

117TH CONGRESS  
1ST SESSION

# S. 3295

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

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IN THE SENATE OF THE UNITED STATES

DECEMBER 1, 2021

Ms. SMITH (for herself and Ms. KLOBUCHAR) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## 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”.

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

7 (a) FINDINGS.—Congress finds as follows:

8 (1) The Centers for Disease Control and Pre-  
9 vention estimates that approximately 1,100,000 peo-  
10 ple in the United States are living with HIV.

1           (2) In 2019, there were 36,398 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. For example, in 2019, approximately  
6 66 percent of new HIV diagnoses were among gay  
7 and bisexual men, 42 percent of new HIV diagnoses  
8 were among Black people, and 22 percent of new  
9 HIV diagnoses were among Latinx people. Recent  
10 studies suggest that transgender women are up to  
11 49 times more likely to be diagnosed with HIV than  
12 the general population. Members of communities at  
13 the intersections of these groups are most heavily  
14 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 about 99 percent. It reduces the  
20 risk of getting HIV from injection drug use by at  
21 least 74 percent.

22           (5) Many individuals at risk of exposure to HIV  
23 do not use PrEP. Of the approximately 1,100,000  
24 people in the United States who could benefit from

1 PrEP, only 23 percent, or nearly 285,000 individ-  
2 uals, filled prescriptions for the drug in 2019.

3 (6) PrEP usage is inconsistent across racial  
4 and gender lines. In 2019, only 8 percent of Black/  
5 African American and 14 percent of Hispanic/Latinx  
6 persons who were eligible for PrEP were prescribed  
7 it, compared to 63 percent of white persons. Addi-  
8 tionally, slightly less than 10 percent of women eligi-  
9 ble for PrEP received a prescription in 2019.

10 (7) There are currently 2 brand name drugs  
11 and 1 generic drug approved by the Food and Drug  
12 Administration for the use of PrEP on a daily basis.  
13 Other types of HIV prevention treatments, including  
14 a long-acting injectable, which is currently under  
15 FDA review, and long-acting oral pills, implants,  
16 and vaginal rings are in the research pipeline. These  
17 new innovations can increase widespread use of  
18 PrEP along with adherence, which can speed the  
19 Nation's goal to end HIV and address inequities in  
20 health care.

21 (8) Section 2713 of the Public Health Service  
22 Act (42 U.S.C. 300gg-13) requires most private  
23 health insurance plans to cover preventive services  
24 without cost-sharing, including such services with a  
25 rating of "A" or "B" under recommendations of the

1 United States Preventive Services Task Force. On  
2 June 11, 2019, the United States Preventive Serv-  
3 ices Task Force issued a final recommendation giv-  
4 ing an “A” grade for PrEP for individuals at high  
5 risk of HIV; non-grandfathered private health insur-  
6 ance plans have to cover PrEP for such individuals  
7 without cost-sharing effective January 2021.

8 (9) Joint guidance issued by the Department of  
9 Labor, the Department of Health and Human Serv-  
10 ices, and the Department of the Treasury on July  
11 19, 2021, clarifies that ancillary services necessary  
12 to maintain the PrEP regime, including subsequent  
13 provider visits, clinical testing, and other services, is  
14 required to be covered by health insurers without  
15 cost-sharing.

16 (10) Permanently expanding access to cost-free  
17 PrEP and ancillary services for all individuals, in-  
18 cluding individuals who do not have health insur-  
19 ance, through legislation, is a critical step towards  
20 eliminating HIV transmission.

21 (11) Post-exposure prophylaxis (referred to in  
22 this section as “PEP”) is a daily antiretroviral  
23 treatment which, when initiated promptly after a  
24 sexual or other exposure to blood or body fluids that

1 is associated with a high risk of HIV transmission,  
2 is highly effective at preventing HIV infection.

3 (12) The Centers for Disease Control and Pre-  
4 vention recommends PEP for an individual who has  
5 experienced a high-risk exposure incident, provided  
6 that the individual tests HIV-negative, initiates such  
7 treatment no later than 72 hours after exposure,  
8 and continues the treatment for 28 days.

