118TH CONGRESS
1ST SESSION

S. ______

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

IN THE SENATE OF THE UNITED STATES

Ms. SMITH introduced the following bill; which was read twice and referred to the Committee on ______________________

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "PrEP Access and Cov-
5 erage Act of 2023".

6 **SEC. 2. FINDINGS; SENSE OF CONGRESS.**

7 (a) FINDINGS.—Congress finds the following:
8 (1) The Centers for Disease Control and Pre-
9 vention estimates that approximately 1,200,000 indi-
10 viduals in the United States are living with HIV.

1 (2) In 2021, there were 36,136 new diagnoses
2 of HIV in the United States.
3 (3) HIV disproportionately impacts gay and bi-
4 sexual men, transgender women, and, in particular,
5 people of color. In 2021, approximately 71 percent
6 of new HIV diagnoses were estimated to be among
7 gay and bisexual men, 40 percent of new HIV diag-
8 noses were among Black people, and 29 percent of
9 new HIV diagnoses were among Latinx people. Re-
10 cent studies suggest that transgender women are up
11 to 49 times more likely to be diagnosed with HIV
12 than the general population. Members of commu-
13 nities at the intersections of these groups are most
14 heavily impacted.
15 (4) Pre-exposure prophylaxis (referred to in this
16 section as ''PrEP'') is a daily antiretroviral medica-
17 tion that helps prevent individuals from acquiring
18 HIV. Daily PrEP use reduces the risk of getting
19 HIV from sex by more than 99 percent. It reduces
20 the risk of getting HIV from injection drug use by
21 at least 74 percent.
22 (5) Many individuals at risk of exposure to HIV
23 do not use PrEP. Of the approximately 1,200,000
24 individuals in the United States who could benefit

1 from PrEP, only 31 percent, or 382,364 individuals,
2 filled prescriptions for the drug in 2022.
3 (6) PrEP usage is inconsistent across racial
4 and gender lines. In 2022, only 11 percent of Black/
5 African-American and 21 percent of Hispanic/Latinx
6 individuals who were eligible for PrEP were pre-
7 scribed it, compared to 82 percent of eligible white
8 individuals. PrEP usage is low among women, in
9 particular among heterosexual women of color.
10 Slightly less than 12 percent of women eligible for
11 PrEP received a prescription in 2022.
12 (7) PrEP use helps strengthen families by al-
13 lowing couples with partners of different HIV
14 statuses to prevent the transmission of HIV.
15 (8) There are currently 2 brand name drugs
16 and 1 generic drug approved by the Food and Drug
17 Administration for the use of PrEP on a daily basis.
18 A long-acting injectable PrEP drug has also been
19 approved by the Food and Drug Administration.
20 Other types of HIV prevention treatments, including
21 other long-acting injectables, long-acting oral pills,
22 implants, and vaginal rings are in the research pipe-
23 line. These innovations can increase widespread use
24 of PrEP along with adherence, which can speed the

1 Nation's goal to end HIV and address inequities in
2 health care.
3 (9) Section 2713 of the Public Health Service
4 Act (42 U.S.C. 300gg–13) requires non-grand-
5 fathered private health insurance plans to cover pre-
6 ventive services without cost-sharing, including such
7 services with a rating of ''A'' or ''B'' under rec-
8 ommendations of the United States Preventive Serv-
9 ices Task Force. On June 11, 2019, the United
10 States Preventive Services Task Force issued a final
11 recommendation giving an ''A'' grade for PrEP for
12 individuals at high risk of HIV; non-grandfathered
13 private health insurance plans have to cover PrEP
14 for such individuals without cost-sharing effective
15 January 2021. Updated United States Preventive
16 Service Task Force guidance incorporating the new
17 long-acting injectable PrEP drug is pending.
18 (10) Joint guidance issued by the Department
19 of Labor, the Department of Health and Human
20 Services, and the Department of the Treasury on
21 July 19, 2021, clarifies that ancillary services nec-
22 essary to maintain the PrEP regime, including sub-
23 sequent provider visits, clinical testing, and other
24 services, is required to be covered by health insurers
25 without cost-sharing.

1 (11) Permanently expanding access to cost-free
2 PrEP and ancillary services for all individuals, in-
3 cluding individuals who do not have health insur-
4 ance, through legislation, is a critical step towards
5 eliminating HIV transmission.
6 (12) Post-exposure prophylaxis (referred to in
7 this section as ‘‘PEP’’) is a daily antiretroviral
8 treatment which, when initiated promptly after a
9 sexual or other exposure to blood or body fluids that
10 are associated with a high risk of HIV transmission,
11 is highly effective at preventing HIV transmission.
12 (13) The Centers for Disease Control and Pre-
13 vention recommends PEP for an individual who has
14 experienced a high-risk exposure incident, provided
15 that the individual tests HIV-negative, initiates such
16 treatment not later than 72 hours after exposure,
17 and continues the treatment for 28 days.
18 (14) Despite PEP’s proven effectiveness in pre-
19 venting HIV transmission after high-risk sexual ex-
20 posures, including sexual assault, awareness of PEP
21 is low among individuals who would benefit from the
22 treatment. Studies suggest that awareness of PEP
23 and of the importance of its prompt initiation is par-
24 ticularly low among young gay and bisexual men of

