

116TH CONGRESS  
1ST SESSION

# H. R. 3815

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

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## IN THE HOUSE OF REPRESENTATIVES

JULY 17, 2019

Mr. SCHIFF (for himself, Mrs. WATSON COLEMAN, Ms. LEE of California, Mr. KHANNA, Ms. MUCARSEL-POWELL, Mr. RUSH, Mr. CRIST, Ms. BARRAGÁN, Ms. HAALAND, Mr. PAPPAS, Mr. MOULTON, Mr. COX of California, Mr. COHEN, and Ms. PRESSLEY) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Oversight and Reform, Veterans' Affairs, Ways and Means, Natural Resources, Armed Services, and Financial Services, 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.

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”.

1 **SEC. 2. FINDINGS.**

2 Congress finds as follows:

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

6 (2) In 2017, there were 38,281 new diagnoses  
7 of HIV in the United States.

8 (3) HIV disproportionately impacts gay and bi-  
9 sexual men, transgender women, and, in particular,  
10 people of color. For example, in 2017 approximately  
11 66 percent of new HIV diagnoses were among gay  
12 and bisexual men, 43 percent of new HIV diagnoses  
13 were among Black people, and 26 percent of new  
14 HIV diagnoses were among Latinx people. Recent  
15 studies suggest that transgender women are up to  
16 49 times more likely to be diagnosed with HIV than  
17 the general population. Members of communities at  
18 the intersections of these groups are most heavily  
19 impacted.

20 (4) Pre-exposure prophylaxis (referred to in this  
21 section as “PrEP”) is a daily antiretroviral medica-  
22 tion that helps prevent individuals from acquiring  
23 HIV. Daily PrEP use reduces the risk of getting  
24 HIV from sex by over 90 percent. It reduces the risk  
25 of getting HIV from injection drug use by over 70  
26 percent.

1           (5) Many individuals at risk of exposure to HIV  
2 do not use PrEP. Of the approximately 1,100,000  
3 people in the United States who could benefit from  
4 PrEP, only 7 percent, or 78,360 individuals, filled  
5 prescriptions for the drug in 2016.

6           (6) PrEP usage is inconsistent across racial  
7 and gender lines. In 2016, PrEP users were 68.7  
8 percent White, 11.2 percent Black, and 13.1 percent  
9 Latinx. However, individuals eligible for PrEP were  
10 26.3 percent White, 43.7 percent Black, and 24.7  
11 percent Latinx. Additionally, only 2.1 percent of  
12 women eligible for PrEP received a prescription in  
13 2016.

14           (7) There is currently only one version of PrEP  
15 approved by the Food and Drug Administration,  
16 marketed under the brand name of Truvada, which,  
17 in 2018, had a list price of over \$20,000 a year in  
18 the United States. A less expensive, generic version  
19 of PrEP is expected to be available in September  
20 2020, and other types of HIV prevention treat-  
21 ments, including oral pills, vaginal rings, and long-  
22 acting injectables, are currently in the research pipe-  
23 line.

24           (8) Section 2713 of the Public Health Service  
25 Act (42 U.S.C. 300gg-13) requires most private

1 health insurance plans to cover preventive services  
2 without cost sharing, including such services with a  
3 rating of “A” or “B” under recommendations of the  
4 United States Preventive Services Task Force. On  
5 June 11, 2019, the United States Preventive Serv-  
6 ices Task Force issued a final recommendation giv-  
7 ing an “A” grade for PrEP for individuals at high  
8 risk of HIV; non-grandfathered private health insur-  
9 ance plans will have to cover PrEP for such individ-  
10 uals without cost sharing by 2021.

11 (9) Despite such recommendation of the United  
12 States Preventive Services Task Force, access bar-  
13 riers to PrEP remain. Ancillary services necessary to  
14 maintain the PrEP regime, including subsequent  
15 provider visits, clinical testing, and other services,  
16 can remain a cost-burden on patients. Additionally,  
17 the new recommendations are not linked to coverage  
18 requirements for individuals with other types of in-  
19 surance, such as Medicare or Medicaid.

