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118TH CONGRESS
1ST SESSION

H. R. 4392

To increase access to pre-exposure prophylaxis to reduce the transmission of HIV.

IN THE HOUSE OF REPRESENTATIVES

JUNE 27, 2023

Mr. SCHIFF (for himself, Mr. BERA, Mr. BEYER, Mr. BOWMAN, Ms. BUSH, Mr. CARBAJAL, Mr. CARSON, Mr. CASTEN, Ms. CHU, Mr. COHEN, Mr. CONNOLLY, Ms. DAVIDS of Kansas, Ms. DEAN of Pennsylvania, Mr. DOGGETT, Mr. ESPAILLAT, Mr. EVANS, Ms. GARCIA of Texas, Mr. GARCÍA of Illinois, Mr. GOMEZ, Mr. GOTTHEIMER, Mr. GRIJALVA, Mr. HUFFMAN, Ms. JACOBS, Ms. JAYAPAL, Mr. JOHNSON of Georgia, Ms. LEE of California, Mr. LYNCH, Ms. MCCOLLUM, Mr. MCGOVERN, Ms. MOORE of Wisconsin, Mr. MOULTON, Mr. NEGUSE, Ms. NORTON, Mr. PANETTA, Mr. PASCRELL, Ms. PINGREE, Mr. POCAN, Ms. PORTER, Mr. QUIGLEY, Ms. SCANLON, Ms. SEWELL, Mr. STANTON, Ms. STEVENS, Ms. STRICKLAND, Mr. TAKANO, Ms. TITUS, Mr. TORRES of New York, Mrs. TORRES of California, Mr. TRONE, Ms. UNDERWOOD, Ms. VELÁZQUEZ, Ms. WASSERMAN SCHULTZ, Mrs. WATSON COLEMAN, and Ms. WILD) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Oversight and Accountability, Ways and Means, Veterans' Affairs, Armed Services, Natural Resources, Financial Services, and Education and the Workforce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To increase access to pre-exposure prophylaxis to reduce the transmission of HIV.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''PrEP Access and Coverage Act of 2023''.

SEC. 2. FINDINGS; SENSE OF CONGRESS.

(a) FINDINGS.—Congress finds the following:

(1) The Centers for Disease Control and Prevention estimates that approximately 1,200,000 individuals in the United States are living with HIV.

(2) In 2021, there were 36,136 new diagnoses of HIV in the United States.

(3) HIV disproportionately impacts gay and bisexual men, transgender women, and, in particular, people of color. In 2021, approximately 71 percent of new HIV diagnoses were estimated to be among gay and bisexual men, 40 percent of new HIV diagnoses were among Black people, and 29 percent of new HIV diagnoses were among Latinx people. Recent studies suggest that transgender women are up to 49 times more likely to be diagnosed with HIV than the general population. Members of communities at the intersections of these groups are most heavily impacted.

(4) Pre-exposure prophylaxis (referred to in this section as ''PrEP'') is a daily antiretroviral medication that helps prevent individuals from acquiring HIV. Daily PrEP use reduces the risk of getting HIV from sex by more than 99 percent. It reduces the risk of getting HIV from injection drug use by at least 74 percent.

(5) Many individuals at risk of exposure to HIV do not use PrEP. Of the approximately 1,200,000 individuals in the United States who could benefit from PrEP, only 31 percent, or 382,364 individuals, filled prescriptions for the drug in 2022.

(6) PrEP usage is inconsistent across racial and gender lines. In 2022, only 11 percent of Black/African American and 21 percent of Hispanic/Latinx individuals who were eligible for PrEP were prescribed it, compared to 82 percent of eligible White individuals. PrEP usage is low among women, in particular among heterosexual women of color, slightly less than 12 percent of women eligible for PrEP received a prescription in 2022.

(7) PrEP use helps strengthen families by allowing couples with partners of different HIV statuses to prevent the transmission of HIV.

(8) There are currently 2 brand name drugs and 1 generic drug approved by the Food and Drug Administration for the use of PrEP on a daily basis. A long-acting injectable PrEP drug has also been approved by the Food and Drug Administration. Other types of HIV prevention treatments, including other long-acting injectables, long-acting oral pills, implants, and vaginal rings are in the research pipeline. These innovations can increase widespread use of PrEP along with adherence, which can speed the Nation's goal to end HIV and address inequities in health care.

