AMENDMENT TO
RULES COMMITTEE PRINT 117–54
OFFERED BY MS. SPEIER OF CALIFORNIA

At the end of division E, add the following:

SEC. 5806. AMENDMENTS RELATING TO COVERAGE IN INDIVIDUAL AND GROUP MARKET FOR QUALIFIED INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.

(a) 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—

(1) in subsection (a)(1)—

(A) in subparagraph (B)—

(i) by striking “subject to subsection (c),”; and

(ii) by striking “and” at the end;

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

(C) 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 accord-
ance with clause (i)); and”;

(2) by striking subsection (e);

(3) by redesignating subsections (d) and (e) as
subsections (e) and (d), respectively;

(4) by inserting after subsection (d), as so re-
designated, the following new subsection:

“(e) CIVIL MONETARY PENALTIES.—

“(1) HEALTH INSURANCE ISSUER.—If a health
insurance issuer charges a qualified individual an
amount for routine patient costs for items and serv-
ices furnished in connection with participation in a
trial that is greater than the amount such qualified
individual would otherwise incur in cost-sharing for
such routine costs for items and services, such issuer shall be subject, in addition to any other penalties that may be prescribed by law, to a civil monetary penalty of not more than $5,000 for each such item or service.

“(2) NONPARTICIPATING PROVIDER.—If a nonparticipating provider charges a qualified individual an amount for routine patient costs for items and services furnished in connection with participation in a trial that is greater than the recognized amount, such provider shall be subject, in addition to any other penalties that may be prescribed by law, to a civil monetary penalty of not more than $5,000 for each such item or service.”; and

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

“(i) 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).”.

(b) 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—
(1) by striking “include all items and services” and inserting “include—

“(i) all items and services”; and

(2) by striking the period at the end and inserting “; and

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

(e) 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.”.

(d) 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—

(1) in subsection (a)—

(A) in paragraph (1)(A), by inserting before “clinical trial referred to in subsection (b)(2)” the following: “approved”;}
(B) in paragraph (2)(A), by striking “a clinical trial” and inserting “an approved clinical trial”;

(C) 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

(D) in paragraph (4), by striking “OUT-OF-NETWORK” and inserting “NONPARTICIPATING PROVIDERS”;

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

(3) in subsection (d)(1)(A)(v), by striking “cooperative group” and inserting “A cooperative group”.

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

SEC. 5807. 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)).