (4) to submit such reports in a standard format.

11 “(c) ENFORCEMENT.—

12 “(1) IN GENERAL.—The Secretary, in consulta-
13 tion with the Secretary of Health and Human Serv-
14 ices and the Secretary of the Treasury, shall enforce
15 this section.

16 “(2) FAILURE TO PROVIDE TIMELY INFORMA-
17 TION.—A health insurance issuer or an entity pro-
18 viding pharmacy benefit management services that
19 violates subsection (a) or fails to provide information
20 required under subsection (b), or a drug manufac-
21 turer that fails to provide information under sub-
22 section (b)(1)(A) in a timely manner, shall be sub-
23 ject to a civil monetary penalty in the amount of
24 \$10,000 for each day during which such violation

1 continues or such information is not disclosed or re-
2 ported.

3 “(3) FALSE INFORMATION.—A health insurance
4 issuer, entity providing pharmacy benefit manage-
5 ment services, or drug manufacturer that knowingly
6 provides false information under this section shall be
7 subject to a civil money penalty in an amount not
8 to exceed \$100,000 for each item of false informa-
9 tion. Such civil money penalty shall be in addition to
10 other penalties as may be prescribed by law.

11 “(4) PROCEDURE.—The provisions of section
12 1128A of the Social Security Act, other than sub-
13 section (a) and (b) and the first sentence of sub-
14 section (c)(1) of such section shall apply to civil
15 monetary penalties under this subsection in the
16 same manner as such provisions apply to a penalty
17 or proceeding under section 1128A of the Social Se-
18 curity Act.

19 “(5) WAIVERS.—The Secretary may waive pen-
20 alties under paragraph (2), or extend the period of
21 time for compliance with a requirement of this sec-
22 tion, for an entity in violation of this section that
23 has made a good-faith effort to comply with this sec-
24 tion.

1 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
2 tion shall be construed to permit a health insurance issuer,
3 group health plan, or other entity to restrict disclosure to,
4 or otherwise limit the access of, the Department of Labor
5 to a report described in subsection (b)(1) or information
6 related to compliance with subsection (a) by such issuer,
7 plan, or entity.

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

11 (B) in section 502(b)(3) (29 U.S.C.
12 1132(b)(3)), by inserting “(other than section
13 726)” after “part 7”.

14 (2) CLERICAL AMENDMENT.—The table of con-
15 tents in section 1 of the Employee Retirement In-
16 come Security Act of 1974 (29 U.S.C. 1001 et seq.)
17 is amended by inserting after the item relating to
18 section 725 the following new item:

“Sec. 726. Oversight of pharmacy benefit manager services.”.

19 (c) IRC.—

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

1 **“SEC. 9826. OVERSIGHT OF PHARMACY BENEFIT MANAGER**
2 **SERVICES.**

3 “(a) IN GENERAL.—For plan years beginning on or
4 after January 1, 2024, a group health plan or an entity
5 or subsidiary providing pharmacy benefits management
6 services on behalf of such a plan shall not enter into a
7 contract with a drug manufacturer, distributor, whole-
8 saler, subcontractor, rebate aggregator, or any associated
9 third party that limits the disclosure of information to
10 plan sponsors in such a manner that prevents the plan,
11 or an entity or subsidiary providing pharmacy benefits
12 management services on behalf of a plan, from making
13 the reports described in subsection (b).

14 “(b) REPORTS.—

15 “(1) IN GENERAL.—For plan years beginning
16 on or after January 1, 2024, not less frequently
17 than once every 6 months, an entity providing phar-
18 macy benefits management services on behalf of a
19 group health plan shall submit to the plan sponsor
20 (as defined in section 3(16)(B) of the Employee Re-
21 tirement Income Security Act of 1974) of such
22 group health plan a report in accordance with this
23 subsection and make such report available to the
24 plan sponsor in a machine-readable format. Each
25 such report shall include, with respect to the applica-
26 ble group health plan—

1 “(A) as applicable, information collected
2 from drug manufacturers by such entity on the
3 total amount of copayment assistance dollars
4 paid, or copayment cards applied, that were
5 funded by the drug manufacturer with respect
6 to the participants and beneficiaries in such
7 plan;

8 “(B) a list of each drug covered by such
9 plan or entity providing pharmacy benefit man-
10 agement services that was dispensed during the
11 reporting period, including, with respect to each
12 such drug during the reporting period—

13 “(i) the brand name, chemical entity,
14 and National Drug Code;

15 “(ii) the number of participants and
16 beneficiaries for whom the drug was filled
17 during the plan year, the total number of
18 prescription fills for the drug (including
19 original prescriptions and refills), and the
20 total number of dosage units of the drug
21 dispensed across the plan year, including
22 whether the dispensing channel was by re-
23 tail, mail order, or specialty pharmacy;