(9) Section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13) requires non-grandfathered private health insurance plans to cover preventive services without cost-sharing, including such services with a rating of ''A'' or ''B'' under recommendations of the United States Preventive Services Task Force. On June 11, 2019, the United States Preventive Services Task Force issued a final recommendation giving an ''A'' grade for PrEP for individuals at high risk of HIV; non-grandfathered private health insurance plans have to cover PrEP for such individuals without cost-sharing effective January 2021. Updated United States Preventive

Service Task Force guidance incorporating the new long-acting injectable PrEP drug is pending.

(10) Joint guidance issued by the Department of Labor, the Department of Health and Human Services, and the Department of the Treasury on July 19, 2021, clarifies that ancillary services necessary to maintain the PrEP regime, including subsequent provider visits, clinical testing, and other services, is required to be covered by health insurers without cost-sharing.

(11) Permanently expanding access to cost-free PrEP and ancillary services for all individuals, including individuals who do not have health insurance, through legislation, is a critical step towards eliminating HIV transmission.

(12) Post-exposure prophylaxis (referred to in this section as ''PEP'') is a daily antiretroviral treatment which, when initiated promptly after a sexual or other exposure to blood or body fluids that are associated with a high risk of HIV transmission, is highly effective at preventing HIV transmission.

(13) The Centers for Disease Control and Prevention recommends PEP for an individual who has experienced a high-risk exposure incident, provided that the individual tests HIV-negative, initiates such

treatment not later than 72 hours after exposure, and continues the treatment for 28 days.

(14) Despite PEP's proven effectiveness in preventing HIV transmission after high-risk sexual exposures, including sexual assault, awareness of PEP is low among individuals who would benefit from the treatment. Studies suggest that awareness of PEP and of the importance of its prompt initiation is particularly low among young gay and bisexual men of color, transgender individuals, and women of all gender identities.

(15) Adequate knowledge of guidelines issued by the Centers for Disease Control and Prevention for assessing indications for PEP and for initiating and sustaining PEP are low among health care providers and staff. Because PEP is an emergency intervention, insufficient knowledge among providers and staff in hospital emergency rooms, urgent care centers, community health centers, and primary care physicians is of particular concern.

(16) Private and public health insurance plans and programs frequently impose requirements for coverage of PEP, including pre-authorization requirements and requirements to obtain the medications through designated specialty pharmacies and

mail-order programs that pose significant obstacles to timely initiation of treatment.

(17) Insurance deductibles and co-payments for PEP medications create significant barriers to PEP utilization by many individuals who have experienced high-risk incidents.

(18) The Federal Government has a compelling interest in preventing new cases of HIV. Lowering the prevalence of HIV protects public health and saves on the cost of HIV treatment.

(b) SENSE OF CONGRESS.—It is the sense of Congress that the Department of Labor, the Department of Health and Human Services, and the Department of the Treasury should ensure compliance with the requirements described in paragraphs (8) and (9) of subsection (a).

SEC. 3. COVERAGE OF HIV TESTING AND PREVENTION SERVICES.

(a) PRIVATE INSURANCE.—

(1) IN GENERAL.—Section 2713(a) of the Public Health Service Act (42 U.S.C. 300gg–13(a)) is amended—

(A) in paragraph (2), by striking ''; and'' and inserting a semicolon;

(B) in paragraph (3), by striking the period and inserting a semicolon;

(C) in paragraph (4), by striking the period and inserting a semicolon;

(D) in paragraph (5), by striking the period and inserting ''; and''; and

(E) by adding at the end the following:

''(6) any prescription drug approved by the Food and Drug Administration for the prevention of HIV (other than a drug subject to preauthorization requirements consistent with section 2729A), administrative fees for such drugs, laboratory and other diagnostic procedures associated with the use of such drugs, and clinical follow-up and monitoring, including any related services recommended in current United States Public Health Service clinical practice guidelines, without limitation.''.

(2) PROHIBITION ON PREAUTHORIZATION REQUIREMENTS.—Subpart II of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–11 et seq.) is amended by adding at the end the following:

''SEC. 2729A. PROHIBITION ON PREAUTHORIZATION REQUIREMENTS WITH RESPECT TO CERTAIN SERVICES.

''A group health plan or a health insurance issuer offering group or individual health insurance coverage shall

not impose any preauthorization requirements with respect to coverage of the services described in section 2713(a)(6), except that a plan or issuer may impose preauthorization requirements with respect to coverage of a particular drug approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of this Act if such plan or issuer provides coverage without any preauthorization requirements for a drug that is therapeutically equivalent.''.