20 (10) Expanding access to cost-free PrEP and  
21 ancillary services for all individuals, including indi-  
22 viduals who do not have health insurance, is a crit-  
23 ical step towards eliminating HIV transmission.

1 **SEC. 3. COVERAGE OF HIV TESTING AND PREVENTION**  
2 **SERVICES.**

3 (a) PRIVATE INSURANCE.—

4 (1) IN GENERAL.—Section 2713(a) of the Pub-  
5 lic Health Service Act (42 U.S.C. 300gg–13(a)) is  
6 amended—

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

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

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

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

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

16 “(6) any prescription drug approved by the  
17 Food and Drug Administration for the prevention of  
18 HIV acquisition, laboratory and other diagnostic  
19 procedures associated with the use of such drugs,  
20 and clinical follow up and monitoring, including any  
21 related services recommended in current United  
22 States Public Health Service clinical practice guide-  
23 lines, without limitation.”.

24 (2) PROHIBITION ON PREAUTHORIZATION RE-  
25 QUIREMENTS.—Subpart II of part A of title XXVII  
26 of the Public Health Service Act (42 U.S.C. 300gg–

1 11 et seq.) is amended by adding at the end the fol-  
2 lowing:

3 **“SEC. 2729. PROHIBITION ON PREAUTHORIZATION RE-**  
4 **QUIREMENTS WITH RESPECT TO CERTAIN**  
5 **SERVICES.**

6 “A group health plan or a health insurance issuer of-  
7 fering group or individual health insurance coverage shall  
8 not impose any pre-authorization requirements with re-  
9 spect to coverage of the services described in section  
10 2713(a)(6).”.

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

15 “(c) Any health benefits plan offered under this chap-  
16 ter shall include benefits for, and may not impose any cost  
17 sharing requirements for, any prescription drug approved  
18 by the Food and Drug Administration for the prevention  
19 of HIV acquisition, laboratory and other diagnostic proce-  
20 dures associated with the use of such drugs, and clinical  
21 follow up and monitoring, including any related services  
22 recommended in current United States Public Health  
23 Service clinical practice guidelines, without limitation.”.

24 (c) **MEDICAID.**—

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

3           (A) in subsection (a)(4)—

4                 (i) by striking “and (D)” and insert-  
5 ing “(D)”; and

6                 (ii) by inserting “; and (E) HIV pre-  
7 vention services” before the semicolon; and

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

10           “(ff) HIV PREVENTION SERVICES.—For purposes of  
11 subsection (a)(4)(E), the term ‘HIV prevention services’  
12 means prescription drugs for the prevention of HIV acqui-  
13 sition, laboratory and other diagnostic procedures associ-  
14 ated with the use of such drugs, and clinical follow up  
15 and monitoring, including any related services rec-  
16 ommended in current United States Public Health Service  
17 clinical practice guidelines, without limitation.”.

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

21           (A) in section 1916, by inserting “HIV  
22 prevention services described in section  
23 1905(a)(4)(E),” after “section 1905(a)(4)(C),”  
24 each place it appears; and

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

3 “(xi) HIV prevention services de-  
4 scribed in section 1905(a)(4)(E).”.

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

8 (A) in the paragraph header, by inserting  
9 “AND HIV PREVENTION SERVICES” after “SUP-  
10 PLIES”; and

11 (B) by inserting “, and, for any individual  
12 described in section 1905(a)(4)(E), medical as-  
13 sistance for HIV prevention services in accord-  
14 ance with such section” before the period.

15 (d) CHIP.—

16 (1) IN GENERAL.—Section 2103(c) of the So-  
17 cial Security Act (42 U.S.C. 1397cc(c)), as amended  
18 by section 5022 of the SUPPORT for Patients and  
19 Communities Act (Public Law 115–271), is amended  
20 by adding at the end the following new paragraph:

21 “(10) HIV PREVENTION SERVICES.—The child  
22 health assistance provided to a targeted low-income  
23 child and the pregnancy-related assistance provided  
24 to a targeted low-income woman shall include cov-

1 erage of HIV prevention services (as defined in sec-  
2 tion 1905(ff)).”.

