**AMENDMENT TO**

**RULES COMMITTEE PRINT 117–51**

**OFFERED BY M__. _____**

Amend section 263 to read as follows:

**SEC. 263. REQUIRING PRESCRIBERS OF CONTROLLED SUBSTANCES TO COMPLETE TRAINING.**

Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

''(l) REQUIRED TRAINING FOR PRESCRIBERS.—

''(1) TRAINING REQUIRED.—As a condition on registration under this section to dispense controlled substances in schedule II, III, IV, or V, the Attorney General shall require any qualified practitioner, beginning with the first applicable registration for the practitioner, to meet the following:

''(A) If the practitioner is a physician (as defined under section 1861(r) of the Social Security Act), the practitioner meets one or more of the following conditions:

''(i) The physician holds a board certification in addiction psychiatry or addic-

tion medicine from the American Board of Medical Specialties.

''(ii) The physician holds a board certification from the American Board of Addiction Medicine.

''(iii) The physician holds a board certification in addiction medicine from the American Osteopathic Association.

''(iv) The physician has, with respect to the treatment and management of patients with opioid or other substance use disorders, or the safe pharmacological management of dental pain and screening, brief intervention, and referral for appropriate treatment of patients with or at risk of developing opioid or other substance use disorders, completed not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by—

''(I) the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the

American Osteopathic Association, the American Dental Association, the American Association of Oral and Maxillofacial Surgeons, the American Psychiatric Association, or any other organization accredited by the Accreditation Council for Continuing Medical Education (commonly known as the 'ACCME') or the Commission on Dental Accreditation;

''(II) any organization accredited by a State medical society accreditor that is recognized by the ACCME or the Commission on Dental Accreditation;

''(III) any organization accredited by the American Osteopathic Association to provide continuing medical education; or

''(IV) any organization approved by the Assistant Secretary for Mental Health and Substance Abuse, the ACCME, or the Commission on Dental Accreditation.

''(v) The physician graduated in good standing from an accredited school of allopathic medicine, osteopathic medicine, dental surgery, or dental medicine in the United States during the 5-year period immediately preceding the date on which the physician first registers or renews under this section and has successfully completed a comprehensive allopathic or osteopathic medicine curriculum or accredited medical residency or dental surgery or dental medicine curriculum that included not less than 8 hours of training on—

''(I) treating and managing patients with opioid and other substance use disorders, including the appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of a substance use disorder; or

''(II) the safe pharmacological management of dental pain and screening, brief intervention, and referral for appropriate treatment of patients with or at risk of developing

opioid and other substance use disorders.

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

''(i) The practitioner has completed not fewer than 8 hours of training with respect to the treatment and management of patients with opioid or other substance use disorders (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Nurses Credentialing Center, the American Psychiatric Association, the American Association of Nurse Practitioners, the American Academy of Physician Associates, or any other organization approved or accredited by the Assistant Secretary for Mental Health and Substance Abuse or the Ac-

creditation Council for Continuing Medical Education.

''(ii) The practitioner has graduated in good standing from an accredited physician assistant school or accredited school of advanced practice nursing in the United States during the 5-year period immediately preceding the date on which the practitioner first registers or renews under this section and has successfully completed a comprehensive physician assistant or advanced practice nursing curriculum that included not fewer than 8 hours of training on treating and managing patients with opioid and other substance use disorders, including the appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of a substance use disorder.

''(2) ONE-TIME TRAINING.—

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

''(B) NOTIFICATION.—Not later than 90 days after the date of the enactment of the Restoring Hope for Mental Health and Well-Being Act of 2022, the Attorney General shall provide to qualified practitioners a single written, electronic notification of the training described in clauses (iv) and (v) of paragraph (1)(A) or clauses (i) and (ii) of paragraph (1)(B).

''(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to preclude the use, by a qualified practitioner, of training received pursuant to this subsection to satisfy registration requirements of a State or for some other lawful purpose.

''(4) DEFINITIONS.—In this section:

''(A) FIRST APPLICABLE REGISTRATION.—The term 'first applicable registration' means the first registration or renewal of registration by a qualified practitioner under this section that occurs on or after the date that is 180 days after the date of enactment of the Restoring Hope for Mental Health and Well-Being Act of 2022.

''(B) QUALIFIED PRACTITIONER.—In this subsection, the term 'qualified practitioner' means a practitioner who—

''(i) is licensed under State law to prescribe controlled substances; and

''(ii) is not solely a veterinarian.''.