(b) COVERAGE UNDER FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM.—Section 8904 of title 5, United States Code, is amended by adding at the end the following:

''(c) Any health benefits plan offered under this chapter shall include benefits for, and may not impose any cost-sharing requirements for, any prescription drug approved by the Food and Drug Administration for the prevention of HIV, administrative fees for such drugs, laboratory and other diagnostic procedures associated with the use of such drugs, and clinical follow-up and monitoring, including any related services recommended in current United States Public Health Service clinical practice guidelines, without limitation.''.

(c) MEDICAID.—

(1) IN GENERAL.—Section 1905 of the Social Security Act (42 U.S.C. 1396d) is amended—

(A) in subsection (a)(4)—

(i) by striking ''; and (D)'' and inserting ''; (D)'';

(ii) by striking ''; and (E)'' and inserting ''; (E)'';

(iii) by striking ''; and (F)'' and inserting ''; (F)''; and

(iv) by striking the semicolon at the end and inserting ''; and (G) HIV prevention services;''; and

(B) by adding at the end the following new subsection:

''(jj) HIV PREVENTION SERVICES.—For purposes of subsection (a)(4)(G), the term 'HIV prevention services' means prescription drugs for the prevention of HIV acquisition, administrative fees for such drugs, laboratory and other diagnostic procedures associated with the use of such drugs, and clinical follow-up and monitoring, including any related services recommended in current United States Public Health Service clinical practice guidelines, without limitation.''.

(2) NO COST-SHARING.—Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) is amended—

(A) in section 1916, by inserting ''HIV prevention services described in section 1905(a)(4)(G),'' after ''section 1905(a)(4)(C),'' each place it appears; and

(B) in section 1916A(b)(3)(B), by adding at the end the following new clause:

''(xv) HIV prevention services described in section 1905(a)(4)(G).''.

(3) INCLUSION IN BENCHMARK COVERAGE.—Section 1937(b)(7) of the Social Security Act (42 U.S.C. 1396u–7(b)(7)) is amended—

(A) in the paragraph header, by inserting ''AND HIV PREVENTION SERVICES'' after ''SUPPLIES''; and

(B) by striking ''includes for any individual described in section 1905(a)(4)(C), medical assistance for family planning services and supplies in accordance with such section'' and inserting ''includes medical assistance for HIV prevention services described in section 1905(a)(4)(G), and includes, for any individual described in section 1905(a)(4)(C), medical as-

sistance for family planning services and supplies in accordance with such section''.

(d) CHIP.—

(1) IN GENERAL.—Section 2103 of the Social Security Act (42 U.S.C. 1397cc), as amended by section 11405(b)(1) of Public Law 117–169, is amended—

(A) in subsection (a), by striking ''and (8)'' and inserting ''(8), (10), (11), and (13)''; and

(B) in subsection (c), by adding at the end the following new paragraph:

''(13) HIV PREVENTION SERVICES.—Regardless of the type of coverage elected by a State under subsection (a), the child health assistance provided for a targeted low-income child, and, in the case of a State that elects to provide pregnancy-related assistance pursuant to section 2112, the pregnancy-related assistance provided for a targeted low-income pregnant woman (as such terms are defined for purposes of such section), shall include coverage of HIV prevention services (as defined in section 1905(jj)).''.

(2) NO COST-SHARING.—Section 2103(e)(2) of the Social Security Act (42 U.S.C. 1397cc(e)(2)) is amended by inserting ''HIV prevention services de-

scribed in subsection (c)(13),'' before ''or for pregnancy-related assistance''.

(3) EFFECTIVE DATE.—

(A) IN GENERAL.—Subject to subparagraph (B), the amendments made by subsection (c) and this subsection shall take effect on January 1, 2025.

(B) DELAY PERMITTED IF STATE LEGISLATION REQUIRED.—In the case of a State plan approved under title XIX or XXI of the Social Security Act which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirements imposed by this section, the State plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of the failure of the plan to meet such additional requirements before the 1st day of the 1st calendar quarter beginning after the close of the 1st regular session of the State legislature that ends after the 1-year period beginning with the date of the enactment of this section. For purposes of the preceding sentence, in the case of a State that has a 2-year legislative

session, each year of the session is deemed to be a separate regular session of the State legislature.

