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111TH CONGRESS
1ST SESSION

# H. R. 3361

To provide a process for public comment and Medicare Evidence Development & Coverage Advisory Committee review of certain Medicare national coverage determinations, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

JULY 28, 2009

Mr. BOUSTANY (for himself, Mr. ROE of Tennessee, Mr. GINGREY of Georgia, Mr. FLEMING, Mr. OLSON, Mr. LINDER, Mr. REICHERT, Mr. BOOZMAN, and Mr. ALEXANDER) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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# A BILL

To provide a process for public comment and Medicare Evidence Development & Coverage Advisory Committee review of certain Medicare national coverage determinations, and for other purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Medicare Patient Safeguards Act of 2009''.

**SEC. 2. FINDINGS.**

The Congress finds the following:

(1) The 2009 Medicare Trustees Report estimates that Medicare spending could grow from 3.2 percent of the U.S. economy to 11.4 percent during the next 75 years and warns of the significant cost burden growth of this magnitude would place on workers, Medicare beneficiaries, and the Federal budget.

(2) In 2009, Congress provided $1,150,000,000 for comparative effectiveness research, including cost-effectiveness analysis.

(3) The Medicare Payment and Advisory Commission suggested that the Centers for Medicare & Medicaid Services use cost effectiveness analysis to look at groups of services used to treat specific illnesses that have small differences in quality but large differences in cost.

(4) MedPAC has reported concerns that the rigid use of cost effectiveness analysis might limit Medicare beneficiaries' access to certain services, ration rather than promote appropriate care, slow innovation, and interfere with the practice of medicine.

(5) MedPAC has listed methodological and reporting shortcomings of cost effectiveness analysis, including not using all available clinical evidence, not

sufficiently reporting on the extent to which the results are applicable to the general population, selectively reporting results, and placing undue emphasis on certain results of such analysis.

(6) While serving as the head of Congressional Budget Office, White House Budget director Peter Orszag said determining which treatment was most cost effective for a given population would involve placing a dollar value on an additional year of life.

(7) While serving as the head of Congressional Budget Office, White House Budget director Peter Orszag suggested the possibility of limiting Medicare coverage for more effective but more expensive services.

(8) CMS recently described cost effectiveness analysis expertise as one of its most critical needs to Medicare Evidence Development & Coverage Advisory Committee, which advises CMS on national coverage determinations (NCDs).

(9) CMS, through proposed rule making, has twice failed in attempts to formally incorporate cost effectiveness analysis into NCDs.

(10) CMS officials report that the agency considers potential cost savings before deciding to make

changes to a NCD that narrows coverage under the Medicare program.

(11) AARP has stated that comparative effectiveness research is intended to help consumers and providers determine the best treatment, not just the least costly treatment. AARP warned that this information from comparative effectiveness research should not be used as a means to deny individuals access to appropriate therapeutic options.

(12) The Congressional Black Caucus, focusing in particular on the exacerbating of health inequities across subpopulation groups, expressed concerns that comparative effectiveness research should not be used as rationale for limiting care to the care that works best for the average patient, rather than providing coverage for the care that works best for each individual patient.

(13) Congressional New Democrats—

(A) argued that any application of comparative effectiveness research must protect against the use of this research to deny access to care solely based on cost; and

(B) urged Congress to ensure that clinical effectiveness and medical outcomes are the

focus of comparative effectiveness research funding.

(14) The American Heart Association—

(A) urges Congress to include patient safeguards in legislation to prevent the misuse of cost effectiveness analysis; and

(B) argues that the primary focus of comparative effectiveness research should be optimizing clinical outcomes and value for patients and society and not for the purpose of minimizing costs.

**SEC. 3. SENSE OF CONGRESS.**

It is the sense of the Congress that—

(1) efforts to make the Medicare program financially sustainable, including the application of comparative effectiveness research, should not—

(A) deprive patients of medically necessary care solely due to the cost of such care; or

(B) limit access to needed health care services due to a patient's age, gender, ethnicity, or disability status; and

(2) Congress should protect patients' access to needed care by ensuring that the Administrator of CMS relies on adequate clinical expertise when the Administrator proposes to narrow coverage for a

product or service under the Medicare program under title XVIII of the Social Security Act.

**SEC. 4. 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 com-

ment 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 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.

**SEC. 5. DEFINITIONS.**

For purposes of this Act:

(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, impair-

ments 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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