1 color, transgender individuals, and women of all gen-
2 der identities.
3 (15) Adequate knowledge of guidelines issued
4 by the Centers for Disease Control and Prevention
5 for assessing indications for PEP and for initiating
6 and sustaining PEP are low among health care pro-
7 viders and staff. Because PEP is an emergency
8 intervention, insufficient knowledge among providers
9 and staff in hospital emergency rooms, urgent care
10 centers, community health centers, and primary care
11 physicians is of particular concern.
12 (16) Private and public health insurance plans
13 and programs frequently impose requirements for
14 coverage of PEP, including pre-authorization re-
15 quirements and requirements to obtain the medica-
16 tions through designated specialty pharmacies and
17 mail-order programs that pose significant obstacles
18 to timely initiation of treatment.
19 (17) Insurance deductibles and co-payments for
20 PEP medications create significant barriers to PEP
21 utilization by many individuals who have experienced
22 high-risk incidents.
23 (18) The Federal Government has a compelling
24 interest in preventing new cases of HIV. Lowering

1 the prevalence of HIV protects public health and
2 saves on the cost of HIV treatment.
3 (b) SENSE OF CONGRESS.—It is the sense of Con-
4 gress that the Department of Labor, the Department of
5 Health and Human Services, and the Department of the
6 Treasury should ensure compliance with the requirements
7 described in paragraphs (9) and (10) of subsection (a).

8 **SEC. 3. COVERAGE OF HIV TESTING AND PREVENTION**
9 **SERVICES.**

10 (a) PRIVATE INSURANCE.—
11 (1) IN GENERAL.—Section 2713(a) of the Pub-
12 lic Health Service Act (42 U.S.C. 300gg–13(a)) is
13 amended—
14 (A) in paragraph (2), by striking ''; and''
15 and inserting a semicolon;
16 (B) in paragraph (3), by striking the pe-
17 riod and inserting a semicolon;
18 (C) in paragraph (4), by striking the pe-
19 riod and inserting a semicolon;
20 (D) in paragraph (5), by striking the pe-
21 riod and inserting ''; and''; and
22 (E) by adding at the end the following:
23 ''(6) any prescription drug approved by the
24 Food and Drug Administration for the prevention of
25 HIV (other than a drug subject to preauthorization

1 requirements consistent with section 2729A), admin-
2 istrative fees for such drugs, laboratory and other
3 diagnostic procedures associated with the use of
4 such drugs, and clinical follow up and monitoring,
5 including any related services recommended in cur-
6 rent United States Public Health Service clinical
7 practice guidelines, without limitation.''.

8 (2) PROHIBITION ON PREAUTHORIZATION RE-
9 QUIREMENTS.—Subpart II of part A of title XXVII
10 of the Public Health Service Act (42 U.S.C. 300gg–
11 11 et seq.) is amended by adding at the end the fol-
12 lowing:

13 **''SEC. 2729A. PROHIBITION ON PREAUTHORIZATION RE-**
14 **QUIREMENTS WITH RESPECT TO CERTAIN**
15 **SERVICES.**

16 ''A group health plan or a health insurance issuer of-
17 fering group or individual health insurance coverage shall
18 not impose any preauthorization requirements with re-
19 spect to coverage of the services described in section
20 2713(a)(6), except that a plan or issuer may impose
21 preauthorization requirements with respect to coverage of
22 a particular drug approved under section 505(c) of the
23 Federal Food, Drug, and Cosmetic Act or section 351(a)
24 of this Act if such plan or issuer provides coverage without

1 any preauthorization requirements for a drug that is ther-
2 apeutically equivalent.''.

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

7 ''(c) Any health benefits plan offered under this chap-
8 ter shall include benefits for, and may not impose any
9 cost-sharing requirements for, any prescription drug ap-
10 proved by the Food and Drug Administration for the pre-
11 vention of HIV, administrative fees for such drugs, labora-
12 tory and other diagnostic procedures associated with the
13 use of such drugs, and clinical follow up and monitoring,
14 including any related services recommended in current
15 United States Public Health Service clinical practice
16 guidelines, without limitation.''.

17 (c) MEDICAID.—

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

20 (A) in subsection (a)(4)—

21 (i) by striking ''; and (D)'' and insert-
22 ing ''; (D)'';

23 (ii) by striking ''; and (E)'' and in-
24 serting ''; (E)'';

