

113TH CONGRESS  
1ST SESSION

# H. R. 3681

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.

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## IN THE HOUSE OF REPRESENTATIVES

DECEMBER 9, 2013

Mr. PAULSEN (for himself, Mr. MATHESON, Mr. SHIMKUS, and Mr. BARROW of Georgia) 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.

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 “Accelerating Innova-  
5 tion in Medicine Act of 2013” or the “AIM Act of 2013”.

1 **SEC. 2. FINDINGS.**

2 Congress finds as follows:

3 (1) Innovation in health care technology is nec-  
4 essary to improve health outcomes and depends in  
5 part on the ability of medical technology developers,  
6 including scientists, physicians, engineers, and pa-  
7 tient advocates, to introduce medical devices into the  
8 marketplace.

9 (2) Even after meeting requirements for mar-  
10 keting set by the Food and Drug Administration,  
11 there may be uncertainties about patient access  
12 through government health care programs, causing  
13 significant delays in bringing innovative medical de-  
14 vices to patients or causing medical technology de-  
15 velopers to abandon potential health care solutions.

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

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

1       uct development will promote innovation and result  
2       in increased patient access to desired products and  
3       services, save taxpayer dollars, and reduce adminis-  
4       trative burdens on physicians and the government.

5           (5) Enabling health care technology manufac-  
6       turers to designate their devices as available to self-  
7       pay patients would permit a window of time during  
8       which additional data may be obtained on outcomes,  
9       comparative clinical effectiveness or other data ele-  
10      ments for possible future coverage by the Medicare  
11      program.

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

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

17       “(p) ESTABLISHMENT OF ACCELERATING INNOVA-  
18      TION IN MEDICINE (AIM) LIST OF MEDICAL DEVICES  
19      VOLUNTARILY EXCLUDED FROM COVERAGE.—

20           “(1) IN GENERAL.—Not later than 90 days  
21      after the date of the enactment of this subsection,  
22      the Secretary shall develop and maintain a listing  
23      (in this section referred to as the ‘AIM list’) of med-  
24      ical devices for which, because of their inclusion in  
25      such listing, no insurance benefit and no payment

1 may be made for such a device under this title either  
2 directly or on a capitated basis such that no claim  
3 for payment may be submitted under this title for  
4 such a device and an individual who consents to re-  
5 ceive such a device is responsible for payment for  
6 the device and services related to furnishing the de-  
7 vice.

8 “(2) PROCEDURES FOR INCLUSION IN AIM  
9 LIST.—

10 “(A) REQUIREMENT FOR WRITTEN CON-  
11 SENT OF MANUFACTURER.—No medical device  
12 may be included in the AIM list without the  
13 written consent of the manufacturer of the de-  
14 vice.

15 “(B) SUBMISSION PROCESS.—A manufac-  
16 turer seeking to have a medical device included  
17 in the AIM list shall submit to the Secretary a  
18 request for inclusion of the device in the AIM  
19 list. In the case of such a device for which—

20 “(i) there is a request for approval or  
21 clearance for marketing and sale of the de-  
22 vice by the Food and Drug Administration  
23 pursuant to authority granted by the Fed-  
24 eral Food, Drug, and Cosmetic Act (21  
25 U.S.C. 301 et seq.), including pursuant to

1 section 510(k) or 515(c) of such Act (21  
2 U.S.C. 360(k), 360e(c)), the request for  
3 inclusion of the device in the AIM list may  
4 not be submitted earlier than the date of  
5 the request for such approval or clearance  
6 and no later than the first business day of  
7 the month beginning at least 30 days after  
8 the date of such approval or clearance; or

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

16 “(3) LISTING PERIODS; REMOVAL FROM LIST.—

17 “(A) 3-YEAR LISTING PERIODS.—A med-  
18 ical device included in the AIM list shall be ini-  
19 tially listed for a period of 3 years and shall re-  
20 main so listed for subsequent 3-year periods  
21 subject to subparagraphs (B) and (C).

22 “(B) REMOVAL AT REQUEST OF MANUFAC-  
23 Turer.—At any time a device of a manufac-  
24 turer included in the AIM list shall be removed  
25 from the AIM list upon the written request of

1 the manufacturer. Subject to subparagraph (C),  
2 such a device of a manufacturer may not be re-  
3 moved from the AIM list except upon the writ-  
4 ten request of the manufacturer.

5 “(C) PROVISION OF DATA ON CLINICAL  
6 STUDIES AS A CONDITION FOR CONTINUED  
7 LISTING.—As a condition for the continued in-  
8 clusion of the device of a manufacturer in the  
9 AIM list for a subsequent 3-year listing period  
10 under subparagraph (A), the manufacturer  
11 shall provide the Secretary with published or  
12 publicly available data on clinical studies com-  
13 pleted for the device at the end of the previous  
14 3-year listing period. If the Secretary deter-  
15 mines that a manufacturer of a device has ma-  
16 terially failed to provide such data for the de-  
17 vice, the Secretary may remove the device from  
18 the AIM list or not renew the listing for the de-  
19 vice or both.

20 “(4) MEDICAL DEVICE DEFINED.—In this sub-  
21 section, the term ‘medical device’ has the meaning  
22 given the term ‘device’ in section 201(h) of the Fed-  
23 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
24 321(h)).

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

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

13           “(7) REQUIREMENT FOR INFORMED CONSENT  
14 IN ORDER FOR PROVIDER TO CHARGE FOR DE-  
15 VICE.—If a physician or other entity furnishes a  
16 medical device included in the AIM list to an indi-  
17 vidual under this title and failed to obtain, before  
18 furnishing the device, an appropriate informed con-  
19 sent under which the individual is informed of and  
20 accepts liability under paragraph (1) for payment  
21 for the device (and related services), the physician or  
22 other entity is deemed to have agreed not to impose  
23 any charge under this title for such device (and for  
24 services related to furnishing the device).”.

1 (b) CONFORMING AMENDMENT.—Section 1862(a) of  
2 the Social Security Act (42 U.S.C. 1395y(a)) is amend-  
3 ed—

4 (1) in paragraph (24), by striking “or” at the  
5 end;

6 (2) in paragraph (25), by striking the period at  
7 the end and inserting “; or”; and

8 (3) by inserting after paragraph (25) the fol-  
9 lowing new paragraph:

10 “(26) where such expenses are for a medical de-  
11 vice included in the AIM list under section 1862(p)  
12 or for items and services related to furnishing such  
13 device.”.

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