9 (13) Despite PEP's proven effectiveness in pre-  
10 venting HIV infection after high-risk sexual expo-  
11 sures, awareness of PEP is low among individuals  
12 who would benefit from the treatment. Studies sug-  
13 gest that awareness of PEP and of the importance  
14 of its prompt initiation is particularly low among  
15 young gay and bisexual men of color, transgender  
16 persons, and women of all gender identities.

17 (14) Adequate knowledge of guidelines issued  
18 by the Centers for Disease Control and Prevention  
19 for assessing indications for PEP and for initiating  
20 and sustaining PEP are low among health care pro-  
21 viders and staff. Because PEP is an emergency  
22 intervention, insufficient knowledge among providers  
23 and staff in hospital emergency rooms, urgent care  
24 centers, community health centers, and primary care  
25 physicians is of particular concern.

1 (15) Private and public health insurance plans  
2 and programs frequently impose requirements for  
3 coverage of PEP, including pre-authorization re-  
4 quirements and requirements to obtain the medica-  
5 tions through designated specialty pharmacies and  
6 mail-order programs that pose significant obstacles  
7 to timely initiation of treatment.

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

12 (b) SENSE OF CONGRESS.—It is the sense of Con-  
13 gress that the Department of Labor, the Department of  
14 Health and Human Services, and the Department of the  
15 Treasury should ensure compliance with the requirements  
16 described in paragraphs (8) and (9) of subsection (a).

17 **SEC. 3. COVERAGE OF HIV TESTING AND PREVENTION**  
18 **SERVICES.**

19 (a) PRIVATE INSURANCE.—

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

23 (A) in paragraph (2), by striking “; and”  
24 and inserting a semicolon;

1 (B) in paragraph (3), by striking the pe-  
2 riod and inserting a semicolon;

3 (C) in paragraph (4), by striking the pe-  
4 riod and inserting a semicolon;

5 (D) in paragraph (5), by striking the pe-  
6 riod and inserting “; and”; and

7 (E) by adding at the end the following:

8 “(6) any prescription drug approved by the  
9 Food and Drug Administration for the prevention of  
10 HIV (other than a drug subject to preauthorization  
11 requirements consistent with section 2729A), admin-  
12 istrative fees for such drugs, laboratory and other  
13 diagnostic procedures associated with the use of  
14 such drugs, and clinical follow up and monitoring,  
15 including any related services recommended in cur-  
16 rent United States Public Health Service clinical  
17 practice guidelines, without limitation.”.

18 (2) PROHIBITION ON PREAUTHORIZATION RE-  
19 QUIREMENTS.—Subpart II of part A of title XXVII  
20 of the Public Health Service Act (42 U.S.C. 300gg–  
21 11 et seq.) is amended by adding at the end the fol-  
22 lowing:

1 **“SEC. 2729A. PROHIBITION ON PREAUTHORIZATION RE-**  
2 **QUIREMENTS WITH RESPECT TO CERTAIN**  
3 **SERVICES.**

4 “A group health plan or a health insurance issuer of-  
5 fering group or individual health insurance coverage shall  
6 not impose any preauthorization requirements with re-  
7 spect to coverage of the services described in section  
8 2713(a)(6), except that a plan or issuer may impose  
9 preauthorization requirements with respect to coverage of  
10 a particular drug approved under section 505(c) of the  
11 Federal Food, Drug, and Cosmetic Act or section 351(a)  
12 of this Act if such plan or issuer provides coverage without  
13 any preauthorization requirements for a drug that is ther-  
14 apeutically equivalent.”.

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

19 “(c) Any health benefits plan offered under this chap-  
20 ter shall include benefits for, and may not impose any  
21 cost-sharing requirements for, any prescription drug ap-  
22 proved by the Food and Drug Administration for the pre-  
23 vention of HIV, administrative fees for such drugs, labora-  
24 tory and other diagnostic procedures associated with the  
25 use of such drugs, and clinical follow up and monitoring,  
26 including any related services recommended in current



1 United States Public Health Service clinical practice  
2 guidelines, without limitation.”.

3 (c) MEDICAID.—

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

6 (A) in subsection (a)(4)—

7 (i) by striking “; and (D)” and insert-  
8 ing “; (D)”;

9 (ii) by striking “; and (E)” and in-  
10 sserting “; (E)”;

11 (iii) by striking “; and (F)” and in-  
12 sserting “; (F)”;