1 (iii) by striking "; and (F)" and in-
2 serting "; (F)"; and
3 (iv) by striking the semicolon at the
4 end and inserting "; and (G) HIV preven-
5 tion services;"; and
6 (B) by adding at the end the following new
7 subsection:
8 "(jj) HIV PREVENTION SERVICES.—For purposes of
9 subsection (a)(4)(G), the term 'HIV prevention services'
10 means prescription drugs for the prevention of HIV acqui-
11 sition, administrative fees for such drugs, laboratory and
12 other diagnostic procedures associated with the use of
13 such drugs, and clinical follow up and monitoring, includ-
14 ing any related services recommended in current United
15 States Public Health Service clinical practice guidelines,
16 without limitation.".
17 (2) NO COST-SHARING.—Title XIX of the So-
18 cial Security Act (42 U.S.C. 1396 et seq.) is amend-
19 ed—
20 (A) in section 1916, by inserting "HIV
21 prevention services described in section
22 1905(a)(4)(G)," after "section 1905(a)(4)(C),"
23 each place it appears; and
24 (B) in section 1916A(b)(3)(B), by adding
25 at the end the following new clause:

1 "(xv) HIV prevention services de-
2 scribed in section 1905(a)(4)(G).".
3 (3) INCLUSION IN BENCHMARK COVERAGE.—
4 Section 1937(b)(7) of the Social Security Act (42
5 U.S.C. 1396u–7(b)(7)) is amended—
6 (A) in the paragraph header, by inserting
7 "AND HIV PREVENTION SERVICES" after "SUP-
8 PLIES"; and
9 (B) by striking "includes for any individual
10 described in section 1905(a)(4)(C), medical as-
11 sistance for family planning services and sup-
12 plies in accordance with such section" and in-
13 serting "includes medical assistance for HIV
14 prevention services described in section
15 1905(a)(4)(G), and includes, for any individual
16 described in section 1905(a)(4)(C), medical as-
17 sistance for family planning services and sup-
18 plies in accordance with such section".
19 (d) CHIP.—
20 (1) IN GENERAL.—Section 2103 of the Social
21 Security Act (42 U.S.C. 1397cc), as amended by
22 section 11405(b)(1) of Public Law 117–169, is
23 amended—

1 (A) in subsection (a), by striking ''and
2 (8)'' and inserting ''(8), (10), (11), and (13)'';
3 and
4 (B) in subsection (c), by adding at the end
5 the following new paragraph:
6 ''(13) HIV PREVENTION SERVICES.—Regard-
7 less of the type of coverage elected by a State under
8 subsection (a), the child health assistance provided
9 for a targeted low-income child, and, in the case of
10 a State that elects to provide pregnancy-related as-
11 sistance pursuant to section 2112, the pregnancy-re-
12 lated assistance provided for a targeted low-income
13 pregnant woman (as such terms are defined for pur-
14 poses of such section), shall include coverage of HIV
15 prevention services (as defined in section 1905(jj)).''.
16 (2) NO COST-SHARING.—Section 2103(e)(2) of
17 the Social Security Act (42 U.S.C. 1397cc(e)(2)) is
18 amended by inserting ''HIV prevention services de-
19 scribed in subsection (c)(13),'' before ''or for preg-
20 nancy-related assistance''.
21 (3) EFFECTIVE DATE.—
22 (A) IN GENERAL.—Subject to subpara-
23 graph (B), the amendments made by subsection
24 (c) and this subsection shall take effect on Jan-
25 uary 1, 2025.

1 (B) DELAY PERMITTED IF STATE LEGISLA-
2 TION REQUIRED.—In the case of a State plan
3 approved under title XIX or XXI of the Social
4 Security Act which the Secretary of Health and
5 Human Services determines requires State leg-
6 islation (other than legislation appropriating
7 funds) in order for the plan to meet the addi-
8 tional requirements imposed by this section, the
9 State plan shall not be regarded as failing to
10 comply with the requirements of such title sole-
11 ly on the basis of the failure of the plan to meet
12 such additional requirements before the 1st day
13 of the 1st calendar quarter beginning after the
14 close of the 1st regular session of the State leg-
15 islature that ends after the 1-year period begin-
16 ning with the date of the enactment of this sec-
17 tion. For purposes of the preceding sentence, in
18 the case of a State that has a 2-year legislative
19 session, each year of the session is deemed to
20 be a separate regular session of the State legis-
21 lature.
22 (e) COVERAGE AND ELIMINATION OF COST-SHARING
23 UNDER MEDICARE.—
24 (1) COVERAGE OF HIV PREVENTION SERVICES
25 UNDER PART B.—

1 (A) COVERAGE.—
2 (i) IN GENERAL.—Section 1861(s)(2)
3 of the Social Security Act (42 U.S.C.
4 1395x(s)(2)) is amended—
5 (I) in subparagraph (II), by
6 striking "and" at the end;
7 (II) in subparagraph (JJ), by in-
8 serting "and" at the end; and
9 (III) by adding at the end the
10 following new subparagraph:
11 "(KK) HIV prevention services (as defined
12 in subsection (nnn));".
13 (ii) DEFINITION.—Section 1861 of
14 the Social Security Act (42 U.S.C. 1395x)
15 is amended by adding at the end the fol-
16 lowing new subsection:
17 "(nnn) HIV PREVENTION SERVICES.—The term
18 'HIV prevention services' means—
19 "(1) drugs or biologicals approved by the Food
20 and Drug Administration for the prevention of HIV;
21 "(2) administrative fees for such drugs;
22 "(3) laboratory and other diagnostic procedures
23 associated with the use of such drugs; and
24 "(4) clinical follow up and monitoring, including
25 any related services recommended in current United

