

AMENDMENT TO RULES COMMITTEE PRINT 114-

22

OFFERED BY MR. STIVERS OF OHIO

H.R. 6, 21st Century Cures Act

Page 183, insert after line 3 the following new section:

1 **SEC. 2202. MEDICARE COVERAGE FOR BREAKTHROUGH DE-**
2 **VICES.**

3 (a) **COVERAGE.**—Section 1861 of the Social Security
4 Act (42 U.S.C. 1395x) is amended—

5 (1) in subsection (s)(2)—

6 (A) in subparagraph (EE), by striking
7 “and” at the end;

8 (B) in subparagraph (FF), by inserting
9 “and” at the end; and

10 (C) by adding at the end the following new
11 subparagraph:

12 “(GG) advanced medical devices (as de-
13 fined in subsection (iii));”; and

14 (2) by adding at the end the following new sub-
15 section:

16 “(iii) **ADVANCED MEDICAL DEVICES.**—

1 “(1) IN GENERAL.—The term ‘advanced med-
2 ical device’ means a medical device that represents
3 a breakthrough technology, has been approved under
4 section 515 of Federal Food, Drug, and Cosmetic
5 Act or cleared under section 510(k) of such Act
6 after December 31, 2010, and is furnished for a
7 medically accepted indication for use with respect to
8 the treatment of cancer.

9 “(2) MEDICALLY ACCEPTED INDICATION.—For
10 purposes of paragraph (1), the term ‘medically ac-
11 cepted indication’ means, with respect to a medical
12 device, any indication—

13 “(A) for which the device is approved
14 under section 515 of Federal Food, Drug, and
15 Cosmetic Act or cleared under section 510(k) of
16 such Act; or

17 “(B) for which the device is determined by
18 the prescribing physician to be appropriate and
19 medically necessary based upon—

20 “(i) supportive clinical evidence pub-
21 lished in peer reviewed medical literature;
22 or

23 “(ii) clinical practice guidelines issued
24 by nationally recognized medical policy,
25 practice, or expert opinion organizations.”.

1 (b) PAYMENT OF BENEFITS.—

2 (1) IN GENERAL.—Section 1833 of the Social
3 Security Act (42 U.S.C. 1395l) is amended by—

4 (A) striking “and” after “subsection (t),”;

5 and

6 (B) adding “, and (AA) with respect to ad-
7 vanced medical devices, as defined in section
8 1861(iii), the amounts paid shall be the amount
9 described in section 1834(s)” before the semi-
10 colon at the end.

11 (2) AMOUNT DESCRIBED.—Section 1834 of the
12 Social Security Act (42 U.S.C. 1395m) is amended
13 by adding at the end the following new subsection:

14 “(s) PAYMENT FOR ADVANCED MEDICAL DE-
15 VICES.—

16 “(1) IN GENERAL.—In the case of an advanced
17 medical device (as defined in section 1861(iii)), the
18 amount of payment under this part for such device
19 and for any supplies and services (except for physi-
20 cian services) used in conjunction with such device
21 shall be the amount that is 106 percent of the man-
22 ufacturer’s average contract price or average month-
23 ly rental charge for such device, as applicable.

1 “(2) CALCULATION OF MANUFACTURER’S AVER-
2 AGE CONTRACT PRICE OR MONTHLY RENTAL
3 CHARGE.—For purposes of paragraph (1)—

4 “(A) the manufacturer’s average contract
5 price for such an advanced medical device shall
6 be calculated on a quarterly basis by dividing
7 the total sales revenues in such quarter with re-
8 spect to such device by the number of such de-
9 vices sold in such quarter; and

10 “(B) the average monthly rental charge for
11 such an advanced medical device shall be cal-
12 culated on a quarterly basis by dividing the
13 monthly rental revenues with respect to such
14 device by the number of such devices rented in
15 such month.

16 In calculating the manufacturer’s average contract
17 price or average monthly rental charge under this
18 paragraph, the Secretary shall exclude from such
19 calculation devices that have been sold or rented for
20 a nominal amount or which have been sold, rented,
21 or otherwise distributed as samples or for trial or
22 testing purposes.”.