13 (iv) by striking the semicolon at the  
14 end and inserting “; and (G) HIV preven-  
15 tion services;”;

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

18 “(jj) HIV PREVENTION SERVICES.—For purposes of  
19 subsection (a)(4)(G), the term ‘HIV prevention services’  
20 means prescription drugs for the prevention of HIV acqui-  
21 sition, administrative fees for such drugs, laboratory and  
22 other diagnostic procedures associated with the use of  
23 such drugs, and clinical follow up and monitoring, includ-  
24 ing any related services recommended in current United

1 States Public Health Service clinical practice guidelines,  
2 without limitation.”.

3 (2) NO COST-SHARING.—Title XIX of the So-  
4 cial Security Act (42 U.S.C. 1396 et seq.) is amend-  
5 ed—

6 (A) in section 1916, by inserting “HIV  
7 prevention services described in section  
8 1905(a)(4)(G),” after “section 1905(a)(4)(C),”  
9 each place it appears; and

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

12 “(xii) HIV prevention services de-  
13 scribed in section 1905(a)(4)(G).”.

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

17 (A) in the paragraph header, by inserting  
18 “AND HIV PREVENTION SERVICES” after “SUP-  
19 PLIES”; and

20 (B) by striking “includes for any individual  
21 described in section 1905(a)(4)(C), medical as-  
22 sistance for family planning services and sup-  
23 plies in accordance with such section” and in-  
24 serting “includes medical assistance for HIV  
25 prevention services described in section

1           1905(a)(4)(G), and includes, for any individual  
2           described in section 1905(a)(4)(C), medical as-  
3           sistance for family planning services and sup-  
4           plies in accordance with such section”.

5           (d) CHIP.—

6           (1) IN GENERAL.—Section 2103 of the Social  
7           Security Act (42 U.S.C. 1397cc) is amended—

8                   (A) in subsection (a), by striking “and  
9                   (8)” and inserting “(8), (10), (11), and (12)”;  
10                  and

11                   (B) in subsection (e), by adding at the end  
12                  the following new paragraph:

13                   “(12) HIV PREVENTION SERVICES.—Regard-  
14                  less of the type of coverage elected by a State under  
15                  subsection (a), the child health assistance provided  
16                  for a targeted low-income child, and, in the case of  
17                  a State that elects to provide pregnancy-related as-  
18                  sistance pursuant to section 2112, the pregnancy-re-  
19                  lated assistance provided for a targeted low-income  
20                  pregnant woman (as such terms are defined for pur-  
21                  poses of such section), shall include coverage of HIV  
22                  prevention services (as defined in section 1905(jj)).”.

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

1 scribed in subsection (c)(12),” before “or for preg-  
2 nancy-related assistance”.

3 (3) EFFECTIVE DATE.—

4 (A) IN GENERAL.—Subject to subpara-  
5 graph (A), the amendments made by subsection  
6 (c) and this subsection shall take effect on Jan-  
7 uary 1, 2023.

8 (B) DELAY PERMITTED IF STATE LEGISLA-  
9 TION REQUIRED.—In the case of a State plan  
10 approved under title XIX of the Social Security  
11 Act which the Secretary of Health and Human  
12 Services determines requires State legislation  
13 (other than legislation appropriating funds) in  
14 order for the plan to meet the additional re-  
15 quirements imposed by this section, the State  
16 plan shall not be regarded as failing to comply  
17 with the requirements of such title solely on the  
18 basis of the failure of the plan to meet such ad-  
19 ditional requirements before the 1st day of the  
20 1st calendar quarter beginning after the close  
21 of the 1st regular session of the State legisla-  
22 ture that ends after the 1-year period beginning  
23 with the date of the enactment of this section.  
24 For purposes of the preceding sentence, in the  
25 case of a State that has a 2-year legislative ses-

1           sion, each year of the session is deemed to be  
 2           a separate regular session of the State legisla-  
 3           ture.

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

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

8           (A) COVERAGE.—

9           (i) IN GENERAL.—Section 1861(s)(2)  
 10 of the Social Security Act (42 U.S.C.  
 11 1395x(s)(2)) is amended—

12           (I) in subparagraph (GG), by  
 13 striking “and” at the end;

14           (II) in subparagraph (HH), by  
 15 striking the period at the end and in-  
 16 sserting “; and”; and

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

19           “(II) HIV prevention services (as defined in  
 20 subsection (lll));”.

