

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Local Coverage Deter-
5 mination Clarification Act of 2017”.

1 **SEC. 2. IMPROVEMENTS IN THE MEDICARE LOCAL COV-**
 2 **ERAGE DETERMINATION (LCD) PROCESS FOR**
 3 **SPECIFIED LCDS.**

4 (a) LCD DEVELOPMENT PROCESS.—Section
 5 1862(l)(5) of the Social Security Act (42 U.S.C.
 6 1395y(l)(5)) is amended by adding at the end the fol-
 7 lowing subparagraph:

8 “(D) PROCESS FOR ISSUING SPECIFIED
 9 LOCAL COVERAGE DETERMINATIONS.—

10 “(i) IN GENERAL.—In the case of a
 11 specified local coverage determination (as
 12 defined in clause (iv)) within an area by a
 13 medicare administrative contractor that
 14 has entered into a contract with the Sec-
 15 retary under section 1874A, such medicare
 16 administrative contractor must take the
 17 following actions with respect to such de-
 18 termination before such determination may
 19 take effect:

20 “(I) Publish on the public Inter-
 21 net website of the medicare adminis-
 22 trative contractor a proposed version
 23 of the specified local coverage deter-
 24 mination (in this section referred to
 25 as a ‘draft determination’), a written
 26 rationale for the draft determination,

1 and a description of all evidence relied
2 upon and considered by the medicare
3 administrative contractor in the devel-
4 opment of the draft determination.

5 “(II) Not later than 60 days
6 after the date on which the medicare
7 administrative contractor publishes
8 the draft determination in accordance
9 with subclause (I), convene one or
10 more open, public meetings to review
11 the draft determination, receive com-
12 ments with respect to the draft deter-
13 mination, and secure the advice of an
14 expert panel (such as a carrier advi-
15 sory committee described in chapter
16 13 of the Medicare Program Integrity
17 Manual in effect on August 31,
18 2015), with respect to the draft deter-
19 mination. The medicare administra-
20 tive contractor shall make available
21 means for the public to attend such
22 meetings remotely, such as via tele-
23 conference.

24 “(III) With respect to each meet-
25 ing convened pursuant to subclause

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

7 “(IV) Provide a period for sub-
8 mission of written public comment on
9 such draft determination that begins
10 on the date on which all records re-
11 quired to be posted with respect to
12 such draft determination under sub-
13 clause (III) are so posted and that is
14 not fewer than 30 days in duration.

15 “(ii) FINALIZING A SPECIFIED LOCAL
16 COVERAGE DETERMINATION.—A medicare
17 administrative contractor that has entered
18 into a contract with the Secretary under
19 section 1874A shall, with respect to a spec-
20 ified local coverage determination, post on
21 the public Internet website of the medicare
22 administrative contractor the following in-
23 formation before the specified local cov-
24 erage determination (in this section re-

1 ferred to as the ‘final determination’) takes
2 effect—

3 “(I) a response the issues raised
4 at meetings convened pursuant to
5 clause (i)(II) with respect to the draft
6 determination;

7 “(II) the rationale for the final
8 determination;

9 “(III) in the case that the medi-
10 care administrative contractor consid-
11 ered qualifying evidence in the devel-
12 opment of the determination that was
13 not described in the written notice
14 provided pursuant to clause (i)(I), a
15 description of such qualifying evi-
16 dence; and

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

21 “(iii) LIMITATION ON DETERMINA-
22 TIONS ACROSS JURISDICTIONS.—Notwith-
23 standing any plan under section
24 1862(l)(5)(A), in the case of a contract
25 with a medicare administrative contractor

1 under section 1874A, such medicare ad-
2 ministrative contractor may not finalize a
3 specified local coverage determination pur-
4 suant to clause (ii) with respect to a geo-
5 graphic area that applies, or has the effect
6 of applying, outside such area. In the case
7 that such a medicare administrative con-
8 tractor wishes to adopt, with respect to a
9 specific geographic area a specified local
10 coverage determination developed for a dif-
11 ferent geographic area, such medicare ad-
12 ministrative contractor may not so adopt
13 such determination unless, prior to so
14 adopting such determination, such medi-
15 care administrative contractor independ-
16 ently evaluates and considers the quali-
17 fying evidence supporting the determina-
18 tion as applicable to such specific geo-
19 graphic area and makes a local coverage
20 determination for such area in accordance
21 with this subparagraph.

