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:

SEC. 2202. MEDICARE COVERAGE FOR BREAKTHROUGH DEVICES.

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

(1) in subsection (s)(2)—

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

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

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

“(GG) advanced medical devices (as defined in subsection (iii));”; and

(2) by adding at the end the following new subsection:

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

“(2) MEDICALLY ACCEPTED INDICATION.—For purposes of paragraph (1), the term ‘medically accepted indication’ means, with respect to a medical device, any indication—

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

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

“(i) supportive clinical evidence published in peer reviewed medical literature; or

“(ii) clinical practice guidelines issued by nationally recognized medical policy, practice, or expert opinion organizations.”.
(b) Payment of Benefits.—

(1) In General.—Section 1833 of the Social Security Act (42 U.S.C. 1395l) is amended by—

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

and

(B) adding “, and (AA) with respect to advanced medical devices, as defined in section 1861(iii), the amounts paid shall be the amount described in section 1834(s)” before the semicolon at the end.

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

“(s) Payment for Advanced Medical Devices.—

“(1) In General.—In the case of an advanced medical device (as defined in section 1861(iii)), the amount of payment under this part for such device and for any supplies and services (except for physician services) used in conjunction with such device shall be the amount that is 106 percent of the manufacturer’s average contract price or average monthly rental charge for such device, as applicable.
“(2) Calculation of manufacturer’s average contract price or monthly rental charge.—For purposes of paragraph (1)—

“(A) the manufacturer’s average contract price for such an advanced medical device shall be calculated on a quarterly basis by dividing the total sales revenues in such quarter with respect to such device by the number of such devices sold in such quarter; and

“(B) the average monthly rental charge for such an advanced medical device shall be calculated on a quarterly basis by dividing the monthly rental revenues with respect to such device by the number of such devices rented in such month.

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