AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 5343 OFFERED BY MR. SMITH OF MISSOURI

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Ensuring Patient Access to Critical Breakthrough Products Act''.

SEC. 2. ENSURING PROMPT COVERAGE OF BREAKTHROUGH DEVICES UNDER THE MEDICARE PROGRAM.

(a) ENSURING COVERAGE THROUGH A TRANSITIONAL COVERAGE PERIOD.—

(1) IN GENERAL.—Section 1862(a)(1) of the Social Security Act (42 U.S.C. 1395y(a)(1)) is amended—

(A) in subparagraph (O), by striking ''and'' at the end;

(B) in subparagraph (P), by adding ''and'' at the end; and

(C) by inserting after subparagraph (P) the following new subparagraph:

''(Q) in the case of a breakthrough device (as defined in section 1861(nnn)) furnished during the transitional coverage period (as so defined) with respect to such device—

''(i) which is not furnished for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member in accordance with the Food and Drug Administration-approved labeling for such device and for the indication for which such device was provided priority review under section 515B of the Federal Food, Drug, and Cosmetic Act;

''(ii) that the Secretary finds, based on a review of clinical data, presents an undue risk of harm that outweighs the potential clinical benefits for individuals entitled to benefits under part A or enrolled under part B; or

''(iii) which is prohibited from being paid under section 1899D(d);''.

(2) DEFINITIONS.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

''(nnn) BREAKTHROUGH DEVICE.—

''(1) IN GENERAL.—The term 'breakthrough device' means a device that—

''(A) is so designated by the Secretary under section 1899D; and

''(B) is furnished at such frequency as specified in the Food and Drug Administration-approved labeling for such device (or, in the case such device has no frequency so specified, at such frequency as determined appropriate by the Secretary).

''(2) TRANSITIONAL COVERAGE PERIOD.—The term 'transitional coverage period' means, with respect to a breakthrough device, the 4-year period that begins on the date that such device is so designated by the Secretary under section 1899D.''.

(3) BREAKTHROUGH DEVICE DETERMINATIONS.—Part E of title XVIII of the Social Security Act (42 U.S.C. 1395x et seq.) is amended by adding at the end the following new section:

''SEC. 1899D. BREAKTHROUGH DEVICES.

''(a) IN GENERAL.—Beginning 18 months after the date of the enactment of this section, upon application (in a form and manner specified by the Secretary) of a manufacturer of a device (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act) that is cleared, classi-

fied, or approved under section 510(k), 513(f)(2), or 515 of such Act on or after the date of the enactment of this section, the Secretary shall designate such device as a breakthrough device if the Secretary determines that such device meets the criteria specified in subsection (b).

''(b) CRITERIA.—For purposes of subsection (a), the criteria specified in this subsection are, with respect to a device, the following:

''(1) The device is provided with priority review pursuant to section 515B of the Federal Food, Drug, and Cosmetic Act.

''(2) In the case such device is cleared under section 510(k) of such Act, such device is so cleared based on clinical data, which may include clinical trial information from an applicable device clinical trial (as such terms are defined in section 402(j) of the Public Health Service Act), that included individuals entitled to benefits under part A or enrolled under part B.

''(3) The device would, without application of section 1862(a)(1), otherwise be covered under part A or B.

''(4) The device does not, based on a review of clinical data, present an undue risk of harm that outweighs the potential clinical benefits for individ-

uals entitled to benefits under part A or enrolled under part B, as determined by the Secretary.

''(5) The device is not a clinical diagnostic laboratory test.

''(c) DETERMINATION PROCESS.—

''(1) IN GENERAL.—The Secretary shall make a determination with respect to the designation of a device that is the subject of an application described in subsection (a) not later than 6 months after such application is submitted to the Secretary.

''(2) EXPLANATION REQUIRED IN CASE OF NONDESIGNATION.—With respect to a device that is the subject of an application described in subsection (a), in the case that the Secretary determines that such device does not meet the criteria specified in subsection (b), the Secretary shall notify the manufacturer of such device of such determination and include in such notification an identification of the specific criterion or criteria that such device failed to meet and an explanation of why such device failed to meet such criterion or criteria.

''(d) PAYMENT PROHIBITION.—No payment may be made under part A or B with respect to a breakthrough device furnished to an individual—

''(1) that is furnished more frequently than as specified in the Food and Drug Administration-approved labeling for such device (or, in the case such device has no frequency so specified, that is furnished more frequently than the Secretary determines appropriate); or

''(2) in the case of such a device that is furnished by a provider of services or supplier that the Secretary determines has an aberrant billing pattern with respect to such device or that is otherwise an outlier with respect to the furnishing of such device compared to similarly situated providers of services and suppliers, is not reasonable and necessary with respect to the individual for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

''(e) REPORTS.—The Secretary shall submit to Congress on an annual basis a report specifying—

''(1) the number of applications received under this section during such year;

''(2) the number of devices designated as breakthrough devices under this section during such year; and

''(3) the number of applications for a designation for a device under this section with respect to

which the Secretary determined that such device did not meet the criteria specified in subsection (b) during such year.''.

(b) ENSURING ISSUANCE OF NATIONAL COVERAGE DETERMINATION DURING TRANSITION PERIOD.—Section 1862(l)(2) of the Social Security Act (42 U.S.C. 1395y(l)(2)) is amended by adding at the end the following new flush sentence:

''In the case of a request for a national coverage determination with respect to a breakthrough device (as defined in section 1861(nnn)), the Secretary shall ensure that a final decision is made on such request (or determine that such device is otherwise covered on a national basis under part A or B) prior to the end of the transitional coverage period (as so defined) for such device if such request was submitted to the Secretary before the date that is 9 months (or 12 months, in the case such request is a request to which subparagraph (B) applies) before the last day of such period.''.

(c) FUNDING.—In addition to amounts otherwise available, there are appropriated to the Centers for Medicare & Medicaid Services Program Management Account, out of any monies in the Treasury not otherwise appropriated, $10,000,000 for each of fiscal years 2026 through

2031, to remain available until expended, to carry out the amendments made by this section.

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