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117TH CONGRESS
2D SESSION

H. R. 8546

To amend title XXVII of the Public Health Service Act to require out-of-network coverage for qualified individuals participating in approved clinical trials, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 27, 2022

Ms. SPEIER (for herself and Mr. MCCAUL) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, 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 amend title XXVII of the Public Health Service Act to require out-of-network coverage for qualified individuals participating in approved clinical trials, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Clinical Trial Coverage Act of 2022''.

SEC. 2. AMENDMENTS RELATING TO COVERAGE IN INDIVIDUAL AND GROUP MARKET AND UNDER MEDICARE PROGRAM FOR QUALIFIED INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.

(a) INDIVIDUAL AND GROUP MARKET.—

(1) REQUIRING OUT-OF-NETWORK COVERAGE OF ROUTINE PATIENT COSTS.—Section 2709 of the Public Health Service Act (42 U.S.C. 300gg–8) is amended—

(A) in subsection (a)(1)—

(i) in subparagraph (B)—

(I) by striking ''subject to subsection (c),''; and

(II) by striking ''and'' at the end;

(ii) by redesignating subparagraph (C) as subparagraph (D); and

(iii) by inserting after subparagraph (B) the following new subparagraph:

''(C) in the case of routine patient costs for items or services furnished to the individual in connection with participation in the trial by a nonparticipating provider—

''(i) shall impose the same cost-sharing requirement (expressed as a copayment amount or coinsurance rate) that would

apply if such item or service was furnished by a participating provider; and

''(ii) shall pay to such nonparticipating provider the amount by which the recognized amount for such item or service exceeds the cost-sharing amount for such item or service (as determined in accordance with clause (i)); and'';

(B) by striking subsection (c);

(C) by redesignating subsections (d) through (h) as subsections (c) through (g), respectively; and

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

''(h) OTHER DEFINITIONS.—For purposes of this section, the terms 'nonparticipating provider', 'participating provider', and 'recognized amount' have the meaning given such terms in section 2799A–1(a)(3).''.

(2) AMENDMENT RELATING TO DEFINITION OF ROUTINE PATIENT COSTS.—Section 2709(a)(2)(A) of the Public Health Service Act (42 U.S.C. 300gg–8(a)(2)(A)) is amended—

(A) by striking ''include all items and services'' and inserting ''include—

''(i) all items and services''; and

(B) by striking the period at the end and inserting ''; and

''(ii) consultation and referral services relating to approved clinical trials furnished to qualified individuals.''.

(3) AMENDMENT RELATING TO DEFINITION OF APPROVED CLINICAL TRIAL.—Section 2709(c)(1)(A) of the Public Health Service Act (42 U.S.C. 300gg–8(c)(1)(A)), as redesignated by paragraph (1), is amended by adding at the end the following new clause:

''(viii) The Patient-Centered Outcomes Research Institute.''.

(4) TECHNICAL AND CONFORMING AMENDMENTS.—Section 2709 of the Public Health Service Act (42 U.S.C. 300gg–8), as amended by the preceding paragraphs, is further amended—

(A) in subsection (a)—

(i) in paragraph (1)(A), by inserting before ''clinical trial referred to in subsection (b)(2)'' the following: ''approved'';

(ii) in paragraph (2)(A), by striking ''a clinical trial'' and inserting ''an approved clinical trial'';

(iii) in paragraph (3)—

(I) by striking ''IN-NETWORK PROVIDERS'' and inserting ''PARTICIPATING PROVIDERS''; and

(II) by striking ''a clinical trial'' and inserting ''an approved clinical trial''; and

(iv) in paragraph (4), by striking ''OUT-OF-NETWORK'' and inserting ''NON-PARTICIPATING PROVIDERS'';

(B) in subsection (b)(2)(A), by striking ''participating health care provider'' and inserting ''participating provider''; and

(C) in subsection (d)(1)(A)(v), by striking ''cooperative group'' and inserting ''A cooperative group''.

(5) EFFECTIVE DATE.—The amendments made by this subsection shall apply with respect to plan years beginning on or after January 1, 2024.

(b) MEDICARE.—

(1) AMENDMENT RELATING TO DEFINITION OF ROUTINE COSTS OF CARE.—Section 1862(m) of the Social Security Act (42 U.S.C. 1395y(m)) is amended—

(A) in paragraph (1), by inserting before ''as defined by the Secretary'' the following: ''subject to paragraph (3),''; and

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

''(3) ROUTINE COSTS OF CARE.—In defining 'routine costs of care' for purposes of paragraph (1), the Secretary shall define such term in a manner that provides for coverage of consultation and referral services furnished to an individual in the course of participation in a category A clinical trial.''.

(2) AMENDMENT RELATING TO DEFINITION OF CATEGORY A CLINICAL TRIAL.—Section 1862(m)(2) of the Social Security Act (42 U.S.C. 1395y(m)(2)) is amended by inserting after ''means a trial'' the following: ''(including a trial funded by the Patient-Centered Outcomes Research Institute)''.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply with respect to items and services furnished on or after January 1, 2024.

SEC. 3. VOLUNTARY NETWORK OF PARTICIPATING PROVIDERS.

(a) IN GENERAL.—The Secretary of Health and Human Services may issue a request for information from group health plans, and health insurance issuers offering

group or individual health coverage to identify an interest in establishing a voluntary network of participating providers administered by a third-party administrator (as designated by the Secretary) for purposes of complying with coverage requirements for clinical trials under section 2709 of the Public Health Service Act (42 U.S.C. 300gg–8).

(b) DEFINITIONS.—In this section:

(1) GROUP HEALTH PLAN.—The term ''group health plan'' has the meaning given such term in section 607(1) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1167(1)).

(2) HEALTH INSURANCE ISSUER.—The term ''health insurance issuer'' has the meaning given such term in section 2791(b)(1) of the Public Health Service Act (42 U.S.C. 300gg–91(b)(1)).

(3) PARTICIPATING PROVIDER.—The term ''participating provider'' has the meaning given such term in section 2799A–1(a)(3)(G)(ii) of the Public Health Service Act (42 U.S.C. 300gg–111(a)(3)(G)(ii)).

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