

114TH CONGRESS
2D SESSION

S. 3392

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

SEPTEMBER 22, 2016

Mr. ISAKSON (for himself and Mr. CARPER) 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 2016”.

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 fiscal intermediary or carrier that has en-
 14 tered into a contract with the Secretary
 15 under section 1874A, such intermediary or
 16 carrier must take the following actions
 17 with respect to such determination before
 18 such determination may take effect:

19 “(I) Publish on the public Inter-
 20 net website of the intermediary or car-
 21 rier a proposed version of the speci-
 22 fied local coverage determination (in
 23 this section referred to as a ‘draft de-
 24 termination’), a written rationale for
 25 the draft determination, and a de-
 26 scription of all evidence relied upon

1 and considered by the intermediary or
2 carrier in the development of the draft
3 determination.

4 “(II) Not later than 60 days
5 after the date on which the inter-
6 mediary or carrier publishes the draft
7 determination in accordance with sub-
8 clause (I), convene one or more open,
9 public meetings to review the draft de-
10 termination, receive comments with
11 respect to the draft determination,
12 and secure the advice of an expert
13 panel (such as a carrier advisory com-
14 mittee described in chapter 13 of the
15 Medicare Program Integrity Manual
16 in effect on August 31, 2015) with re-
17 spect to the draft determination. The
18 intermediary or carrier shall make
19 available means for the public to at-
20 tend such meetings remotely, such as
21 via teleconference.

22 “(III) With respect to each meet-
23 ing convened pursuant to subclause
24 (II), post on the public Internet
25 website of the intermediary or carrier,

1 not later than 14 days after such
2 meeting is convened, a record of the
3 meeting minutes for such meeting.

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

12 “(ii) FINALIZING A SPECIFIED LOCAL
13 COVERAGE DETERMINATION.—A fiscal
14 intermediary or carrier that has entered
15 into a contract with the Secretary under
16 section 1874A shall, with respect to a spec-
17 ified local coverage determination, post on
18 the public Internet website of the fiscal
19 intermediary or carrier the following infor-
20 mation before the specified local coverage
21 determination (in this section referred to
22 as the ‘final determination’) takes effect—

23 “(I) a response the issues raised
24 at meetings convened pursuant to

1 clause (i)(II) with respect to the draft
2 determination;

3 “(II) the rationale for the final
4 determination;

5 “(III) in the case that the inter-
6 mediary or carrier considered quali-
7 fying evidence in the development of
8 the determination that was not de-
9 scribed in the written notice provided
10 pursuant to clause (i)(I), a description
11 of such qualifying evidence; and

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

16 “(iii) LIMITATION ON DETERMINA-
17 TIONS ACROSS JURISDICTIONS.—Notwith-
18 standing any plan under section
19 1862(l)(5)(A), in the case of a contract
20 with a fiscal intermediary or carrier under
21 section 1874A, such intermediary or car-
22 rier may not finalize a specified local cov-
23 erage determination pursuant to clause (ii)
24 with respect to a geographic area that ap-
25 plies, or has the effect of applying, outside

such area. In the case that such an intermediary or carrier wishes to adopt, with respect to a specific geographic area a specified local coverage determination developed for a different geographic area, such intermediary or carrier may not so adopt such determination unless, prior to so adopting such determination, such intermediary or carrier 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 fiscal intermediary or carrier that has entered into a contract with the Secretary under section 1874A and is based

1 upon a specified local coverage deter-
2 mination that previously has been
3 made with respect to another geo-
4 graphic area, or by another such
5 intermediary or carrier);

6 “(II) a revised local coverage de-
7 termination for such geographic area
8 that restricts one or more existing
9 coverage criteria for such area (such
10 as by adding noncovered indications
11 to an existing local coverage deter-
12 mination or by deleting previously cov-
13 ered ICD–9 or ICD–10 codes);

14 “(III) a revised local coverage de-
15 termination that makes a substantive
16 revision to one or more existing local
17 coverage determinations; and

18 “(IV) any other local coverage
19 determination specified by the Sec-
20 retary pursuant to regulations.

21 “(v) QUALIFYING EVIDENCE DE-
22 FINED.—For purposes of this subpara-
23 graph, the term ‘qualifying evidence’
24 means either of the following:

1 “(I) Scientific evidence published
 2 in peer-reviewed medical literature,
 3 such as randomized clinical trials or
 4 other studies.

