115TH CONGRESS
1ST SESSION

S. 794

To amend title XVIII of the Social Security Act in order to improve the process whereby Medicare administrative contractors issue local coverage determinations under the Medicare program, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 30, 2017

Mr. ISAKSON (for himself, Mr. CARPER, Mr. BOOZMAN, and Ms. STABENOW) introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To amend title XVIII of the Social Security Act in order to improve the process whereby Medicare administrative contractors issue local coverage determinations under the Medicare program, 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 ''Local Coverage Determination Clarification Act of 2017''.

SEC. 2. IMPROVEMENTS IN THE MEDICARE LOCAL COVERAGE DETERMINATION (LCD) PROCESS FOR SPECIFIED LCDS.

(a) LCD DEVELOPMENT PROCESS.—Section 1862(l)(5) of the Social Security Act (42 U.S.C. 1395y(l)(5)) is amended by adding at the end the following subparagraph:

''(D) PROCESS FOR ISSUING SPECIFIED LOCAL COVERAGE DETERMINATIONS.—

''(i) IN GENERAL.—In the case of a specified local coverage determination (as defined in clause (iv)) within an area by a medicare admi''nistrative contractor that has entered into a contract with the Secretary under section 1874A, such medicare administrative contractor must take the following actions with respect to such determination before such determination may take effect:

''(I) Publish on the public Internet website of the medicare administrative contractor a proposed version of the specified local coverage determination (in this section referred to as a 'draft determination'), a written rationale for the draft determination,

and a description of all evidence relied upon and considered by the medicare administrative contractor in the development of the draft determination.

''(II) Not later than 60 days after the date on which the medicare administrative contractor publishes the draft determination in accordance with subclause (I), convene one or more open, public meetings to review the draft determination, receive comments with respect to the draft determination, and secure the advice of an expert panel (such as a carrier advisory committee described in chapter 13 of the Medicare Program Integrity Manual in effect on August 31, 2015), with respect to the draft determination. The medicare administrative contractor shall make available means for the public to attend such meetings remotely, such as via teleconference.

''(III) With respect to each meeting convened pursuant to subclause

(II), post on the public Internet website of the medicare administrative contractor, not later than 14 days after such meeting is convened, a record of the meeting minutes for such meeting.

''(IV) Provide a period for submission of written public comment on such draft determination that begins on the date on which all records required to be posted with respect to such draft determination under subclause (III) are so posted and that is not fewer than 30 days in duration.

''(ii) FINALIZING A SPECIFIED LOCAL COVERAGE DETERMINATION.—A medicare administrative contractor that has entered into a contract with the Secretary under section 1874A shall, with respect to a specified local coverage determination, post on the public Internet website of the medicare administrative contractor the following information before the specified local coverage determination (in this section re-

ferred to as the 'final determination') takes effect—

"(I) a response the issues raised at meetings convened pursuant to clause (i)(II) with respect to the draft determination;

"(II) the rationale for the final determination;

"(III) in the case that the medicare administrative contractor considered qualifying evidence in the development of the determination that was not described in the written notice provided pursuant to clause (i)(I), a description of such qualifying evidence; and

"(IV) an effective date for the final determination that is not less than 30 days after the date on which such determination is so posted.

"(iii) LIMITATION ON DETERMINATIONS ACROSS JURISDICTIONS.—Notwithstanding any plan under section 1862(l)(5)(A), in the case of a contract with a medicare administrative contractor

under section 1874A, such medicare administrative contractor may not finalize a specified local coverage determination pursuant to clause (ii) with respect to a geographic area that applies, or has the effect of applying, outside such area. In the case that such a medicare administrative contractor wishes to adopt, with respect to a specific geographic area a specified local coverage determination developed for a different geographic area, such medicare administrative contractor may not so adopt such determination unless, prior to so adopting such determination, such medicare administrative contractor independently evaluates and considers the qualifying evidence supporting the determination as applicable to such specific geographic area and makes a local coverage determination for such area in accordance with this subparagraph.

