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.

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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. 290ll(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-
ti	itle:
14	Subtitle D—Media and Mental
15	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.
14	SEC. 432. RESEARCH ON THE HEALTH AND DEVELOPMENT
15	EFFECTS OF MEDIA ON INFANTS, CHILDREN,
16	AND ADOLESCENTS.
17	Subpart 7 of part C of title IV of the Public Health
18	Service Act (42 U.S.C. 285g et seq.) is amended by adding
19	at the end the following:
20	"SEC. 452H. RESEARCH ON THE HEALTH AND DEVELOP-
21	MENT EFFECTS OF MEDIA ON INFANTS, CHIL-
22	DREN, AND ADOLESCENTS.
23	"(a) In General.—The Director of the National In-
24	stitutes of Health, in coordination with or acting through
25	the Director of the Institute, shall conduct and support

1	research and related activities concerning the health and
2	developmental effects of media on infants, children, and
3	adolescents, which may include the positive and negative
4	effects of exposure to and use of media, such as social
5	media, applications, websites, television, motion pictures
6	artificial intelligence, mobile devices, computers, video
7	games, virtual and augmented reality, and other media
8	formats as they become available. Such research shall at
9	tempt to better understand the relationships between
10	media and technology use and individual differences and
11	characteristics of children and shall include longitudinally
12	designed studies to assess the impact of media on youth
13	over time. Such research shall include consideration of
14	core areas of child and adolescent health and development
15	including the following:
16	"(1) Cognitive.—The role and impact of
17	media use and exposure in the development of chil-
18	dren and adolescents within such cognitive areas as
19	language development, executive functioning, atten-
20	tion, creative problem solving skills, visual and spa-
21	tial skills, literacy, critical thinking, and other learn-
22	ing abilities, and the impact of early technology use
23	on developmental trajectories.
24	"(2) Physical.—The role and impact of media
25	use and exposure on children's and adolescent's

1 physical development and health behaviors, including 2 diet, exercise, sleeping and eating routines, and 3 other areas of physical development. 4 "(3) Socio-emotional.—The role and impact 5 of media use and exposure on children's and adoles-6 cents' social-emotional competencies, including self-7 awareness, self-regulation, social awareness, relation-8 ship skills, empathy, distress tolerance, perception of 9 social cues, awareness of one's relationship with the 10 media, and decision-making, as well as outcomes 11 such as violations of privacy, perpetration of or ex-12 posure to violence, bullying or other forms of aggression, depression, anxiety, substance use, misuse or 13 14 disorder, and suicidal ideation/behavior and self-15 harm. 16 "(b) DEVELOPING RESEARCH AGENDA.—The Director of the National Institutes of Health, in consultation with the Director of the Institute, other appropriate na-18 tional research institutes, academies, and centers, the 19 20 Trans-NIH Pediatric Research Consortium, and non-Fed-21 eral experts as needed, shall develop a research agenda 22 on the health and developmental effects of media on in-23 fants, children, and adolescents to inform research activities under subsection (a). In developing such research 25 agenda, the Director may use whatever means necessary

- 1 (such as scientific workshops and literature reviews) to as-
- 2 sess current knowledge and research gaps in this area.
- 3 "(c) Research Program.—In coordination with the
- 4 Institute and other national research institutes and cen-
- 5 ters, and utilizing the National Institutes of Health's proc-
- 6 ess of scientific peer review, the Director of the National
- 7 Institutes of Health shall fund an expanded research pro-
- 8 gram on the health and developmental effects of media
- 9 on infants, children, and adolescents.
- 10 "(d) Report to Congress.—Not later than 1 year
- 11 after the date of enactment of this Act, the Director of
- 12 the National Institutes of Health shall submit a report to
- 13 Congress on the progress made in gathering data and ex-
- 14 panding research on the health and developmental effects
- 15 of media on infants, children, and adolescents in accord-
- 16 ance with this section. Such report shall summarize the
- 17 grants and research funded, by year, under this section.".

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

1 TITLE V—MEDICAID AND CHIP

2	SEC. 501. MEDICAID AND CHIP REQUIREMENTS FOR
3	HEALTH SCREENINGS AND REFERRALS FOR
4	ELIGIBLE JUVENILES IN PUBLIC INSTITU-
5	TIONS.
6	(a) Medicaid State Plan Requirement.—Section
7	1902 of the Social Security Act (42 U.S.C. 1396a) is
8	amended—
9	(1) in subsection (a)(84)—
10	(A) in subparagraph (A), by inserting ",
11	subject to subparagraph (D)," after "but";
12	(B) in subparagraph (B), by striking
13	"and" at the end;
14	(C) in subparagraph (C), by adding "and"
15	at the end; and
16	(D) by adding at the end the following new
17	subparagraph:
18	"(D) beginning on the first day of the first
19	calendar quarter that begins two years after the
20	date of enactment of this subparagraph, in the
21	case of individuals who are eligible juveniles de-
22	scribed in subsection $(nn)(2)$, are within 30
23	days of the date on which such eligible juvenile
24	is scheduled to be released from a public insti-
25	tution following adjudication, the State shall

