Suspend the Rules and Pass the Bill, H.R. 3635, With an Amendment

(The amendment strikes all after the enacting clause and inserts a new text)

115TH CONGRESS
2D SESSION

H. R. 3635

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 HOUSE OF REPRESENTATIVES

AUGUST 1, 2017

Ms. JENKINS of Kansas (for herself and Mr. KIND) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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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,*

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 reasonably consider qualifying evidence relevant to such determination.

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

7 “(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).

12 “(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).

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

22 “(vi) The determination is erroneous for another reason that the intermediary or 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 prty is not required to file a request under
14 paragraph (8) or (9) prior to filing a complaint
15 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.