24 “(iii) the wholesale acquisition cost,
25 listed as cost per days supply and cost per

1 pill, or in the case of a drug in another
2 form, per dose;

3 “(iv) the total out-of-pocket spending
4 by participants and beneficiaries on such
5 drug, including participant and beneficiary
6 spending through copayments, coinsurance,
7 and deductibles; and

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

11 “(I) a list of all other drugs in
12 the same therapeutic category or
13 class, including brand name drugs
14 and biological products and generic
15 drugs or biosimilar biological products
16 that are in the same therapeutic cat-
17 egory or class as such drug; and

18 “(II) the rationale for preferred
19 formulary placement of such drug in
20 that therapeutic category or class, if
21 applicable;

22 “(C) a list of each therapeutic category or
23 class of drugs that were dispensed under the
24 health plan during the reporting period, and,

1 with respect to each such therapeutic category
2 or class of drugs, during the reporting period—

3 “(i) total gross spending by the plan,
4 before manufacturer rebates, fees, or other
5 manufacturer remuneration;

6 “(ii) the number of participants and
7 beneficiaries who filled a prescription for a
8 drug in that category or class;

9 “(iii) if applicable to that category or
10 class, a description of the formulary tiers
11 and utilization mechanisms (such as prior
12 authorization or step therapy) employed
13 for drugs in that category or class;

14 “(iv) the total out-of-pocket spending
15 by participants and beneficiaries, including
16 participant and beneficiary spending
17 through copayments, coinsurance, and
18 deductibles; and

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

22 “(I) the amount received, or ex-
23 pected to be received, from drug man-
24 ufacturers in rebates, fees, alternative
25 discounts, or other remuneration—

1 “(aa) that has been paid, or
2 is to be paid, by drug manufac-
3 turers for claims incurred during
4 the reporting period; or

5 “(bb) that is related to utili-
6 zation of drugs, in such thera-
7 peutic category or class;

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

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

23 “(D) total gross spending on prescription
24 drugs by the plan during the reporting period,

1 before rebates and other manufacturer fees or
2 remuneration;

3 “(E) total amount received, or expected to
4 be received, by the health plan in drug manu-
5 facturer rebates, fees, alternative discounts, and
6 all other remuneration received from the manu-
7 facturer or any third party, other than the plan
8 sponsor, related to utilization of drug or drug
9 spending under that health plan during the re-
10 porting period;

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

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

20 “(2) PRIVACY REQUIREMENTS.—Entities pro-
21 viding pharmacy benefits management services on
22 behalf of a group health plan shall provide informa-
23 tion under paragraph (1) in a manner consistent
24 with the privacy, security, and breach notification
25 regulations promulgated under section 264(c) of the

1 Health Insurance Portability and Accountability Act
2 of 1996, and shall restrict the use and disclosure of
3 such information according to such privacy regula-
4 tions.

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 an entity providing phar-
15 macy benefits management services on behalf of
16 a group health plan from placing reasonable re-
17 strictions on the public disclosure of the infor-
18 mation contained in a report described in para-
19 graph (1), except that such entity may not re-
20 strict disclosure of such report to the Depart-
21 ment of Health and Human Services, the De-
22 partment of Labor, the Department of the
23 Treasury, or applicable State agencies.

24 “(C) LIMITED FORM OF REPORT.—The
25 Secretary shall define through rulemaking a

1 limited form of the report under paragraph (1)
2 required of plan sponsors who are drug manu-
3 facturers, drug wholesalers, or other direct par-
4 ticipants in the drug supply chain, in order to
5 prevent anti-competitive behavior.

6 “(4) REPORT TO GAO.—An entity providing
7 pharmacy benefits management services on behalf of
8 a group health plan shall submit to the Comptroller
9 General of the United States each of the first 4 re-
10 ports submitted to a plan sponsor under paragraph
11 (1) with respect to such plan, and other such reports
12 as requested, in accordance with the privacy require-
13 ments under paragraph (2), the disclosure and re-
14 disclosure standards under paragraph (3), the stand-
15 ards specified pursuant to paragraph (5), and such
16 other information that the Comptroller General de-
17 termines necessary to carry out the study under sec-
18 tion 602(d) of the Restoring Hope for Mental
19 Health and Well-Being Act of 2022.

20 “(5) STANDARD FORMAT.—Not later than June
21 1, 2023, the Secretary shall specify through rule-
22 making standards for entities required to submit re-
23 ports under paragraph (4) to submit such reports in
24 a standard format.

25 “(c) ENFORCEMENT.—

1 “(1) IN GENERAL.—The Secretary, in consulta-
2 tion with the Secretary of Labor and the Secretary
3 of Health and Human Services, shall enforce this
4 section.

