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114TH CONGRESS
2D SESSION

H. R. 4714

To amend title XVIII of the Social Security Act to ensure Medicare coverage of certain costs associated with FDA-approved clinical trials.

IN THE HOUSE OF REPRESENTATIVES

MARCH 3, 2016

Mr. YOUNG of Indiana (for himself and Mr. PETERS) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend title XVIII of the Social Security Act to ensure Medicare coverage of certain costs associated with FDA-approved clinical trials.

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 ''Removing Barriers to Clinical Research Act of 2016''.

SEC. 2. MEDICARE COVERAGE OF CERTAIN COSTS ASSOCIATED WITH FDA-APPROVED CLINICAL TRIALS.

(a) IN GENERAL.—Section 1862(m) of the Social Security Act (42 U.S.C. 13957(m)) is amended—

(1) in the subsection heading—

(A) by striking ''ROUTINE'' and inserting ''CERTAIN''; and

(B) by striking ''CATEGORY A'' and inserting ''MEDICAL'';

(2) in paragraph (1)—

(A) by striking ''category A'' and inserting ''category A or category B''; and

(B) by striking ''payment for coverage of routine'' and inserting the following: ''payment for coverage of—

''(A) in the case of category A and category B clinical trials, routine'';

(C) in subparagraph (A), as added by subparagraph (B) of this subsection, by striking the period at the end and inserting ''; or''; and

(D) by adding at the end the following new subparagraph:

''(B) in the case of category B clinical trials, the costs of the devices under investigation.''; and

(3) by adding at the end the following new paragraphs:

''(3) CATEGORY B CLINICAL TRIAL.—For purposes of paragraph (1), a 'category B clinical trial' means a trial of a medical device if—

''(A) the trial is of a nonexperiemental/investigational (category B) medical device (as defined in regulations under section 405.201(b) of title 42, Code of Federal Regulations (as in effect as of January 1, 2015)); and

''(B) the trial meets criteria established by the Secretary to ensure that the trial conforms to appropriate scientific and ethical standards.

''(4) AUTOMATIC QUALIFICATION OF CERTAIN TRIALS.—A trial of a medical device shall be deemed to be meet the definition of a category A or category B clinical trial under paragraph (2) or (3), respectively, as the case may be, if the trial is conducted under the investigational use exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)).''.

(b) CONFORMING AMENDMENT.—Paragraph (3) of section 731(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (42 U.S.C. 1395y note) is repealed.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to costs incurred on or after the date that is 90 days after the date of the enactment of this Act.

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