1 States Public Health Service clinical practice guide-
2 lines, without limitation.''.
3 (B) ELIMINATION OF COINSURANCE.—Sec-
4 tion 1833(a)(1) of the Social Security Act (42
5 U.S.C. 1395l(a)(1)) is amended—
6 (i) by striking ''and (HH)'' and in-
7 serting ''(HH)''; and
8 (ii) by inserting before the semicolon
9 at the end the following: '', and (II) with
10 respect to HIV prevention services (as de-
11 fined in section 1861(nnn)), the amount
12 paid shall be 100 percent of (i) except as
13 provided in clause (ii), the lesser of the ac-
14 tual charge for the service or the amount
15 determined under the fee schedule that ap-
16 plies to such services under this part, and
17 (ii) in the case of such services that are
18 covered OPD services (as defined in sub-
19 section (t)(1)(B)), the amount determined
20 under subsection (t)''.
21 (C) EXEMPTION FROM PART B DEDUCT-
22 IBLE.—The first sentence of section 1833(b) of
23 the Social Security Act (42 U.S.C. 1395l(b)) is
24 amended—

1 (i) by striking ", and (13)" and in-
2 serting "(13)"; and
3 (ii) by striking "1861(n).." and in-
4 serting "1861(n), and (14) such deductible
5 shall not apply with respect to HIV pre-
6 vention services (as defined in section
7 1861(nnn)(1)).".
8 (D) EFFECTIVE DATE.—The amendments
9 made by this paragraph shall apply to items
10 and services furnished on or after January 1,
11 2025.
12 (2) ELIMINATION OF COST-SHARING FOR
13 DRUGS FOR THE PREVENTION OF HIV UNDER PART
14 D.—
15 (A) IN GENERAL.—Section 1860D–2 of
16 the Social Security Act (42 U.S.C. 1395w–
17 102(b)) is amended—
18 (i) in subsection (b)—
19 (I) in paragraph (1)(A), by strik-
20 ing "and (9)" and inserting ", (9),
21 and (10)";
22 (II) in paragraph (2)—
23 (aa) in subparagraph (A),
24 by striking "and (9)" and insert-
25 ing ", (9), and (10)";

1 (bb) in subparagraph (C)(i),
2 in the matter preceding subclause
3 (I), by striking "and (9)" and in-
4 serting "(9), and (10)"; and
5 (cc) in subparagraph (D)(i),
6 in the matter preceding subclause
7 (I), by striking "and (9)" and in-
8 serting "(9), and (10)";
9 (III) in paragraph (3)(A), in the
10 matter preceding clause (i), by strik-
11 ing "and (9)" and inserting "(9), and
12 (10)";
13 (IV) in paragraph (4)(A)(i), by
14 striking "and (9)" and inserting ",
15 (9), and (10)"; and
16 (V) by adding at the end the fol-
17 lowing new paragraph:
18 "(10) ELIMINATION OF COST-SHARING FOR
19 DRUGS FOR THE PREVENTION OF HIV.—For plan
20 years beginning on or after January 1, 2025, with
21 respect to a covered part D drug that is for the pre-
22 vention of HIV—
23 "(A) the deductible under paragraph (1)
24 shall not apply; and

1 ''(B) there shall be no coinsurance or other
2 cost-sharing under this part with respect to
3 such drug.''; and
4 (ii) in subsection (c), by adding at the
5 end the following new paragraph:
6 ''(7) TREATMENT OF COST-SHARING FOR
7 DRUGS FOR THE PREVENTION OF HIV.—The cov-
8 erage is provided in accordance with subsection
9 (b)(10).''.
10 (B) CONFORMING AMENDMENTS TO COST-
11 SHARING FOR LOW-INCOME INDIVIDUALS.—Sec-
12 tion 1860D–14(a) of the Social Security Act
13 (42 U.S.C. 1395w–114(a)) is amended—
14 (i) in paragraph (1)(D), in each of
15 clauses (ii) and (iii), by striking ''para-
16 graph (6)'' and inserting ''paragraphs (6)
17 and (7)'';
18 (ii) in paragraph (2)—
19 (I) in subparagraph (B), by
20 striking ''and (9)'' and inserting '',
21 (9), and (10)'';
22 (II) in subparagraph (D), by
23 striking ''paragraph (6)'' and insert-
24 ing ''paragraphs (6) and (7)''; and