1	have in place a plan to ensure, and in accord-
2	ance with such plan, provide—
3	"(i) for, in the 30 days prior to the
4	release of such an eligible juvenile from
5	such public institution (or not later than
6	one week after release from the public in-
7	stitution), and in coordination with such
8	institution—
9	"(I) any screening or diagnostic
10	service which meets reasonable stand-
11	ards of medical and dental practice,
12	as determined by the State, or as in-
13	dicated as medically necessary, in ac-
14	cordance with paragraphs (1)(A) and
15	(5) of section $1905(r)$; and
16	"(II) a mental health or other be-
17	havioral health screening that is a
18	screening service described under sec-
19	tion 1905(r)(1), or a diagnostic serv-
20	ice described under paragraph (5) of
21	such section, if such screening or di-
22	agnostic service was not otherwise
23	conducted pursuant to this clause;
24	"(ii) for, not later than one week after
25	release from the public institution, refer-

1	rals for such eligible juvenile to the appro-
2	priate care and services available under the
3	State plan (or waiver of such plan) in the
4	geographic region of the home or residence
5	of such eligible juvenile, based on such
6	screenings; and
7	"(iii) for, following the release of such
8	eligible juvenile from such institution, not
9	less than 30 days of targeted case manage-
10	ment services furnished by a provider in
11	the geographic region of the home or resi-
12	dence of such eligible juvenile."; and
13	(2) in subsection $(nn)(3)$, by striking " (30) "
14	and inserting "(31)".
15	(b) Authorization of Federal Financial Par-
16	TICIPATION.—The subdivision (A) of section 1905(a) of
17	the Social Security Act (42 U.S.C. 1396d(a)) following
18	paragraph (31) of such section is amended by inserting
19	", or in the case of an eligible juvenile described in section
20	1902(a)(84)(D) with respect to the screenings, diagnostic
21	services, referrals, and case management required under
22	such subparagraph (D)" after "(except as a patient in a
23	medical institution".
24	(c) CHIP Conforming Amendments.—

1	(1) Section 2103(c) of the Social Security Act
2	(42 U.S.C. 1397cc(e)) is amended by adding at the
3	end the following new paragraph:
4	"(12) Required coverage of screenings,
5	DIAGNOSTIC SERVICES, REFERRALS, AND CASE MAN-
6	AGEMENT FOR CERTAIN INMATES PRE-RELEASE.—
7	With respect to individuals described in section
8	2110(b)(7), the State shall provide screenings, diag-
9	nostic services, referrals, and case management oth-
10	erwise covered under the State child health plan (or
11	waiver of such plan) during the period described in
12	such section with respect to such screenings, serv-
13	ices, referrals, and case management.".
14	(2) Section 2110(b) of the Social Security Act
15	(42 U.S.C. 1397jj(b)) is amended—
16	(A) in paragraph (2)(A), by inserting "ex-
17	cept as provided in paragraph (7)," before "a
18	child who is an inmate of a public institution";
19	and
20	(B) 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) during the
5	period with respect to which such screenings, serv-
6	ices, referrals, and case management is respectively
7	required under such section.".
8	SEC. 502. GUIDANCE ON REDUCING ADMINISTRATIVE BAR-
9	RIERS TO PROVIDING HEALTH CARE SERV-
10	ICES IN SCHOOLS.
11	(a) In General.—Not later than 12 months after
12	the date of enactment of this Act, the Secretary of Health
13	and Human Services shall issue guidance to State Med-
14	icaid agencies, elementary and secondary schools, and
15	school-based health centers on reducing administrative
16	barriers to such schools and centers furnishing medical as-
17	sistance and obtaining payment for such assistance under
18	titles XIX and XXI of the Social Security Act (42 U.S.C.
19	1396 et seq., 1397aa et seq.).
20	(b) Contents of Guidance.—The guidance issued
21	pursuant to subsection (a) shall—
22	(1) include revisions to the May 2003 Medicaid
23	School-Based Administrative Claiming Guide, the
24	1997 Medicaid and Schools Technical Assistance

1	Guide, and other relevant guidance in effect on the
2	date of enactment of this Act;
3	(2) provide information on payment under titles
4	XIX and XXI of the Social Security Act (42 U.S.C.
5	1396 et seq., 1397aa et seq.) for the provision of
6	medical assistance, including such assistance pro-
7	vided in accordance with an individualized education
8	program or under the policy described in the State
9	Medicaid Director letter on payment for services
10	issued on December 15, 2014 (#14-006);
11	(3) take into account reasons why small and
12	rural local education agencies may not provide med-
13	ical assistance and provide information on best prac-
14	tices to encourage such agencies to provide such as-
15	sistance; and
16	(4) include best practices and examples of
17	methods that State Medicaid agencies and local edu-
18	cation agencies have used to pay for, and increase
19	the availability of, medical assistance.
20	(c) Definitions.—In this Act:
21	(1) Individualized education program.—
22	The term "individualized education program" has
23	the meaning given such term in section 602(14) of
24	the Individuals with Disabilities Education Act (20
25	U.S.C. 1401(14)).

