

Union Calendar No. 724

115TH CONGRESS
2^D SESSION

H. R. 3635

[Report No. 115–933, Part I]

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

SEPTEMBER 10, 2018

Additional sponsors: Mr. MEEHAN, Mr. SESSIONS, Mr. CROWLEY, Mr. MULLIN, Mr. PETERSON, Mr. MARCHANT, Mr. ENGEL, Mr. UPTON, Ms. SEWELL of Alabama, Mr. MOULTON, Mr. TONKO, Mr. LOEBSACK, Mr. RUSH, Ms. SCHAKOWSKY, Mr. ROE of Tennessee, Mr. STIVERS, Mr. BLUMENAUER, Ms. DEGETTE, Mr. BRENDAN F. BOYLE of Pennsylvania, Mr. BILIRAKIS, Mr. COSTELLO of Pennsylvania, Mr. AUSTIN SCOTT of Georgia, Mr. CARTER of Georgia, Mr. SCHWEIKERT, Mr. MICHAEL F. DOYLE of Pennsylvania, Ms. KUSTER of New Hampshire, Mr. DESJARLAIS, Mr. HARRIS, Mr. BISHOP of Michigan, Ms. MATSUI, Mr. THOMPSON of California, Mr. HARPER, Mr. CÁRDENAS, Mr. CURBELO of Florida, Mr. YOUNG of Iowa, Mr. MARSHALL, Mr. LANCE, Mr. FLORES, Mrs. BLACKBURN, Mr. MCNERNEY, Mr. FERGUSON, Mr. RUIZ, Mr. PAULSEN, Mr. SEAN PATRICK MALONEY of New York, Mr. KUSTOFF of Tennessee, Mr. PETERS, Mr. KHANNA, Mr. KELLY of Pennsylvania, Mr. BUTTERFIELD, Mrs. BLACK, Ms. CLARKE of New York, Ms. NORTON, Mr. WALBERG, Mr. COOK, Mr. THOMPSON of Pennsylvania, Mr. RUPPERSBERGER, Mr. TIPTON, Mr. DEFazio, Miss RICE of New York, Mr. CRAMER, Mr. KENNEDY, Mr. WENSTRUP, Ms. HERRERA BEUTLER, Mr. BIGGS, Mr. HUIZENGA, Mr. HURD, Mr. CRAWFORD, Mr. SMITH of Nebraska, Mr.

THOMPSON of Mississippi, Mr. WESTERMAN, Mrs. LESKO, Mr. BYRNE, Ms. EDDIE BERNICE JOHNSON of Texas, Mr. DUNCAN of Tennessee, Mr. BRAT, Mr. CLEAVER, Mr. POLIQUIN, Mr. DUNN, Mr. RENACCI, and Mr. COFFMAN

SEPTEMBER 10, 2018

Reported from the Committee on Ways and Means with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

SEPTEMBER 10, 2018

Committee on Energy and Commerce discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

[For text of introduced bill, see copy of bill as introduced on August 1, 2017]

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 2018”.*

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

9 *(a) LCD DEVELOPMENT PROCESS.—Section*
 10 *1862(l)(5)(D) of the Social Security Act (42 U.S.C.*
 11 *1395y(l)(5)(D)) is amended to read as follows:*

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

14 *“(i) IN GENERAL.—In the case of a*
 15 *specified local coverage determination (as*
 16 *defined in clause (iii)) within an area by a*
 17 *fiscal intermediary or carrier that has en-*
 18 *tered into a contract with the Secretary*
 19 *under section 1874A, such intermediary or*
 20 *carrier must take the following actions with*
 21 *respect to such determination before such*
 22 *determination may take effect:*

23 *“(I) Publish on the public Inter-*
 24 *net website of the intermediary or car-*
 25 *rier a proposed version of the specified*

1 *local coverage determination (in this*
2 *subparagraph referred to as a ‘draft*
3 *determination’), a written rationale for*
4 *the draft determination, and a descrip-*
5 *tion of all evidence relied upon and*
6 *considered by the intermediary or car-*
7 *rier in the development of the draft de-*
8 *termination.*

9 *“(II) Not later than 60 days after*
10 *the date on which the intermediary or*
11 *carrier publishes the draft determina-*
12 *tion in accordance with subclause (I),*
13 *convene one or more open, public meet-*
14 *ings to review the draft determination,*
15 *receive comments with respect to the*
16 *draft determination, and secure the ad-*
17 *vice of an expert panel (such as a car-*
18 *rier advisory committee described in*
19 *chapter 13 of the Medicare Program*
20 *Integrity Manual in effect on August*
21 *31, 2015) with respect to the draft de-*
22 *termination. The intermediary or car-*
23 *rier shall make available means for the*
24 *public to attend such meetings re-*
25 *motely, such as via teleconference.*

1 “(III) With respect to each meet-
2 ing convened pursuant to subclause
3 (II), post on the public Internet website
4 of the intermediary or carrier, not
5 later than 14 days after such meeting
6 is convened, a record of the meeting
7 minutes for such meeting.