22 “(iv) SPECIFIED LOCAL COVERAGE
23 DETERMINATION DEFINED.—For purposes
24 of this subparagraph, the term ‘specified

1 local coverage determination’ means, with
2 respect to a geographic area—

3 “(I) a new local coverage deter-
4 mination (regardless of whether such
5 determination made by a medicare ad-
6 ministrative contractor that has en-
7 tered into a contract with the Sec-
8 retary under section 1874A and is
9 based upon a specified local coverage
10 determination that previously has
11 been made with respect to another ge-
12 ographic area, or by another such
13 medicare administrative contractor);

14 “(II) a revised local coverage de-
15 termination for such geographic area
16 that restricts one or more existing
17 coverage criteria for such area (such
18 as by adding noncovered indications
19 to an existing local coverage deter-
20 mination or by deleting previously cov-
21 ered ICD–9 or ICD–10 codes);

22 “(III) a revised local coverage de-
23 termination that makes a substantive
24 revision to one or more existing local
25 coverage determinations; and

1 “(IV) any other local coverage
2 determination specified by the Sec-
3 retary pursuant to regulations.

4 “(v) QUALIFYING EVIDENCE DE-
5 FINED.—For purposes of this subpara-
6 graph, the term ‘qualifying evidence’
7 means either of the following:

8 “(I) Scientific evidence published
9 in peer-reviewed medical literature,
10 such as randomized clinical trials or
11 other studies.

12 “(II) A general consensus of the
13 applicable medical community (such
14 as a consensus evinced through a rec-
15 ognized standard of practice in such
16 medical community) that is supported
17 by information provided by a recog-
18 nized medical authority, such as a
19 professional medical society.”.

20 (b) LCD RECONSIDERATION PROCESS.—Section
21 1869(f) of the Social Security Act (42 U.S.C. 1395ff(f))
22 is amended—

23 (1) in paragraph (2)(A), by inserting “(and, as
24 applicable, the limitations under paragraphs (8) and
25 (9))” before the colon;

1 (2) in paragraph (5), by inserting “(other than
2 under paragraphs (8) and (9))” after “this sub-
3 section”;

4 (3) by redesignating paragraph (8) as para-
5 graph (12); and

6 (4) by inserting after paragraph (7) the fol-
7 lowing new paragraphs:

8 “(8) MEDICARE ADMINISTRATIVE CONTRACTOR
9 RECONSIDERATION PROCESS FOR SPECIFIED LOCAL
10 COVERAGE DETERMINATIONS.—For purposes of
11 paragraph (2)(A), the limitations described in this
12 paragraph are that, upon the filing of a request by
13 an interested party with respect to a specified local
14 coverage determination by a medicare administrative
15 contractor that has entered into a contract with the
16 Secretary under section 1874A, the medicare admin-
17 istrative contractor shall reconsider such determina-
18 tion in accordance with the following process:

19 “(A) Not later than 30 days after such a
20 request is filed with the medicare administrative
21 contractor by the interested party with respect
22 to such determination, the medicare administra-
23 tive contractor shall—

24 “(i) determine whether the request is
25 an applicable request; and

1 “(ii) in the case that the request is
2 not an applicable request, inform the inter-
3 ested party of the reasons why such re-
4 quest is not an applicable request.

5 “(B) In the case that the medicare admin-
6 istrative contractor determines under subpara-
7 graph (A) that the request described in such
8 subparagraph is an applicable request, the
9 medicare administrative contractor shall, not
10 later than 90 days after the date on which the
11 request was filed with the medicare administra-
12 tive contractor, take the actions described in
13 subparagraphs (C), (D), and (E) with respect
14 to the determination.

15 “(C) The action described in this subpara-
16 graph is the action of specifying whether any of
17 the following statements is applicable to the de-
18 termination:

19 “(i) The determination did not apply,
20 or inaccurately applied, qualifying evidence
21 relevant to such determination.

22 “(ii) The determination used language
23 that exceeded the scope of the intended
24 purpose of the determination.

1 “(iii) The determination was incorrect
2 in its determination of whether such item
3 or service is reasonable and necessary for
4 the diagnosis or treatment of illness or in-
5 jury under section 1862(a)(1)(A).

6 “(iv) The determination failed to de-
7 scribe, with respect to such an item or
8 service, the clinical conditions to be used
9 for purposes of determining whether such
10 item or service is reasonable and necessary
11 for the diagnosis or treatment of illness or
12 injury under section 1862(a)(1)(A).

13 “(v) The determination does not apply
14 with respect to items or services to which
15 it was intended to apply.

16 “(vi) The determination is erroneous
17 for another reason that the medicare ad-
18 ministrative contractor identifies.

19 “(D) The action described in this subpara-
20 graph, with respect to the determination, is the
21 action of taking, based on the specification
22 under subparagraph (C) of whether any of the
23 statements in such subparagraph applied to
24 such determination, one or more of the fol-
25 lowing actions:

1 “(i) Making no change in the deter-
2 mination.

3 “(ii) Rescinding a part of the deter-
4 mination (including, as applicable, the en-
5 tire determination).