1	(2) School-based health center.—The
2	term "school-based health center" has the meaning
3	given such term in section 2110(c)(9) of the Social
4	Security Act (42 U.S.C. 1397jj(c)(9)), and includes
5	an entity that provides Medicaid-covered services in
6	school-based settings for which Federal financial
7	participation is permitted.
8	SEC. 503. GUIDANCE TO STATES ON SUPPORTING PEDI-
9	ATRIC BEHAVIORAL HEALTH SERVICES
10	UNDER MEDICAID AND CHIP.
11	Not later than 18 months after the date of enactment
12	of this Act, the Secretary of Health and Human Services
13	shall issue guidance to States on how to expand the provi-
14	sion of, and access to, behavioral health services, including
15	mental health services, for children covered under State
16	plans (or waivers of such plans) under title XIX of the
17	Social Security Act (42 U.S.C. 1396 et seq.), or State
18	child health plans (or waivers of such plans) under title
19	XXI of such Act (42 U.S.C. 1397aa et seq.), including
20	a description of best practices for—
21	(1) expanding access to such services;
22	(2) expanding access to such services in under-
23	served communities;

1	(3) flexibilities that States may offer for pedi-
2	atric hospitals and other pediatric behavioral health
3	providers to expand access to services; and
4	(4) recruitment and retention of providers of
5	such services.
6	SEC. 504. ENSURING CHILDREN RECEIVE TIMELY ACCESS
7	TO CARE.
8	(a) Guidance to States on Flexibilities to En-
9	SURE PROVIDER CAPACITY TO PROVIDE PEDIATRIC BE-
10	HAVIORAL HEALTH, INCLUDING MENTAL HEALTH, CRI-
11	SIS CARE.—Not later than 18 months after the date of
12	enactment of this Act, the Secretary of Health and
13	Human Services shall provide guidance to States on exist-
14	ing flexibilities under State plans (or waivers of such
15	plans) under title XIX of the Social Security Act (42)
16	U.S.C. 1396 et seq.), or State child health plans under
17	title XXI of such Act (42 U.S.C. 1397aa et seq.), to sup-
18	port children experiencing a behavioral health crisis or in
19	need of intensive behavioral health, including mental
20	health, services.
21	(b) Ensuring Consistent Review and State Im-
22	PLEMENTATION OF EARLY AND PERIODIC SCREENING,
23	DIAGNOSTIC, AND TREATMENT SERVICES.—Section
24	1905(r) of the Social Security Act (42 U.S.C. 1396d(r))
25	is amended by adding at the end the following: "Not later

- 1 than January 1, 2025, and every 5 years thereafter, the
- 2 Secretary shall review implementation of the requirements
- 3 of this subsection by States, including such requirements
- 4 relating to services provided by managed care organiza-
- 5 tions, prepaid inpatient health plans, prepaid ambulatory
- 6 health plans, and primary care case managers, to identify
- 7 and disseminate best practices for ensuring comprehensive
- 8 coverage of services, to identify gaps and deficiencies in
- 9 meeting Federal requirements, and to provide guidance to
- 10 States on addressing identified gaps and disparities and
- 11 meeting Federal coverage requirements in order to ensure
- 12 children have access to health services.".
- 13 SEC. 505. STRATEGIES TO INCREASE ACCESS TO TELE-
- 14 HEALTH UNDER MEDICAID AND CHIP.
- Not later than 1 year after the date of the enactment
- 16 of this Act, and in the event updates are available, once
- 17 every five years thereafter, the Secretary of Health and
- 18 Human Services shall update guidance issued by the Cen-
- 19 ters for Medicare & Medicaid Services to States, the State
- 20 Medicaid & CHIP Telehealth Toolkit, or any successor
- 21 guidance, to describe strategies States may use to over-
- 22 come existing barriers and increase access to telehealth
- 23 services under the Medicaid program under title XIX of
- 24 the Social Security Act (42 U.S.C. 1396 et seq.) and the
- 25 Children's Health Insurance Program under title XXI of

1	such Act (42 U.S.C. 1397aa et seq.). Such updated guid-
2	ance shall include examples of and promising practices re-
3	garding—
4	(1) telehealth delivery of covered services;
5	(2) recommended voluntary billing codes, modi-
6	fiers, and place-of-service designations for telehealth
7	and other virtual health care services;
8	(3) strategies States can use for the simplifica-
9	tion or alignment of provider credentialing and en-
10	rollment protocols with respect to telehealth across
11	States, State Medicaid plans under title XIX, State
12	child health plans under title XXI, Medicaid man-
13	aged care organizations, prepaid inpatient health
14	plans, prepaid ambulatory health plans, and primary
15	care case managers, including during national public
16	health emergencies; and
17	(4) strategies States can use to integrate tele-
18	health and other virtual health care services into
19	value-based health care models.
20	SEC. 506. REMOVAL OF LIMITATIONS ON FEDERAL FINAN-
21	CIAL PARTICIPATION FOR INMATES WHO ARE
22	ELIGIBLE JUVENILES PENDING DISPOSITION
23	OF CHARGES.
24	(a) Medicaid.—