(e) COVERAGE AND ELIMINATION OF COST-SHARING UNDER MEDICARE.—

(1) COVERAGE OF HIV PREVENTION SERVICES UNDER PART B.—

(A) COVERAGE.—

(i) IN GENERAL.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)) is amended—

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

(II) in subparagraph (JJ), by inserting ''and'' at the end; and

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

''(KK) HIV prevention services (as defined in subsection (nnn));''.

(ii) DEFINITION.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

''(nnn) HIV PREVENTION SERVICES.—The term 'HIV prevention services' means—

''(1) drugs or biologicals approved by the Food and Drug Administration for the prevention of HIV;

''(2) administrative fees for such drugs;

''(3) laboratory and other diagnostic procedures associated with the use of such drugs; and

''(4) clinical follow-up and monitoring, including any related services recommended in current United States Public Health Service clinical practice guidelines, without limitation.''.

(B) ELIMINATION OF COINSURANCE.—Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1)) is amended—

(i) by striking ''and (HH)'' and inserting ''(HH)''; and

(ii) by inserting before the semicolon at the end the following: '', and (II) with respect to HIV prevention services (as defined in section 1861(nnn)), the amount paid shall be 100 percent of (i) except as provided in clause (ii), the lesser of the actual charge for the service or the amount determined under the fee schedule that applies to such services under this part, and (ii) in the case of such services that are covered OPD services (as defined in sub-

section (t)(1)(B)), the amount determined under subsection (t)''.

(C) EXEMPTION FROM PART B DEDUCTIBLE.—The first sentence of section 1833(b) of the Social Security Act (42 U.S.C. 1395l(b)) is amended—

(i) by striking '', and (13)'' and inserting ''(13)''; and

(ii) by striking ''1861(n)..'' and inserting ''1861(n), and (14) such deductible shall not apply with respect to HIV prevention services (as defined in section 1861(nnn)(1)).''.

(D) EFFECTIVE DATE.—The amendments made by this paragraph shall apply to items and services furnished on or after January 1, 2025.

(2) ELIMINATION OF COST-SHARING FOR DRUGS FOR THE PREVENTION OF HIV UNDER PART D.—

(A) IN GENERAL.—Section 1860D–2 of the Social Security Act (42 U.S.C. 1395w–102(b)) is amended—

(i) in subsection (b)—

(I) in paragraph (1)(A), by striking ''and (9)'' and inserting '', (9), and (10)'';

(II) in paragraph (2)—

(aa) in subparagraph (A), by striking ''and (9)'' and inserting '', (9), and (10)'';

(bb) in subparagraph (C)(i), in the matter preceding subclause (I), by striking ''and (9)'' and inserting ''(9), and (10)''; and

(cc) in subparagraph (D)(i), in the matter preceding subclause (I), by striking ''and (9)'' and inserting ''(9), and (10)'';

(III) in paragraph (3)(A), in the matter preceding clause (i), by striking ''and (9)'' and inserting ''(9), and (10)'';

(IV) in paragraph (4)(A)(i), by striking ''and (9)'' and inserting '', (9), and (10)''; and

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

''(10) ELIMINATION OF COST-SHARING FOR DRUGS FOR THE PREVENTION OF HIV.—For plan years beginning on or after January 1, 2025, with respect to a covered part D drug that is for the prevention of HIV—

''(A) the deductible under paragraph (1) shall not apply; and

''(B) there shall be no coinsurance or other cost-sharing under this part with respect to such drug.''; and

(ii) in subsection (c), by adding at the end the following new paragraph:

''(7) TREATMENT OF COST-SHARING FOR DRUGS FOR THE PREVENTION OF HIV.—The coverage is provided in accordance with subsection (b)(10).''.

(B) CONFORMING AMENDMENTS TO COST-SHARING FOR LOW-INCOME INDIVIDUALS.—Section 1860D–14(a) of the Social Security Act (42 U.S.C. 1395w–114(a)) is amended—

(i) in paragraph (1)(D), in each of clauses (ii) and (iii), by striking ''paragraph (6)'' and inserting ''paragraphs (6) and (7)'';

(ii) in paragraph (2)—

(I) in subparagraph (B), by striking ''and (9)'' and inserting '', (9), and (10)'';

(II) in subparagraph (D), by striking ''paragraph (6)'' and inserting ''paragraphs (6) and (7)''; and

(III) in subparagraph (E), by striking ''paragraph (6)'' and inserting ''paragraphs (6) and (7)''; and

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

''(7) NO APPLICATION OF COST-SHARING OR DEDUCTIBLE FOR DRUGS FOR THE PREVENTION OF HIV.—For plan years beginning on or after January 1, 2025, with respect to a covered part D drug that is for the prevention of HIV—

''(A) the deductible under section 1860D–2(b)(1) shall not apply; and

''(B) there shall be no cost-sharing under this section with respect to such drug.''.