21           (ii) DEFINITION.—Section 1861 of  
 22 the Social Security Act (42 U.S.C. 1395x)  
 23 is amended by adding at the end the fol-  
 24 lowing new subsection:

1 “(lll) HIV PREVENTION SERVICES.—The term ‘HIV  
2 prevention services’ means—

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

5 “(2) administrative fees for such drugs;

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

8 “(4) clinical follow up and monitoring, including  
9 any related services recommended in current United  
10 States Public Health Service clinical practice guide-  
11 lines, without limitation.”.

12 (B) ELIMINATION OF COINSURANCE.—Sec-  
13 tion 1833(a)(1) of the Social Security Act (42  
14 U.S.C. 1395l(a)(1)) is amended—

15 (i) by striking “and (DD)” and in-  
16 serting “(DD)”; and

17 (ii) by inserting before the semicolon  
18 at the end the following: “and (EE) with  
19 respect to HIV prevention services (as de-  
20 fined in section 1861(lll)), the amount paid  
21 shall be 100 percent of (i) except as pro-  
22 vided in clause (ii), the lesser of the actual  
23 charge for the service or the amount deter-  
24 mined under the fee schedule that applies  
25 to such services under this part, and (ii) in

1 the case of such services that are covered  
2 OPD services (as defined in subsection  
3 (t)(1)(B)), the amount determined under  
4 subsection (t)”.

5 (C) EXEMPTION FROM PART B DEDUCT-  
6 IBLE.—Section 1833(b) of the Social Security  
7 Act (42 U.S.C. 1395l(b)) is amended—

8 (i) in paragraph (11), by striking  
9 “and” at the end; and

10 (ii) in paragraph (12), by striking the  
11 period at the end and inserting “, and (13)  
12 such deductible shall not apply with re-  
13 spect to HIV prevention services (as de-  
14 fined in section 1861(lll)).”.

15 (D) EFFECTIVE DATE.—The amendments  
16 made by this paragraph shall apply to items  
17 and services furnished on or after January 1,  
18 2023.

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

22 (A) IN GENERAL.—Section 1860D–2(b) of  
23 the Social Security Act (42 U.S.C. 1395w–  
24 102(b)) is amended—

1 (i) in paragraph (1)(A), by striking  
 2 “The coverage” and inserting “Subject to  
 3 paragraph (8), the coverage”;

4 (ii) in paragraph (2)(A), by striking  
 5 “and (D)” and inserting “and (D) and  
 6 paragraph (8)”;

7 (iii) in paragraph (3)(A), by striking  
 8 “and (4)” and inserting “(4), and (8)”;

9 (iv) in paragraph (4)(A)(i), by strik-  
 10 ing “The coverage” and inserting “Subject  
 11 to paragraph (8), the coverage”; and

12 (v) by adding at the end the following  
 13 new paragraph:

14 “(8) ELIMINATION OF COST-SHARING FOR  
 15 DRUGS FOR THE PREVENTION OF HIV.—

16 “(A) IN GENERAL.—For plan year 2023  
 17 and each subsequent plan year, there shall be  
 18 no cost-sharing under this part (including  
 19 under section 1814D–14) for covered part D  
 20 drugs that are for the prevention of HIV.

21 “(B) COST-SHARING.—For purposes of  
 22 subparagraph (A), the elimination of cost-shar-  
 23 ing shall include the following:



1           “(i) NO APPLICATION OF DEDUCT-  
2           IBLE.—The waiver of the deductible under  
3           paragraph (1).

4           “(ii) NO APPLICATION OF COINSUR-  
5           ANCE.—The waiver of coinsurance under  
6           paragraph (2).

7           “(iii) NO APPLICATION OF INITIAL  
8           COVERAGE LIMIT.—The initial coverage  
9           limit under paragraph (3) shall not apply.

10           “(iv) NO COST-SHARING ABOVE AN-  
11           NUAL OUT-OF-POCKET THRESHOLD.—The  
12           waiver of cost-sharing under paragraph  
13           (4).”.