1 (III) in subparagraph (E), by
2 striking "paragraph (6)" and insert-
3 ing "paragraphs (6) and (7)"; and
4 (iii) by adding at the end the fol-
5 lowing new paragraph:
6 "(7) NO APPLICATION OF COST-SHARING OR
7 DEDUCTIBLE FOR DRUGS FOR THE PREVENTION OF
8 HIV.—For plan years beginning on or after January
9 1, 2025, with respect to a covered part D drug that
10 is for the prevention of HIV—
11 "(A) the deductible under section 1860D–
12 2(b)(1) shall not apply; and
13 "(B) there shall be no cost-sharing under
14 this section with respect to such drug.".
15 (f) COVERAGE OF HIV PREVENTION TREATMENT BY
16 DEPARTMENT OF VETERANS AFFAIRS.—
17 (1) ELIMINATION OF MEDICATION COPAY-
18 MENTS.—Section 1722A(a) of title 38, United
19 States Code, is amended by adding at the end the
20 following new paragraph:
21 "(5) Paragraph (1) does not apply to a medication
22 for the prevention of HIV.".
23 (2) ELIMINATION OF HOSPITAL CARE AND MED-
24 ICAL SERVICES COPAYMENTS.—Section 1710 of such
25 title is amended—

1 (A) in subsection (f)—
2 (i) by redesignating paragraph (5) as
3 paragraph (6); and
4 (ii) by inserting after paragraph (4)
5 the following new paragraph (5):
6 "(5) A veteran shall not be liable to the United States
7 under this subsection for any amounts for laboratory and
8 other diagnostic procedures associated with the use of any
9 prescription drug approved by the Food and Drug Admin-
10 istration for the prevention of HIV, administrative fees for
11 such drugs, or for laboratory or other diagnostic proce-
12 dures associated with the use of such drugs, or clinical
13 follow up and monitoring, including any related services
14 recommended in current United States Public Health
15 Service clinical practice guidelines, without limitation.";
16 and
17 (B) in subsection (g)(3), by adding at the
18 end the following new subparagraph:
19 "(C) Any prescription drug approved by the
20 Food and Drug Administration for the prevention of
21 HIV, administrative fees for such drugs, laboratory
22 and other diagnostic procedures associated with the
23 use of such drugs, and clinical follow up and moni-
24 toring, including any related services recommended

1 in current United States Public Health Service clin-
2 ical practice guidelines, without limitation.''.
3 (3) INCLUSION AS PREVENTIVE HEALTH SERV-
4 ICE.—Section 1701(9) of such title is amended—
5 (A) in subparagraph (K), by striking ``;
6 and'' and inserting a semicolon;
7 (B) by redesignating subparagraph (L) as
8 subparagraph (M); and
9 (C) by inserting after subparagraph (K)
10 the following new subparagraph (L):
11 ``(L) any prescription drug approved by
12 the Food and Drug Administration for the pre-
13 vention of HIV, administrative fees for such
14 drugs, laboratory and other diagnostic proce-
15 dures associated with the use of such drugs,
16 and clinical follow up and monitoring, including
17 any related services recommended in current
18 United States Public Health Service clinical
19 practice guidelines, without limitation; and''.
20 (g) COVERAGE OF HIV PREVENTION TREATMENT BY
21 DEPARTMENT OF DEFENSE.—
22 (1) IN GENERAL.—Chapter 55 of title 10,
23 United States Code, is amended by inserting after
24 section 1074o the following new section:

1 **"§ 1074p. Coverage of HIV prevention treatment**
2 "(a) IN GENERAL.—The Secretary of Defense shall
3 ensure coverage under the TRICARE program of HIV
4 prevention treatment described in subsection (b) for any
5 beneficiary under section 1074(a) of this title.
6 "(b) HIV PREVENTION TREATMENT DESCRIBED.—
7 HIV prevention treatment described in this subsection in-
8 cludes any prescription drug approved by the Food and
9 Drug Administration for the prevention of HIV, adminis-
10 trative fees for such drugs, laboratory and other diagnostic
11 procedures associated with the use of such drugs, and clin-
12 ical follow up and monitoring, including any related serv-
13 ices recommended in current United States Public Health
14 Service clinical practice guidelines, without limitation.
15 "(c) NO COST-SHARING.—Notwithstanding section
16 1075, 1075a, or 1074g(a)(6) of this title or any other pro-
17 vision of law, there is no cost-sharing requirement for HIV
18 prevention treatment covered under this section.".
19 (2) CLERICAL AMENDMENT.—The table of sec-
20 tions at the beginning of such chapter is amended
21 by inserting after the item relating to section 1074o
22 the following new item:

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

23 (h) INDIAN HEALTH SERVICE TESTING, MONI-
24 TORING, AND PRESCRIPTION DRUGS FOR THE PREVEN-
25 TION OF HIV.—Title II of the Indian Health Care Im-

1 provement Act is amended by inserting after section 223
2 (25 U.S.C. 1621v) the following:

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

5 "(a) IN GENERAL.—The Secretary, acting through
6 the Director of HIV/AIDS Prevention and Treatment
7 under section 832, Indian tribes, and tribal organizations,
8 shall provide, without limitation, funding for any prescrip-
9 tion drug approved by the Food and Drug Administration
10 for the prevention of human immunodeficiency virus (com-
11 monly known as 'HIV'), administrative fees for that drug,
12 laboratory and other diagnostic procedures associated with
13 the use of that drug, and clinical follow-up and moni-
14 toring, including any related services recommended in cur-
15 rent United States Public Health Service clinical practice
16 guidelines.

17 "(b) AUTHORIZATION OF APPROPRIATIONS.—There
18 are authorized to be appropriated such sums as are nec-
19 essary to carry out this section.".