1 (1) In General.—The subdivision (A) of sec-2 tion 1905(a) of the Social Security Act (42 U.S.C. 3 1396d(a)) following paragraph (31) of such section, 4 as amended by section 501(b), is further amended 5 by inserting ", or, at the option of the State, for an 6 individual who is an eligible juvenile (as defined in 7 section 1902(nn)(2)), while such individual is an in-8 mate of a public institution (as defined in section 9 1902(nn)(3)) pending disposition of charges" after 10 "or in the case of an eligible juvenile described in 11 section 1902(a)(84)(D) with respect to the 12 screenings, diagnostic services, referrals, and case management required under such subparagraph 13 14 (D)". 15 (2) Conforming.—Section 1902(a)(84)(A) of 16 the Social Security Act (42 U.S.C. 1396a(a)(84)(A)) 17 is amended by inserting "(or in the case of a State 18 electing the option described in the subdivision (A) 19 following paragraph (31) of section 1905(a), during 20 such period beginning after the disposition of 21 charges with respect to such individual)" after "is 22 such an inmate". 23 (b) CHIP.—Section 2110(b)(7) of the Social Security Act (42 U.S.C. 13977 ij(b)(7)), as added by section 501(c)(2)(B), is further amended by inserting "or, at the 25

- 1 option of the State, for an individual who is a juvenile,
- 2 while such individual is an inmate of a public institution
- 3 pending disposition of charges" after "if such child is an
- 4 eligible juvenile (as described in section 1902(a)(84)(D))
- 5 with respect to screenings, diagnostic services, referrals,
- 6 and case management otherwise covered under the State
- 7 child health plan (or waiver of such plan)".
- 8 (c) Effective Date.—The amendments made by
- 9 this section shall take effect on the first day of the first
- 10 calendar quarter that begins after the date that is 18
- 11 months after the date of enactment of this Act and shall
- 12 apply to items and services furnished for periods beginning
- 13 on or after such date.

14 TITLE VI—MISCELLANEOUS

15 **PROVISIONS**

- 16 SEC. 601. DETERMINATION OF BUDGETARY EFFECTS.
- 17 The budgetary effects of this Act, for the purpose of
- 18 complying with the Statutory Pay-As-You-Go Act of 2010,
- 19 shall be determined by reference to the latest statement
- 20 titled "Budgetary Effects of PAYGO Legislation" for this
- 21 Act, submitted for printing in the Congressional Record
- 22 by the Chairman of the House Budget Committee, pro-
- 23 vided that such statement has been submitted prior to the
- 24 vote on passage.

1	SEC. 602. OVERSIGHT OF PHARMACY BENEFIT MANAGER
2	SERVICES.
3	(a) PHSA.—Title XXVII of the Public Health Serv-
4	ice Act (42 U.S.C. 300gg et seq.) is amended—
5	(1) in part D (42 U.S.C. 300gg-111 et seq.),
6	by adding at the end the following new section:
7	"SEC. 2799A-11. OVERSIGHT OF PHARMACY BENEFIT MAN-
8	AGER SERVICES.
9	"(a) In General.—For plan years beginning on or
10	after January 1, 2024, a group health plan or health in-
11	surance issuer offering group health insurance coverage
12	or an entity or subsidiary providing pharmacy benefits
13	management services on behalf of such a plan or issuer
14	shall not enter into a contract with a drug manufacturer,
15	distributor, wholesaler, subcontractor, rebate aggregator,
16	or any associated third party that limits the disclosure of
17	information to plan sponsors in such a manner that pre-
18	vents the plan or issuer, or an entity or subsidiary pro-
19	viding pharmacy benefits management services on behalf
20	of a plan or issuer, from making the reports described in
21	subsection (b).
22	"(b) Reports.—
23	"(1) In general.—For plan years beginning
24	on or after January 1, 2024, not less frequently
25	than once every 6 months, a health insurance issuer
26	offering group health insurance coverage or an enti-

1 ty providing pharmacy benefits management services 2 on behalf of a group health plan or an issuer pro-3 viding group health insurance coverage shall submit 4 to the plan sponsor (as defined in section 3(16)(B) 5 of the Employee Retirement Income Security Act of 6 1974) of such group health plan or health insurance 7 coverage a report in accordance with this subsection 8 and make such report available to the plan sponsor 9 in a machine-readable format. Each such report 10 shall include, with respect to the applicable group 11 health plan or health insurance coverage— 12 "(A) as applicable, information collected 13 from drug manufacturers by such issuer or en-14 tity on the total amount of copayment assist-15 ance dollars paid, or copayment cards applied, that were funded by the drug manufacturer 16 17 with respect to the participants and bene-18 ficiaries in such plan or coverage; 19 "(B) a list of each drug covered by such 20 plan, issuer, or entity providing pharmacy ben-21 efit management services that was dispensed 22 during the reporting period, including, with re-23 spect to each such drug during the reporting 24 period—

1	"(i) the brand name, chemical entity,
2	and National Drug Code;
3	"(ii) the number of participants and
4	beneficiaries for whom the drug was filled
5	during the plan year, the total number of
6	prescription fills for the drug (including
7	original prescriptions and refills), and the
8	total number of dosage units of the drug
9	dispensed across the plan year, including
10	whether the dispensing channel was by re-
11	tail, mail order, or specialty pharmacy;
12	"(iii) the wholesale acquisition cost,
13	listed as cost per days supply and cost per
14	pill, or in the case of a drug in another
15	form, per dose;
16	"(iv) the total out-of-pocket spending
17	by participants and beneficiaries on such
18	drug, including participant and beneficiary
19	spending through copayments, coinsurance,
20	and deductibles; and
21	"(v) for any drug for which gross
22	spending of the group health plan or
23	health insurance coverage exceeded
24	\$10,000 during the reporting period—