14           (B) CONFORMING AMENDMENTS TO COST-  
15           SHARING FOR LOW-INCOME INDIVIDUALS.—Sec-  
16           tion 1860D–14(a) of the Social Security Act  
17           (42 U.S.C. 1395w–114(a)) is amended—

18           (i) in paragraph (1), in the matter  
19           preceding subparagraph (A), by striking  
20           “*In the case*” and inserting “*Subject to*  
21           section 1860D–2(b)(8), *in the case*”; and

22           (ii) in paragraph (2), in the matter  
23           preceding subparagraph (A), by striking  
24           “*In the case*” and inserting “*Subject to*  
25           section 1860D–2(b)(8), *in the case*”.

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

3 (1) ELIMINATION OF MEDICATION COPAY-  
4 MENTS.—Section 1722A(a) of title 38, United  
5 States Code, is amended by adding at the end the  
6 following new paragraph:

7 “(5) Paragraph (1) does not apply to a medication  
8 for the prevention of HIV.”.

9 (2) ELIMINATION OF HOSPITAL CARE AND MED-  
10 ICAL SERVICES COPAYMENTS.—Section 1710 of such  
11 title is amended—

12 (A) in subsection (f)—

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

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

17 “(5) A veteran shall not be liable to the United States  
18 under this subsection for any amounts for laboratory and  
19 other diagnostic procedures associated with the use of any  
20 prescription drug approved by the Food and Drug Admin-  
21 istration for the prevention of HIV, administrative fees for  
22 such drugs, or for laboratory or other diagnostic proce-  
23 dures associated with the use of such drugs, or clinical  
24 follow up and monitoring, including any related services  
25 recommended in current United States Public Health

1 Service clinical practice guidelines, without limitation.”;  
2 and

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

5 “(C) Any prescription drug approved by the  
6 Food and Drug Administration for the prevention of  
7 HIV, administrative fees for such drugs, laboratory  
8 and other diagnostic procedures associated with the  
9 use of such drugs, and clinical follow up and moni-  
10 toring, including any related services recommended  
11 in current United States Public Health Service clin-  
12 ical practice guidelines, without limitation.”.

13 (3) INCLUSION AS PREVENTIVE HEALTH SERV-  
14 ICE.—Section 1701(9) of such title is amended—

15 (A) in subparagraph (K), by striking “;  
16 and” and inserting a semicolon;

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

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

21 “(L) any prescription drug approved by  
22 the Food and Drug Administration for the pre-  
23 vention of HIV, administrative fees for such  
24 drugs, laboratory and other diagnostic proce-  
25 dures associated with the use of such drugs,

1 and clinical follow up and monitoring, including  
2 any related services recommended in current  
3 United States Public Health Service clinical  
4 practice guidelines, without limitation; and”.

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

7 (1) IN GENERAL.—Chapter 55 of title 10,  
8 United States Code, is amended by inserting after  
9 section 1079c the following new section:

10 **“§ 1079d. Coverage of HIV prevention treatment**

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

15 “(b) HIV PREVENTION TREATMENT DESCRIBED.—  
16 HIV prevention treatment described in this subsection in-  
17 cludes any prescription drug approved by the Food and  
18 Drug Administration for the prevention of HIV, adminis-  
19 trative fees for such drugs, laboratory and other diagnostic  
20 procedures associated with the use of such drugs, and clin-  
21 ical follow up and monitoring, including any related serv-  
22 ices recommended in current United States Public Health  
23 Service clinical practice guidelines, without limitation.

24 “(c) NO COST-SHARING.—Notwithstanding section  
25 1075, 1075a, or 1074g(a)(6) of this title or any other pro-

1 vision of law, there is no cost-sharing requirement for HIV  
2 prevention treatment covered under this section.”.

3           (2) CLERICAL AMENDMENT.—The table of sec-  
4 tions at the beginning of such chapter is amended  
5 by inserting after the item relating to section 1079c  
6 the following new item:

“1079d. Coverage of HIV prevention treatment.”.