3 (2) NO COST SHARING.—Section 2103(e)(2) of  
4 the Social Security Act (42 U.S.C. 1397cc(e)(2)) is  
5 amended by inserting “, for HIV prevention services  
6 described in subsection (c)(10),” after “subsection  
7 (c)(1)(D)”.

8 (3) CONFORMING AMENDMENT.—Section  
9 2103(a) of the Social Security Act (42 U.S.C.  
10 1397cc(a)), as amended by section 5022 of the  
11 SUPPORT for Patients and Communities Act (Pub-  
12 lic Law 115–271), is amended in the matter pre-  
13 ceding paragraph (1) by striking “and (8)” and in-  
14 serting “(8), and (10)”.

15 (4) EFFECTIVE DATE.—

16 (A) IN GENERAL.—Subject to subpara-  
17 graph (A), the amendments made by subsection  
18 (c) and this subsection shall take effect on Jan-  
19 uary 1, 2021.

20 (B) DELAY PERMITTED IF STATE LEGISLA-  
21 TION REQUIRED.—In the case of a State plan  
22 approved under title XIX of the Social Security  
23 Act which the Secretary of Health and Human  
24 Services determines requires State legislation  
25 (other than legislation appropriating funds) in

1 order for the plan to meet the additional re-  
2 quirements imposed by this section, the State  
3 plan shall not be regarded as failing to comply  
4 with the requirements of such title solely on the  
5 basis of the failure of the plan to meet such ad-  
6 ditional requirements before the 1st day of the  
7 1st calendar quarter beginning after the close  
8 of the 1st regular session of the State legisla-  
9 ture that ends after the 1-year period beginning  
10 with the date of the enactment of this section.  
11 For purposes of the preceding sentence, in the  
12 case of a State that has a 2-year legislative ses-  
13 sion, each year of the session is deemed to be  
14 a separate regular session of the State legisla-  
15 ture.

16 (e) WAIVER OF COST SHARING UNDER MEDICARE.—

17 (1) PART B.—

18 (A) INCLUSION AS A PREVENTIVE SERV-  
19 ICE.—Section 1861(ddd)(3) of the Social Secu-  
20 rity Act (42 U.S.C. 1395x(ddd)(3)) is amended  
21 by adding at the end the following new sub-  
22 paragraph:

23 “(D) Drugs or biologicals approved by the  
24 Food and Drug Administration for the preven-  
25 tion of HIV acquisition, laboratory and other

1 diagnostic procedures associated with the use of  
2 such drugs, and clinical follow up and moni-  
3 toring, including any related services rec-  
4 ommended in current United States Public  
5 Health Service clinical practice guidelines, with-  
6 out limitation.”.

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

10 (i) by striking “and (CC)” and insert-  
11 ing “(CC)”; and

12 (ii) by inserting before the semicolon  
13 at the end the following:“ , and (DD) with  
14 respect to preventive services described in  
15 subparagraph (D) of section 1861(ddd)(3),  
16 the amount paid shall be 100 percent of (i)  
17 except as provided in clause (ii), the lesser  
18 of the actual charge for the service or the  
19 amount determined under the fee schedule  
20 that applies to such treatment under this  
21 part, and (ii) in the case of such services  
22 that are covered OPD services (as defined  
23 in subsection (t)(1)(B)), the amount deter-  
24 mined under subsection (t)”.

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

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

6 (ii) in paragraph (10), by striking the  
7 period at the end and inserting “, and (11)  
8 such deductible shall not apply with re-  
9 spect to preventive services described in  
10 subparagraph (D) of section  
11 1861(ddd)(3).”.

12 (D) EFFECTIVE DATE.—The amendments  
13 made by this paragraph shall apply to items  
14 and services furnished on or after January 1,  
15 2021.