1	"(I) a list of all other drugs in
2	the same therapeutic category or
3	class, including brand name drugs
4	and biological products and generic
5	drugs or biosimilar biological products
6	that are in the same therapeutic cat-
7	egory or class as such drug; and
8	"(II) the rationale for preferred
9	formulary placement of such drug in
10	that therapeutic category or class, if
11	applicable;
12	"(C) a list of each therapeutic category or
13	class of drugs that were dispensed under the
14	health plan or health insurance coverage during
15	the reporting period, and, with respect to each
16	such therapeutic category or class of drugs,
17	during the reporting period—
18	"(i) total gross spending by the plan,
19	before manufacturer rebates, fees, or other
20	manufacturer remuneration;
21	"(ii) the number of participants and
22	beneficiaries who filled a prescription for a
23	drug in that category or class;
24	"(iii) if applicable to that category or
25	class, a description of the formulary tiers

1	and utilization mechanisms (such as prior
2	authorization or step therapy) employed
3	for drugs in that category or class;
4	"(iv) the total out-of-pocket spending
5	by participants and beneficiaries, including
6	participant and beneficiary spending
7	through copayments, coinsurance, and
8	deductibles; and
9	"(v) for each therapeutic category or
10	class under which 3 or more drugs are in-
11	cluded on the formulary of such plan or
12	coverage—
13	"(I) the amount received, or ex-
14	pected to be received, from drug man-
15	ufacturers in rebates, fees, alternative
16	discounts, or other remuneration—
17	"(aa) that has been paid, or
18	is to be paid, by drug manufac-
19	turers for claims incurred during
20	the reporting period; or
21	"(bb) that is related to utili-
22	zation of drugs, in such thera-
23	peutic category or class;
24	"(II) the total net spending, after
25	deducting rebates, price concessions,

1	alternative discounts or other remu-
2	neration from drug manufacturers, by
3	the health plan or health insurance
4	coverage on that category or class of
5	drugs; and
6	"(III) the net price per course of
7	treatment or single fill, such as a 30-
8	day supply or 90-day supply, incurred
9	by the health plan or health insurance
10	coverage and its participants and
11	beneficiaries, after manufacturer re-
12	bates, fees, and other remuneration
13	for drugs dispensed within such thera-
14	peutic category or class during the re-
15	porting period;
16	"(D) total gross spending on prescription
17	drugs by the plan or coverage during the re-
18	porting period, before rebates and other manu-
19	facturer fees or remuneration;
20	"(E) total amount received, or expected to
21	be received, by the health plan or health insur-
22	ance coverage in drug manufacturer rebates,
23	fees, alternative discounts, and all other remu-
24	neration received from the manufacturer or any
25	third party, other than the plan sponsor, re-

1	lated to utilization of drug or drug spending
2	under that health plan or health insurance cov-
3	erage during the reporting period;
4	"(F) the total net spending on prescription
5	drugs by the health plan or health insurance
6	coverage during the reporting period; and
7	"(G) amounts paid directly or indirectly in
8	rebates, fees, or any other type of remuneration
9	to brokers, consultants, advisors, or any other
10	individual or firm who referred the group health
11	plan's or health insurance issuer's business to
12	the pharmacy benefit manager.
13	"(2) Privacy requirements.—Health insur-
14	ance issuers offering group health insurance cov-
15	erage and entities providing pharmacy benefits man-
16	agement services on behalf of a group health plan
17	shall provide information under paragraph (1) in a
18	manner consistent with the privacy, security, and
19	breach notification regulations promulgated under
20	section 264(c) of the Health Insurance Portability
21	and Accountability Act of 1996, and shall restrict
22	the use and disclosure of such information according
23	to such privacy regulations.
24	"(3) Disclosure and redisclosure.—

1	"(A) Limitation to business associ-
2	ATES.—A group health plan receiving a report
3	under paragraph (1) may disclose such informa-
4	tion only to business associates of such plan as
5	defined in section 160.103 of title 45, Code of
6	Federal Regulations (or successor regulations).
7	"(B) CLARIFICATION REGARDING PUBLIC
8	DISCLOSURE OF INFORMATION.—Nothing in
9	this section prevents a health insurance issuer
10	offering group health insurance coverage or an
11	entity providing pharmacy benefits management
12	services on behalf of a group health plan from
13	placing reasonable restrictions on the public dis-
14	closure of the information contained in a report
15	described in paragraph (1), except that such
16	issuer or entity may not restrict disclosure of
17	such report to the Department of Health and
18	Human Services, the Department of Labor, the
19	Department of the Treasury, or applicable
20	State agencies.
21	"(C) Limited form of report.—The
22	Secretary shall define through rulemaking a
23	limited form of the report under paragraph (1)
24	required of plan sponsors who are drug manu-
25	facturers, drug wholesalers, or other direct par-

