

116TH CONGRESS
2D SESSION

S. 4742

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 SENATE OF THE UNITED STATES

SEPTEMBER 29, 2020

Mr. BURR (for himself and Mr. CARDIN) introduced the following bill; which was read twice and referred to the Committee on Finance

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 (29), by striking “and”
at the end;

(B) by redesignating paragraph (30) as
paragraph (31); and

(C) by inserting after paragraph (29) the
following new paragraph:

“(30) subject to subsection (gg), 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:

“(gg)(1) ROUTINE PATIENT COSTS.—For purposes
of subsection (a)(30), 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—

16 “(I) provided to the individual solely
 17 to satisfy data collection and analysis
 18 needs for the qualifying clinical trial and is
 19 not used in the direct clinical management
 20 of the individual; and

21 “(II) not otherwise covered under the
 22 State plan or waiver.

23 “(2) QUALIFYING CLINICAL TRIAL DEFINED.—

24 “(A) IN GENERAL.—For purposes of this sub-
 25 section and subsection (a)(30), the term ‘qualifying

1 clinical trial' means a clinical trial (in any clinical
2 phase of development) that is conducted in relation
3 to the prevention, detection, or treatment of any se-
4 rious or life-threatening disease or condition and is
5 described in any of the following clauses:

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

10 “(I) The National Institutes of
11 Health.

12 “(II) The Centers for Disease Control
13 and Prevention.

14 “(III) The Agency for Healthcare Re-
15 search and Quality.

16 “(IV) The Centers for Medicare &
17 Medicaid Services.

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

23 “(VI) A qualified non-governmental
24 research entity identified in the guidelines

1 issued by the National Institutes of Health
2 for center support grants.

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

6 “(aa) The Department of Vet-
7 erans Affairs.

8 “(bb) The Department of De-
9 fense.

10 “(cc) The Department of Energy.

11 “(ii) The clinical trial is conducted pursu-
12 ant to an investigational new drug exemption
13 under section 505(i) of the Federal Food, Drug,
14 and Cosmetic Act (21 U.S.C. 355(i)) or an ex-
15 emption for a biological product undergoing in-
16 vestigation under section 351(a)(3) of the Pub-
17 lic Health Service Act (42 U.S.C. 262(a)(3)).

18 “(iii) The clinical trial is a drug trial that
19 is exempt from having such an investigational
20 new drug application.

21 “(B) CONDITIONS.—For purposes of subpara-
22 graph (A)(i)(VII), the conditions described in this
23 subparagraph, with respect to a clinical trial ap-
24 proved or funded by an entity described in such sub-
25 paragraph (A)(i)(VII), are that the clinical trial has

1 been reviewed and approved through a system of
2 peer review that the Secretary determines—

3 “(i) to be comparable to the system of peer
4 review of studies and investigations used by the
5 National Institutes of Health; and

6 “(ii) assures unbiased review of the highest
7 scientific standards by qualified individuals with
8 no interest in the outcome of the review.

9 “(3) COVERAGE DETERMINATION REQUIREMENTS.—
10 A determination with respect to coverage under subsection
11 (a)(30) for an individual participating in a qualifying clin-
12 ical trial—

13 “(A) shall be expedited and completed within
14 24 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 on attestation regarding the
20 appropriateness of the qualifying clinical trial by the
21 health care provider and principal investigator de-
22 scribed in subparagraph (B), which shall be made
23 using a streamlined, uniform form developed for na-
24 tional use by the Secretary and that includes the op-
25 tion to reference information regarding the quali-

1 fying clinical trial that is publicly available on a
 2 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 (29)” and inserting “(29), and (30)”.

12 (c) INCLUSION IN BENCHMARK COVERAGE.—Section
 13 1937(b)(5) of such Act is amended by inserting before the
 14 period at the end the following: “, and beginning January
 15 1, 2020, coverage of routine patient costs for items and
 16 services furnished in connection with participation in a
 17 qualifying clinical trial (as defined in section 1905(gg))”.

18 (d) EFFECTIVE DATE.—

19 (1) IN GENERAL.—The amendments made by
 20 this section shall apply with respect to items and
 21 services furnished on or after the date of the enact-
 22 ment of this Act.

23 (2) EXCEPTION FOR STATE LEGISLATION.—In
 24 the case of a State plan under title XIX of the So-
 25 cial Security Act (42 U.S.C. 1396 et seq.) that the

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

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