20 (i) EFFECTIVE DATE.—The amendments made by
21 subsections (a), (b), (e), (f), (g), and (h) shall take effect
22 with respect to plan years beginning on or after January
23 1, 2025.

1 **SEC. 4. PROHIBITION ON DENIAL OF COVERAGE OR IN-**
2 **CREASE IN PREMIUMS OF LIFE, DISABILITY,**
3 **OR LONG-TERM CARE INSURANCE FOR INDI-**
4 **VIDUALS TAKING MEDICATION FOR THE PRE-**
5 **VENTION OF HIV ACQUISITION.**

6 (a) PROHIBITION.—Notwithstanding any other provi-
7 sion of law, it shall be unlawful to—

8 (1) decline or limit coverage of an individual
9 under any life insurance policy, disability insurance
10 policy, or long-term care insurance policy, on ac-
11 count of the individual taking medication for the
12 purpose of preventing the acquisition of HIV;

13 (2) preclude an individual from taking medica-
14 tion for the purpose of preventing the acquisition of
15 HIV as a condition of receiving a life insurance pol-
16 icy, disability insurance policy, or long-term care in-
17 surance policy;

18 (3) consider whether an individual is taking
19 medication for the purpose of preventing the acquisi-
20 tion of HIV in determining the premium rate for
21 coverage of such individual under a life insurance
22 policy, disability insurance policy, or long-term care
23 insurance policy; or

24 (4) otherwise discriminate in the offering,
25 issuance, cancellation, amount of such coverage,
26 price, or any other condition of a life insurance pol-

1 icy, disability insurance policy, or long-term care in-
2 surance policy for an individual, based solely and
3 without any additional actuarial risks upon whether
4 the individual is taking medication for the purpose
5 of preventing the acquisition of HIV.

6 (b) ENFORCEMENT.—A State insurance regulator
7 may take such actions to enforce subsection (a) as are spe-
8 cifically authorized under the laws of such State.

9 (c) DEFINITIONS.—In this section:

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

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

19 (3) LONG-TERM CARE INSURANCE POLICY.—
20 The term ''long-term care insurance policy'' means
21 a contract for which the only insurance protection
22 provided under the contract is coverage of qualified
23 long-term care services (as defined in section
24 7702B(c) of the Internal Revenue Code of 1986).

1 **SEC. 5. PUBLIC EDUCATION CAMPAIGN.**

2 Part P of title III of the Public Health Service Act
3 (42 U.S.C. 280g et seq.) is amended by adding at the end
4 the following:

5 **''SEC. 399V–8. PRE-EXPOSURE PROPHYLAXIS AND POST-EX-**
6 **POSURE PROPHYLAXIS EDUCATION CAM-**
7 **PAIGNS.**

8 ''(a) PUBLIC EDUCATION CAMPAIGN.—
9 ''(1) IN GENERAL.—The Secretary, acting
10 through the Director of the Centers for Disease
11 Control and Prevention, in consultation with the Di-
12 rector of the Office of Infectious Disease and HIV/
13 AIDS Policy, shall establish a public health cam-
14 paign for the purpose of educating the public on
15 medication for the prevention of HIV acquisition.
16 ''(2) REQUIREMENTS.—In carrying out this
17 subsection, the Secretary shall ensure cultural com-
18 petency and efficacy within high-need communities
19 in which PrEP or PEP are underutilized by devel-
20 oping the campaign in collaboration with organiza-
21 tions that are indigenous to communities that are
22 overrepresented in the domestic HIV epidemic, in-
23 cluding communities of color and the lesbian, gay,
24 bisexual, transgender, and queer community. The
25 Secretary shall ensure that the campaign is designed
26 to increase awareness of the safety and effectiveness

1 of PrEP and PEP, the recommended clinical prac-
2 tices for providing PrEP-related and PEP-related
3 clinical care, and the local availability of PrEP and
4 PEP providers, and to counter stigma associated
5 with the use of PrEP and PEP.

6 ''(3) EVALUATION OF PROGRAM.—The Sec-
7 retary shall develop measures to evaluate the effec-
8 tiveness of activities conducted under this subsection
9 that are aimed at reducing disparities in access to
10 PrEP and PEP and supporting the local commu-
11 nity. Such measures shall evaluate community out-
12 reach activities, language services, workforce cultural
13 competence, and other areas as determined by the
14 Secretary.

15 ''(b) PROVIDER EDUCATION CAMPAIGN.—

16 ''(1) IN GENERAL.—The Secretary, acting
17 through the Director of the Centers for Disease
18 Control and Prevention, the Administrator of the
19 Health Resources and Services Administration, and
20 the Office of Infectious Disease and HIV/AIDS Pol-
21 icy, shall establish a provider campaign for the pur-
22 pose of educating prescribers and other associated
23 health professionals on medication for the prevention
24 of HIV acquisition.

