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:

SEC. 4007. MEDICARE COVERAGE FOR INTERIM MEDICAL TECHNOLOGIES AND REPLACEMENT MEDICAL TECHNOLOGIES.

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

(1) in subsection (a)(1)—

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

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

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

“(Q) in the case of a medical device that is not determined by the Secretary to be reasonable and necessary under subparagraph (A),
which is not a replacement medical technology
(as defined in subsection (q)).’’; and

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

“(p) COVERAGE FOR INTERIM MEDICAL TECHNOLOGIES.—

“(1) IN GENERAL.—In the case of an interim medical technology to which subsection (a)(1)(A) applies, payment may be made under part A or part B, before the completion of the reasonable and necessary determination under such subsection, for any expenses incurred for such technology before the date of such completion with respect to the use of the device described in paragraph (2)(A).

“(2) INTERIM MEDICAL TECHNOLOGY DESCRIBED.—For purposes of this subsection, the term ‘interim medical technology’ means a medical device—

“(A) approved under section 515 of Federal Food, Drug, and Cosmetic Act or cleared under section 510(k) of such Act for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease or other condition;
“(B) the manufacturer or sponsor of which requests be subject to interim coverage under this subsection; and

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

“(3) IMPLEMENTATION.—The Secretary shall implement this subsection in a manner that is the least burdensome for providers and stakeholders (such as by promoting consistency in the implementation of this subsection among medicare administrative contractors).

“(4) NO EFFECT ON TIMELINE OF REASONABLE OR NECESSARY DETERMINATION.—Nothing in this subsection may be construed to effect the application of the reasonable and necessary determinations required under subsection (a)(1)(A) with respect to an interim medical technology.

“(q) REPLACEMENT MEDICAL TECHNOLOGIES DEFINED.—For purposes of section 1862(a)(1)(Q), the term ‘replacement medical technology’ means a medical device—

“(1) approved under section 515 of Federal Food, Drug, and Cosmetic Act or cleared under section 510(k) of such Act for use in the diagnosis,
cure, mitigation, treatment, or prevention of a disease or other condition;

“(2) with respect to such a use, that has been determined to result in medical benefits that are comparable to the benefits that would result from the use of a medical device that the Secretary has determined meets the requirement described in section 1862(a)(1)(A); and

“(3) the coverage of which results in expenditures under this title that are less than the expenditures that would result under such title if this subsection did not apply.”.

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