''(iv) SPECIFIED LOCAL COVERAGE DETERMINATION DEFINED.—For purposes of this subparagraph, the term 'specified

local coverage determination' means, with respect to a geographic area—

"(I) a new local coverage determination (regardless of whether such determination made by a medicare administrative contractor that has entered into a contract with the Secretary under section 1874A and is based upon a specified local coverage determination that previously has been made with respect to another geographic area, or by another such medicare administrative contractor);

"(II) a revised local coverage determination for such geographic area that restricts one or more existing coverage criteria for such area (such as by adding noncovered indications to an existing local coverage determination or by deleting previously covered ICD–9 or ICD–10 codes);

"(III) a revised local coverage determination that makes a substantive revision to one or more existing local coverage determinations; and

''(IV) any other local coverage determination specified by the Secretary pursuant to regulations.

''(v) QUALIFYING EVIDENCE DEFINED.—For purposes of this subparagraph, the term 'qualifying evidence' means either of the following:

''(I) Scientific evidence published in peer-reviewed medical literature, such as randomized clinical trials or other studies.

''(II) A general consensus of the applicable medical community (such as a consensus evinced through a recognized standard of practice in such medical community) that is supported by information provided by a recognized medical authority, such as a professional medical society.''.

(b) LCD RECONSIDERATION PROCESS.—Section 1869(f) of the Social Security Act (42 U.S.C. 1395ff(f)) is amended—

(1) in paragraph (2)(A), by inserting ''(and, as applicable, the limitations under paragraphs (8) and (9))'' before the colon;

(2) in paragraph (5), by inserting ''(other than under paragraphs (8) and (9))'' after ''this subsection'';

(3) by redesignating paragraph (8) as paragraph (12); and

(4) by inserting after paragraph (7) the following new paragraphs:

''(8) MEDICARE ADMINISTRATIVE CONTRACTOR RECONSIDERATION PROCESS FOR SPECIFIED LOCAL COVERAGE DETERMINATIONS.—For purposes of paragraph (2)(A), the limitations described in this paragraph are that, upon the filing of a request by an interested party with respect to a specified local coverage determination by a medicare administrative contractor that has entered into a contract with the Secretary under section 1874A, the medicare administrative contractor shall reconsider such determination in accordance with the following process:

''(A) Not later than 30 days after such a request is filed with the medicare administrative contractor by the interested party with respect to such determination, the medicare administrative contractor shall—

''(i) determine whether the request is an applicable request; and

"(ii) in the case that the request is not an applicable request, inform the interested party of the reasons why such request is not an applicable request.

"(B) In the case that the medicare administrative contractor determines under subparagraph (A) that the request described in such subparagraph is an applicable request, the medicare administrative contractor shall, not later than 90 days after the date on which the request was filed with the medicare administrative contractor, take the actions described in subparagraphs (C), (D), and (E) with respect to the determination.

"(C) The action described in this subparagraph is the action of specifying whether any of the following statements is applicable to the determination:

"(i) The determination did not apply, or inaccurately applied, qualifying evidence relevant to such determination.

"(ii) The determination used language that exceeded the scope of the intended purpose of the determination.

''(iii) The determination was incorrect in its determination of whether such item or service is reasonable and necessary for the diagnosis or treatment of illness or injury under section 1862(a)(1)(A).

''(iv) The determination failed to describe, with respect to such an item or service, the clinical conditions to be used for purposes of determining whether such item or service is reasonable and necessary for the diagnosis or treatment of illness or injury under section 1862(a)(1)(A).

''(v) The determination does not apply with respect to items or services to which it was intended to apply.

''(vi) The determination is erroneous for another reason that the medicare administrative contractor identifies.

''(D) The action described in this subparagraph, with respect to the determination, is the action of taking, based on the specification under subparagraph (C) of whether any of the statements in such subparagraph applied to such determination, one or more of the following actions:

''(i) Making no change in the determination.

''(ii) Rescinding a part of the determination (including, as applicable, the entire determination).

''(iii) Modifying the determination to restrict the coverage provided under this title for an item or service that is subject to the determination.

''(iv) Modifying the determination to expand the coverage provided under this title for an item or service that is subject to the determination.

''(E) The action described in this subparagraph is the action of making publicly available a written description of the action taken under subparagraph (D) with respect to the determination.