Page 150, after line 5, insert the following:

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

Section 597(c) of the Public Health Service Act (42 U.S.C. 290ll(c)) is amended by striking ''$12,669,000 for each of fiscal years 2018 through 2022'' and inserting ''$25,000,000 for each of fiscal years 2023 through 2027''.

At the end of title IV, add the following new subtitle:

# Subtitle D—Social Media and Adolescent Mental Health

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

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

(1) smartphone and social media use by adolescents; and

(2) the effects of such use on—

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

(B) any disparities in the mental health outcomes of rural, minority, and other underserved populations.

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

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

# TITLE V—MEDICAID AND CHIP

**SEC. 501. MEDICAID AND CHIP REQUIREMENTS FOR HEALTH SCREENINGS AND REFERRALS FOR ELIGIBLE JUVENILES IN PUBLIC INSTITUTIONS.**

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

(1) in subsection (a)(84)—

(A) in subparagraph (A), by inserting ", subject to subparagraph (D)," after "but";

(B) in subparagraph (B), by striking ''and'' at the end;

(C) in subparagraph (C), by adding ''and'' at the end; and

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

''(D) beginning on the first day of the first calendar quarter that begins two years after the date of enactment of this subparagraph, in the case of individuals who are eligible juveniles described in subsection (nn)(2), are within 30 days of the date on which such eligible juvenile is scheduled to be released from a public institution following adjudication, the State shall have in place a plan to ensure, and in accordance with such plan, provide—

''(i) for, in the 30 days prior to the release of such an eligible juvenile from such public institution (or not later than one week after release from the public institution), and in coordination with such institution—

''(I) any screening or diagnostic service which meets reasonable standards of medical and dental practice,

as determined by the State, or as indicated as medically necessary, in accordance with paragraphs (1)(A) and (5) of section 1905(r); and

''(II) a mental health or other behavioral health screening that is a screening service described under section 1905(r)(1), or a diagnostic service described under paragraph (5) of such section, if such screening or diagnostic service was not otherwise conducted pursuant to this clause;

''(ii) for, not later than one week after release from the public institution, referrals for such eligible juvenile to the appropriate care and services available under the State plan (or waiver of such plan) in the geographic region of the home or residence of such eligible juvenile, based on such screenings; and

''(iii) for, following the release of such eligible juvenile from such institution, not less than 30 days of targeted case management services furnished by a provider in

the geographic region of the home or residence of such eligible juvenile.''; and

(2) in subsection (nn)(3), by striking ''(30)'' and inserting ''(31)''.

(b) AUTHORIZATION OF FEDERAL FINANCIAL PARTICIPATION.—The subdivision (A) of section 1905(a) of the Social Security Act (42 U.S.C. 1396d(a)) following paragraph (31) of such section is amended by inserting '', or in the case of an eligible juvenile described in section 1902(a)(84)(D) with respect to the screenings, diagnostic services, referrals, and case management required under such subparagraph (D)'' after ''(except as a patient in a medical institution''.

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

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

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

''(7) EXCEPTION TO EXCLUSION OF CHILDREN WHO ARE INMATES OF A PUBLIC INSTITUTION.—A child shall not be considered to be described in paragraph (2)(A) if such child is an eligible juvenile (as

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

**SEC. 502. GUIDANCE ON REDUCING ADMINISTRATIVE BARRIERS TO PROVIDING HEALTH CARE SERVICES IN SCHOOLS.**

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

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

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

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

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

(3) take into account reasons why small and rural local education agencies may not provide medical assistance and provide information on best practices to encourage such agencies to provide such assistance; and

(4) include best practices and examples of methods that State Medicaid agencies and local education agencies have used to pay for, and increase the availability of, medical assistance.

(c) DEFINITIONS.—In this Act:

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

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

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

**SEC. 503. GUIDANCE TO STATES ON SUPPORTING PEDIATRIC BEHAVIORAL HEALTH SERVICES UNDER MEDICAID AND CHIP.**

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

(1) expanding access to such services;

(2) expanding access to such services in underserved communities;

(3) flexibilities that States may offer for pediatric hospitals and other pediatric behavioral health providers to expand access to services; and

(4) recruitment and retention of providers of such services.