1 "(2) REQUIREMENTS.—In carrying out this
2 subsection, the Secretary shall increase awareness
3 and readiness among health care providers to offer
4 PrEP or PEP, as appropriate, with a focus on areas
5 of high-need communities in which PrEP or PEP is
6 underutilized by developing an educational campaign
7 with input from health care providers and organiza-
8 tions that are indigenous to communities that are
9 overrepresented in the domestic HIV epidemic, in-
10 cluding communities of color and the lesbian, gay,
11 bisexual, transgender, and queer community. The
12 Secretary shall ensure that the campaign is designed
13 to increase awareness of the safety and effectiveness
14 of PrEP and PEP, the recommended clinical prac-
15 tices for providing PrEP-related and PEP-related
16 clinical care, cultural competency among PrEP and
17 PEP prescribers, and to counter stigma associated
18 with the use of PrEP and PEP.
19 "(3) EVALUATION OF PROGRAM.—The Sec-
20 retary shall develop measures to evaluate the effec-
21 tiveness of activities conducted under this subsection
22 that are aimed at increasing the number of health
23 care professionals offering PrEP and PEP and re-
24 ducing disparities in access to PrEP and PEP. Such
25 measures shall evaluate availability of PrEP and

1 PEP services, education and outreach activities, lan-
2 guage services, workforce cultural competence, and
3 other areas as determined by the Secretary.
4 ''(c) DEFINITIONS.—In this section and section
5 399V–9—
6 ''(1) the term 'PEP' means any drug or com-
7 bination of drugs approved by the Food and Drug
8 Administration for preventing HIV transmission
9 after a sexual or other exposure associated with a
10 high risk of HIV transmission; and
11 ''(2) the term 'PrEP' means any drug approved
12 by the Food and Drug Administration for the pur-
13 pose of pre-exposure prophylaxis with respect to
14 HIV.
15 ''(d) AUTHORIZATION OF APPROPRIATIONS.—To
16 carry out this section, there are authorized to be appro-
17 priated such sums as may be necessary for each of fiscal
18 years 2024 through 2029.''.
19 **SEC. 6. PATIENT CONFIDENTIALITY.**
20 The Secretary of Health and Human Services shall
21 amend the regulations promulgated under section 264(c)
22 of the Health Insurance Portability and Accountability
23 Act of 1996 (42 U.S.C. 1320d–2 note), as necessary, to
24 ensure that individuals are able to access the benefits de-
25 scribed in section 2713(a)(6) under a family plan without

1 any other individual enrolled in such family plan, including
2 a primary subscriber of or policyholder, being informed of
3 such use of such benefits.

4 **SEC. 7. PRE-EXPOSURE PROPHYLAXIS AND POST-EXPO-**
5 **SURE PROPHYLAXIS FUNDING.**

6 Part P of title III of the Public Health Service Act
7 (42 U.S.C. 280g et seq.), as amended by section 5, is fur-
8 ther amended by adding at the end the following:

9 **"SEC. 399V–9. PRE-EXPOSURE PROPHYLAXIS AND POST-EX-**
10 **POSURE PROPHYLAXIS FUNDING.**

11 "(a) IN GENERAL.—Not later than 1 year after the
12 date of the enactment of the PrEP Access and Coverage
13 Act of 2023, the Secretary shall establish a program that
14 awards grants to States, territories, Indian Tribes, and
15 directly eligible entities for the establishment and support
16 of pre-exposure prophylaxis (referred to in this section as
17 'PrEP') and post-exposure prophylaxis (referred to in this
18 section as 'PEP') programs.

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

22 "(1) submit an application to the Secretary at
23 such time, in such manner, and containing such in-
24 formation as the Secretary may require, including a
25 plan describing how any funds awarded will be used

1 to increase access to PrEP for uninsured and under-
2 insured individuals and reduce disparities in access
3 to PrEP and PEP for uninsured and underinsured
4 individuals and reduce disparities in access to PrEP
5 and PEP; and
6 ''(2) appoint a PrEP and PEP grant adminis-
7 trator to manage the program.
8 ''(c) DIRECTLY ELIGIBLE ENTITY.—For purposes of
9 this section, the term 'directly eligible entity'—
10 ''(1) means a Federally qualified health center
11 or other nonprofit entity engaged in providing PrEP
12 and PEP information and services; and
13 ''(2) may include—
14 ''(A) a Federally qualified health center
15 (as defined in section 1861(aa)(4) of the Social
16 Security Act);
17 ''(B) a family planning grantee (other than
18 States) funded under section 1001;
19 ''(C) a rural health clinic (as defined in
20 section 1861(aa)(2) of the Social Security Act);
21 ''(D) a health facility operated by or pur-
22 suant to a contract with the Indian Health
23 Service;
24 ''(E) a community-based organization, clin-
25 ic, hospital, or other health facility that pro-