7           (h) INDIAN HEALTH SERVICE TESTING, MONI-  
8 TORING, AND PRESCRIPTION DRUGS FOR THE PREVEN-  
9 TION OF HIV.—The Indian Health Care Improvement Act  
10 is amended by inserting after section 223 (25 U.S.C.  
11 1621v) the following:

12 **“SEC. 224. TESTING, MONITORING, AND PRESCRIPTION**  
13 **DRUGS FOR THE PREVENTION OF HIV.**

14           “(a) IN GENERAL.—The Secretary, acting through  
15 the Service, Indian tribes, and tribal organizations, shall  
16 provide funding for any prescription drug approved by the  
17 Food and Drug Administration for the prevention of  
18 human immunodeficiency virus (commonly known as  
19 ‘HIV’), administrative fees for such a drug, laboratory and  
20 other diagnostic procedures associated with the use of  
21 such a drug, and clinical follow up and monitoring, includ-  
22 ing any related services recommended in current United  
23 States Public Health Service clinical practice guidelines,  
24 without limitation.

1       “(b) AUTHORIZATION OF APPROPRIATIONS.—There  
 2 are authorized to be appropriated such sums as may be  
 3 necessary to carry out this section.”.

4       (i) EFFECTIVE DATE.—The amendments made by  
 5 subsections (a), (b), (e), (f), (g), and (h) shall take effect  
 6 with respect to plan years beginning on or after January  
 7 1, 2023.

8 **SEC. 4. PROHIBITION ON DENIAL OF COVERAGE OR IN-**  
 9 **CREASE IN PREMIUMS OF LIFE, DISABILITY,**  
 10 **OR LONG-TERM CARE INSURANCE FOR INDI-**  
 11 **VIDUALS TAKING MEDICATION FOR THE PRE-**  
 12 **VENTION OF HIV ACQUISITION.**

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

15           (1) decline or limit coverage of a person under  
 16 any life insurance policy, disability insurance policy,  
 17 or long-term care insurance policy, on account of the  
 18 individual taking medication for the purpose of pre-  
 19 venting the acquisition of HIV;

20           (2) preclude an individual from taking medica-  
 21 tion for the purpose of preventing the acquisition of  
 22 HIV as a condition of receiving a life insurance pol-  
 23 icy, disability insurance policy, or long-term care in-  
 24 surance policy;

1           (3) consider whether an individual is taking  
2 medication for the purpose of preventing the acquisi-  
3 tion of HIV in determining the premium rate for  
4 coverage of such individual under a life insurance  
5 policy, disability insurance policy, or long-term care  
6 insurance policy; or

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

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

18       (c) DEFINITIONS.—In this section:

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

24           (2) LIFE INSURANCE POLICY.—The term “life  
25 insurance policy” means a contract under which an

1       entity promises to pay a designated beneficiary a  
2       sum of money upon the death of the insured.

3               (3) LONG-TERM CARE INSURANCE POLICY.—

4       The term “long-term care insurance policy” means  
5       a contract for which the only insurance protection  
6       provided under the contract is coverage of qualified  
7       long-term care services (as defined in section  
8       7702B(c) of the Internal Revenue Code of 1986).

9       **SEC. 5. PUBLIC EDUCATION CAMPAIGN.**

10       Part P of title III of the Public Health Service Act  
11       (42 U.S.C. 280g et seq.) is amended by adding at the end  
12       the following:

13       **“SEC. 399V-7. PRE-EXPOSURE PROPHYLAXIS AND POST-EX-**  
14                       **POSURE PROPHYLAXIS EDUCATION CAM-**  
15                       **PAIGNS.**

16       “(a) PUBLIC EDUCATION CAMPAIGN.—

17               “(1) IN GENERAL.—The Secretary, acting  
18       through the Director of the Centers for Disease  
19       Control and Prevention, in consultation with the Di-  
20       rector of the Office of Infectious Disease and HIV/  
21       AIDS Policy, shall establish a public health cam-  
22       paign for the purpose of educating the public on  
23       medication for the prevention of HIV acquisition.

24               “(2) REQUIREMENTS.—In carrying out this  
25       subsection, the Secretary shall ensure cultural com-



1       petency and efficacy within high-need communities  
2       in which PrEP or PEP are underutilized by devel-  
3       oping the campaign in collaboration with organiza-  
4       tions that are indigenous to communities that are  
5       overrepresented in the domestic HIV epidemic, in-  
6       cluding communities of color and the lesbian, gay,  
7       bisexual, transgender, and queer community. The  
8       Secretary shall ensure that the campaign is designed  
9       to increase awareness of the safety and effectiveness  
10      of PrEP and PEP, the recommended clinical prac-  
11      tices for providing PrEP-related and PEP-related  
12      clinical care, and the local availability of PrEP and  
13      PEP providers, and to counter stigma associated  
14      with the use of PrEP and PEP.

