

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.

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## 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.

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 “Inclusive Clinical  
5       Trials Act”.

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

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

6 **“SEC. 1947. PARTICIPATION IN AN APPROVED CLINICAL**  
7 **TRIAL.**

8 “(a) COVERAGE OF ROUTINE PATIENT COSTS ASSO-  
9 CIATED WITH APPROVED CLINICAL TRIALS.—

10 “(1) INCLUSION.—Subject to paragraph (2),  
11 routine patient costs shall include all items and serv-  
12 ices consistent with the medical assistance provided  
13 under the State plan that would otherwise be pro-  
14 vided to the individual under such State plan if such  
15 individual was not enrolled in an approved clinical  
16 trial, including any items or services related to the  
17 prevention, detection, and treatment of any medical  
18 complications that arise as a result of participation  
19 in the approved clinical trial.

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

22 “(A) the investigational item, device, or  
23 service itself;

24 “(B) items and services that are provided  
25 solely to satisfy data collection and analysis

1 needs and that are not used in the direct clin-  
2 ical management of the patient; or

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

6 “(3) INFORMATION CONCERNING CLINICAL  
7 TRIALS.—

8 “(A) IN GENERAL.—Subject to subpara-  
9 graph (B), the Secretary, in consultation with  
10 relevant stakeholders, shall develop a single  
11 standardized electronic form for use by the indi-  
12 vidual or the referring health care provider to  
13 submit to the State agency administering the  
14 State plan in order to verify that the clinical  
15 trial meets the conditions established for an ap-  
16 proved clinical trial (as defined in subsection  
17 (c)).

18 “(B) EXCLUDED INFORMATION.—For pur-  
19 poses of subparagraph (A) or any such request  
20 by the State agency for information regarding  
21 a clinical trial, an individual or referring health  
22 care provider shall not be required to submit—

23 “(i) the clinical protocol document for  
24 the clinical trial; or

1 “(ii) subject to subparagraph (C), any  
2 additional information other than such in-  
3 formation as is required pursuant to the  
4 form described in subparagraph (A).

5 “(C) OPTIONAL INFORMATION.—For pur-  
6 poses of subparagraphs (A) and (B)(ii), the  
7 form may include a requirement that the refer-  
8 ring health care provider attest that the indi-  
9 vidual is eligible to participate in the clinical  
10 trial pursuant to the trial protocol and that in-  
11 dividual participation in such trial would be ap-  
12 propriate.

13 “(D) REVIEW OF INFORMATION.—

14 “(i) IN GENERAL.—A State plan  
15 under this title shall establish a process for  
16 timely review by the State agency of the  
17 form and information submitted pursuant  
18 to subparagraph (A) and, not later than  
19 48 hours after receipt of such form, con-  
20 firmation that the information provided in  
21 such form satisfies the requirements estab-  
22 lished under such subparagraph, with such  
23 process to include establishment and oper-  
24 ation of a 24-hour, toll-free telephone num-

1           ber and email address to provide for expedited communication.

2  
3           “(ii) FAILURE TO RESPOND.—If an  
4           individual or the referring health care provider does not receive a response or request for additional information from the  
5           State agency following the 48-hour period  
6           described in clause (i), the information  
7           provided in the form may be presumed to  
8           satisfy the requirements established under  
9           this paragraph.

10  
11           “(b) ENCOURAGEMENT OF PARTICIPATION IN APPROVED CLINICAL TRIALS.—

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

18           “(A) participating in the approved clinical  
19           trial;

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

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

3 “(C) a participating provider under the  
4 State plan or has been deemed to be a partici-  
5 pating provider under the State plan for pur-  
6 poses of providing medical assistance to the in-  
7 dividual during their participation in the ap-  
8 proved clinical trial.

9 “(2) INFORMATIONAL MATERIALS.—The State  
10 agency administering the plan approved under this  
11 title shall develop informational materials and pro-  
12 grams to encourage participating providers to make  
13 appropriate referrals to physicians and other appro-  
14 priate health care professionals who can provide in-  
15 dividuals with access to approved clinical trials.

16 “(c) DEFINITION OF APPROVED CLINICAL TRIAL.—  
17 The term ‘approved clinical trial’ has the same meaning  
18 as provided under subsection (d) of section 2709 of the  
19 Public Health Service Act that relates to coverage for indi-  
20 viduals participating in approved clinical trials.”.

21 (b) CONFORMING AMENDMENT.—Section 1902(a) of  
22 the Social Security Act (42 U.S.C. 1396a(a)) is amend-  
23 ed—

24 (1) by striking “and” at the end of paragraph  
25 (84);

1           (2) by striking the period at the end of para-  
2           graph (85) and inserting “; and”; and

3           (3) by inserting after paragraph (85) the fol-  
4           lowing new paragraph:

5           “(86) provide that participation in an approved  
6           clinical trial and coverage of routine patient costs  
7           associated with such trial for an individual eligible  
8           for medical assistance under this title is conducted  
9           in accordance with the requirements under section  
10          1947.”.

11       (c) EFFECTIVE DATE.—

12           (1) IN GENERAL.—Except as provided in para-  
13           graph (2), the amendments made by this section  
14           shall apply to calendar quarters beginning on or  
15           after October 1, 2020.

16           (2) DELAY PERMITTED FOR STATE PLAN  
17           AMENDMENT.—In the case of a State plan for med-  
18           ical assistance under title XIX of the Social Security  
19           Act (42 U.S.C. 1396 et seq.) which the Secretary of  
20           Health and Human Services determines requires  
21           State legislation (other than legislation appro-  
22           priating funds) in order for the plan to meet the ad-  
23           ditional requirements imposed by the amendments  
24           made by this section, the State plan shall not be re-  
25           garded as failing to comply with the requirements of

1       such title solely on the basis of its failure to meet  
2       these additional requirements before the first day of  
3       the first calendar quarter beginning after the close  
4       of the first regular session of the State legislature  
5       that begins after the date of enactment of this Act.  
6       For purposes of the previous sentence, in the case  
7       of a State that has a 2-year legislative session, each  
8       year of such session shall be deemed to be a sepa-  
9       rate regular session of the State legislature.

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