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

(a) GUIDANCE TO STATES ON FLEXIBILITIES TO ENSURE PROVIDER CAPACITY TO PROVIDE PEDIATRIC BEHAVIORAL HEALTH, INCLUDING MENTAL HEALTH, CRISIS CARE.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall provide guidance to States on existing flexibilities under State plans (or waivers of such plans) under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.), or State child health plans under title XXI of such Act (42 U.S.C. 1397aa et seq.), to support children experiencing a behavioral health crisis or in need of intensive behavioral health, including mental health, services.

(b) ENSURING CONSISTENT REVIEW AND STATE IMPLEMENTATION OF EARLY AND PERIODIC SCREENING, DIAGNOSTIC, AND TREATMENT SERVICES.—Section 1905(r) of the Social Security Act (42 U.S.C. 1396d(r)) is amended by adding at the end the following: ''Not later than January 1, 2025, and every 5 years thereafter, the Secretary shall review implementation of the requirements of this subsection by States, including such requirements relating to services provided by managed care organizations, prepaid inpatient health plans, prepaid ambulatory health plans, and primary care case managers, to identify

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

**SEC. 505. STRATEGIES TO INCREASE ACCESS TO TELEHEALTH UNDER MEDICAID AND CHIP.**

Not later than 1 year after the date of the enactment of this Act, and in the event updates are available, once every five years thereafter, the Secretary of Health and Human Services shall update guidance issued by the Centers for Medicare & Medicaid Services to States, the State Medicaid & CHIP Telehealth Toolkit, or any successor guidance, to describe strategies States may use to overcome existing barriers and increase access to telehealth services under the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) and the Children's Health Insurance Program under title XXI of such Act (42 U.S.C. 1397aa et seq.). Such updated guidance shall include examples of and promising practices regarding—

(1) telehealth delivery of covered services;

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

(3) strategies States can use for the simplification or alignment of provider credentialing and enrollment protocols with respect to telehealth across States, State Medicaid plans under title XIX, State child health plans under title XXI, Medicaid managed care organizations, prepaid inpatient health plans, prepaid ambulatory health plans, and primary care case managers, including during national public health emergencies; and

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

**SEC. 506. REMOVAL OF LIMITATIONS ON FEDERAL FINANCIAL PARTICIPATION FOR INMATES WHO ARE ELIGIBLE JUVENILES PENDING DISPOSITION OF CHARGES.**

(a) MEDICAID.—

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

individual who is an eligible juvenile (as defined in section 1902(nn)(2)), while such individual is an inmate of a public institution (as defined in section 1902(nn)(3)) pending disposition of charges'' after ''or in the case of an eligible juvenile described in section 1902(a)(84)(D) with respect to the screenings, diagnostic services, referrals, and case management required under such subparagraph (D)''.

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

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

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

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

# TITLE VI—MISCELLANEOUS PROVISIONS

## SEC. 601. DETERMINATION OF BUDGETARY EFFECTS.

The budgetary effects of this Act, for the purpose of complying with the Statutory Pay-As-You-Go Act of 2010, shall be determined by reference to the latest statement titled ''Budgetary Effects of PAYGO Legislation'' for this Act, submitted for printing in the Congressional Record by the Chairman of the House Budget Committee, provided that such statement has been submitted prior to the vote on passage.

## SEC. 602. OVERSIGHT OF PHARMACY BENEFIT MANAGER SERVICES.

(a) PHSA.—Title XXVII of the Public Health Service Act (42 U.S.C. 300gg et seq.) is amended—

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

**"SEC. 2799A–11. OVERSIGHT OF PHARMACY BENEFIT MANAGER SERVICES.**

"(a) IN GENERAL.—For plan years beginning on or after January 1, 2024, a group health plan or health insurance issuer offering group health insurance coverage or an entity or subsidiary providing pharmacy benefits management services on behalf of such a plan or issuer shall not enter into a contract with a drug manufacturer, distributor, wholesaler, subcontractor, rebate aggregator, or any associated third party that limits the disclosure of information to plan sponsors in such a manner that prevents the plan or issuer, or an entity or subsidiary providing pharmacy benefits management services on behalf of a plan or issuer, from making the reports described in subsection (b).

