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116TH CONGRESS
2D SESSION

H. R. 9006

To amend title XIX of the Social Security Act to provide for coverage under the Medicaid program under such title of routine patient costs associated with participation in certain clinical trials, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 17, 2020

Mr. GARCÍA of Illinois introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend title XIX of the Social Security Act to provide for coverage under the Medicaid program under such title of routine patient costs associated with participation in certain 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 ''Inclusive Clinical Trials Act''.

SEC. 2. PARTICIPATION BY MEDICAID BENEFICIARIES IN APPROVED CLINICAL TRIALS.

(a) IN GENERAL.—Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) is amended by adding at the end the following new section:

"SEC. 1947. PARTICIPATION IN AN APPROVED CLINICAL TRIAL.

''(a) COVERAGE OF ROUTINE PATIENT COSTS ASSOCIATED WITH APPROVED CLINICAL TRIALS.—

''(1) INCLUSION.—Subject to paragraph (2), routine patient costs shall include all items and services consistent with the medical assistance provided under the State plan that would otherwise be provided to the individual under such State plan if such individual was not enrolled in an approved clinical trial, including any items or services related to the prevention, detection, and treatment of any medical complications that arise as a result of participation in the approved clinical trial.

''(2) EXCLUSION.—For purposes of paragraph (1), routine patient costs does not include—

''(A) the investigational item, device, or service itself;

''(B) items and services that are provided solely to satisfy data collection and analysis

needs and that are not used in the direct clinical management of the patient; or

''(C) a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

''(3) INFORMATION CONCERNING CLINICAL TRIALS.—

''(A) IN GENERAL.—Subject to subparagraph (B), the Secretary, in consultation with relevant stakeholders, shall develop a single standardized electronic form for use by the individual or the referring health care provider to submit to the State agency administering the State plan in order to verify that the clinical trial meets the conditions established for an approved clinical trial (as defined in subsection (c)).

''(B) EXCLUDED INFORMATION.—For purposes of subparagraph (A) or any such request by the State agency for information regarding a clinical trial, an individual or referring health care provider shall not be required to submit—

''(i) the clinical protocol document for the clinical trial; or

"(ii) subject to subparagraph (C), any additional information other than such information as is required pursuant to the form described in subparagraph (A).

"(C) OPTIONAL INFORMATION.—For purposes of subparagraphs (A) and (B)(ii), the form may include a requirement that the referring health care provider attest that the individual is eligible to participate in the clinical trial pursuant to the trial protocol and that individual participation in such trial would be appropriate.

"(D) REVIEW OF INFORMATION.—

"(i) IN GENERAL.—A State plan under this title shall establish a process for timely review by the State agency of the form and information submitted pursuant to subparagraph (A) and, not later than 48 hours after receipt of such form, confirmation that the information provided in such form satisfies the requirements established under such subparagraph, with such process to include establishment and operation of a 24-hour, toll-free telephone num-

ber and email address to provide for expedited communication.

''(ii) FAILURE TO RESPOND.—If an individual or the referring health care provider does not receive a response or request for additional information from the State agency following the 48-hour period described in clause (i), the information provided in the form may be presumed to satisfy the requirements established under this paragraph.

''(b) ENCOURAGEMENT OF PARTICIPATION IN APPROVED CLINICAL TRIALS.—

''(1) REASONABLY ACCESSIBLE PROVIDER.—For purposes of participation in an approved clinical trial by an individual eligible for medical assistance under this title, the State agency administering the State plan shall make reasonable efforts to ensure that the individual is provided with access to a provider who is—

''(A) participating in the approved clinical trial;

''(B) located not more than 25 miles from the residence of the individual (or, if no such

provider is available, as close as possible to the residence of the individual); and

''(C) a participating provider under the State plan or has been deemed to be a participating provider under the State plan for purposes of providing medical assistance to the individual during their participation in the approved clinical trial.

''(2) INFORMATIONAL MATERIALS.—The State agency administering the plan approved under this title shall develop informational materials and programs to encourage participating providers to make appropriate referrals to physicians and other appropriate health care professionals who can provide individuals with access to approved clinical trials.

''(c) DEFINITION OF APPROVED CLINICAL TRIAL.—The term 'approved clinical trial' has the same meaning as provided under subsection (d) of section 2709 of the Public Health Service Act that relates to coverage for individuals participating in approved clinical trials.''.

(b) CONFORMING AMENDMENT.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)) is amended—

(1) by striking ''and'' at the end of paragraph (84);

(2) by striking the period at the end of paragraph (85) and inserting ''; and''; and

(3) by inserting after paragraph (85) the following new paragraph:

''(86) provide that participation in an approved clinical trial and coverage of routine patient costs associated with such trial for an individual eligible for medical assistance under this title is conducted in accordance with the requirements under section 1947.''.

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by this section shall apply to calendar quarters beginning on or after October 1, 2020.

(2) DELAY PERMITTED FOR STATE PLAN AMENDMENT.—In the case of a State plan for medical assistance under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirements imposed by the amendments made by this section, the State plan shall not be regarded as failing to comply with the requirements of

such title solely on the basis of its failure to meet these additional requirements 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 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 such session shall be deemed to be a separate regular session of the State legislature.

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