16 (2) PART D.—

17 (A) IN GENERAL.—Section 1860D–2(b) of  
18 the Social Security Act (42 U.S.C. 1395w–  
19 102(b)) is amended—

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

23 (ii) in paragraph (2)(A), by striking  
24 “and (D)” and inserting “and (D) and  
25 paragraph (8)”;

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

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

6 (v) by adding at the end the following  
7 new paragraph:

8 “(8) LIMITATIONS ON COST-SHARING FOR  
9 DRUGS FOR THE PREVENTION OF HIV ACQUI-  
10 SITION.—

11 “(A) IN GENERAL.—For plan year 2021  
12 and each subsequent plan year, there shall be  
13 no cost-sharing under this part (including  
14 under section 1814D–14) for covered part D  
15 drugs that are for the prevention of HIV acqui-  
16 sition.

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

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

23 “(ii) NO APPLICATION OF COINSUR-  
24 ANCE.—There waiver of coinsurance under  
25 paragraph (2).

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

4           “(iv) NO COST SHARING ABOVE AN-  
5           NUAL OUT-OF-POCKET THRESHOLD.—The  
6           waiver of cost sharing under paragraph  
7           (4).”.

8           (B) CONFORMING AMENDMENTS TO COST  
9           SHARING FOR LOW-INCOME INDIVIDUALS.—Sec-  
10          tion 1860D–14(a) of the Social Security Act  
11          (42 U.S.C. 1395w–114(a)) is amended—

12           (i) in paragraph (1), in the matter  
13           preceding subparagraph (A), by striking  
14           “*In the case*” and inserting “*Subject to*  
15           section 1860D–2(b)(8), *in the case*”; and

16           (ii) in paragraph (2), in the matter  
17           preceding subparagraph (A), by striking  
18           “*In the case*” and inserting “*Subject to*  
19           section 1860D–2(b)(8), *in the case*”.

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

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

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

3 (2) ELIMINATION OF HOSPITAL CARE AND MED-  
4 ICAL SERVICES COPAYMENTS.—Section 1710 of such  
5 title is amended—

6 (A) in subsection (f)—

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

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

11 “(5) A veteran shall not be liable to the United States  
12 under this subsection for any amounts for laboratory and  
13 other diagnostic procedures associated with the use of any  
14 prescription drug approved by the Food and Drug Admin-  
15 istration for the prevention of HIV acquisition, or for lab-  
16 oratory or other diagnostic procedures associated with the  
17 use of such drugs, or clinical follow up and monitoring,  
18 including any related services recommended in current  
19 United States Public Health Service clinical practice  
20 guidelines, without limitation.”; and

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

23 “(C) Any prescription drug approved by the  
24 Food and Drug Administration for the prevention of  
25 HIV acquisition, laboratory and other diagnostic

1 procedures associated with the use of such drugs,  
2 and clinical follow up and monitoring, including any  
3 related services recommended in current United  
4 States Public Health Service clinical practice guide-  
5 lines, without limitation.”.

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

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

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

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

14 “(L) any prescription drug approved by  
15 the Food and Drug Administration for the pre-  
16 vention of HIV acquisition, laboratory and  
17 other diagnostic procedures associated with the  
18 use of such drugs, and clinical follow up and  
19 monitoring, including any related services rec-  
20 ommended in current United States Public  
21 Health Service clinical practice guidelines, with-  
22 out limitation; and”.

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

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

4   **“§ 1079d. Coverage of HIV prevention treatment**

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

9           “(b) HIV PREVENTION TREATMENT DESCRIBED.—  
10          HIV prevention treatment described in this subsection in-  
11          cludes any prescription drug approved by the Food and  
12          Drug Administration for the prevention of HIV acquisi-  
13          tion, laboratory and other diagnostic procedures associ-  
14          ated with the use of such drugs, and clinical follow up  
15          and monitoring, including any related services rec-  
16          ommended in current United States Public Health Service  
17          clinical practice guidelines, without limitation.

18          “(c) NO COST-SHARING.—Notwithstanding section  
19          1075, 1075a, or 1074g(a)(6) of this title or any other pro-  
20          vision of law, there is no cost-sharing requirement for HIV  
21          prevention treatment covered under this section.”.

