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:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Local Coverage Determination Clarification Act of 2018”.

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

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

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

“(i) IN GENERAL.—In the case of a specified local coverage determination (as defined in clause (iii)) within an area by a fiscal intermediary or carrier that has entered into a contract with the Secretary under section 1874A, such intermediary or carrier 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 intermediary or carrier a proposed version of the specified local coverage determination (in this subparagraph 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 intermediary or carrier in the development of the draft determination.

“(II) Not later than 60 days after the date on which the intermediary or carrier 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 intermediary or carrier 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 intermediary or carrier, 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 fiscal intermediary or carrier 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 fiscal intermediary or carrier the following information before the specified local coverage determination (in this subparagraph referred to as the ‘final determination’) takes effect—

“(I) a response to 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 intermediary or carrier 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) 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 upon a specified local coverage determination that previously has been made with respect to another geographic area, or by another such intermediary or carrier);

“(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 non-covered 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; or

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

“(iv) 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 “(other than the reconsideration process described in paragraphs (8) and (9))” after “local coverage determination”;

(2) in paragraph (5), by inserting “(other than under the reconsideration process described in paragraphs (8) and (9))” after “local coverage determination”;

(3) by redesignating paragraph (8) as paragraph (13); and

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

“(8) CARRIER OR FISCAL INTERMEDIARY RECONSIDERATION PROCESS FOR SPECIFIED LOCAL COVERAGE DETERMINATIONS.—Upon the filing of a request by an interested party with respect to a specified local coverage determination by a fiscal intermediary or carrier that has entered into a contract with the Secretary under section 1874A, the intermediary or carrier shall reconsider such determination in accordance with the following process:
“(A) Not later than 30 days after such a request is filed with the fiscal intermediary or carrier by the interested party with respect to such determination, the intermediary or carrier 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 intermediary or carrier determines under subparagraph (A) that the request described in such subparagraph is an applicable request, the intermediary or carrier shall, not later than 90 days after the date on which the request was filed with the intermediary or carrier, 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 intermediary or carrier 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.—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 an intermediary or carrier 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 intermediary or carrier’ in clause (vi) of paragraph (8)(C) were a reference to the Secretary.

“(10) Rule of Construction.—Nothing in paragraph (8) or (9) may be construed as affecting
the right of an aggrieved party to file a complaint under paragraph (2)(A) and receive a determination in accordance with the provisions of such paragraph.

“(11) 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 2019 or a subsequent fiscal year, that is solely with respect to a specified local coverage determination, 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 fiscal intermediary or carrier 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 (iv) of section 1862(l)(5)(D).

“(D) The term ‘specified local coverage determination’ has the meaning given such term by clause (iii) of such section.

“(12) REPORT.—Not later than December 31 of each year (beginning with 2019), the Secretary shall submit to Congress a report containing the following:

“(A) The number of requests filed with fiscal intermediaries and carriers under paragraph (8), and the number of appeals filed with the Secretary under paragraph (9), during the 1-year period ending on such date.

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

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

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

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

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

SEC. 3. 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 amended by subsection (a), and paragraphs
(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.