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115TH CONGRESS
1ST SESSION

H. R. 2503

To amend title XVIII of the Social Security Act to promote health care technology innovation and access to medical devices and services for which patients choose to self-pay under the Medicare program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 17, 2017

Mr. PAULSEN (for himself, Mr. KIND, and Mrs. MIMI WALTERS of California) 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 promote health care technology innovation and access to medical devices and services for which patients choose to self-pay under the Medicare program, 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 "Accelerating Innovation in Medicine Act of 2017" or the "AIM Act of 2017".

SEC. 2. FINDINGS.

Congress finds as follows:

(1) Innovation in health care technology is necessary to improve health outcomes and depends in part on the ability of medical technology developers, including scientists, physicians, engineers, and patient advocates, to introduce medical devices into the marketplace.

(2) Even after meeting requirements for marketing set by the Food and Drug Administration, there may be uncertainties about patient access through government health care programs, causing significant delays in bringing innovative medical devices to patients or causing medical technology developers to abandon potential health care solutions.

(3) Patients covered by the Medicare program are often willing to enter into self-pay arrangements with physicians and other providers to purchase items or services, yet under current laws restricting such freedom of choice, the self-pay arrangements may be associated with regulatory impediments or a risk of civil penalties.

(4) Enabling health care technology manufacturers to designate products to be directly available to self-pay patients and excluded from government health program payments at an early stage of prod-

uct development will promote innovation and result in increased patient access to desired products and services, save taxpayer dollars, and reduce administrative burdens on physicians and the government.

(5) Enabling health care technology manufacturers to designate their devices as available to self-pay patients would permit a window of time during which additional data may be obtained on outcomes, comparative clinical effectiveness or other data elements for possible future coverage by the Medicare program.

SEC. 3. ESTABLISHMENT OF MANUFACTURER OPT-OUT PROGRAM FOR MEDICAL DEVICES.

(a) IN GENERAL.—Section 1862 of the Social Security Act (42 U.S.C. 1395y) is amended adding at the end the following new subsection:

''(p) ESTABLISHMENT OF ACCELERATING INNOVATION IN MEDICINE (AIM) LIST OF MEDICAL DEVICES VOLUNTARILY EXCLUDED FROM COVERAGE.—

''(1) IN GENERAL.—Not later than 90 days after the date of the enactment of this subsection, the Secretary shall develop and maintain a listing (in this section referred to as the 'AIM list') of medical devices for which, because of their inclusion in such listing, no insurance benefit and no payment

may be made for such a device (or for any items or services related to furnishing such device) under this title either directly or on a capitated basis such that no claim for payment may be submitted under this title for such a device (or for any items or services related to furnishing such device) and an individual who consents to receive such a device is responsible for payment for the device (and for any items and services related to furnishing such device).

''(2) PROCEDURES FOR INCLUSION IN AIM LIST.—

''(A) REQUIREMENT FOR WRITTEN CONSENT OF MANUFACTURER.—No medical device may be included in the AIM list without the written consent of the manufacturer of the device.

''(B) SUBMISSION PROCESS.—A manufacturer seeking to have a medical device included in the AIM list shall submit to the Secretary a request for inclusion of the device in the AIM list. In the case of such a device for which—

''(i) there is a request for approval or clearance for marketing and sale of the device by the Food and Drug Administration pursuant to authority granted by the Fed-

eral Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), including pursuant to section 510(k) or 515(c) of such Act (21 U.S.C. 360(k), 360e(c)), the request for inclusion of the device in the AIM list may not be submitted earlier than the date of the request for such approval or clearance and no later than the first business day of the month beginning at least 30 days after the date of such approval or clearance; or

''(ii) the device is exempt from such approval and clearance requirements, the request may be submitted at a time that is not later than the first business day of the month beginning at least 30 days after the date of the first sale of the device by its manufacturer.

''(3) LISTING PERIODS; REMOVAL FROM LIST.—

''(A) 3-YEAR LISTING PERIODS.—A medical device included in the AIM list shall be initially listed for a period of 3 years and shall remain so listed for subsequent 3-year periods subject to subparagraphs (B) and (C).

''(B) REMOVAL AT REQUEST OF MANUFACTURER.—At any time a device of a manufac-

turer included in the AIM list shall be removed from the AIM list upon the written request of the manufacturer. Subject to subparagraph (C), such a device of a manufacturer may not be removed from the AIM list except upon the written request of the manufacturer.

''(C) PROVISION OF DATA ON CLINICAL STUDIES AS A CONDITION FOR CONTINUED LISTING.—As a condition for the continued inclusion of the device of a manufacturer in the AIM list for a subsequent 3-year listing period under subparagraph (A), the manufacturer shall provide the Secretary with published or publicly available data on clinical studies completed for the device at the end of the previous 3-year listing period. If the Secretary determines that a manufacturer of a device has materially failed to provide such data for the device, the Secretary may remove the device from the AIM list or not renew the listing for the device or both.

''(4) MEDICAL DEVICE DEFINED.—In this subsection, the term 'medical device' has the meaning given the term 'device' in section 201(h) of the Fed-

eral Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

''(5) POSTING OF LISTED DEVICES ON WEBSITE.—The Secretary shall post on a public website of the Department of Health and Human Services or other publicly accessible manner a list of the medical devices included in the AIM list and shall provide for updating the website on a real-time basis (but no less frequently than monthly) to reflect changes in the medical devices in the AIM list.

''(6) REGULATIONS NOT REQUIRED.—Nothing in this subsection shall be construed as requiring the Secretary to promulgate regulations to carry out this subsection.

''(7) REQUIREMENT FOR INFORMED CONSENT IN ORDER FOR PROVIDER TO CHARGE FOR DEVICE.—If a physician or other entity furnishes a medical device included in the AIM list to an individual under this title and failed to obtain, before furnishing the device, an appropriate informed consent under which the individual is informed of and accepts liability under paragraph (1) for payment for the device (and for items and services related to furnishing such device), the physician or other entity is deemed to have agreed not to impose any charge

under this title for such device (and for items and services related to furnishing such device).''.

(b) CONFORMING AMENDMENT.—Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)) is amended—

(1) in paragraph (24), by striking ''or'' at the end;

(2) in paragraph (25), by striking the period at the end and inserting ''; or''; and

(3) by inserting after paragraph (25) the following new paragraph:

''(26) where such expenses are for a medical device included in the AIM list under section 1862(p) (or for items and services related to furnishing such device).''.

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