1 ticipants in the drug supply chain, in order to 2 prevent anti-competitive behavior. 3 "(4) Report to gao.—A health insurance 4 issuer offering group health insurance coverage or 5 an entity providing pharmacy benefits management 6 services on behalf of a group health plan shall sub-7 mit to the Comptroller General of the United States 8 each of the first 4 reports submitted to a plan spon-9 sor under paragraph (1) with respect to such cov-10 erage or plan, and other such reports as requested, 11 in accordance with the privacy requirements under 12 paragraph (2), the disclosure and redisclosure stand-13 ards under paragraph (3), the standards specified 14 pursuant to paragraph (5), and such other informa-15 tion that the Comptroller General determines nec-16 essary to carry out the study under section 602(d) 17 of the Restoring Hope for Mental Health and Well-18 Being Act of 2022. 19 "(5) STANDARD FORMAT.—Not later than June 20 1, 2023, the Secretary shall specify through rule-21 making standards for health insurance issuers and 22 entities required to submit reports under paragraph (4) to submit such reports in a standard format. 23 "(c) Enforcement.— 24

1 "(1) IN GENERAL.—The Secretary, in consulta-2 tion with the Secretary of Labor and the Secretary 3 of the Treasury, shall enforce this section. 4 "(2) Failure to provide timely informa-5 TION.—A health insurance issuer or an entity pro-6 viding pharmacy benefit management services that 7 violates subsection (a) or fails to provide information 8 required under subsection (b), or a drug manufac-9 turer that fails to provide information under sub-10 section (b)(1)(A) in a timely manner, shall be sub-11 ject to a civil monetary penalty in the amount of 12 \$10,000 for each day during which such violation 13 continues or such information is not disclosed or re-14 ported. 15 "(3) False information.—A health insurance 16 issuer, entity providing pharmacy benefit manage-17 ment services, or drug manufacturer that knowingly 18 provides false information under this section shall be 19 subject to a civil money penalty in an amount not 20 to exceed \$100,000 for each item of false informa-21 tion. Such civil money penalty shall be in addition to 22 other penalties 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 health insurance issuer,
14	group health plan, or other entity to restrict disclosure to,
15	or otherwise limit the access of, the Department of Health
16	and Human Services to a report described in subsection
17	(b)(1) or information related to compliance with sub-
18	section (a) by such issuer, plan, or entity.
19	"(e) Definition.—In this section, the term 'whole-
20	sale acquisition cost' has the meaning given such term in
21	section 1847A(c)(6)(B) of the Social Security Act."; and
22	(2) in section 2723 (42 U.S.C. 300gg-22)—
23	(A) in subsection (a)—

1	(i) in paragraph (1), by inserting
2	"(other than subsections (a) and (b) of
3	section 2799A-11)" after "part D"; and
4	(ii) in paragraph (2), by inserting
5	"(other than subsections (a) and (b) of
6	section 2799A-11)" after "part D"; and
7	(B) in subsection (b)—
8	(i) in paragraph (1), by inserting
9	"(other than subsections (a) and (b) of
10	section 2799A-11)" after "part D";
11	(ii) in paragraph (2)(A), by inserting
12	"(other than subsections (a) and (b) of
13	section 2799A-11)" after "part D"; and
14	(iii) in paragraph (2)(C)(ii), by insert-
15	ing "(other than subsections (a) and (b) of
16	section 2799A-11)" after "part D".
17	(b) ERISA.—
18	(1) In general.—Subtitle B of title I of the
19	Employee Retirement Income Security Act of 1974
20	(29 U.S.C. 1021 et seq.) is amended—
21	(A) in subpart B of part 7 (29 U.S.C.
22	1185 et seq.), by adding at the end the fol-
23	lowing:

1 "SEC. 726. OVERSIGHT OF PHARMACY BENEFIT MANAGER 2 SERVICES. 3 "(a) IN GENERAL.—For plan years beginning on or after January 1, 2024, a group health plan (or health in-4 5 surance issuer offering group health insurance coverage in connection with such a plan) or an entity or subsidiary 6 providing pharmacy benefits management services on behalf of such a plan or issuer shall not enter into a contract 9 with a drug manufacturer, distributor, wholesaler, subcontractor, rebate aggregator, or any associated third party 10 that limits the disclosure of information to plan sponsors 11 in such a manner that prevents the plan or issuer, or an 12 entity or subsidiary providing pharmacy benefits manage-13 ment services on behalf of a plan or issuer, from making the reports described in subsection (b). 15 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 such group health plan or group health insurance

coverage a report in accordance with this subsection

1	and make such report available to the plan sponsor
2	in a machine-readable format. Each such report
3	shall include, with respect to the applicable group
4	health plan or health insurance coverage—
5	"(A) as applicable, information collected
6	from drug manufacturers by such issuer or en-
7	tity on the total amount of copayment assist-
8	ance dollars paid, or copayment cards applied,
9	that were funded by the drug manufacturer
10	with respect to the participants and bene-
11	ficiaries in such plan or coverage;
12	"(B) a list of each drug covered by such
13	plan, issuer, or entity providing pharmacy ben-
14	efit management services that was dispensed
15	during the reporting period, including, with re-
16	spect to each such drug during the reporting
17	period—
18	"(i) the brand name, chemical entity,
19	and National Drug Code;
20	"(ii) the number of participants and
21	beneficiaries for whom the drug was filled
22	during the plan year, the total number of
23	prescription fills for the drug (including
24	original prescriptions and refills), and the
25	total number of dosage units of the drug