"(b) REPORTS.—

"(1) IN GENERAL.—For plan years beginning on or after January 1, 2024, not less frequently than once every 6 months, a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan or an issuer providing group health insurance coverage shall submit to the plan sponsor (as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974) of such group health plan or health insurance

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

''(A) as applicable, information collected from drug manufacturers by such issuer or entity on the total amount of copayment assistance dollars paid, or copayment cards applied, that were funded by the drug manufacturer with respect to the participants and beneficiaries in such plan or coverage;

''(B) a list of each drug covered by such plan, issuer, or entity providing pharmacy benefit management services that was dispensed during the reporting period, including, with respect to each such drug during the reporting period—

''(i) the brand name, chemical entity, and National Drug Code;

''(ii) the number of participants and beneficiaries for whom the drug was filled during the plan year, the total number of prescription fills for the drug (including original prescriptions and refills), and the

total number of dosage units of the drug dispensed across the plan year, including whether the dispensing channel was by retail, mail order, or specialty pharmacy;

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

''(iv) the total out-of-pocket spending by participants and beneficiaries on such drug, including participant and beneficiary spending through copayments, coinsurance, and deductibles; and

''(v) for any drug for which gross spending of the group health plan or health insurance coverage exceeded $10,000 during the reporting period—

''(I) a list of all other drugs in the same therapeutic category or class, including brand name drugs and biological products and generic drugs or biosimilar biological products that are in the same therapeutic category or class as such drug; and

''(II) the rationale for preferred formulary placement of such drug in that therapeutic category or class, if applicable;

''(C) a list of each therapeutic category or class of drugs that were dispensed under the health plan or health insurance coverage during the reporting period, and, with respect to each such therapeutic category or class of drugs, during the reporting period—

''(i) total gross spending by the plan, before manufacturer rebates, fees, or other manufacturer remuneration;

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

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

''(iv) the total out-of-pocket spending by participants and beneficiaries, including participant and beneficiary spending

through copayments, coinsurance, and deductibles; and

''(v) for each therapeutic category or class under which 3 or more drugs are included on the formulary of such plan or coverage—

''(I) the amount received, or expected to be received, from drug manufacturers in rebates, fees, alternative discounts, or other remuneration—

''(aa) that has been paid, or is to be paid, by drug manufacturers for claims incurred during the reporting period; or

''(bb) that is related to utilization of drugs, in such therapeutic category or class;

''(II) the total net spending, after deducting rebates, price concessions, alternative discounts or other remuneration from drug manufacturers, by the health plan or health insurance coverage on that category or class of drugs; and

''(III) the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply, incurred by the health plan or health insurance coverage and its participants and beneficiaries, after manufacturer rebates, fees, and other remuneration for drugs dispensed within such therapeutic category or class during the reporting period;

''(D) total gross spending on prescription drugs by the plan or coverage during the reporting period, before rebates and other manufacturer fees or remuneration;

''(E) total amount received, or expected to be received, by the health plan or health insurance coverage in drug manufacturer rebates, fees, alternative discounts, and all other remuneration received from the manufacturer or any third party, other than the plan sponsor, related to utilization of drug or drug spending under that health plan or health insurance coverage during the reporting period;

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

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

''(2) PRIVACY REQUIREMENTS.—Health insurance issuers offering group health insurance coverage and entities providing pharmacy benefits management services on behalf of a group health plan shall provide information under paragraph (1) in a manner consistent with the privacy, security, and breach notification regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and shall restrict the use and disclosure of such information according to such privacy regulations.

''(3) DISCLOSURE AND REDISCLOSURE.—

''(A) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such information only to business associates of such plan as

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

''(B) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section prevents a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1), except that such issuer or entity may not restrict disclosure of such report to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, or applicable State agencies.

''(C) LIMITED FORM OF REPORT.—The Secretary shall define through rulemaking a limited form of the report under paragraph (1) required of plan sponsors who are drug manufacturers, drug wholesalers, or other direct participants in the drug supply chain, in order to prevent anti-competitive behavior.

''(4) REPORT TO GAO.—A health insurance issuer offering group health insurance coverage or

an entity providing pharmacy benefits management services on behalf of a group health plan shall submit to the Comptroller General of the United States each of the first 4 reports submitted to a plan sponsor under paragraph (1) with respect to such coverage or plan, and other such reports as requested, in accordance with the privacy requirements under paragraph (2), the disclosure and redisclosure standards under paragraph (3), the standards specified pursuant to paragraph (5), and such other information that the Comptroller General determines necessary to carry out the study under section 602(d) of the Restoring Hope for Mental Health and Well-Being Act of 2022.