5 “(II) A general consensus of the
 6 applicable medical community (such
 7 as a consensus evinced through a rec-
 8 ognized standard of practice in such
 9 medical community) that is supported
 10 by information provided by a recog-
 11 nized medical authority, such as a
 12 professional medical society.”.

13 (b) LCD RECONSIDERATION PROCESS.—Section
 14 1869(f) of the Social Security Act (42 U.S.C. 1395ff(f))
 15 is amended—

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

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

22 (3) by redesignating paragraph (8) as para-
 23 graph (12); and

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

1 “(8) CARRIER OR FISCAL INTERMEDIARY RE-
2 CONSIDERATION PROCESS FOR SPECIFIED LOCAL
3 COVERAGE DETERMINATIONS.—For purposes of
4 paragraph (2)(A), the limitations described in this
5 paragraph are that, upon the filing of a request by
6 an interested party with respect to a specified local
7 coverage determination by a fiscal intermediary or
8 carrier that has entered into a contract with the
9 Secretary under section 1874A, the intermediary or
10 carrier shall reconsider such determination in ac-
11 cordance with the following process:

12 “(A) Not later than 30 days after such a
13 request is filed with the fiscal intermediary or
14 carrier by the interested party with respect to
15 such determination, the intermediary or carrier
16 shall—

17 “(i) determine whether the request is
18 an applicable request; and

19 “(ii) in the case that the request is
20 not an applicable request, inform the inter-
21 ested party of the reasons why such re-
22 quest is not an applicable request.

23 “(B) In the case that the intermediary or
24 carrier determines under subparagraph (A) that
25 the request described in such subparagraph is

1 an applicable request, the intermediary or car-
2 rier shall, not later than 90 days after the date
3 on which the request was filed with the inter-
4 mediary or carrier, take the actions described in
5 subparagraphs (C), (D), and (E) with respect
6 to the determination.

7 “(C) The action described in this subpara-
8 graph is the action of specifying whether any of
9 the following statements is applicable to the de-
10 termination:

11 “(i) The determination did not apply,
12 or inaccurately applied, qualifying evidence
13 relevant to such determination.

14 “(ii) The determination used language
15 that exceeded the scope of the intended
16 purpose of the determination.

17 “(iii) The determination was incorrect
18 in its determination of whether such item
19 or service is reasonable and necessary for
20 the diagnosis or treatment of illness or in-
21 jury under section 1862(a)(1)(A).

22 “(iv) The determination failed to de-
23 scribe, with respect to such an item or
24 service, the clinical conditions to be used
25 for purposes of determining whether such

1 item or service is reasonable and necessary
2 for the diagnosis or treatment of illness or
3 injury under section 1862(a)(1)(A).

4 “(v) The determination does not apply
5 with respect to items or services to which
6 it was intended to apply.

7 “(vi) The determination is erroneous
8 for another reason that the intermediary or
9 carrier identifies.

10 “(D) The action described in this subpara-
11 graph, with respect to the determination, is the
12 action of taking, based on the specification
13 under subparagraph (C) of whether any of the
14 statements in such subparagraph applied to
15 such determination, one or more of the fol-
16 lowing actions:

17 “(i) Making no change in the deter-
18 mination.

19 “(ii) Rescinding a part of the deter-
20 mination (including, as applicable, the en-
21 tire determination).

22 “(iii) Modifying the determination to
23 restrict the coverage provided under this
24 title for an item or service that is subject
25 to the determination.

1 “(iv) Modifying the determination to
2 expand the coverage provided under this
3 title for an item or service that is subject
4 to the determination.

5 “(E) The action described in this subpara-
6 graph is the action of making publicly available
7 a written description of the action taken under
8 subparagraph (D) with respect to the deter-
9 mination.

10 “(9) AGENCY EVALUATION OF RECONSIDER-
11 ATION DECISION.—For purposes of paragraph
12 (2)(A), the limitations described in this paragraph
13 are that, in the case that an interested party that
14 filed an applicable request under paragraph (8) with
15 respect to a specified local coverage determination
16 files with the Secretary, on a date that is not later
17 than 120 days after the date on which an inter-
18 mediary or carrier takes an action described under
19 paragraph (8)(D) with respect to such determina-
20 tion, an appeal with respect to such decision in such
21 form and manner as the Secretary may require, the
22 Secretary shall, not later than 30 days after such
23 appeal is filed—

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

4 “(B) based on such specification, take one
 5 of the actions described in subparagraph (D) of
 6 such paragraph with respect to the determina-
 7 tion.

