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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

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 TREATMENT 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 CONNECTION WITH PARTICIPATION IN QUALIFYING CLINICAL TRIALS.

(a) IN GENERAL.—Section 1905 of the Social Security 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 subsection:

''(gg)(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—

''(I) 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; and

''(II) not otherwise covered under the State plan or waiver.

''(2) QUALIFYING CLINICAL TRIAL DEFINED.—

''(A) IN GENERAL.—For purposes of this subsection and subsection (a)(30), the term 'qualifying

clinical trial' means a clinical trial (in any clinical phase of development) that is conducted in relation to the prevention, detection, or treatment of any serious or life-threatening disease or 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 following:

"(I) The National Institutes of Health.

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

"(III) The Agency for Healthcare Research 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 Defense or the Department of Veterans Affairs.

"(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 pursuant to an investigational new drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) or an exemption for a biological product undergoing investigation under section 351(a)(3) of the Public Health Service Act (42 U.S.C. 262(a)(3)).

''(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) COVERAGE DETERMINATION REQUIREMENTS.—A determination with respect to coverage under subsection (a)(30) for an individual participating in a qualifying clinical trial—

"(A) shall be expedited and completed within 24 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 on attestation regarding the appropriateness of the qualifying clinical trial by the health care provider and principal investigator described in subparagraph (B), which shall be made using a streamlined, uniform form developed for national use by the Secretary and that includes the option to reference information regarding the quali-

fying 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 protocols of the qualifying clinical trial, or any other documentation 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) INCLUSION IN BENCHMARK COVERAGE.—Section 1937(b)(5) of such Act is amended by inserting before the period at the end the following: '', and beginning January 1, 2020, coverage of routine patient costs for items and services furnished in connection with participation in a qualifying clinical trial (as defined in section 1905(gg))''.

(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 enactment of this Act.

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

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.

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