15           “(3) EVALUATION OF PROGRAM.—The Sec-  
16      retary shall develop measures to evaluate the effec-  
17      tiveness of activities conducted under this subsection  
18      that are aimed at reducing disparities in access to  
19      PrEP and PEP and supporting the local commu-  
20      nity. Such measures shall evaluate community out-  
21      reach activities, language services, workforce cultural  
22      competence, and other areas as determined by the  
23      Secretary.

24           “(b) PROVIDER EDUCATION CAMPAIGN.—

1           “(1) IN GENERAL.—The Secretary, acting  
2 through the Director of the Centers for Disease  
3 Control and Prevention and the Administration of  
4 the Health Resources Services Administration and  
5 the Office of Infectious Disease and HIV/AIDS Pol-  
6 icy, shall establish a provider campaign for the pur-  
7 pose of educating prescribers and other associated  
8 health professionals on medication for the prevention  
9 of HIV acquisition.

10           “(2) REQUIREMENTS.—In carrying out this  
11 subsection, the Secretary shall increase awareness  
12 and readiness among health care providers to offer  
13 PrEP or PEP, as appropriate, with a focus on areas  
14 of high-need communities in which PrEP or PEP is  
15 underutilized by developing an educational campaign  
16 with input from health care providers and organiza-  
17 tions that are indigenous to communities that are  
18 overrepresented in the domestic HIV epidemic, in-  
19 cluding communities of color and the lesbian, gay,  
20 bisexual, transgender, and queer community. The  
21 Secretary shall ensure that the campaign is designed  
22 to increase awareness of the safety and effectiveness  
23 of PrEP and PEP, the recommended clinical prac-  
24 tices for providing PrEP-related and PEP-related  
25 clinical care, cultural competency among PrEP and

1 PEP prescribers, and to counter stigma associated  
2 with the use of PrEP and PEP.

3 “(3) EVALUATION OF PROGRAM.—The Sec-  
4 retary shall develop measures to evaluate the effec-  
5 tiveness of activities conducted under this subsection  
6 that are aimed at increasing the number of health  
7 care professionals offering PrEP and PEP and re-  
8 ducing disparities in access to PrEP and PEP. Such  
9 measures shall evaluate availability of PrEP and  
10 PEP services, education and outreach activities, lan-  
11 guage services, workforce cultural competence, and  
12 other areas as determined by the Secretary.

13 “(c) DEFINITIONS.—In this section and section  
14 399V–8—

15 “(1) the term ‘PEP’ means any drug or com-  
16 bination of drugs approved by the Food and Drug  
17 Administration for preventing HIV infection after a  
18 sexual or other exposure associated with a high risk  
19 of HIV transmission; and

20 “(2) the term ‘PrEP’ means any drug approved  
21 by the Food and Drug Administration for the pur-  
22 pose of pre-exposure prophylaxis with respect to  
23 HIV.

24 “(d) AUTHORIZATION OF APPROPRIATIONS.—To  
25 carry out this section, there are authorized to be appro-

1 priated such sums as may be necessary for each of fiscal  
 2 years 2023 through 2028.”.

3 **SEC. 6. PATIENT CONFIDENTIALITY.**

4       The Secretary of Health and Human Services shall  
 5 amend the regulations promulgated under section 264(c)  
 6 of the Health Insurance Portability and Accountability  
 7 Act of 1996 (42 U.S.C. 1320d–2 note), as necessary, to  
 8 ensure that individuals are able to access the benefits de-  
 9 scribed in section 2713(a)(6) under a family plan without  
 10 any other individual enrolled in such family plan, including  
 11 a primary subscriber of or policyholder, being informed of  
 12 such use of such benefits.

13 **SEC. 7. PRE-EXPOSURE PROPHYLAXIS AND POST-EXPO-  
 14                                   SURE PROPHYLAXIS FUNDING.**

15       Part P of title III of the Public Health Service Act  
 16 (42 U.S.C. 280g et seq.), as amended by section 5, is fur-  
 17 ther amended by adding at the end the following:

18 **“SEC. 399V-8. PRE-EXPOSURE PROPHYLAXIS AND POST-EX-  
 19                                   POSURE PROPHYLAXIS FUNDING.**

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

1 ‘PrEP’) and post-exposure prophylaxis (referred to in this  
2 section as ‘PEP’) programs.