1	dispensed across the plan year, including
2	whether the dispensing channel was by re-
3	tail, mail order, or specialty pharmacy;
4	"(iii) the wholesale acquisition cost,
5	listed as cost per days supply and cost per
6	pill, or in the case of a drug in another
7	form, per dose;
8	"(iv) the total out-of-pocket spending
9	by participants and beneficiaries on such
10	drug, including participant and beneficiary
11	spending through copayments, coinsurance,
12	and deductibles; and
13	"(v) for any drug for which gross
14	spending of the group health plan or
15	health insurance coverage exceeded
16	\$10,000 during the reporting period—
17	"(I) a list of all other drugs in
18	the same therapeutic category or
19	class, including brand name drugs
20	and biological products and generic
21	drugs or biosimilar biological products
22	that are in the same therapeutic cat-
23	egory or class as such drug; and
24	"(II) the rationale for preferred
25	formulary placement of such drug in

1	that therapeutic category or class, if
2	applicable;
3	"(C) a list of each therapeutic category or
4	class of drugs that were dispensed under the
5	health plan or health insurance coverage during
6	the reporting period, and, with respect to each
7	such therapeutic category or class of drugs,
8	during the reporting period—
9	"(i) total gross spending by the plan,
10	before manufacturer rebates, fees, or other
11	manufacturer remuneration;
12	"(ii) the number of participants and
13	beneficiaries who filled a prescription for a
14	drug in that category or class;
15	"(iii) if applicable to that category or
16	class, a description of the formulary tiers
17	and utilization mechanisms (such as prior
18	authorization or step therapy) employed
19	for drugs in that category or class;
20	"(iv) the total out-of-pocket spending
21	by participants and beneficiaries, including
22	participant and beneficiary spending
23	through copayments, coinsurance, and
24	deductibles; and

1	"(v) for each therapeutic category or
2	class under which 3 or more drugs are in-
3	cluded on the formulary of such plan or
4	coverage—
5	"(I) the amount received, or ex-
6	pected to be received, from drug man-
7	ufacturers in rebates, fees, alternative
8	discounts, or other remuneration—
9	"(aa) that has been paid, or
10	is to be paid, by drug manufac-
11	turers for claims incurred during
12	the reporting period; or
13	"(bb) that is related to utili-
14	zation of drugs, in such thera-
15	peutic category or class;
16	"(II) the total net spending, after
17	deducting rebates, price concessions,
18	alternative discounts or other remu-
19	neration from drug manufacturers, by
20	the health plan or health insurance
21	coverage on that category or class of
22	drugs; and
23	"(III) the net price per course of
24	treatment or single fill, such as a 30-
25	day supply or 90-day supply, incurred

1	by the health plan or health insurance
2	coverage and its participants and
3	beneficiaries, after manufacturer re-
4	bates, fees, and other remuneration
5	for drugs dispensed within such thera-
6	peutic category or class during the re-
7	porting period;
8	"(D) total gross spending on prescription
9	drugs by the plan or coverage during the re-
10	porting period, before rebates and other manu-
11	facturer fees or remuneration;
12	"(E) total amount received, or expected to
13	be received, by the health plan or health insur-
14	ance coverage in drug manufacturer rebates,
15	fees, alternative discounts, and all other remu-
16	neration received from the manufacturer or any
17	third party, other than the plan sponsor, re-
18	lated to utilization of drug or drug spending
19	under that health plan or health insurance cov-
20	erage during the reporting period;
21	"(F) the total net spending on prescription
22	drugs by the health plan or health insurance
23	coverage during the reporting period; and
24	"(G) amounts paid directly or indirectly in
25	rebates, fees, or any other type of remuneration

1	to brokers, consultants, advisors, or any other
2	individual or firm who referred the group health
3	plan's or health insurance issuer's business to
4	the pharmacy benefit manager.
5	"(2) Privacy requirements.—Health insur-
6	ance issuers offering group health insurance cov-
7	erage and entities providing pharmacy benefits man-
8	agement services on behalf of a group health plan
9	shall provide information under paragraph (1) in a
10	manner consistent with the privacy, security, and
11	breach notification regulations promulgated under
12	section 264(c) of the Health Insurance Portability
13	and Accountability Act of 1996, and shall restrict
14	the use and disclosure of such information according
15	to such privacy regulations.
16	"(3) DISCLOSURE AND REDISCLOSURE.—
17	"(A) Limitation to business associ-
18	ATES.—A group health plan receiving a report
19	under paragraph (1) may disclose such informa-
20	tion only to business associates of such plan as
21	defined in section 160.103 of title 45, Code of
22	Federal Regulations (or successor regulations).
23	"(B) Clarification regarding public
24	DISCLOSURE OF INFORMATION.—Nothing in
25	this section prevents a health insurance issuer