1 vides services to individuals at risk for or living
2 with HIV; and
3 ‘‘(F) a nonprofit private entity providing
4 comprehensive primary care to populations at
5 risk of HIV, including faith-based and commu-
6 nity-based organizations.
7 ‘‘(d) AWARDS.—In determining whether to award a
8 grant, and the grant amount for each grant awarded, the
9 Secretary shall consider the grant application and the
10 need for PrEP and PEP services in the area, the number
11 of uninsured and underinsured individuals in the area, and
12 how the State, territory, or Indian Tribe coordinates
13 PrEP and PEP activities with the directly funded entity,
14 if the State, territory, or Indian Tribe applies for the
15 funds.
16 ‘‘(e) USE OF FUNDS.—
17 ‘‘(1) IN GENERAL.—Any State, territory, Indian
18 Tribe, or directly eligible entity that is awarded
19 funds under subsection (a) shall use such funds for
20 eligible PrEP and PEP expenses.
21 ‘‘(2) ELIGIBLE PREP EXPENSES.—The Sec-
22 retary shall publish a list of expenses that qualify as
23 eligible PrEP and PEP expenses for purposes of this
24 section, which shall include—

1 "(A) any prescription drug approved by
2 the Food and Drug Administration for the pre-
3 vention of HIV, administrative fees for such
4 drugs, laboratory and other diagnostic proce-
5 dures associated with the use of such drugs,
6 and clinical follow up and monitoring, including
7 any related services recommended in current
8 United States Public Health Service clinical
9 practice guidelines, without limitation;
10 "(B) outreach and public education activi-
11 ties directed toward populations overrepresented
12 in the domestic HIV epidemic that increase
13 awareness about the existence of PrEP and
14 PEP, provide education about access to and
15 health care coverage of PrEP and PEP, PrEP
16 and PEP adherence programs, and counter
17 stigma associated with the use of PrEP and
18 PEP;
19 "(C) outreach activities directed toward
20 physicians and other providers that provide
21 education about PrEP and PEP; and
22 "(D) adherence services and counseling, in-
23 cluding personnel costs for PrEP navigators to
24 retain patients in care.

1 “(f) REPORT TO CONGRESS.—The Secretary shall, in
2 each of the first 5 years beginning one year after the date
3 of the enactment of the PrEP Access and Coverage Act
4 of 2023, submit to Congress, and make public on the
5 internet website of Department of Health and Human
6 Services, a report on the impact of any grants provided
7 to States, territories, Indian Tribes, and directly eligible
8 entities for the establishment and support of pre-exposure
9 prophylaxis programs under this section.
10 “(g) AUTHORIZATION OF APPROPRIATIONS.—To
11 carry out this section, there are authorized to be appro-
12 priated such sums as may be necessary for each of fiscal
13 years 2024 through 2029.”.
14 **SEC. 8. CLARIFICATION.**
15 This Act, including the amendments made by this
16 Act, shall apply notwithstanding any other provision of
17 law, including Public Law 103–141.
18 **SEC. 9. PRIVATE RIGHT OF ACTION.**
19 Any person aggrieved by a violation of this Act, in-
20 cluding the amendments made by this Act, may commence
21 a civil action in an appropriate United States District
22 Court or other court of competent jurisdiction to obtain
23 relief as allowed by law as either an individual or member
24 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 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 Pre-

1 vention, shall monitor compliance by group health
2 plans and health insurance issuers with coverage re-
3 quirements established under title XXVII of the
4 Public Health Service Act (42 U.S.C. 300gg et seq.),
5 as amended by section 3) and shall take appropriate
6 enforcement actions under the Public Health Service
7 Act, the Employee Retirement Income Security Act
8 of 1974, and the Internal Revenue Code of 1986.
9 (2) INSURER SUBMISSIONS TO THE SEC-
10 RETARY.—Beginning not later than 1 year after the
11 date of enactment of this Act, each group health
12 plan and health insurance issuer offering group or
13 individual health insurance coverage shall submit to
14 the Secretary of Health and Human Services, at
15 such time as such secretary, in coordination with the
16 Secretary of Labor and the Secretary of the Treas-
17 ury, shall require, but not less frequently than annu-
18 ally for the 10-year period beginning on such date
19 of enactment, data demonstrating compliance with
20 the coverage requirements described in paragraph
21 (1), including aggregate data on the number of
22 claims received by such plans and issuers for HIV
23 prevention services and the cost-sharing for enrollees
24 with respect to such claims.

1 (3) REPORTS TO CONGRESS.—Not later than 2
2 years after the enactment of this Act and every 2
3 years thereafter for the 10-year period beginning on
4 such date of enactment, the Secretary of Health and
5 Human Services, the Secretary of Labor, and the
6 Secretary of the Treasury (collectively referred to in
7 this section as the ''Secretaries'') shall jointly submit
8 to Congress and make publicly available a report to
9 assess the prevalence of noncompliance with the cov-
10 erage requirements described in paragraph (1). Each
11 such report shall include—
12 (A) aggregate information about group
13 health plans and health insurance issuers that
14 the Secretaries determine to be out of compli-
15 ance with such requirements; and
16 (B) steps the Secretaries have taken to ad-
17 dress incidences of such noncompliance.
18 (4) DEFINITIONS.—In this subsection, the
19 terms ''group health plan'', ''health insurance cov-
20 erage'', and ''health insurance issuer'' have the
21 meanings given such terms in section 2729 of the
22 Public Health Service Act (42 U.S.C. 300gg–91).