6 “(iii) Modifying the determination to
7 restrict the coverage provided under this
8 title for an item or service that is subject
9 to the determination.

10 “(iv) Modifying the determination to
11 expand the coverage provided under this
12 title for an item or service that is subject
13 to the determination.

14 “(E) The action described in this subpara-
15 graph is the action of making publicly available
16 a written description of the action taken under
17 subparagraph (D) with respect to the deter-
18 mination.

19 “(9) AGENCY EVALUATION OF RECONSIDER-
20 ATION DECISION.—For purposes of paragraph
21 (2)(A), the limitations described in this paragraph
22 are that, in the case that an interested party that
23 filed an applicable request under paragraph (8) with
24 respect to a specified local coverage determination
25 files with the Secretary, on a date that is not later

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

8 “(A) specify which, if any, of the state-
 9 ments in subparagraph (C) of paragraph (8) is
 10 applicable to the determination; and

11 “(B) based on such specification, take one
 12 of the actions described in subparagraph (D) of
 13 such paragraph with respect to the determina-
 14 tion.

15 The Secretary shall apply subparagraph (A) as
 16 though the reference to ‘the medicare administrative
 17 contractor’ in clause (vi) of paragraph (8)(C) were
 18 a reference to the Secretary.

19 “(10) DEFINITIONS APPLICABLE TO PARA-
 20 GRAPHS (8) AND (9).—For purposes of paragraphs
 21 (8) and (9):

22 “(A) The term ‘applicable request’ means
 23 a request that is submitted in fiscal year 2018
 24 or a subsequent fiscal year, that is solely with
 25 respect to a specified local coverage determina-

1 tion, and that includes a description of the ra-
2 tionale for such request and any evidence sup-
3 porting such request. For purposes of the pre-
4 ceding sentence, the Secretary may not require,
5 as a condition of treating a request with respect
6 to such a determination as an applicable re-
7 quest, that the request contain qualifying evi-
8 dence that was not considered in the develop-
9 ment of such determination.

10 “(B) The term ‘interested party’ means,
11 with respect to a specified local coverage deter-
12 mination within an area by a medicare adminis-
13 trative contractor that has entered into a con-
14 tract with the Secretary under section 1874A—

15 “(i) a provider of services or supplier
16 that, in such area, furnishes, provides, or
17 supplies items or services that are subject
18 to such determination; or

19 “(ii) an organization that represents
20 such a provider of services or supplier.

21 “(C) The term ‘qualifying evidence’ has
22 the meaning given such term by clause (v) of
23 section 1862(l)(5)(D).

1 “(D) The term ‘specified local coverage de-
2 termination’ has the meaning given such term
3 by clause (iv) of such section.

4 “(11) APPOINTMENT OF OMBUDSMAN.—

5 “(A) IN GENERAL.—The Secretary shall,
6 within the Centers for Medicare & Medicaid
7 Services, appoint a Medicare Reviews and Ap-
8 peals Ombudsman (referred to in this para-
9 graph as the ‘Ombudsman’).

10 “(B) DUTIES.—The Ombudsman shall,
11 with respect to specified local coverage deter-
12 minations, carry out the following duties:

13 “(i) Provide interested parties (as de-
14 fined in paragraph (10)(B)) with adminis-
15 trative and technical assistance in filing re-
16 quests under paragraph (8) and appeals
17 under paragraph (9).

18 “(ii) Make publicly available in a uni-
19 form, consistent, and easily understood for-
20 mat the following information for each 12-
21 month period:

22 “(I) The number of requests filed
23 with medicare administrative contrac-
24 tors under paragraph (8), and of ap-

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

3 “(II) With respect to such re-
4 quests during such period, the number
5 of times that medicare administrative
6 contractors took, with respect to the
7 actions described subparagraph
8 (A)(iv) of such paragraph, each such
9 action.

10 “(III) With respect to such ap-
11 peals during such period, the number
12 of times that the Secretary took each
13 such action.

14 “(IV) With respect to the num-
15 bers made available under subclauses
16 (I), (II), and (III), the number of
17 each such number that is attributable
18 to—

19 “(aa) each medicare admin-
20 istrative contractor; and

21 “(bb) each interested party
22 (as defined in paragraph
23 (10)(B)).

24 “(V) Measures of the responsive-
25 ness of medicare administrative con-

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

4 “(VI) Recommendations to the
5 Secretary with respect to ways to im-
6 prove—

7 “(aa) the efficacy and effi-
8 ciency of the process described in
9 paragraph (8); and

10 “(bb) communication with
11 individuals entitled to benefits
12 under part A or enrolled under
13 part B, providers of services, and
14 suppliers regarding such proc-
15 ess.”.

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

○