

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

At the end of division E, add the following:

1 **SEC. 5806. AMENDMENTS RELATING TO COVERAGE IN INDI-**
2 **VIDUAL AND GROUP MARKET FOR QUALI-**
3 **FIED INDIVIDUALS PARTICIPATING IN AP-**
4 **PROVED CLINICAL TRIALS.**

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

8 (1) in subsection (a)(1)—

9 (A) in subparagraph (B)—

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

12 (ii) by striking “and” at the end;

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

15 (C) by inserting after subparagraph (B)
16 the following new subparagraph:

17 “(C) in the case of routine patient costs
18 for items or services furnished to the individual

1 in connection with participation in the trial by
2 a nonparticipating provider—

3 “(i) shall impose the same cost-shar-
4 ing requirement (expressed as a copayment
5 amount or coinsurance rate) that would
6 apply if such item or service was furnished
7 by a participating provider; and

8 “(ii) shall pay to such nonpartici-
9 pating provider the amount by which the
10 recognized amount for such item or service
11 exceeds the cost-sharing amount for such
12 item or service (as determined in accord-
13 ance with clause (i)); and”;

14 (2) by striking subsection (c);

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

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

19 “(e) CIVIL MONETARY PENALTIES.—

20 “(1) HEALTH INSURANCE ISSUER.—If a health
21 insurance issuer charges a qualified individual an
22 amount for routine patient costs for items and serv-
23 ices furnished in connection with participation in a
24 trial that is greater than the amount such qualified
25 individual would otherwise incur in cost-sharing for

1 such routine costs for items and services, such issuer
2 shall be subject, in addition to any other penalties
3 that may be prescribed by law, to a civil monetary
4 penalty of not more than \$5,000 for each such item
5 or service.

6 “(2) NONPARTICIPATING PROVIDER.— If a
7 nonparticipating provider charges a qualified indi-
8 vidual an amount for routine patient costs for items
9 and services furnished in connection with participa-
10 tion in a trial that is greater than the recognized
11 amount, such provider shall be subject, in addition
12 to any other penalties that may be prescribed by
13 law, to a civil monetary penalty of not more than
14 \$5,000 for each such item or service.”; and

15 (5) by adding at the end the following new sub-
16 section:

17 “(i) OTHER DEFINITIONS.—For purposes of this sec-
18 tion, the terms ‘nonparticipating provider’, ‘participating
19 provider’, and ‘recognized amount’ have the meaning given
20 such terms in section 2799A–1(a)(3).”.

21 (b) AMENDMENT RELATING TO DEFINITION OF ROU-
22 TINE PATIENT COSTS.—Section 2709(a)(2)(A) of the
23 Public Health Service Act (42 U.S.C. 300gg–8(a)(2)(A))
24 is amended—

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

3 “(i) all items and services”; and

4 (2) by striking the period at the end and insert-
5 ing “; and

6 “(ii) consultation and referral services
7 relating to approved clinical trials fur-
8 nished to qualified individuals.”.

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

14 “(viii) The Patient-Centered Out-
15 comes Research Institute.”.

16 (d) TECHNICAL AND CONFORMING AMENDMENTS.—
17 Section 2709 of the Public Health Service Act (42 U.S.C.
18 300gg–8), as amended by the preceding paragraphs, is
19 further amended—

20 (1) in subsection (a)—

21 (A) in paragraph (1)(A), by inserting be-
22 fore “clinical trial referred to in subsection
23 (b)(2)” the following: “approved”;

1 (B) in paragraph (2)(A), by striking “a
2 clinical trial” and inserting “an approved clin-
3 ical trial”;

4 (C) in paragraph (3)—

5 (i) by striking “IN-NETWORK PRO-
6 VIDERS” and inserting “PARTICIPATING
7 PROVIDERS”; and

8 (ii) by striking “a clinical trial” and
9 inserting “an approved clinical trial”; and

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

13 (2) in subsection (b)(2)(A), by striking “partici-
14 pating health care provider” and inserting “partici-
15 pating provider”; and

16 (3) in subsection (d)(1)(A)(v), by striking “co-
17 operative group” and inserting “A cooperative
18 group”.

19 (e) EFFECTIVE DATE.—The amendments made by
20 this section shall apply with respect to plan years begin-
21 ning on or after January 1, 2024.

22 **SEC. 5807. VOLUNTARY NETWORK OF PARTICIPATING PRO-**
23 **VIDERS.**

24 (a) IN GENERAL.—The Secretary of Health and
25 Human Services may issue a request for information from

1 group health plans, and health insurance issuers offering
2 group or individual health coverage to identify an interest
3 in establishing a voluntary network of participating pro-
4 viders administered by a third-party administrator (as
5 designated by the Secretary) for purposes of complying
6 with coverage requirements for clinical trials under section
7 2709 of the Public Health Service Act (42 U.S.C. 300gg-
8 8).

9 (b) DEFINITIONS.—In this section:

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

14 (2) HEALTH INSURANCE ISSUER.—The term
15 “health insurance issuer” has the meaning given
16 such term in section 2791(b)(1) of the Public Health
17 Service Act (42 U.S.C. 300gg-91(b)(1)).

18 (3) PARTICIPATING PROVIDER.—The term
19 “participating provider” has the meaning given such
20 term in section 2799A-1(a)(3)(G)(ii) of the Public
21 Health Service Act (42 U.S.C.300gg-
22 111(a)(3)(G)(ii)).