5 “(2) FAILURE TO PROVIDE TIMELY INFORMA-
6 TION.—An entity providing pharmacy benefit man-
7 agement services that violates subsection (a) or fails
8 to provide information required under subsection
9 (b), or a drug manufacturer that fails to provide in-
10 formation under subsection (b)(1)(A) in a timely
11 manner, shall be subject to a civil monetary penalty
12 in the amount of \$10,000 for each day during which
13 such violation continues or such information is not
14 disclosed or reported.

15 “(3) FALSE INFORMATION.—An entity pro-
16 viding pharmacy benefit management services, or
17 drug manufacturer that knowingly provides false in-
18 formation under this section shall be subject to a
19 civil money penalty in an amount not to exceed
20 \$100,000 for each item of false information. Such
21 civil money penalty shall be in addition to other pen-
22 alties as may be prescribed by law.

23 “(4) PROCEDURE.—The provisions of section
24 1128A of the Social Security Act, other than sub-
25 section (a) and (b) and the first sentence of sub-

1 section (c)(1) of such section shall apply to civil
2 monetary penalties under this subsection in the
3 same manner as such provisions apply to a penalty
4 or proceeding under section 1128A of the Social Se-
5 curity Act.

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

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

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

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

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

25 (d) GAO STUDY.—

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

5 (A) pharmacy networks of group health
6 plans, health insurance issuers, and entities
7 providing pharmacy benefit management serv-
8 ices under such group health plan or group or
9 individual health insurance coverage, including
10 networks that have pharmacies that are under
11 common ownership (in whole or part) with
12 group health plans, health insurance issuers, or
13 entities providing pharmacy benefit manage-
14 ment services or pharmacy benefit administra-
15 tive services under group health plan or group
16 or individual health insurance coverage;

17 (B) as it relates to pharmacy networks
18 that include pharmacies under common owner-
19 ship described in subparagraph (A)—

20 (i) whether such networks are de-
21 signed to encourage enrollees of a plan or
22 coverage to use such pharmacies over other
23 network pharmacies for specific services or
24 drugs, and if so, the reasons the networks

1 give for encouraging use of such phar-
2 macies; and

3 (ii) whether such pharmacies are used
4 by enrollees disproportionately more in the
5 aggregate or for specific services or drugs
6 compared to other network pharmacies;

7 (C) whether group health plans and health
8 insurance issuers offering group or individual
9 health insurance coverage have options to elect
10 different network pricing arrangements in the
11 marketplace with entities that provide phar-
12 macy benefit management services, the preva-
13 lence of electing such different network pricing
14 arrangements;

15 (D) pharmacy network design parameters
16 that encourage enrollees in the plan or coverage
17 to fill prescriptions at mail order, specialty, or
18 retail pharmacies that are wholly or partially-
19 owned by that issuer or entity; and

20 (E) the degree to which mail order, spe-
21 cialty, or retail pharmacies that dispense pre-
22 scription drugs to an enrollee in a group health
23 plan or health insurance coverage that are
24 under common ownership (in whole or part)
25 with group health plans, health insurance

1 issuers, or entities providing pharmacy benefit
2 management services or pharmacy benefit ad-
3 ministrative services under group health plan or
4 group or individual health insurance coverage
5 receive reimbursement that is greater than the
6 median price charged to the group health plan
7 or health insurance issuer when the same drug
8 is dispensed to enrollees in the plan or coverage
9 by other pharmacies included in the pharmacy
10 network of that plan, issuer, or entity that are
11 not wholly or partially owned by the health in-
12 surance issuer or entity providing pharmacy
13 benefit management services.

14 (2) REQUIREMENT.—The Comptroller General
15 of the United States shall ensure that the report
16 under paragraph (1) does not contain information
17 that would allow a reader to identify a specific plan
18 or entity providing pharmacy benefits management
19 services or otherwise contain commercial or financial
20 information that is privileged or confidential.

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

1 **SEC. 603. MEDICARE IMPROVEMENT FUND.**

2 Section 1898(b)(1) of the Social Security Act (42
3 U.S.C. 1395iii(b)(1)) is amended by striking
4 “\$5,000,000” and inserting “\$1,034,000,000”.

5 **SEC. 604. LIMITATIONS ON AUTHORITY.**

6 In carrying out any program of the Substance Abuse
7 and Mental Health Services Administration whose statu-
8 tory authorization is enacted or amended by this Act, the
9 Secretary of Health and Human Services shall not allocate
10 funding, or require award recipients to prioritize, dedicate,
11 or allocate funding, without consideration of the incidence,
12 prevalence, or determinants of mental health or substance
13 use issues, unless such allocation or requirement is con-
14 sistent with statute, regulation, or other Federal law.

