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

JANUARY 30, 2019

Mr. LUJÁN (for himself and Mr. BILIRAKIS) 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 Representatives of the United States of America in Congress assembled,

2 SECTION 1. SHORT TITLE.

3 This Act may be cited as the “Covering Life-saving Investigations Needed in Cancer and Other Life-threatening Conditions through Timely use of Resources for 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 (ff), 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:

“(ff)(1) ROUTINE PATIENT COSTS.—For purposes of subsection (a)(30), with respect to a State and an indi-
vidual enrolled under the State plan (or a waiver of such plan) who participates in a qualifying clinical trial, routine patient costs—

“(A) include any item or service provided to the individual under the qualifying clinical trial, including any item or service provided to prevent, diagnose, or treat complications resulting from such participation, to the extent that the provision of such an item or service to the individual outside the course of such participation would otherwise be covered under the State plan (or waiver); and

“(B) does not include—

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

“(ii) an item or service that is provided to the individual solely to satisfy data collection and analysis needs for the qualifying clinical trial and is not used in the direct clinical management of the individual.

“(2) QUALIFYING CLINICAL TRIAL DEFINED.—

“(A) IN GENERAL.—For purposes of this subsection and subsection (a)(30), the term ‘qualifying clinical trial’ means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of
cancer or any other life-threatening condition and is
described in any of the following clauses:

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

“(I) The National Institutes of
Health.

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

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

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

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

“(VI) A qualified non-governmental
research entity identified in the guidelines
issued by the National Institutes of Health
for center support grants.
“(VII) Any of the following if the conditions described in subparagraph (B) are met:

“(aa) The Department of Veterans Affairs.

“(bb) The Department of Defense.

“(cc) The Department of Energy.

“(ii) The clinical trial is conducted under an investigational new drug application reviewed by the Food and Drug Administration.

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

“(B) CONDITIONS.—For purposes of subparagraph (A)(i)(VII), the conditions described in this subparagraph, with respect to a clinical trial approved or funded by an entity described in such subparagraph (A)(i)(VII), are that the clinical trial has been reviewed and approved through a system of peer review that the Secretary determines—

“(i) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health; and
“(ii) assures unbiased review of the highest
scientific standards by qualified individuals with
no interest in the outcome of the review.

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

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

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

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

“(C) shall be based solely on attestation regard-
ing the appropriateness of the qualifying clinical
trial by the health care provider and principal invest-
igator described in subparagraph (B), which shall
be made using a streamlined, uniform form devel-
oped for national use by the Secretary and that in-
cludes the option to reference information regarding
the qualifying clinical trial that is publicly available
on a website maintained by the Secretary, such as
clinicaltrials.gov (or a successor website); and
“(D) shall not require submission of the proto-
cols of the qualifying clinical trial, or any other doc-
umentation that may be proprietary or determined
by the Secretary to be burdensome to provide.”.

(b) Requiring Mandatory Coverage Under
State Plan.—Section 1902(a)(10)(A) of such Act is
amended, in the matter preceding clause (i), by striking
“and (29)” and inserting “(29), and (30)”.

(c) Ensuring Access for Medicaid Expansion
Population.—Section 1937(b)(5) of such Act is amend-
ed by inserting before the period at the end the following:
“, and beginning January 1, 2020, coverage of routine pa-
tient costs for items and services furnished in connection
with participation in a qualifying clinical trial (as defined
in section 1905(ff))”.

(d) Effective Date.—
(1) In general.—The amendments made by
this section shall apply with respect to items and
services furnished on or after the date of the enact-
ment of this Act.

(2) Exception for state legislation.—In
the case of a State plan under title XIX of the So-
Secretary of Health and Human Services determines requires State legislation in order for the respective plan to meet any requirement imposed by amendments made by this section, the respective plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet such an additional requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of the enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of the session shall be considered to be a separate regular session of the State legislature.