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

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

1 (h) INDIAN HEALTH SERVICE TESTING, MONI-  
2 TORING, AND PRESCRIPTION DRUGS FOR THE PREVEN-  
3 TION OF HIV ACQUISITION.—The Indian Health Care Im-  
4 provement Act is amended by inserting after section 223  
5 (25 U.S.C. 1621v) the following:

6 **“SEC. 224. TESTING, MONITORING, AND PRESCRIPTION**  
7 **DRUGS FOR THE PREVENTION OF HIV ACQUI-**  
8 **SITION.**

9 “(a) IN GENERAL.—The Secretary, acting through  
10 the Service, Indian tribes, and tribal organizations, shall  
11 provide funding for any prescription drug approved by the  
12 Food and Drug Administration for the prevention of HIV  
13 acquisition, laboratory and other diagnostic procedures as-  
14 sociated with the use of such drugs, and clinical follow  
15 up and monitoring, including any related services rec-  
16 ommended in current United States Public Health Service  
17 clinical practice guidelines, without limitation.

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

21 (i) EFFECTIVE DATE.—The amendments made by  
22 subsections (a), (b), (e), (f), (g), and (h) shall take effect  
23 with respect to plan years beginning on or after January  
24 1, 2021.

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 a person under  
9 any life insurance policy, disability insurance policy,  
10 or long-term care insurance policy, on account of the  
11 individual taking medication for the purpose of pre-  
12 venting 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-7. PRE-EXPOSURE PROPHYLAXIS PUBLIC EDU-**  
6 **CATION CAMPAIGN.**

7 “(a) IN GENERAL.—The Secretary, acting through  
8 the Director of the Centers for Disease Control and Pre-  
9 vention, shall establish a public health campaign for the  
10 purpose of educating the public on medication for the pre-  
11 vention of HIV acquisition.

12 “(b) REQUIREMENTS.—In carrying out this section,  
13 the Secretary shall ensure cultural competency and effi-  
14 cacy within high-need communities in which PrEP is un-  
15 derutilized by developing the campaign in collaboration  
16 with organizations that are indigenous to communities  
17 that are overrepresented in the domestic HIV epidemic,  
18 including communities of color and the lesbian, gay, bisex-  
19 ual, transgender, and queer community. The Secretary  
20 shall ensure that the campaign is designed to increase  
21 awareness of the safety and effectiveness of PrEP, the rec-  
22 ommended clinical practices for providing PrEP-related  
23 clinical care, and the local availability of PrEP providers,  
24 and to counter stigma associated with the use of PrEP.

25 “(c) EVALUATION OF PROGRAM.—The Secretary  
26 shall develop measures to evaluate the effectiveness of ac-

1 tivities conducted under this section that are aimed at re-  
2 ducing disparities in access to PrEP and supporting the  
3 local community. Such measures shall evaluate community  
4 outreach activities, language services, workforce cultural  
5 competence, and other areas as determined by the Sec-  
6 retary.

7 “(d) PREP.—In this section, the term ‘PrEP’ means  
8 any drug approved by the Food and Drug Administration  
9 for the purpose of pre-exposure prophylaxis with respect  
10 to HIV.

11 “(e) AUTHORIZATION OF APPROPRIATIONS.—There  
12 are authorized to be appropriated such sums as may be  
13 necessary for each of fiscal years 2021 through 2026.”.

14 **SEC. 6. PATIENT CONFIDENTIALITY.**

15 The Secretary of Health and Human Services shall  
16 amend the regulations promulgated under section 264(c)  
17 of the Health Insurance Portability and Accountability  
18 Act of 1996 (42 U.S.C. 1320d–2 note), as necessary, to  
19 ensure that individuals are able to access the benefits de-  
20 scribed in section 2713(a)(6) under a family plan without  
21 any other individual enrolled in such family plan, including  
22 a primary subscriber of or policyholder, being informed of  
23 such use of such benefits.

