

115TH CONGRESS
2D SESSION

H. R. 6836

To amend title XIX of the Social Security Act to promote access to life-saving therapies for Medicaid enrollees by ensuring coverage of routine patient costs for items and services furnished in connection with participation in qualifying clinical trials, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 17, 2018

Mr. BILIRAKIS (for himself and Mr. BEN RAY LUJÁN of New Mexico) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend title XIX of the Social Security Act to promote access to life-saving therapies for Medicaid enrollees by ensuring coverage of routine patient costs for items and services furnished in connection with participation in qualifying clinical trials, and for other purposes.

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 “Covering Life-saving
5 Investigations Needed in Cancer and Other Life-threat-
6 ening Conditions through Timely use of Resources for
7 Easy and Affordable Treatment from Medicaid for Enroll-

ees in Need Today Act” or the “CLINICAL TREAT-
MENT Act”.

**SEC. 2. PROMOTING ACCESS TO LIFE-SAVING THERAPIES
FOR MEDICAID ENROLLEES BY ENSURING
COVERAGE OF ROUTINE PATIENT COSTS FOR
ITEMS AND SERVICES FURNISHED IN CON-
NECTION WITH PARTICIPATION IN QUALI-
FYING CLINICAL TRIALS.**

(a) IN GENERAL.—Section 1905 of the Social Secu-
rity Act (42 U.S.C. 1396d) is amended—

(1) in subsection (a)—

(A) in paragraph (28), by striking “and”
at the end;

(B) by redesignating paragraph (29) as
paragraph (30); and

(C) by inserting after paragraph (28) the
following new paragraph:

“(29) subject to subsection (ee), routine patient
costs for items and services furnished in connection
with participation in a qualifying clinical trial (as
defined in such subsection); and”; and

(2) by adding at the end the following new sub-
section:

“(ee)(1) ROUTINE PATIENT COSTS.—For purposes
of subsection (a)(29), with respect to a State and an indi-

1 individual enrolled under the State plan (or a waiver of such
2 plan) who participates in a qualifying clinical trial, routine
3 patient costs—

4 “(A) include any item or service provided to the
5 individual under the qualifying clinical trial, includ-
6 ing any item or service provided to prevent, diag-
7 nose, or treat complications resulting from such par-
8 ticipation, to the extent that the provision of such an
9 item or service to the individual outside the course
10 of such participation would otherwise be covered
11 under the State plan (or waiver); and

12 “(B) does not include—

13 “(i) the investigational item or service that
14 is the subject of the qualifying clinical trial; or

15 “(ii) an item or service that is provided to
16 the individual solely to satisfy data collection
17 and analysis needs for the qualifying clinical
18 trial and is not used in the direct clinical man-
19 agement of the individual.

20 “(2) QUALIFYING CLINICAL TRIAL DEFINED.—

21 “(A) IN GENERAL.—For purposes of this sub-
22 section and subsection (a)(29), the term ‘qualifying
23 clinical trial’ means a phase I, phase II, phase III,
24 or phase IV clinical trial that is conducted in rela-
25 tion to the prevention, detection, or treatment of

1 cancer or any other life-threatening condition and is
2 described in any of the following clauses:

3 “(i) The study or investigation is approved
4 or funded (which may include funding through
5 in-kind contributions) by one or more of the fol-
6 lowing:

7 “(I) The National Institutes of
8 Health.

9 “(II) The Centers for Disease Control
10 and Prevention.

11 “(III) The Agency for Healthcare Re-
12 search and Quality.

13 “(IV) The Centers for Medicare &
14 Medicaid Services.

15 “(V) A cooperative group or center of
16 any of the entities described in subclauses
17 (I) through (IV) or the Department of De-
18 fense or the Department of Veterans Af-
19 fairs.

20 “(VI) A qualified non-governmental
21 research entity identified in the guidelines
22 issued by the National Institutes of Health
23 for center support grants.

1 “(VII) Any of the following if the con-
2 ditions described in subparagraph (B) are
3 met:

4 “(aa) The Department of Vet-
5 erans Affairs.