(f) COVERAGE OF HIV PREVENTION TREATMENT BY DEPARTMENT OF VETERANS AFFAIRS.—

(1) ELIMINATION OF MEDICATION COPAYMENTS.—Section 1722A(a) of title 38, United

States Code, is amended by adding at the end the following new paragraph:

''(5) Paragraph (1) does not apply to a medication for the prevention of HIV.''.

(2) ELIMINATION OF HOSPITAL CARE AND MEDICAL SERVICES COPAYMENTS.—Section 1710 of such title is amended—

(A) in subsection (f)—

(i) by redesignating paragraph (5) as paragraph (6); and

(ii) by inserting after paragraph (4) the following new paragraph (5):

''(5) A veteran shall not be liable to the United States under this subsection for any amounts for laboratory and other diagnostic procedures associated with the use of any prescription drug approved by the Food and Drug Administration for the prevention of HIV, administrative fees for such drugs, or for laboratory or other diagnostic procedures associated with the use of such drugs, or clinical follow-up and monitoring, including any related services recommended in current United States Public Health Service clinical practice guidelines, without limitation.''; and

(B) in subsection (g)(3), by adding at the end the following new subparagraph:

''(C) Any prescription drug approved by the Food and Drug Administration for the prevention of HIV, administrative fees for such drugs, laboratory and other diagnostic procedures associated with the use of such drugs, and clinical follow-up and monitoring, including any related services recommended in current United States Public Health Service clinical practice guidelines, without limitation.''.

(3) INCLUSION AS PREVENTIVE HEALTH SERVICE.—Section 1701(9) of such title is amended—

(A) in subparagraph (K), by striking ''; and'' and inserting a semicolon;

(B) by redesignating subparagraph (L) as subparagraph (M); and

(C) by inserting after subparagraph (K) the following new subparagraph (L):

''(L) any prescription drug approved by the Food and Drug Administration for the prevention of HIV, administrative fees for such drugs, laboratory and other diagnostic procedures associated with the use of such drugs, and clinical follow-up and monitoring, including any related services recommended in current United States Public Health Service clinical practice guidelines, without limitation; and''.

(g) COVERAGE OF HIV PREVENTION TREATMENT BY DEPARTMENT OF DEFENSE.—

(1) IN GENERAL.—Chapter 55 of title 10, United States Code, is amended by inserting after section 1074o the following new section:

"§ 1074p. Coverage of HIV prevention treatment

''(a) IN GENERAL.—The Secretary of Defense shall ensure coverage under the TRICARE program of HIV prevention treatment described in subsection (b) for any beneficiary under section 1074(a) of this title.

''(b) HIV PREVENTION TREATMENT DESCRIBED.—HIV prevention treatment described in this subsection includes any prescription drug approved by the Food and Drug Administration for the prevention of HIV, administrative fees for such drugs, laboratory and other diagnostic procedures associated with the use of such drugs, and clinical follow-up and monitoring, including any related services recommended in current United States Public Health Service clinical practice guidelines, without limitation.

''(c) NO COST-SHARING.—Notwithstanding section 1075, 1075a, or 1074g(a)(6) of this title or any other provision of law, there is no cost-sharing requirement for HIV prevention treatment covered under this section.''.

(2) CLERICAL AMENDMENT.—The table of sections at the beginning of such chapter is amended

by inserting after the item relating to section 1074o the following new item:

"1074p. Coverage of HIV prevention treatment.".

(h) INDIAN HEALTH SERVICE TESTING, MONITORING, AND PRESCRIPTION DRUGS FOR THE PREVENTION OF HIV.—Title II of the Indian Health Care Improvement Act is amended by inserting after section 223 (25 U.S.C. 1621v) the following:

"SEC. 224. TESTING, MONITORING, AND PRESCRIPTION DRUGS FOR THE PREVENTION OF HIV.