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

16 “(i) *FINALIZING A SPECIFIED LOCAL*
17 *COVERAGE DETERMINATION.*—A fiscal inter-
18 mediary or carrier that has entered into a
19 contract with the Secretary under section
20 1874A shall, with respect to a specified local
21 coverage determination, post on the public
22 Internet website of the fiscal intermediary
23 or carrier the following information before
24 the specified local coverage determination

1 *(in this subparagraph referred to as the*
2 *‘final determination’) takes effect—*

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

7 *“(II) the rationale for the final*
8 *determination;*

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

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

20 *“(iii) SPECIFIED LOCAL COVERAGE DE-*
21 *TERMINATION DEFINED.—For purposes of*
22 *this subparagraph, the term ‘specified local*
23 *coverage determination’ means, with respect*
24 *to a geographic area—*

1 “(I) a new local coverage deter-
2 mination (regardless of whether such
3 determination made by a fiscal inter-
4 mediary or carrier that has entered
5 into a contract with the Secretary
6 under section 1874A and is based upon
7 a specified local coverage determina-
8 tion that previously has been made
9 with respect to another geographic
10 area, or by another such intermediary
11 or carrier);

12 “(II) a revised local coverage de-
13 termination for such geographic area
14 that restricts one or more existing cov-
15 erage criteria for such area (such as by
16 adding non-covered indications to an
17 existing local coverage determination
18 or by deleting previously covered ICD-
19 9 or ICD-10 codes);

20 “(III) a revised local coverage de-
21 termination that makes a substantive
22 revision to one or more existing local
23 coverage determinations; or

1 “(IV) any other local coverage de-
2 termination specified by the Secretary
3 pursuant to regulations.

4 “(iv) *QUALIFYING EVIDENCE DE-*
5 *FINED.*—For purposes of this subparagraph,
6 the term ‘qualifying evidence’ means either
7 of the following:

8 “(I) Scientific evidence published
9 in peer-reviewed medical literature,
10 such as randomized clinical trials or
11 other studies.

12 “(II) A general consensus of the
13 applicable medical community (such as
14 a consensus evinced through a recog-
15 nized standard of practice in such
16 medical community) that is supported
17 by information provided by a recog-
18 nized medical authority, such as a pro-
19 fessional medical society.”.

20 (b) *LCD RECONSIDERATION PROCESS.*—Section
21 1869(f) of the Social Security Act (42 U.S.C. 1395ff(f)) is
22 amended—

23 (1) in paragraph (2)(A), by inserting “(other
24 than the reconsideration process described in para-

1 *graphs (8) and (9))” after “local coverage determina-*
2 *tion”;*

3 *(2) in paragraph (5), by inserting “(other than*
4 *under the reconsideration process described in para-*
5 *graphs (8) and (9))” after “local coverage determina-*
6 *tion”;*

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

9 *(4) by inserting after paragraph (7) the fol-*
10 *lowing new paragraphs:*

11 *“(8) CARRIER OR FISCAL INTERMEDIARY RECON-*
12 *SIDERATION PROCESS FOR SPECIFIED LOCAL COV-*
13 *ERAGE DETERMINATIONS.—Upon the filing of a re-*
14 *quest by an interested party with respect to a speci-*
15 *fied local coverage determination by a fiscal inter-*
16 *mediary or carrier that has entered into a contract*
17 *with the Secretary under section 1874A, the inter-*
18 *mediary or carrier shall reconsider such determina-*
19 *tion in accordance with the following process:*

20 *“(A) Not later than 30 days after such a re-*
21 *quest is filed with the fiscal intermediary or car-*
22 *rier by the interested party with respect to such*
23 *determination, the intermediary or carrier*
24 *shall—*

1 “(i) determine whether the request is
2 an applicable request; and

3 “(ii) in the case that the request is not
4 an applicable request, inform the interested
5 party of the reasons why such request is not
6 an applicable request.

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

16 “(C) The action described in this subpara-
17 graph is the action of specifying whether any of
18 the following statements is applicable to the de-
19 termination:

20 “(i) The determination did not apply,
21 or inaccurately applied, qualifying evidence
22 relevant to such determination.

23 “(ii) The determination used language
24 that exceeded the scope of the intended pur-
25 pose of the determination.

