

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 3635
OFFERED BY MR. BRADY OF TEXAS**

Strike all after the enacting clause and insert the following:

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) LCD DEVELOPMENT PROCESS.—Section
8 1862(l)(5)(D) of the Social Security Act (42 U.S.C.
9 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 fiscal intermediary or carrier that has en-
16 tered into a contract with the Secretary
17 under section 1874A, such intermediary or
18 carrier must take the following actions

1 with respect to such determination before
2 such determination may take effect:

3 “(I) Publish on the public Inter-
4 net website of the intermediary or car-
5 rier a proposed version of the speci-
6 fied local coverage determination (in
7 this subparagraph referred to as a
8 ‘draft determination’), a written ra-
9 tionale for the draft determination,
10 and a description of all evidence relied
11 upon and considered by the inter-
12 mediary or carrier in the development
13 of the draft determination.

14 “(II) Not later than 60 days
15 after the date on which the inter-
16 mediary or carrier publishes the draft
17 determination in accordance with sub-
18 clause (I), convene one or more open,
19 public meetings to review the draft de-
20 termination, receive comments with
21 respect to the draft determination,
22 and secure the advice of an expert
23 panel (such as a carrier advisory com-
24 mittee described in chapter 13 of the
25 Medicare Program Integrity Manual

1 in effect on August 31, 2015) with re-
2 spect to the draft determination. The
3 intermediary or carrier shall make
4 available means for the public to at-
5 tend such meetings remotely, such as
6 via teleconference.

7 “(III) With respect to each meet-
8 ing convened pursuant to subclause
9 (II), post on the public Internet
10 website of the intermediary or carrier,
11 not later than 14 days after such
12 meeting is convened, a record of the
13 meeting minutes for such meeting.

14 “(IV) Provide a period for sub-
15 mission of written public comment on
16 such draft determination that begins
17 on the date on which all records re-
18 quired to be posted with respect to
19 such draft determination under sub-
20 clause (III) are so posted and that is
21 not fewer than 30 days in duration.

22 “(ii) FINALIZING A SPECIFIED LOCAL
23 COVERAGE DETERMINATION.—A fiscal
24 intermediary or carrier that has entered
25 into a contract with the Secretary under

1 section 1874A shall, with respect to a spec-
2 ified local coverage determination, post on
3 the public Internet website of the fiscal
4 intermediary or carrier the following infor-
5 mation before the specified local coverage
6 determination (in this subparagraph re-
7 ferred to as the ‘final determination’) takes
8 effect—

9 “(I) a response to the issues
10 raised at meetings convened pursuant
11 to clause (i)(II) with respect to the
12 draft determination;

13 “(II) the rationale for the final
14 determination;

15 “(III) in the case that the inter-
16 mediary or carrier considered quali-
17 fying evidence in the development of
18 the determination that was not de-
19 scribed in the written notice provided
20 pursuant to clause (i)(I), a description
21 of such qualifying evidence; and

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

1 “(iii) SPECIFIED LOCAL COVERAGE
2 DETERMINATION DEFINED.—For purposes
3 of this subparagraph, the term ‘specified
4 local coverage determination’ means, with
5 respect to a geographic area—

6 “(I) a new local coverage deter-
7 mination (regardless of whether such
8 determination made by a fiscal inter-
9 mediary or carrier that has entered
10 into a contract with the Secretary
11 under section 1874A and is based
12 upon a specified local coverage deter-
13 mination that previously has been
14 made with respect to another geo-
15 graphic area, or by another such
16 intermediary or carrier);

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

1 “(III) a revised local coverage de-
2 termination that makes a substantive
3 revision to one or more existing local
4 coverage determinations; or

5 “(IV) any other local coverage
6 determination specified by the Sec-
7 retary pursuant to regulations.

8 “(iv) QUALIFYING EVIDENCE DE-
9 FINED.—For purposes of this subpara-
10 graph, the term ‘qualifying evidence’
11 means either of the following:

12 “(I) Scientific evidence published
13 in peer-reviewed medical literature,
14 such as randomized clinical trials or
15 other studies.