1 offering group health insurance coverage or an 2 entity providing pharmacy benefits management 3 services on behalf of a group health plan from 4 placing reasonable restrictions on the public dis-5 closure of the information contained in a report 6 described in paragraph (1), except that such 7 issuer or entity may not restrict disclosure of 8 such report to the Department of Health and 9 Human Services, the Department of Labor, the 10 Department of the Treasury, or applicable 11 State agencies. 12 "(C) Limited form of report.—The 13 Secretary shall define through rulemaking a 14 limited form of the report under paragraph (1) 15 required of plan sponsors who are drug manu-16 facturers, drug wholesalers, or other direct par-17 ticipants in the drug supply chain, in order to 18 prevent anti-competitive behavior. 19 "(4) Report to gao.—A health insurance 20 issuer offering group health insurance coverage or 21 an entity providing pharmacy benefits management 22 services on behalf of a group health plan shall sub-23 mit to the Comptroller General of the United States 24 each of the first 4 reports submitted to a plan spon-

sor under paragraph (1) with respect to such cov-

1	erage or plan, and other such reports as requested,
2	in accordance with the privacy requirements under
3	paragraph (2), the disclosure and redisclosure stand-
4	ards under paragraph (3), the standards specified
5	pursuant to paragraph (5), and such other informa-
6	tion that the Comptroller General determines nec-
7	essary to carry out the study under section 602(d)
8	of the Restoring Hope for Mental Health and Well-
9	Being Act of 2022.
10	"(5) STANDARD FORMAT.—Not later than June
11	1, 2023, the Secretary shall specify through rule-
12	making standards for health insurance issuers and
13	entities required to submit reports under paragraph
14	(4) to submit such reports in a standard format.
15	"(e) Enforcement.—
16	"(1) In general.—The Secretary, in consulta-
17	tion with the Secretary of Health and Human Serv-
18	ices and the Secretary of the Treasury, shall enforce
19	this section.
20	"(2) Failure to provide timely informa-
21	TION.—A health insurance issuer or an entity pro-
22	viding pharmacy benefit management services that
23	violates subsection (a) or fails to provide information
24	required under subsection (b), or a drug manufac-
25	turer that fails to provide information under sub-

1 section (b)(1)(A) in a timely manner, shall be sub-2 ject to a civil monetary penalty in the amount of 3 \$10,000 for each day during which such violation 4 continues or such information is not disclosed or re-5 ported. 6 "(3) False information.—A health insurance 7 issuer, entity providing pharmacy benefit manage-8 ment services, or drug manufacturer that knowingly 9 provides false information under this section shall be 10 subject to a civil money penalty in an amount not 11 to exceed \$100,000 for each item of false informa-12 tion. Such civil money penalty shall be in addition to other penalties as may be prescribed by law. 13 14 "(4) Procedure.—The provisions of section 15 1128A of the Social Security Act, other than sub-16 section (a) and (b) and the first sentence of sub-17 section (c)(1) of such section shall apply to civil 18 monetary penalties under this subsection in the 19 same manner as such provisions apply to a penalty 20 or proceeding under section 1128A of the Social Se-21 curity Act. 22 "(5) WAIVERS.—The Secretary may waive pen-23 alties under paragraph (2), or extend the period of 24 time for compliance with a requirement of this sec-

tion, for an entity in violation of this section that

1	has made a good-faith effort to comply with this sec-
2	tion.
3	"(d) Rule of Construction.—Nothing in this sec-
4	tion shall be construed to permit a health insurance issuer,
5	group health plan, or other entity to restrict disclosure to,
6	or otherwise limit the access of, the Department of Labor
7	to a report described in subsection $(b)(1)$ or information
8	related to compliance with subsection (a) by such issuer,
9	plan, or entity.
10	"(e) Definition.—In this section, the term 'whole-
11	sale acquisition cost' has the meaning given such term in
12	section 1847A(c)(6)(B) of the Social Security Act."; and
13	(B) in section 502(b)(3) (29 U.S.C.
14	1132(b)(3)), by inserting "(other than section
15	726)" after "part 7".
16	(2) CLERICAL AMENDMENT.—The table of con-
17	tents in section 1 of the Employee Retirement In-
18	come Security Act of 1974 (29 U.S.C. 1001 et seq.)
19	is amended by inserting after the item relating to
20	section 725 the following new item:
	"Sec. 726. Oversight of pharmacy benefit manager services.".
21	(c) IRC.—
22	(1) In General.—Subchapter B of chapter
23	100 of the Internal Revenue Code of 1986 is amend-
24	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 after January 1, 2024, a group health plan or an entity 4 5 or subsidiary providing pharmacy benefits management services on behalf of such a plan shall not enter into a 6 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 plan sponsors in such a manner that prevents the plan, 10 or an entity or subsidiary providing pharmacy benefits 11 management services on behalf of a plan, from making 12 the reports described in subsection (b). 13 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

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—

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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. "(c) Enforcement.— 25

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.".

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 administrative services under group health plan or 3 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 DEFINITIONS.—In this subsection, the (3)22 terms "group health plan", "health insurance cov-23 erage", 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).

24

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 "\$1,029,000,000".

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.