''(5) STANDARD FORMAT.—Not later than June 1, 2023, the Secretary shall specify through rulemaking standards for health insurance issuers and entities required to submit reports under paragraph (4) to submit such reports in a standard format.

''(c) ENFORCEMENT.—

''(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Labor and the Secretary of the Treasury, shall enforce this section.

''(2) FAILURE TO PROVIDE TIMELY INFORMATION.—A health insurance issuer or an entity pro-

viding pharmacy benefit management services that violates subsection (a) or fails to provide information required under subsection (b), or a drug manufacturer that fails to provide information under subsection (b)(1)(A) in a timely manner, shall be subject to a civil monetary penalty in the amount of $10,000 for each day during which such violation continues or such information is not disclosed or reported.

''(3) FALSE INFORMATION.—A health insurance issuer, entity providing pharmacy benefit management services, or drug manufacturer that knowingly provides false information under this section shall be subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalty shall be in addition to other penalties as may be prescribed by law.

''(4) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsection (a) and (b) and the first sentence of subsection (c)(1) of such section shall apply to civil monetary penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.

''(5) WAIVERS.—The Secretary may waive penalties under paragraph (2), or extend the period of time for compliance with a requirement of this section, for an entity in violation of this section that has made a good-faith effort to comply with this section.

''(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a health insurance issuer, group health plan, or other entity to restrict disclosure to, or otherwise limit the access of, the Department of Health and Human Services to a report described in subsection (b)(1) or information related to compliance with subsection (a) by such issuer, plan, or entity.

''(e) DEFINITION.—In this section, the term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act.''; and

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

(A) in subsection (a)—

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

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

(B) in subsection (b)—

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

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

(iii) in paragraph (2)(C)(ii), by inserting ''(other than subsections (a) and (b) of section 2799A–11)'' after ''part D''.

(b) ERISA.—

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

(A) in subpart B of part 7 (29 U.S.C. 1185 et seq.), by adding at the end the following:

**''SEC. 726. OVERSIGHT OF PHARMACY BENEFIT MANAGER SERVICES.**

''(a) IN GENERAL.—For plan years beginning on or after January 1, 2024, a group health plan (or health insurance issuer offering group health insurance coverage in connection with such a plan) or an entity or subsidiary providing pharmacy benefits management services on behalf of such a plan or issuer shall not enter into a contract with a drug manufacturer, distributor, wholesaler, subcon-

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

''(b) REPORTS.—

''(1) IN GENERAL.—For plan years beginning on or after January 1, 2024, not less frequently than once every 6 months, a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan or an issuer providing group health insurance coverage shall submit to the plan sponsor (as defined in section 3(16)(B)) of such group health plan or group health insurance coverage a report in accordance with this subsection and make such report available to the plan sponsor in a machine-readable format. Each such report shall include, with respect to the applicable group health plan or health insurance coverage—

''(A) as applicable, information collected from drug manufacturers by such issuer or entity on the total amount of copayment assistance dollars paid, or copayment cards applied,

that were funded by the drug manufacturer with respect to the participants and beneficiaries in such plan or coverage;

''(B) a list of each drug covered by such plan, issuer, or entity providing pharmacy benefit management services that was dispensed during the reporting period, including, with respect to each such drug during the reporting period—

''(i) the brand name, chemical entity, and National Drug Code;

''(ii) the number of participants and beneficiaries for whom the drug was filled during the plan year, the total number of prescription fills for the drug (including original prescriptions and refills), and the total number of dosage units of the drug dispensed across the plan year, including whether the dispensing channel was by retail, mail order, or specialty pharmacy;

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

''(iv) the total out-of-pocket spending by participants and beneficiaries on such drug, including participant and beneficiary spending through copayments, coinsurance, and deductibles; and

''(v) for any drug for which gross spending of the group health plan or health insurance coverage exceeded $10,000 during the reporting period—

''(I) a list of all other drugs in the same therapeutic category or class, including brand name drugs and biological products and generic drugs or biosimilar biological products that are in the same therapeutic category or class as such drug; and

''(II) the rationale for preferred formulary placement of such drug in that therapeutic category or class, if applicable;

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

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

''(i) total gross spending by the plan, before manufacturer rebates, fees, or other manufacturer remuneration;

