

115TH CONGRESS  
2D SESSION

# H. R. 3635

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IN THE SENATE OF THE UNITED STATES

SEPTEMBER 17, 2018

Received; read twice and referred to the Committee on Finance

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## AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Local Coverage Deter-  
3 mination Clarification Act of 2018”.

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

7 (a) DEVELOPMENT PROCESS FOR SPECIFIED  
8 LCDs.—Section 1862(l)(5)(D) of the Social Security Act  
9 (42 U.S.C. 1395y(l)(5)(D)) is amended to read as follows:

10 “(D) PROCESS FOR ISSUING SPECIFIED  
11 LOCAL COVERAGE DETERMINATIONS.—

12 “(i) IN GENERAL.—In the case of a  
13 specified local coverage determination (as  
14 defined in clause (iii)) within an area by a  
15 medicare administrative contractor, such  
16 medicare administrative contractor must  
17 take the following actions with respect to  
18 such determination before such determina-  
19 tion may take effect:

20 “(I) Publish on the public Inter-  
21 net website of the intermediary or car-  
22 rier a proposed version of the speci-  
23 fied local coverage determination (in  
24 this subparagraph referred to as a  
25 ‘draft determination’), a written ra-  
26 tionale for the draft determination,

1 and a description of all evidence relied  
2 upon and considered by the inter-  
3 mediary or carrier in the development  
4 of the draft determination.

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

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

1 website of the intermediary or carrier,  
2 not later than 14 days after such  
3 meeting is convened, a record of the  
4 minutes for such meeting, which may  
5 be a recording of the meeting.

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

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

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

5           “(II) the rationale for the final  
6           determination;

7           “(III) in the case that the inter-  
8           mediary or carrier considered quali-  
9           fying evidence (as defined in clause  
10          (v)) that was not described in the  
11          written notice provided pursuant to  
12          clause (i)(I), a description of such  
13          qualifying evidence; and

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

18          “(iii) SPECIFIED LOCAL COVERAGE  
19          DETERMINATION DEFINED.—For purposes  
20          of this subparagraph, the term ‘specified  
21          local coverage determination’ means, with  
22          respect to the relevant geographic area—

23                 “(I) a new local coverage deter-  
24                 mination;

1                   “(II) a revised local coverage de-  
2                   termination for such geographic area  
3                   that restricts one or more existing  
4                   terms of coverage for such area (such  
5                   as by adding requirement to an exist-  
6                   ing local coverage determination that  
7                   results in decreased coverage or by de-  
8                   leting previously covered ICD–9 or  
9                   ICD–10 codes (for reasons other than  
10                  routine coding changes));

11                  “(III) a revised local coverage de-  
12                  termination that makes a substantive  
13                  revision to one or more existing local  
14                  coverage determinations; or

15                  “(IV) any other local coverage  
16                  determination specified by the Sec-  
17                  retary pursuant to regulations.

18                  “(iv) QUALIFYING EVIDENCE DE-  
19                  FINED.—For purposes of this subpara-  
20                  graph, the term ‘qualifying evidence’  
21                  means publicly available evidence of gen-  
22                  eral acceptance by the medical community,  
23                  such as published original research in peer-  
24                  reviewed medical journals, systematic re-  
25                  views and meta-analyses, evidence-based

1 consensus statements, and clinical guide-  
2 lines.”.

3 (b) LCD RECONSIDERATION PROCESS.—Section  
4 1869(f) of the Social Security Act (42 U.S.C. 1395ff(f))  
5 is amended—

6 (1) in paragraph (2)(A), by inserting “(includ-  
7 ing the reconsiderations described in paragraphs (8)  
8 and (9))” after “local coverage determination”;

9 (2) in paragraph (5), by inserting “(except for  
10 a reconsideration described in paragraphs (8) and  
11 (9))” after “the coverage determination”;

12 (3) by redesignating paragraph (8) as para-  
13 graph (13); and

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

16 “(8) CARRIER OR FISCAL INTERMEDIARY RE-  
17 CONSIDERATION PROCESS FOR SPECIFIED LOCAL  
18 COVERAGE DETERMINATIONS.—Upon the filing of a  
19 request by an interested party (as defined in para-  
20 graph (11)(B))with respect to a specified local cov-  
21 erage determination by a fiscal intermediary or car-  
22 rier that has entered into a contract with the Sec-  
23 retary under section 1874A, the intermediary or car-  
24 rier shall reconsider such determination in accord-  
25 ance with the following process:

1           “(A) Not later than 30 days after such a  
2 request is filed with the fiscal intermediary or  
3 carrier by the interested party with respect to  
4 such determination, the intermediary or carrier  
5 shall—

6                   “(i) determine whether the request is  
7 an applicable request; and

8                   “(ii) in the case that the request is  
9 not an applicable request, inform the inter-  
10 ested party of the reasons why such re-  
11 quest is not an applicable request.

12           “(B) In the case that the intermediary or  
13 carrier determines under subparagraph (A) that  
14 the request described in such subparagraph is  
15 an applicable request, the intermediary or car-  
16 rier shall, not later than 90 days after the date  
17 on which the request was filed with the inter-  
18 mediary or carrier, take the actions described in  
19 subparagraphs (C), (D), and (E) with respect  
20 to the determination.

21           “(C) The action described in this subpara-  
22 graph is the action of specifying whether any of  
23 the following statements is applicable to the de-  
24 termination:



1           “(i) The determination did not rea-  
2           sonably consider qualifying evidence rel-  
3           evant to such determination.

4           “(ii) The determination used language  
5           that exceeded the scope of the intended  
6           purpose of the determination.