"(a) IN GENERAL.—The Secretary, acting through the Director of HIV/AIDS Prevention and Treatment under section 832, Indian tribes, and tribal organizations, shall provide, without limitation, funding for any prescription drug approved by the Food and Drug Administration for the prevention of human immunodeficiency virus (commonly known as 'HIV'), administrative fees for that drug, laboratory and other diagnostic procedures associated with the use of that drug, and clinical follow-up and monitoring, including any related services recommended in current United States Public Health Service clinical practice guidelines.

"(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this section.".

(i) EFFECTIVE DATE.—The amendments made by subsections (a), (b), (e), (f), (g), and (h) shall take effect with respect to plan years beginning on or after January 1, 2025.

SEC. 4. PROHIBITION ON DENIAL OF COVERAGE OR INCREASE IN PREMIUMS OF LIFE, DISABILITY, OR LONG-TERM CARE INSURANCE FOR INDIVIDUALS TAKING MEDICATION FOR THE PREVENTION OF HIV ACQUISITION.

(a) PROHIBITION.—Notwithstanding any other provision of law, it shall be unlawful to—

(1) decline or limit coverage of an individual under any life insurance policy, disability insurance policy, or long-term care insurance policy, on account of the individual taking medication for the purpose of preventing the acquisition of HIV;

(2) preclude an individual from taking medication for the purpose of preventing the acquisition of HIV as a condition of receiving a life insurance policy, disability insurance policy, or long-term care insurance policy;

(3) consider whether an individual is taking medication for the purpose of preventing the acquisition of HIV in determining the premium rate for coverage of such individual under a life insurance

policy, disability insurance policy, or long-term care insurance policy; or

(4) otherwise discriminate in the offering, issuance, cancellation, amount of such coverage, price, or any other condition of a life insurance policy, disability insurance policy, or long-term care insurance policy for an individual, based solely and without any additional actuarial risks upon whether the individual is taking medication for the purpose of preventing the acquisition of HIV.

(b) ENFORCEMENT.—A State insurance regulator may take such actions to enforce subsection (a) as are specifically authorized under the laws of such State.

(c) DEFINITIONS.—In this section:

(1) DISABILITY INSURANCE POLICY.—The term ''disability insurance policy'' means a contract under which an entity promises to pay a person a sum of money in the event that an illness or injury resulting in a disability prevents such person from working.

(2) LIFE INSURANCE POLICY.—The term ''life insurance policy'' means a contract under which an entity promises to pay a designated beneficiary a sum of money upon the death of the insured.

(3) LONG-TERM CARE INSURANCE POLICY.—The term ''long-term care insurance policy'' means

a contract for which the only insurance protection provided under the contract is coverage of qualified long-term care services (as defined in section 7702B(c) of the Internal Revenue Code of 1986).

SEC. 5. PUBLIC EDUCATION CAMPAIGN.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

"SEC. 399V–8. PRE-EXPOSURE PROPHYLAXIS AND POST-EXPOSURE PROPHYLAXIS EDUCATION CAMPAIGNS.

''(a) PUBLIC EDUCATION CAMPAIGN.—

''(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, in consultation with the Director of the Office of Infectious Disease and HIV/AIDS Policy, shall establish a public health campaign for the purpose of educating the public on medication for the prevention of HIV acquisition.

''(2) REQUIREMENTS.—In carrying out this subsection, the Secretary shall ensure cultural competency and efficacy within high-need communities in which PrEP or PEP are underutilized by developing the campaign in collaboration with organizations that are indigenous to communities that are

overrepresented in the domestic HIV epidemic, including communities of color and the lesbian, gay, bisexual, transgender, and queer community. The Secretary shall ensure that the campaign is designed to increase awareness of the safety and effectiveness of PrEP and PEP, the recommended clinical practices for providing PrEP-related and PEP-related clinical care, and the local availability of PrEP and PEP providers, and to counter stigma associated with the use of PrEP and PEP.

''(3) EVALUATION OF PROGRAM.—The Secretary shall develop measures to evaluate the effectiveness of activities conducted under this subsection that are aimed at reducing disparities in access to PrEP and PEP and supporting the local community. Such measures shall evaluate community outreach activities, language services, workforce cultural competence, and other areas as determined by the Secretary.

''(b) PROVIDER EDUCATION CAMPAIGN.—

''(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, the Administrator of the Health Resources Services Administration, and the Office of Infectious Disease and HIV/AIDS Policy,

shall establish a provider campaign for the purpose of educating prescribers and other associated health professionals on medication for the prevention of HIV acquisition.