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

6 “(1) submit an application to the Secretary at  
7 such time, in such manner, and containing such in-  
8 formation as the Secretary may require, including a  
9 plan describing how any funds awarded will be used  
10 to increase access to PrEP for uninsured and under-  
11 insured individuals and reduce disparities in access  
12 to PrEP and PEP for uninsured and underinsured  
13 individuals and reduce disparities in access to PrEP  
14 and PEP; and

15 “(2) appoint a PrEP and PEP grant adminis-  
16 trator to manage the program.

17 “(c) DIRECTLY ELIGIBLE ENTITY.—For purposes of  
18 this section, the term ‘directly eligible entity’—

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

22 “(2) may include—

23 “(A) a Federally qualified health center  
24 (as defined in section 1861(aa)(4) of the Social  
25 Security Act (42 U.S.C. 1395x(aa)(4)));

1           “(B) a family planning grantee (other than  
2 States) funded under section 1001 of the Public  
3 Health Service Act (42 U.S.C. 300);

4           “(C) a rural health clinic (as defined in  
5 section 1861(aa)(2) of the Social Security Act  
6 (42 U.S.C. 1395x(aa)(2)));

7           “(D) a health facility operated by or pur-  
8 suant to a contract with the Indian Health  
9 Service;

10           “(E) a community-based organization, clin-  
11 ic, hospital, or other health facility that pro-  
12 vides services to individuals at risk for or living  
13 with HIV; and

14           “(F) a nonprofit private entity providing  
15 comprehensive primary care to populations at  
16 risk of HIV, including faith-based and commu-  
17 nity-based organizations.

18           “(d) AWARDS.—In determining whether to award a  
19 grant, and the grant amount for each grant awarded, the  
20 Secretary shall consider the grant application and the  
21 need for PrEP and PEP services in the area, the number  
22 of uninsured and underinsured individuals in the area, and  
23 how the State, territory, or Indian Tribe coordinates  
24 PrEP and PEP activities with the directly funded entity,

1 if the State, territory, or Indian Tribe applies for the  
2 funds.

3 “(e) USE OF FUNDS.—

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

8 “(2) ELIGIBLE PREP EXPENSES.—The Sec-  
9 retary shall publish a list of expenses that qualify as  
10 eligible PrEP and PEP expenses for purposes of this  
11 section, which shall include—

12 “(A) any prescription drug approved by  
13 the Food and Drug Administration for the pre-  
14 vention of HIV, administrative fees for such  
15 drugs, laboratory and other diagnostic proce-  
16 dures associated with the use of such drugs,  
17 and clinical follow up and monitoring, including  
18 any related services recommended in current  
19 United States Public Health Service clinical  
20 practice guidelines, without limitation;

21 “(B) outreach and public education activi-  
22 ties directed toward populations overrepresented  
23 in the domestic HIV epidemic that increase  
24 awareness about the existence of PrEP and  
25 PEP, provide education about access to and

1 health care coverage of PrEP and PEP, PrEP  
2 and PEP adherence programs, and counter  
3 stigma associated with the use of PrEP and  
4 PEP; and

5 “(C) outreach activities directed toward  
6 physicians and other providers that provide  
7 education about PrEP and PEP.

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

17 “(g) AUTHORIZATION OF APPROPRIATIONS.—To  
18 carry out this section, there are authorized to be appro-  
19 priated such sums as may be necessary for each of fiscal  
20 years 2023 through 2028.”.

21 **SEC. 8. CLARIFICATION.**

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



1 **SEC. 9. PRIVATE RIGHT OF ACTION.**

2 Any person aggrieved by a violation of this Act, in-  
3 cluding the amendments made by this Act, may commence  
4 a civil action in an appropriate United States District  
5 Court or other court of competent jurisdiction to obtain  
6 relief as allowed by law as either an individual or member  
7 of a class. If the plaintiff is the prevailing party in such  
8 an action, the court shall order the defendant to pay the  
9 costs and reasonable attorney fees of the plaintiff.

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