8 The Secretary shall apply subparagraph (A) as
 9 though the reference to ‘the intermediary or carrier’
 10 in clause (vi) of paragraph (8)(D) were a reference
 11 to the Secretary.

12 “(10) DEFINITIONS APPLICABLE TO PARA-
 13 GRAPHS (8) AND (9).—For purposes of paragraphs
 14 (8) and (9):

15 “(A) The term ‘applicable request’ means
 16 a request that is submitted in fiscal year 2018
 17 or a subsequent fiscal year, that is solely with
 18 respect to a specified local coverage determina-
 19 tion, and that includes a description of the ra-
 20 tionale for such request and any evidence sup-
 21 porting such request. For purposes of the pre-
 22 ceding sentence, the Secretary may not require,
 23 as a condition of treating a request with respect
 24 to such a determination as an applicable re-
 25 quest, that the request contain qualifying evi-

1 dence that was not considered in the develop-
2 ment of such determination.

3 “(B) The term ‘interested party’ means,
4 with respect to a specified local coverage deter-
5 mination within an area by a fiscal inter-
6 mediary or carrier that has entered into a con-
7 tract with the Secretary under section 1874A—

8 “(i) a provider of services or supplier
9 that, in such area, furnishes, provides, or
10 supplies items or services that are subject
11 to such determination; or

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

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

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

20 “(11) APPOINTMENT OF OMBUDSMAN.—

21 “(A) IN GENERAL.—The Secretary shall,
22 within the Centers for Medicare & Medicaid
23 Services, appoint a Medicare Reviews and Ap-
24 peals Ombudsman (referred to in this para-
25 graph as the ‘Ombudsman’).

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

4 “(i) Provide interested parties (as de-
5 fined in paragraph (10)(B)) with adminis-
6 trative and technical assistance in filing re-
7 quests under paragraph (8) and appeals
8 under paragraph (9).

9 “(ii) Make publicly available in a uni-
10 form, consistent, and easily understood for-
11 mat the following information for each 12-
12 month period:

13 “(I) The number of requests filed
14 with fiscal intermediaries and carriers
15 under paragraph (8), and of appeals
16 filed with the Secretary under para-
17 graph (9), during such period.

18 “(II) With respect to such re-
19 quests during such period, the number
20 of times that intermediaries and car-
21 riers took, with respect to the actions
22 described subparagraph (A)(iv) of
23 such paragraph, each such action.

24 “(III) With respect to such ap-
25 peals during such period, the number

1 of times that the Secretary took each
2 such action.

3 “(IV) With respect to the num-
4 bers made available under subclauses
5 (I), (II), and (III), the number of
6 each such number that is attributable
7 to—

8 “(aa) each fiscal inter-
9 mediary or carrier; and

10 “(bb) each interested party
11 (as defined in paragraph
12 (10)(B)).

13 “(V) Measures of the responsive-
14 ness of fiscal intermediaries and car-
15 riers with respect to requests filed
16 with such intermediaries and carriers
17 under paragraph (8).

18 “(VI) Recommendations to the
19 Secretary with respect to ways to im-
20 prove—

21 “(aa) the efficacy and effi-
22 ciency of the process described in
23 paragraph (8); and

24 “(bb) communication with
25 individuals entitled to benefits

1 under part A or enrolled under
2 part B, providers of services, and
3 suppliers regarding such proc-
4 ess.”.

5 **SEC. 3. PROMULGATION OF REGULATIONS; APPLICATION**
6 **DATE.**

7 The Secretary of Health and Human Services shall
8 promulgate regulations to carry out paragraph (5)(D) of
9 section 1862(l) of the Social Security Act (42 U.S.C.
10 1395y(l)), as added by subsection (a), and paragraphs (8)
11 and (9) of section 1869(f) of such Act (42 U.S.C.
12 1395ff(f)), as inserted by subsection (b), in such a manner
13 as to ensure that the processes described in such para-
14 graphs are fully implemented by October 1, 2017.

○