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

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

''(iv) the total out-of-pocket spending by participants and beneficiaries, including participant and beneficiary spending through copayments, coinsurance, and deductibles; and

''(v) for each therapeutic category or class under which 3 or more drugs are included on the formulary of such plan or coverage—

''(I) the amount received, or expected to be received, from drug man-

ufacturers in rebates, fees, alternative discounts, or other remuneration—

"(aa) that has been paid, or is to be paid, by drug manufacturers for claims incurred during the reporting period; or

"(bb) that is related to utilization of drugs, in such therapeutic category or class;

"(II) the total net spending, after deducting rebates, price concessions, alternative discounts or other remuneration from drug manufacturers, by the health plan or health insurance coverage on that category or class of drugs; and

"(III) the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply, incurred by the health plan or health insurance coverage and its participants and beneficiaries, after manufacturer rebates, fees, and other remuneration for drugs dispensed within such thera-

peutic category or class during the reporting period;

''(D) total gross spending on prescription drugs by the plan or coverage during the reporting period, before rebates and other manufacturer fees or remuneration;

''(E) total amount received, or expected to be received, by the health plan or health insurance coverage in drug manufacturer rebates, fees, alternative discounts, and all other remuneration received from the manufacturer or any third party, other than the plan sponsor, related to utilization of drug or drug spending under that health plan or health insurance coverage during the reporting period;

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

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

''(2) PRIVACY REQUIREMENTS.—Health insurance issuers offering group health insurance coverage and entities providing pharmacy benefits management services on behalf of a group health plan shall provide information under paragraph (1) in a manner consistent with the privacy, security, and breach notification regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and shall restrict the use and disclosure of such information according to such privacy regulations.

''(3) DISCLOSURE AND REDISCLOSURE.—

''(A) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such information only to business associates of such plan as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations).

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

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

''(C) LIMITED FORM OF REPORT.—The Secretary shall define through rulemaking a limited form of the report under paragraph (1) required of plan sponsors who are drug manufacturers, drug wholesalers, or other direct participants in the drug supply chain, in order to prevent anti-competitive behavior.

''(4) REPORT TO GAO.—A health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan shall submit to the Comptroller General of the United States each of the first 4 reports submitted to a plan sponsor under paragraph (1) with respect to such coverage or plan, and other such reports as requested, in accordance with the privacy requirements under paragraph (2), the disclosure and redisclosure standards under paragraph (3), the standards specified

pursuant to paragraph (5), and such other information that the Comptroller General determines necessary to carry out the study under section 602(d) of the Restoring Hope for Mental Health and Well-Being Act of 2022.

''(5) STANDARD FORMAT.—Not later than June 1, 2023, the Secretary shall specify through rulemaking standards for health insurance issuers and entities required to submit reports under paragraph (4) to submit such reports in a standard format.

''(c) ENFORCEMENT.—

''(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Health and Human Services and the Secretary of the Treasury, shall enforce this section.

''(2) FAILURE TO PROVIDE TIMELY INFORMATION.—A health insurance issuer or an entity providing pharmacy benefit management services that violates subsection (a) or fails to provide information required under subsection (b), or a drug manufacturer that fails to provide information under subsection (b)(1)(A) in a timely manner, shall be subject to a civil monetary penalty in the amount of $10,000 for each day during which such violation

continues or such information is not disclosed or reported.

''(3) FALSE INFORMATION.—A health insurance issuer, entity providing pharmacy benefit management services, or drug manufacturer that knowingly provides false information under this section shall be subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalty shall be in addition to other penalties as may be prescribed by law.

''(4) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsection (a) and (b) and the first sentence of subsection (c)(1) of such section shall apply to civil monetary penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.

''(5) WAIVERS.—The Secretary may waive penalties under paragraph (2), or extend the period of time for compliance with a requirement of this section, for an entity in violation of this section that has made a good-faith effort to comply with this section.

''(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a health insurance issuer, group health plan, or other entity to restrict disclosure to, or otherwise limit the access of, the Department of Labor to a report described in subsection (b)(1) or information related to compliance with subsection (a) by such issuer, plan, or entity.

''(e) DEFINITION.—In this section, the term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act.''; and

(B) in section 502(b)(3) (29 U.S.C. 1132(b)(3)), by inserting ''(other than section 726)'' after ''part 7''.

(2) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001 et seq.) is amended by inserting after the item relating to section 725 the following new item:

''Sec. 726. Oversight of pharmacy benefit manager services.''.