7           “(iii) The determination was incorrect  
8           in its determination of whether such item  
9           or service is reasonable and necessary for  
10          the diagnosis or treatment of illness or in-  
11          jury under section 1862(a)(1)(A).

12          “(iv) The determination failed to de-  
13          scribe, with respect to such an item or  
14          service, the clinical conditions to be used  
15          for purposes of determining whether such  
16          item or service is reasonable and necessary  
17          for the diagnosis or treatment of illness or  
18          injury under section 1862(a)(1)(A).

19          “(v) The determination does not apply  
20          with respect to items or services to which  
21          it was intended to apply.

22          “(vi) The determination is erroneous  
23          for another reason that the intermediary or  
24          carrier identifies.

1           “(D) The action described in this subpara-  
2 graph, with respect to the determination, is the  
3 action of taking, based on the specification  
4 under subparagraph (C) of whether any of the  
5 statements in such subparagraph applied to  
6 such determination, one or more of the fol-  
7 lowing actions:

8                   “(i) Making no change in the deter-  
9 mination.

10                   “(ii) Rescinding all or a part of the  
11 determination.

12                   “(iii) Modifying the determination to  
13 restrict the coverage provided under this  
14 title for an item or service that is subject  
15 to the determination.

16                   “(iv) Modifying the determination to  
17 expand the coverage provided under this  
18 title for an item or service that is subject  
19 to the determination.

20           “(E) The action described in this subpara-  
21 graph is the action of making publicly available  
22 a written description of the action taken under  
23 subparagraph (D) with respect to the deter-  
24 mination, including the evidence considered by  
25 the medicare administrative contractor.

1           “(9) AGENCY REVIEW OF RECONSIDERATION  
2           DECISION.—The Secretary shall establish a process  
3           to review a medicare administrative contractor’s  
4           technical compliance with the requirements, includ-  
5           ing ensuring that the medicare administrative con-  
6           tractor independently reviewed the evidence involved,  
7           of the reconsideration under paragraph (8).

8           “(10) RULE OF CONSTRUCTION.—Nothing in  
9           paragraph (8) may be construed as affecting the  
10          right of an aggrieved party to file a complaint under  
11          paragraph (2)(A) and receive a determination in ac-  
12          cordance with the provisions of such paragraph. An  
13          aggrieved party is not required to file a request  
14          under paragraph (8) or (9) prior to filing a com-  
15          plaint under paragraph (2).

16          “(11) DEFINITIONS APPLICABLE TO PARA-  
17          GRAPHS (8) AND (9).—For purposes of paragraphs  
18          (8) and (9):

19                 “(A) The term ‘applicable request’ means  
20                 a request that is submitted in fiscal year 2019  
21                 or a subsequent fiscal year, that is solely with  
22                 respect to a specified local coverage determina-  
23                 tion, and that includes a description of the ra-  
24                 tionale for such request and any information or  
25                 evidence supporting such request. For purposes

1 of the preceding sentence, the Secretary may  
2 not require, as a condition of treating a request  
3 with respect to such a determination as an ap-  
4 plicable request, that the request contain quali-  
5 fying evidence that was not considered in the  
6 development of such determination.

7 “(B) The term ‘interested party’ means,  
8 with respect to a specified local coverage deter-  
9 mination within an area by a fiscal inter-  
10 mediary or carrier that has entered into a con-  
11 tract with the Secretary under section 1874A,  
12 a beneficiary or stakeholder (including a med-  
13 ical professional society or physician).

14 “(C) The term ‘qualifying evidence’ has  
15 the meaning given such term by clause (iv) 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 (iii) of such section.

20 “(12) REPORT.—Not later than December 31  
21 of each year (beginning with 2019), the Secretary  
22 shall submit to Congress a report containing the fol-  
23 lowing:

24 “(A) The number of requests filed with fis-  
25 cal intermediaries and carriers under paragraph

1 (8), and the number of appeals filed with the  
2 Secretary under paragraph (9), during the 1-  
3 year period ending on such date.

4 “(B) With respect to such requests filed  
5 with such intermediaries and carriers under  
6 paragraph (8) during such period, the number  
7 of times that intermediaries and carriers took,  
8 with respect to the actions described in sub-  
9 paragraphs (C) through (E) of such paragraph,  
10 each such action.

11 “(C) With respect to such appeals filed  
12 with the Secretary under paragraph (9) during  
13 such period, the number of times that the Sec-  
14 retary took, with respect to the actions de-  
15 scribed in subparagraph (D) of paragraph (8),  
16 each such action.

17 “(D) Recommendations on ways to im-  
18 prove—

19 “(i) the efficacy and the efficiency of  
20 the process described in paragraph (8);  
21 and

22 “(ii) communication with individuals  
23 entitled to benefits under part A or en-  
24 rolled under part B, providers of services,  
25 and suppliers regarding such process.”.

1 **SEC. 3. PROMULGATION OF REGULATIONS; APPLICATION**2 **DATE.**

3 The Secretary of Health and Human Services shall  
4 promulgate regulations to carry out paragraph (5)(D) of  
5 section 1862(l) of the Social Security Act (42 U.S.C.  
6 1395y(l)), as amended by subsection (a), and paragraphs  
7 (8) and (9) of section 1869(f) of such Act (42 U.S.C.  
8 1395ff(f)), as inserted by subsection (b), in such a manner  
9 as to ensure that the processes described in such para-  
10 graphs are fully implemented by January 1, 2020.

Passed the House of Representatives September 12,  
2018.

Attest:

KAREN L. HAAS,

*Clerk.*