''(2) REQUIREMENTS.—In carrying out this subsection, the Secretary shall increase awareness and readiness among health care providers to offer PrEP or PEP, as appropriate, with a focus on areas of high-need communities in which PrEP or PEP is underutilized by developing an educational campaign with input from health care providers and organizations that are indigenous to communities that are overrepresented in the domestic HIV epidemic, including communities of color and the lesbian, gay, bisexual, transgender, and queer community. The Secretary shall ensure that the campaign is designed to increase awareness of the safety and effectiveness of PrEP and PEP, the recommended clinical practices for providing PrEP-related and PEP-related clinical care, cultural competency among PrEP and PEP prescribers, and to counter stigma associated with the use of PrEP and PEP.

''(3) EVALUATION OF PROGRAM.—The Secretary shall develop measures to evaluate the effectiveness of activities conducted under this subsection

that are aimed at increasing the number of health care professionals offering PrEP and PEP and reducing disparities in access to PrEP and PEP. Such measures shall evaluate availability of PrEP and PEP services, education and outreach activities, language services, workforce cultural competence, and other areas as determined by the Secretary.

''(c) DEFINITIONS.—In this section and section 399V–9—

''(1) the term 'PEP' means any drug or combination of drugs approved by the Food and Drug Administration for preventing HIV transmission after a sexual or other exposure associated with a high risk of HIV transmission; and

''(2) the term 'PrEP' means any drug approved by the Food and Drug Administration for the purpose of pre-exposure prophylaxis with respect to HIV.

''(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2024 through 2029.''.

SEC. 6. PATIENT CONFIDENTIALITY.

The Secretary of Health and Human Services shall amend the regulations promulgated under section 264(c)

of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note), as necessary, to ensure that individuals are able to access the benefits described in section 2713(a)(6) under a family plan without any other individual enrolled in such family plan, including a primary subscriber of or policyholder, being informed of such use of such benefits.

SEC. 7. PRE-EXPOSURE PROPHYLAXIS AND POST-EXPOSURE PROPHYLAXIS FUNDING.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.), as amended by section 5, is further amended by adding at the end the following:

"SEC. 399V–9. PRE-EXPOSURE PROPHYLAXIS AND POST-EXPOSURE PROPHYLAXIS FUNDING.

''(a) IN GENERAL.—Not later than 1 year after the date of the enactment of the PrEP Access and Coverage Act, the Secretary shall establish a program that awards grants to States, territories, Indian Tribes, and directly eligible entities for the establishment and support of pre-exposure prophylaxis (referred to in this section as 'PrEP') and post-exposure prophylaxis (referred to in this section as 'PEP') programs.

''(b) APPLICATIONS.—To be eligible to receive a grant under subsection (a), a State, territory, Indian Tribe, or directly eligible entity shall—

''(1) submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require, including a plan describing how any funds awarded will be used to increase access to PrEP for uninsured and underinsured individuals and reduce disparities in access to PrEP and PEP for uninsured and underinsured individuals and reduce disparities in access to PrEP and PEP; and

''(2) appoint a PrEP and PEP grant administrator to manage the program.

''(c) DIRECTLY ELIGIBLE ENTITY.—For purposes of this section, the term 'directly eligible entity'—

''(1) means a Federally qualified health center or other nonprofit entity engaged in providing PrEP and PEP information and services; and

''(2) may include—

''(A) a Federally qualified health center (as defined in section 1861(aa)(4) of the Social Security Act);

''(B) a family planning grantee (other than States) funded under section 1001;

''(C) a rural health clinic (as defined in section 1861(aa)(2) of the Social Security Act);

''(D) a health facility operated by or pursuant to a contract with the Indian Health Service;

''(E) a community-based organization, clinic, hospital, or other health facility that provides services to individuals at risk for or living with HIV; and

''(F) a nonprofit private entity providing comprehensive primary care to populations at risk of HIV, including faith-based and community-based organizations.

''(d) AWARDS.—In determining whether to award a grant, and the grant amount for each grant awarded, the Secretary shall consider the grant application and the need for PrEP and PEP services in the area, the number of uninsured and underinsured individuals in the area, and how the State, territory, or Indian Tribe coordinates PrEP and PEP activities with the directly funded entity, if the State, territory, or Indian Tribe applies for the funds.

''(e) USE OF FUNDS.—

''(1) IN GENERAL.—Any State, territory, Indian Tribe, or directly eligible entity that is awarded funds under subsection (a) shall use such funds for eligible PrEP and PEP expenses.