1 “(iii) *The determination was incorrect*
2 *in its determination of whether such item or*
3 *service is reasonable and necessary for the*
4 *diagnosis or treatment of illness or injury*
5 *under section 1862(a)(1)(A).*

6 “(iv) *The determination failed to de-*
7 *scribe, with respect to such an item or serv-*
8 *ice, the clinical conditions to be used for*
9 *purposes of determining whether such item*
10 *or service is reasonable and necessary for*
11 *the diagnosis or treatment of illness or in-*
12 *jury under section 1862(a)(1)(A).*

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

16 “(vi) *The determination is erroneous*
17 *for another reason that the intermediary or*
18 *carrier identifies.*

19 “(D) *The action described in this subpara-*
20 *graph, with respect to the determination, is the*
21 *action of taking, based on the specification under*
22 *subparagraph (C) of whether any of the state-*
23 *ments in such subparagraph applied to such de-*
24 *termination, one or more of the following ac-*
25 *tions:*

1 “(i) *Making no change in the deter-*
2 *mination.*

3 “(ii) *Rescinding a part of the deter-*
4 *mination (including, as applicable, the en-*
5 *tire determination).*

6 “(iii) *Modifying the determination to*
7 *restrict the coverage provided under this*
8 *title for an item or service that is subject to*
9 *the determination.*

10 “(iv) *Modifying the determination to*
11 *expand the coverage provided under this*
12 *title for an item or service that is subject to*
13 *the determination.*

14 “(E) *The action described in this subpara-*
15 *graph is the action of making publicly available*
16 *a written description of the action taken under*
17 *subparagraph (D) with respect to the determina-*
18 *tion.*

19 “(9) *AGENCY EVALUATION OF RECONSIDERATION*
20 *DECISION.—In the case that an interested party that*
21 *filed an applicable request under paragraph (8) with*
22 *respect to a specified local coverage determination*
23 *files with the Secretary, on a date that is not later*
24 *than 120 days after the date on which an inter-*
25 *mediary or carrier takes an action described under*

1 paragraph (8)(D) with respect to such determination,
2 an appeal with respect to such decision in such form
3 and manner as the Secretary may require, the Sec-
4 retary shall, not later than 30 days after such appeal
5 is filed—

6 “(A) specify which, if any, of the statements
7 in subparagraph (C) of paragraph (8) is appli-
8 cable to the determination; and

9 “(B) based on such specification, take one of
10 the actions described in subparagraph (D) of
11 such paragraph with respect to the determina-
12 tion.

13 The Secretary shall apply subparagraph (A) as
14 though the reference to ‘the intermediary or carrier’
15 in clause (vi) of paragraph (8)(C) were a reference to
16 the Secretary.

17 “(10) *RULE OF CONSTRUCTION.*—Nothing in
18 paragraph (8) or (9) may be construed as affecting
19 the right of an aggrieved party to file a complaint
20 under paragraph (2)(A) and receive a determination
21 in accordance with the provisions of such paragraph.

22 “(11) *DEFINITIONS APPLICABLE TO PARAGRAPHS*
23 *(8) AND (9).*—For purposes of paragraphs (8) and (9):

24 “(A) The term ‘applicable request’ means a
25 request that is submitted in fiscal year 2019 or

1 *a subsequent fiscal year, that is solely with re-*
2 *spect to a specified local coverage determination,*
3 *and that includes a description of the rationale*
4 *for such request and any evidence supporting*
5 *such request. For purposes of the preceding sen-*
6 *tence, the Secretary may not require, as a condi-*
7 *tion of treating a request with respect to such a*
8 *determination as an applicable request, that the*
9 *request contain qualifying evidence that was not*
10 *considered in the development of such determina-*
11 *tion.*

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

17 *“(i) a provider of services or supplier*
18 *that, in such area, furnishes, provides, or*
19 *supplies items or services that are subject to*
20 *such determination; or*

21 *“(ii) an organization that represents*
22 *such a provider of services or supplier.*

23 *“(C) The term ‘qualifying evidence’ has the*
24 *meaning given such term by clause (iv) of sec-*
25 *tion 1862(l)(5)(D).*

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

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

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

12 “(B) With respect to such requests filed with
13 such intermediaries and carriers under para-
14 graph (8) during such period, the number of
15 times that intermediaries and carriers took, with
16 respect to the actions described in subparagraphs
17 (C) through (E) of such paragraph, each such ac-
18 tion.

19 “(C) With respect to such appeals filed with
20 the Secretary under paragraph (9) during such
21 period, the number of times that the Secretary
22 took, with respect to the actions described in sub-
23 paragraph (D) of paragraph (8), each such ac-
24 tion.

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

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

5 “(ii) *communication with individuals*
6 *entitled to benefits under part A or enrolled*
7 *under part B, providers of services, and*
8 *suppliers regarding such process.”.*

9 **SEC. 3. PROMULGATION OF REGULATIONS; APPLICATION**
10 **DATE.**

11 *The Secretary of Health and Human Services shall*
12 *promulgate regulations to carry out paragraph (5)(D) of*
13 *section 1862(l) of the Social Security Act (42 U.S.C.*
14 *1395y(l)), as amended by subsection (a), and paragraphs*
15 *(8) and (9) of section 1869(f) of such Act (42 U.S.C.*
16 *1395ff(f)), as inserted by subsection (b), in such a manner*
17 *as to ensure that the processes described in such paragraphs*
18 *are fully implemented by July 1, 2019.*

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H. R. 3635

[Report No. 115-933, Part I]

A BILL

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