(c) IRC.—

(1) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following:

**"SEC. 9826. OVERSIGHT OF PHARMACY BENEFIT MANAGER SERVICES.**

"(a) IN GENERAL.—For plan years beginning on or after January 1, 2024, a group health plan or an entity or subsidiary providing pharmacy benefits management services on behalf of such a plan shall not enter into a contract with a drug manufacturer, distributor, wholesaler, subcontractor, rebate aggregator, or any associated third party that limits the disclosure of information to plan sponsors in such a manner that prevents the plan, or an entity or subsidiary providing pharmacy benefits management services on behalf of a plan, from making the reports described in subsection (b).

"(b) REPORTS.—

"(1) IN GENERAL.—For plan years beginning on or after January 1, 2024, not less frequently than once every 6 months, an entity providing pharmacy benefits management services on behalf of a group health plan shall submit to the plan sponsor (as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974) of such group health plan a report in accordance with this subsection and make such report available to the plan sponsor in a machine-readable format. Each such report shall include, with respect to the applicable group health plan—

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

''(B) a list of each drug covered by such plan or entity providing pharmacy benefit management services that was dispensed during the reporting period, including, with respect to each such drug during the reporting period—

''(i) the brand name, chemical entity, and National Drug Code;

''(ii) the number of participants and beneficiaries for whom the drug was filled during the plan year, the total number of prescription fills for the drug (including original prescriptions and refills), and the total number of dosage units of the drug dispensed across the plan year, including whether the dispensing channel was by retail, mail order, or specialty pharmacy;

''(iii) the wholesale acquisition cost, listed as cost per days supply and cost per

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

''(iv) the total out-of-pocket spending by participants and beneficiaries on such drug, including participant and beneficiary spending through copayments, coinsurance, and deductibles; and

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

''(I) a list of all other drugs in the same therapeutic category or class, including brand name drugs and biological products and generic drugs or biosimilar biological products that are in the same therapeutic category or class as such drug; and

''(II) the rationale for preferred formulary placement of such drug in that therapeutic category or class, if applicable;

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

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

''(i) total gross spending by the plan, before manufacturer rebates, fees, or other manufacturer remuneration;

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

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

''(iv) the total out-of-pocket spending by participants and beneficiaries, including participant and beneficiary spending through copayments, coinsurance, and deductibles; and

''(v) for each therapeutic category or class under which 3 or more drugs are included on the formulary of such plan—

''(I) the amount received, or expected to be received, from drug manufacturers in rebates, fees, alternative discounts, or other remuneration—

''(aa) that has been paid, or is to be paid, by drug manufacturers for claims incurred during the reporting period; or

''(bb) that is related to utilization of drugs, in such therapeutic category or class;

''(II) the total net spending, after deducting rebates, price concessions, alternative discounts or other remuneration from drug manufacturers, by the health plan on that category or class of drugs; and

''(III) the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply, incurred by the health plan and its participants and beneficiaries, after manufacturer rebates, fees, and other remuneration for drugs dispensed within such therapeutic category or class during the reporting period;

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

before rebates and other manufacturer fees or remuneration;

''(E) total amount received, or expected to be received, by the health plan in drug manufacturer rebates, fees, alternative discounts, and all other remuneration received from the manufacturer or any third party, other than the plan sponsor, related to utilization of drug or drug spending under that health plan during the reporting period;

''(F) the total net spending on prescription drugs by the health plan during the reporting period; and

''(G) amounts paid directly or indirectly in rebates, fees, or any other type of remuneration to brokers, consultants, advisors, or any other individual or firm who referred the group health plan's business to the pharmacy benefit manager.

''(2) PRIVACY REQUIREMENTS.—Entities providing pharmacy benefits management services on behalf of a group health plan shall provide information under paragraph (1) in a manner consistent with the privacy, security, and breach notification regulations promulgated under section 264(c) of the

Health Insurance Portability and Accountability Act of 1996, and shall restrict the use and disclosure of such information according to such privacy regulations.

''(3) DISCLOSURE AND REDISCLOSURE.—

''(A) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such information only to business associates of such plan as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations).

''(B) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section prevents an entity providing pharmacy benefits management services on behalf of a group health plan from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1), except that such entity may not restrict disclosure of such report to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, or applicable State agencies.