''(2) ELIGIBLE PREP EXPENSES.—The Secretary shall publish a list of expenses that qualify as eligible PrEP and PEP expenses for purposes of this section, which shall include—

''(A) any prescription drug approved by the Food and Drug Administration for the prevention of HIV, administrative fees for such drugs, laboratory and other diagnostic procedures associated with the use of such drugs, and clinical follow-up and monitoring, including any related services recommended in current United States Public Health Service clinical practice guidelines, without limitation;

''(B) outreach and public education activities directed toward populations overrepresented in the domestic HIV epidemic that increase awareness about the existence of PrEP and PEP, provide education about access to and health care coverage of PrEP and PEP, PrEP and PEP adherence programs, and counter stigma associated with the use of PrEP and PEP;

''(C) outreach activities directed toward physicians and other providers that provide education about PrEP and PEP; and

''(D) adherence services and counseling, including personnel costs for PrEP navigators to retain patients in care.

''(f) REPORT TO CONGRESS.—The Secretary shall, in each of the first 5 years beginning one year after the date of the enactment of the PrEP Access and Coverage Act of 2023, submit to Congress, and make public on the internet website of Department of Health and Human Services, a report on the impact of any grants provided to States, territories, Indian Tribes, and directly eligible entities for the establishment and support of pre-exposure prophylaxis programs under this section.

''(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2024 through 2029.''.

SEC. 8. CLARIFICATION.

This Act, including the amendments made by this Act, shall apply notwithstanding any other provision of law, including Public Law 103–141.

SEC. 9. PRIVATE RIGHT OF ACTION.

Any person aggrieved by a violation of this Act, including the amendments made by this Act, may commence a civil action in an appropriate United States District Court or other court of competent jurisdiction to obtain

relief as allowed by law as either an individual or member of a class. If the plaintiff is the prevailing party in such an action, the court shall order the defendant to pay the costs and reasonable attorney fees of the plaintiff.

SEC. 10. ENFORCEMENT.

(a) IN GENERAL.—The Secretary of Health and Human Services, in consultation with the Centers for Disease Control and Prevention, shall—

(1) issue guidance regarding the implementation of the coverage requirements established under this Act, including the amendments made by this Act, including with respect to implementation of such coverage requirements;

(2) develop and disseminate educational materials, including billing and coding documents;

(3) provide technical assistance to State insurance commissioners;

(4) provide technical assistance to eligible entities for regarding responding to consumer complaints and assisting in resolving such complaints; and

(5) work with other Federal agencies to assist in enforcement and compliance.

(b) COMPLIANCE.—

(1) IN GENERAL.—The Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury, in consultation with the Director of the Centers for Disease Control and Prevention, shall monitor compliance by group health plans and health insurance issuers with coverage requirements established under title XXVII of the Public Health Service Act (42 U.S.C. 300gg et seq.), as amended by section 3) and shall take appropriate enforcement actions under the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986.

(2) INSURER SUBMISSIONS TO THE SECRETARY.—Beginning not later than 1 year after the date of enactment of this Act, each group health plan and health insurance issuer offering group or individual health insurance coverage shall submit to the Secretary of Health and Human Services, at such time as such secretary, in coordination with the Secretary of Labor and the Secretary of the Treasury, shall require, but not less frequently than annually for the 10-year period beginning on such date of enactment, data demonstrating compliance with the coverage requirements described in paragraph (1), including aggregate data on the number of

claims received by such plans and issuers for HIV prevention services and the cost-sharing for enrollees with respect to such claims.

(3) REPORTS TO CONGRESS.—Not later than 2 years after the enactment of this Act and every 2 years thereafter for the 10-year period beginning on such date of enactment, the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury (collectively referred to in this section as the ''Secretaries'') shall jointly submit to Congress and make publicly available a report to assess the prevalence of noncompliance with the coverage requirements described in paragraph (1). Each such report shall include—

(A) aggregate information about group health plans and health insurance issuers that the Secretaries determine to be out of compliance with such requirements; and

(B) steps the Secretaries have taken to address incidences of such noncompliance.

(4) DEFINITIONS.—In this subsection, the terms ''group health plan'', ''health insurance coverage'', and ''health insurance issuer'' have the

meanings given such terms in section 2729 of the Public Health Service Act (42 U.S.C. 300gg–91).

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