1 **SEC. 7. PRE-EXPOSURE PROPHYLAXIS FUNDING.**

2 (a) IN GENERAL.—Not later than 1 year after the  
3 date of enactment of this Act, the Secretary of Health and  
4 Human Services (in this Act referred to as the “Sec-  
5 retary”) shall establish a program that provides grants to  
6 States, territories, and Indian Tribes for the establishment  
7 and support of pre-exposure prophylaxis (referred to in  
8 this section as “PrEP”) programs, or establishes a pro-  
9 gram for providing Federal funding directly to eligible en-  
10 tities within a State, territory, or Indian Tribal territory,  
11 in the case of a State, territory, or Indian Tribe that does  
12 not apply for such a grant.

13 (b) GRANT PROGRAM.—

14 (1) APPLICATIONS.—To be eligible to receive a  
15 grant under subsection (a), a State, territory, or In-  
16 dian Tribe shall—

17 (A) submit an application to the Secretary  
18 at such time, in such manner, and containing  
19 such information as the Secretary may require,  
20 including a description of how any funds award-  
21 ed will be used and a plan describing how any  
22 funds awarded will be used to increase access to  
23 PrEP for uninsured individuals and reduce dis-  
24 parities in access to PrEP; and

25 (B) appoint a PrEP grant administrator to  
26 manage the program.

1           (2) USE OF FUNDS.—Any State, Territory of  
2 the United States, or Indian tribe that is awarded  
3 funds under subsection (a) shall use such funds for  
4 eligible PrEP expenses.

5 (c) FEDERAL PROGRAM.—

6           (1) IN GENERAL.—In the case of a State, terri-  
7 tory, or Indian Tribe that does not submit an appli-  
8 cation under subsection (b), the Secretary shall pro-  
9 vide funding to any of the following, within the ap-  
10 plicable State, territory, or Indian Tribal territory:

11           (A) Federally qualified health centers (as  
12 defined in section 1861(aa)(4) of the Social Se-  
13 curity Act (42 U.S.C. 1395x(aa)(4))).

14           (B) Family planning grantees (other than  
15 States) funded under section 1001 of the Public  
16 Health Service Act (42 U.S.C. 300).

17           (C) Rural health clinics (as defined in sec-  
18 tion 1861(aa)(2) of the Social Security Act (42  
19 U.S.C. 1395x(aa)(2))).

20           (D) Health facilities operated by or pursu-  
21 ant to a contract with the Indian Health Serv-  
22 ice.

23           (E) Community-based organizations, clin-  
24 ics, hospitals, and other health facilities that

1 provide services to individuals at risk for or liv-  
2 ing with HIV.

3 (F) Nonprofit private entities providing  
4 comprehensive primary care to populations at  
5 risk of HIV, including faith-based and commu-  
6 nity-based organizations.

7 (2) USE OF FUNDS.—Any entity receiving fund-  
8 ing under paragraph (1) shall use such funds for eli-  
9 gible PrEP expenses.

10 (d) ELIGIBLE PREP EXPENSES.—

11 (1) IN GENERAL.—The Secretary shall publish  
12 a list of expenses that qualify as eligible PrEP ex-  
13 penses for purposes of this section.

14 (2) INCLUSIONS.—Such list shall include—

15 (A) any prescription drug approved by the  
16 Food and Drug Administration for the preven-  
17 tion of HIV acquisition, laboratory and other  
18 diagnostic procedures associated with the use of  
19 such drugs, and clinical follow up and moni-  
20 toring, including any related services rec-  
21 ommended in current United States Public  
22 Health Service clinical practice guidelines, with-  
23 out limitation;

24 (B) outreach and public education activi-  
25 ties directed toward populations overrepresented

1 in the domestic HIV epidemic that increase  
2 awareness about the existence of PrEP, provide  
3 education about access to and health care cov-  
4 erage of PrEP, and counter stigma associated  
5 with the use of PrEP; and

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

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

17 (f) AUTHORIZATION OF APPROPRIATIONS.—There  
18 are authorized to be appropriated to carry out this section  
19 \$60,000,000 for each of the first 5 fiscal years beginning  
20 after the date of the enactment of this section.

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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