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

limited form of the report under paragraph (1) required of plan sponsors who are drug manufacturers, drug wholesalers, or other direct participants in the drug supply chain, in order to prevent anti-competitive behavior.

''(4) REPORT TO GAO.—An entity providing pharmacy benefits management services on behalf of a group health plan shall submit to the Comptroller General of the United States each of the first 4 reports submitted to a plan sponsor under paragraph (1) with respect to such plan, and other such reports as requested, in accordance with the privacy requirements under paragraph (2), the disclosure and redisclosure standards under paragraph (3), the standards specified pursuant to paragraph (5), and such other information that the Comptroller General determines necessary to carry out the study under section 602(d) of the Restoring Hope for Mental Health and Well-Being Act of 2022.

''(5) STANDARD FORMAT.—Not later than June 1, 2023, the Secretary shall specify through rulemaking standards for entities required to submit reports under paragraph (4) to submit such reports in a standard format.

''(c) ENFORCEMENT.—

''(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Labor and the Secretary of Health and Human Services, shall enforce this section.

''(2) FAILURE TO PROVIDE TIMELY INFORMATION.—An entity providing pharmacy benefit management services that violates subsection (a) or fails to provide information required under subsection (b), or a drug manufacturer that fails to provide information under subsection (b)(1)(A) in a timely manner, shall be subject to a civil monetary penalty in the amount of $10,000 for each day during which such violation continues or such information is not disclosed or reported.

''(3) FALSE INFORMATION.—An entity providing pharmacy benefit management services, or drug manufacturer that knowingly provides false information under this section shall be subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalty shall be in addition to other penalties as may be prescribed by law.

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

section (c)(1) of such section shall apply to civil monetary penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.

''(5) WAIVERS.—The Secretary may waive penalties under paragraph (2), or extend the period of time for compliance with a requirement of this section, for an entity in violation of this section that has made a good-faith effort to comply with this section.

''(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a group health plan or other entity to restrict disclosure to, or otherwise limit the access of, the Department of the Treasury to a report described in subsection (b)(1) or information related to compliance with subsection (a) by such plan or entity.

''(e) DEFINITION.—In this section, the term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act.''.

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

''Sec. 9826. Oversight of pharmacy benefit manager services.''.

(d) GAO STUDY.—

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

(A) pharmacy networks of group health plans, health insurance issuers, and entities providing pharmacy benefit management services under such group health plan or group or individual health insurance coverage, including networks that have pharmacies that are under common ownership (in whole or part) with group health plans, health insurance issuers, or entities providing pharmacy benefit management services or pharmacy benefit administrative services under group health plan or group or individual health insurance coverage;

(B) as it relates to pharmacy networks that include pharmacies under common ownership described in subparagraph (A)—

(i) whether such networks are designed to encourage enrollees of a plan or coverage to use such pharmacies over other network pharmacies for specific services or drugs, and if so, the reasons the networks

give for encouraging use of such pharmacies; and

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

(C) whether group health plans and health insurance issuers offering group or individual health insurance coverage have options to elect different network pricing arrangements in the marketplace with entities that provide pharmacy benefit management services, the prevalence of electing such different network pricing arrangements;

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

(E) the degree to which mail order, specialty, or retail pharmacies that dispense prescription drugs to an enrollee in a group health plan or health insurance coverage that are under common ownership (in whole or part) with group health plans, health insurance

issuers, or entities providing pharmacy benefit management services or pharmacy benefit administrative services under group health plan or group or individual health insurance coverage receive reimbursement that is greater than the median price charged to the group health plan or health insurance issuer when the same drug is dispensed to enrollees in the plan or coverage by other pharmacies included in the pharmacy network of that plan, issuer, or entity that are not wholly or partially owned by the health insurance issuer or entity providing pharmacy benefit management services.

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

(3) DEFINITIONS.—In this subsection, the terms ''group health plan'', ''health insurance coverage'', and ''health insurance issuer'' have the meanings given such terms in section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91).

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

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

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

In carrying out any program of the Substance Abuse and Mental Health Services Administration whose statutory authorization is enacted or amended by this Act, the Secretary of Health and Human Services shall not allocate funding, or require award recipients to prioritize, dedicate, or allocate funding, without consideration of the incidence, prevalence, or determinants of mental health or substance use issues, unless such allocation or requirement is consistent with statute, regulation, or other Federal law.