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

1 (b) LCD RECONSIDERATION PROCESS.—Section
2 1869(f) of the Social Security Act (42 U.S.C. 1395ff(f))
3 is amended—

4 (1) in paragraph (2)(A), by inserting “(other
5 than the reconsideration process described in para-
6 graphs (8) and (9))” after “local coverage deter-
7 mination”;

8 (2) in paragraph (5), by inserting “(other than
9 under the reconsideration process described in para-
10 graphs (8) and (9))” after “local coverage deter-
11 mination”;

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 with respect to a
20 specified local coverage determination by a fiscal
21 intermediary or carrier that has entered into a con-
22 tract with the Secretary under section 1874A, the
23 intermediary or carrier shall reconsider such deter-
24 mination in accordance 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 apply,
2 or inaccurately applied, qualifying evidence
3 relevant 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 a part of the deter-
11 mination (including, as applicable, the en-
12 tire determination).

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

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

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

1 “(9) AGENCY EVALUATION OF RECONSIDER-
2 ATION DECISION.—In the case that an interested
3 party that filed an applicable request under para-
4 graph (8) with respect to a specified local coverage
5 determination files with the Secretary, on a date
6 that is not later than 120 days after the date on
7 which an intermediary or carrier takes an action de-
8 scribed under paragraph (8)(D) with respect to such
9 determination, an appeal with respect to such deci-
10 sion in such form and manner as the Secretary may
11 require, the Secretary shall, not later than 30 days
12 after such appeal is filed—

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

16 “(B) based on such specification, take one
17 of the actions described in subparagraph (D) of
18 such paragraph with respect to the determina-
19 tion.

20 The Secretary shall apply subparagraph (A) as
21 though the reference to ‘the intermediary or carrier’
22 in clause (vi) of paragraph (8)(C) were a reference
23 to the Secretary.

24 “(10) RULE OF CONSTRUCTION.—Nothing in
25 paragraph (8) or (9) may be construed as affecting

1 the right of an aggrieved party to file a complaint
2 under paragraph (2)(A) and receive a determination
3 in accordance with the provisions of such paragraph.

4 “(11) DEFINITIONS APPLICABLE TO PARA-
5 GRAPHS (8) AND (9).—For purposes of paragraphs
6 (8) and (9):

7 “(A) The term ‘applicable request’ means
8 a request that is submitted in fiscal year 2019
9 or a subsequent fiscal year, that is solely with
10 respect to a specified local coverage determina-
11 tion, and that includes a description of the ra-
12 tionale for such request and any evidence sup-
13 porting such request. For purposes of the pre-
14 ceding sentence, the Secretary may not require,
15 as a condition of treating a request with respect
16 to such a determination as an applicable re-
17 quest, that the request contain qualifying evi-
18 dence that was not considered in the develop-
19 ment of such determination.

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

1 “(i) a provider of services or supplier
2 that, in such area, furnishes, provides, or
3 supplies items or services that are subject
4 to such determination; or

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

7 “(C) The term ‘qualifying evidence’ has
8 the meaning given such term by clause (iv) of
9 section 1862(l)(5)(D).

10 “(D) The term ‘specified local coverage de-
11 termination’ has the meaning given such term
12 by clause (iii) of such section.

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

17 “(A) The number of requests filed with fis-
18 cal intermediaries and carriers under paragraph
19 (8), and the number of appeals filed with the
20 Secretary under paragraph (9), during the 1-
21 year period ending on such date.

22 “(B) With respect to such requests filed
23 with such intermediaries and carriers under
24 paragraph (8) during such period, the number
25 of times that intermediaries and carriers took,

1 with respect to the actions described in sub-
2 paragraphs (C) through (E) of such paragraph,
3 each such action.

4 “(C) With respect to such appeals filed
5 with the Secretary under paragraph (9) during
6 such period, the number of times that the Sec-
7 retary took, with respect to the actions de-
8 scribed in subparagraph (D) of paragraph (8),
9 each such action.

10 “(D) Recommendations on ways to im-
11 prove—

12 “(i) the efficacy and the efficiency of
13 the process described in paragraph (8);
14 and

15 “(ii) communication with individuals
16 entitled to benefits under part A or en-
17 rolled under part B, providers of services,
18 and suppliers regarding such process.”.

19 **SEC. 3. PROMULGATION OF REGULATIONS; APPLICATION**
20 **DATE.**

21 The Secretary of Health and Human Services shall
22 promulgate regulations to carry out paragraph (5)(D) of
23 section 1862(l) of the Social Security Act (42 U.S.C.
24 1395y(l)), as amended by subsection (a), and paragraphs
25 (8) and (9) of section 1869(f) of such Act (42 U.S.C.

1 1395ff(f)), as inserted by subsection (b), in such a manner
2 as to ensure that the processes described in such para-
3 graphs are fully implemented by July 1, 2019.

