AMENDMENT

OFFERED BY MR. BOUSTANY OF LOUISIANA

In division B, insert after section 1401 (relating to Comparative effectiveness research) the following new section (and update the table of contents accordingly):

SECTION 1402. PROCESS FOR CERTAIN NATIONAL COVERAGE DETERMINATIONS.

(a) REQUIREMENTS FOR THE ISSUANCE OF CERTAIN MEDICARE NATIONAL COVERAGE DETERMINATIONS.—Unless all of the conditions under subsection (b) are met, the Administrator may not issue a final national coverage determination (referred to in this Act as a NCD)—

(1) if the NCD restricts local or national coverage for an item or service that, before the date of the issuance of such NCD, was routinely covered under the Medicare program under title XVIII of the Social Security Act;

(2) if the NCD would result in significant cost savings for the Medicare program;

(3) if there is controversy in the available peer-reviewed medical and scientific literature about the evidence supporting the NCD;

(4) if the NCD restricts local or national coverage for an item or service that—

(A) is supported by current clinical practice guidelines—

(i) included in the National Guideline Clearinghouse maintained by the Agency for Healthcare Research and Quality; or

(ii) maintained by a State medical society; or

(B) is endorsed by the National Quality Forum or by another national organization that evaluates voluntary consensus-based provides quality measures and is designated by the Secretary for purposes of making an endorsement under this subparagraph; or

(5) if the Administrator determines that—

(A) significant differences in opinion exist among experts concerning—

(i) what evidence should be reviewed in developing the NCD; or

(ii) how data should be interpreted for purposes of developing the NCD; and

(B) an independent analysis of the evidence and data analysis would be valuable in developing the final NCD.

(b) REQUIRED CONDITIONS.—The conditions under this subsection are as follows:

(1) REQUEST FOR REVIEW.—Before the start of the public comment period for a proposed NCD that contains all the restrictions on the coverage of products and services included in the final NCD, the Administrator makes a formal request to MEDCAC for a review of the scientific and clinical evidence supporting and opposing the NCD.

(2) MEDCAC REVIEW SUBCOMMITTEE.—

(A) IN GENERAL.—MEDCAC convenes a subcommittee to—

(i) review the evidence supporting the proposed NCD (including clinical practice guidelines published by medical specialty societies), taking into account—

(I) the evidence related to subpopulations of beneficiaries (including men, women, racial and ethnic minorities, the elderly, individuals with disabilities, and individuals with genetic variations); and

(II) the extent to which patient preference is a factor in the use of the

item or service that is the subject of the NCD;

(ii) conduct an evaluation of the clinical and scientific evidence relating to the clinical benefits and risks of a technology affected by such NCD; and

(iii) determine if the NCD will limit the access of Medicare beneficiaries to medically necessary care.

(B) MEMBERSHIP.—The subcommittee under subparagraph (A) shall have 15 members, each of whom—

(i) shall be a clinical expert in the medical specialty or specialties that are most relevant to the topic of the NCD; and

(ii) to the extent feasible, shall have expertise in the development of clinical practice guidelines.

(C) OUTSIDE EXPERTS ALLOWED.—MEDCAC may include individuals who are not members of MEDCAC in the membership of the subcommittee convened under subparagraph (A).

(3) SUBCOMMITTEE COMMENT.—

(A) IN GENERAL.—Not later than the last day of the period under paragraph (1), the subcommittee convened under paragraph (3)(A) shall submit to the Administrator a public comment on the NCD that contains an evaluation of whether—

(i) the NCD is appropriate based on the subcommittee's activities under paragraph (2)(A);

(ii) the NCD is consistent with clinical guidelines;

(iii) the NCD would adversely impact access the access of subpopulations to items or services which may benefit such subpopulations; or

(iv) the NCD would adversely impact access to treatment options that are primarily selected by patients, with their physicians, based on patient preference and quality of life criteria.

(B) NCDS THAT PREVENT ACCESS TO CARE.—If MEDCAC determines that the proposed NCD could prevent Medicare patients from receiving medically necessary care, the MEDCAC panel shall include in such public

comment a recommendation that the proposed NCD not be issued as a final NCD.

(c) RESTRICTION ON ADDITIONAL LIMITATION ON COVERAGE.—The Administrator may not issue a final NCD that contains any restrictions on the coverage of products and services that were not included in the proposed NCD reviewed under subsection (b).

(d) CONSTRUCTION.—Nothing in this Act shall be construed as preventing a Medicare beneficiary from using private funds to purchase supplemental health insurance coverage or to directly purchase medically necessary care.

(e) DEFINITIONS.—For purposes of this section:

(1) ADMINISTRATOR.—The term "Administrator" means the Administrator of CMS.

(2) CMS.—The term "CMS" means the Centers for Medicare & Medicaid Services.

(3) MEDCAC.—The term "MEDCAC" means the Medicare Evidence Development & Coverage Advisory Committee established by the Secretary of Health and Human Services pursuant to section 222 of the Public Health Service Act.

(4) MEDICALLY NECESSARY SERVICES.—The term "medically necessary care" means health care services or products that a prudent physician would provide to a patient for the purpose of preventing,

diagnosing, treating or rehabilitating an illness, injury, disease or its associated symptoms, impairments or functional limitations in a manner that is—

(A) in accordance with generally accepted standards of medical practice;

(B) clinically appropriate in terms of type, frequency, extent, site and duration; and

(C) not primarily for the convenience of the patient, physician, or other health care provider.

(5) MEDPAC.—The term "MedPAC" means the Medicare Payment Advisory Commission established under Section 1805 of the Social Security Act.

(6) NATIONAL COVERAGE DETERMINATION.—The term "national coverage determination" has the meaning given such term in section 1869(f)(1)(B) of the Social Security Act.

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