''(9) AGENCY EVALUATION OF RECONSIDERATION DECISION.—For purposes of paragraph (2)(A), the limitations described in this paragraph are that, in the case that an interested party that filed an applicable request under paragraph (8) with respect to a specified local coverage determination files with the Secretary, on a date that is not later

than 120 days after the date on which a medicare administrative contractor takes an action described under paragraph (8)(D) with respect to such determination, an appeal with respect to such decision in such form and manner as the Secretary may require, the Secretary shall, not later than 30 days after such appeal is filed—

"(A) specify which, if any, of the statements in subparagraph (C) of paragraph (8) is applicable to the determination; and

"(B) based on such specification, take one of the actions described in subparagraph (D) of such paragraph with respect to the determination.

The Secretary shall apply subparagraph (A) as though the reference to 'the medicare administrative contractor' in clause (vi) of paragraph (8)(C) were a reference to the Secretary.

"(10) DEFINITIONS APPLICABLE TO PARAGRAPHS (8) AND (9).—For purposes of paragraphs (8) and (9):

"(A) The term 'applicable request' means a request that is submitted in fiscal year 2018 or a subsequent fiscal year, that is solely with respect to a specified local coverage determina-

tion, and that includes a description of the rationale for such request and any evidence supporting such request. For purposes of the preceding sentence, the Secretary may not require, as a condition of treating a request with respect to such a determination as an applicable request, that the request contain qualifying evidence that was not considered in the development of such determination.

''(B) The term 'interested party' means, with respect to a specified local coverage determination within an area by a medicare administrative contractor that has entered into a contract with the Secretary under section 1874A—

''(i) a provider of services or supplier that, in such area, furnishes, provides, or supplies items or services that are subject to such determination; or

''(ii) an organization that represents such a provider of services or supplier.

''(C) The term 'qualifying evidence' has the meaning given such term by clause (v) of section 1862(l)(5)(D).

''(D) The term 'specified local coverage determination' has the meaning given such term by clause (iv) of such section.

''(11) APPOINTMENT OF OMBUDSMAN.—

''(A) IN GENERAL.—The Secretary shall, within the Centers for Medicare & Medicaid Services, appoint a Medicare Reviews and Appeals Ombudsman (referred to in this paragraph as the 'Ombudsman').

''(B) DUTIES.—The Ombudsman shall, with respect to specified local coverage determinations, carry out the following duties:

''(i) Provide interested parties (as defined in paragraph (10)(B)) with administrative and technical assistance in filing requests under paragraph (8) and appeals under paragraph (9).

''(ii) Make publicly available in a uniform, consistent, and easily understood format the following information for each 12-month period:

''(I) The number of requests filed with medicare administrative contractors under paragraph (8), and of ap-

peals filed with the Secretary under paragraph (9), during such period.

"(II) With respect to such requests during such period, the number of times that medicare administrative contractors took, with respect to the actions described subparagraph (A)(iv) of such paragraph, each such action.

"(III) With respect to such appeals during such period, the number of times that the Secretary took each such action.

"(IV) With respect to the numbers made available under subclauses (I), (II), and (III), the number of each such number that is attributable to—

"(aa) each medicare administrative contractor; and

"(bb) each interested party (as defined in paragraph (10)(B)).

"(V) Measures of the responsiveness of medicare administrative con-

tractors with respect to requests filed with such medicare administrative contractors under paragraph (8).

"(VI) Recommendations to the Secretary with respect to ways to improve—

"(aa) the efficacy and efficiency of the process described in paragraph (8); and

"(bb) communication with individuals entitled to benefits under part A or enrolled under part B, providers of services, and suppliers regarding such process.".

(c) PROMULGATION OF REGULATIONS; APPLICATION DATE.—The Secretary of Health and Human Services shall promulgate regulations to carry out paragraph (5)(D) of section 1862(l) of the Social Security Act (42 U.S.C. 1395y(l)), as added by subsection (a), and paragraphs (8) and (9) of section 1869(f) of such Act (42 U.S.C. 1395ff(f)), as inserted by subsection (b), in such a manner as to ensure that the processes described in such paragraphs are fully implemented by October 1, 2017.

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