

**AMENDMENT TO RULES COMMITTEE PRINT 114-**

**22**

**OFFERED BY MR. STIVERS OF OHIO**

**H.R. 6, 21st Century Cures Act**

Page 343, insert after line 18 the following new section:

1 **SEC. 4007. MEDICARE COVERAGE FOR INTERIM MEDICAL**  
2 **TECHNOLOGIES AND REPLACEMENT MED-**  
3 **ICAL TECHNOLOGIES.**

4 (a) IN GENERAL.—Section 1862 of the Social Secu-  
5 rity Act (42 U.S.C. 1395y) is amended—

6 (1) in subsection (a)(1)—

7 (A) in subparagraph (A), by inserting “,  
8 subject to subsection (p),” after “are”;

9 (B) in subparagraph (O), by striking  
10 “and” at the end;

11 (C) in subparagraph (P), by striking the  
12 semicolon at the end and inserting “, and”; and

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

15 “(Q) in the case of a medical device that  
16 is not determined by the Secretary to be rea-  
17 sonable and necessary under subparagraph (A),

1           which is not a replacement medical technology  
2           (as defined in subsection (q)).”; and

3           (2) by adding at the end the following new sub-  
4           sections:

5           “(p) COVERAGE FOR INTERIM MEDICAL TECH-  
6           NOLOGIES.—

7           “(1) IN GENERAL.—In the case of an interim  
8           medical technology to which subsection (a)(1)(A) ap-  
9           plies, payment may be made under part A or part  
10          B, before the completion of the reasonable and nec-  
11          essary determination under such subsection, for any  
12          expenses incurred for such technology before the  
13          date of such completion with respect to the use of  
14          the device described in paragraph (2)(A).

15          “(2) INTERIM MEDICAL TECHNOLOGY DE-  
16          SCRIBED.—For purposes of this subsection, the term  
17          ‘interim medical technology’ means a medical de-  
18          vice—

19                  “(A) approved under section 515 of Fed-  
20                  eral Food, Drug, and Cosmetic Act or cleared  
21                  under section 510(k) of such Act for use in the  
22                  diagnosis, cure, mitigation, treatment, or pre-  
23                  vention of a disease or other condition;

1           “(B) the manufacturer or sponsor of which  
2           requests be subject to interim coverage under  
3           this subsection; and

4           “(C) that is not reasonable and necessary  
5           to carry out the purposes of section 1142.

6           “(3) IMPLEMENTATION.—The Secretary shall  
7           implement this subsection in a manner that is the  
8           least burdensome for providers and stakeholders  
9           (such as by promoting consistency in the implemen-  
10          tation of this subsection among medicare adminis-  
11          trative contractors).

12          “(4) NO EFFECT ON TIMELINE OF REASON-  
13          ABLE OR NECESSARY DETERMINATION.—Nothing in  
14          this subsection may be construed to effect the appli-  
15          cation of the reasonable and necessary determina-  
16          tions required under subsection (a)(1)(A) with re-  
17          spect to an interim medical technology.

18          “(q) REPLACEMENT MEDICAL TECHNOLOGIES DE-  
19          FINED.—For purposes of section 1862(a)(1)(Q), the term  
20          ‘replacement medical technology’ means a medical de-  
21          vice—

22                 “(1) approved under section 515 of Federal  
23                 Food, Drug, and Cosmetic Act or cleared under sec-  
24                 tion 510(k) of such Act for use in the diagnosis,

1 cure, mitigation, treatment, or prevention of a dis-  
2 ease or other condition;

3 “(2) with respect to such a use, that has been  
4 determined to result in medical benefits that are  
5 comparable to the benefits that would result from  
6 the use of a medical device that the Secretary has  
7 determined meets the requirement described in sec-  
8 tion 1862(a)(1)(A); and

9 “(3) the coverage of which results in expendi-  
10 tures under this title that are less than the expendi-  
11 tures that would result under such title if this sub-  
12 section did not apply.”.

13 (b) LOCAL COVERAGE DETERMINATIONS.—Section  
14 1869(f)(2)(B) of the Social Security Act (42 U.S.C.  
15 1395ff(f)(2)(B)) is amended by inserting “or section  
16 1862(a)(1)(Q)” before the period at the end.