6 “(bb) The Department of De-
7 fense.

8 “(cc) The Department of Energy.

9 “(ii) The clinical trial is conducted under
10 an investigational new drug application re-
11 viewed by the Food and Drug Administration.

12 “(iii) The clinical trial is a drug trial that
13 is exempt from having such an investigational
14 new drug application.

15 “(B) CONDITIONS.—For purposes of subpara-
16 graph (A)(i)(VII), the conditions described in this
17 subparagraph, with respect to a clinical trial ap-
18 proved or funded by an entity described in such sub-
19 paragraph (A)(i)(VII), are that the clinical trial has
20 been reviewed and approved through a system of
21 peer review that the Secretary determines—

22 “(i) to be comparable to the system of peer
23 review of studies and investigations used by the
24 National Institutes of Health; and

1 “(ii) assures unbiased review of the highest
2 scientific standards by qualified individuals with
3 no interest in the outcome of the review.

4 “(3) LIFE-THREATENING CONDITION DEFINED.—
5 For purposes of this subsection, the term ‘life-threatening
6 condition’ means any disease or condition from which the
7 likelihood of death is probable unless the course of the dis-
8 ease or condition is interrupted.

9 “(4) COVERAGE DETERMINATION REQUIREMENTS.—
10 A determination with respect to coverage under subsection
11 (a)(29) for an individual participating in a qualifying clin-
12 ical trial—

13 “(A) shall be expedited and completed within
14 48 hours;

15 “(B) shall be made without limitation on the
16 geographic location or network affiliation of the
17 health care provider treating such individual or the
18 principal investigator of the qualifying clinical trial;

19 “(C) shall be based solely on attestation regard-
20 ing the appropriateness of the qualifying clinical
21 trial by the health care provider and principal inves-
22 tigator described in subparagraph (B), which shall
23 be made using a streamlined, uniform form devel-
24 oped for national use by the Secretary and that in-
25 cludes the option to reference information regarding

1 the qualifying clinical trial that is publicly available
 2 on a website maintained by the Secretary, such as
 3 clinicaltrials.gov (or a successor website); and

4 “(D) shall not require submission of the proto-
 5 cols of the qualifying clinical trial, or any other doc-
 6 umentation that may be proprietary or determined
 7 by the Secretary to be burdensome to provide.”.

8 (b) REQUIRING MANDATORY COVERAGE UNDER
 9 STATE PLAN.—Section 1902(a)(10)(A) of such Act is
 10 amended, in the matter preceding clause (i), by striking
 11 “and (28)” and inserting “(28), and (29)”.

12 (c) ENSURING ACCESS FOR MEDICAID EXPANSION
 13 POPULATION.—Section 1937(b)(5) of such Act is amend-
 14 ed by inserting before the period at the end the following:
 15 “, and beginning January 1, 2020, coverage of routine pa-
 16 tient costs for items and services furnished in connection
 17 with participation in a qualifying clinical trial (as defined
 18 in section 1905(ee))”.

19 (d) EFFECTIVE DATE.—

20 (1) IN GENERAL.—The amendments made by
 21 this section shall take effect with respect to items
 22 and services furnished on or after the date of the en-
 23 actment of this Act.

24 (2) EXCEPTION FOR STATE LEGISLATION.—In
 25 the case of a State plan under title XIX of the So-

1 cial Security Act (42 U.S.C. 1396 et seq.) that the
2 Secretary of Health and Human Services determines
3 requires State legislation in order for the respective
4 plan to meet any requirement imposed by amend-
5 ments made by this section, the respective plan shall
6 not be regarded as failing to comply with the re-
7 quirements of such title solely on the basis of its
8 failure to meet such an additional requirement be-
9 fore the first day of the first calendar quarter begin-
10 ning after the close of the first regular session of the
11 State legislature that begins after the date of the en-
12 actment of this Act. For purposes of the previous
13 sentence, in the case of a State that has a 2-year
14 legislative session, each year of the session shall be
15 considered to be a separate regular session of the
16 State legislature.

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