

119TH CONGRESS
2D SESSION

S. _____

To amend title XVIII of the Social Security Act to ensure timely review of local coverage determination requests under the Medicare program.

IN THE SENATE OF THE UNITED STATES

Mr. LUJÁN (for himself and Mr. COTTON) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend title XVIII of the Social Security Act to ensure timely review of local coverage determination requests under the Medicare program.

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 “Timely Access to Cov-
5 erage Decisions Act”.

1 **SEC. 2. ENSURING TIMELY REVIEW OF LOCAL COVERAGE**
2 **DETERMINATION REQUESTS UNDER THE**
3 **MEDICARE PROGRAM.**

4 (a) IN GENERAL.—Section 1862(l)(5) of the Social
5 Security Act (42 U.S.C. 1395y(l)(5)) is amended by add-
6 ing at the end the following new subparagraph:

7 “(E) TIMEFRAME FOR DECISIONS ON RE-
8 QUESTS FOR LOCAL COVERAGE DETERMINA-
9 TIONS.—

10 “(i) IN GENERAL.—The Secretary
11 shall require each Medicare administrative
12 contractor that receives a formal LCD re-
13 quest on or after the date that is 90 days
14 after the date of enactment of this sub-
15 paragraph to determine whether such re-
16 quest is a complete request or an incom-
17 plete request not later than 60 days after
18 such contractor receives such request.

19 “(ii) NOTIFICATION WITH RESPECT
20 TO INCOMPLETE REQUESTS.—In the case
21 that a Medicare administrative contractor
22 makes a determination described in clause
23 (i) with respect to a formal LCD request
24 that such request is incomplete, such con-
25 tractor shall, not later than 60 days after
26 the date on which such contractor received

1 such request, transmit to the entity that
2 submitted such request a written notifica-
3 tion of such determination that includes a
4 specification of each item of additional in-
5 formation needed to make such request
6 complete.

7 “(iii) DECISION TIMELINE FOR COM-
8 PLETE REQUESTS.—In the case that a
9 Medicare administrative contractor makes
10 a determination described in clause (i) with
11 respect to a formal LCD request that such
12 request is complete, such contractor shall,
13 not later than 1 year after the date on
14 which such contractor received such re-
15 quest, take the actions described in clauses
16 (i) and (ii) of subparagraph (D).

17 “(iv) FORMAL LCD REQUEST DE-
18 FINED.—In this subparagraph, the term
19 ‘formal LCD request’ means a document
20 that identifies itself as a formal request for
21 a local coverage determination.”.

22 (b) RECONSIDERATION REQUESTS.—Section
23 1862(l)(5) of the Social Security Act (42 U.S.C.
24 1395y(l)(5)), as amended by subsection (a), is further

1 amended by adding at the end the following new subpara-
2 graphs:

3 “(F) TIMEFRAME FOR DECISIONS ON RE-
4 CONSIDERATION REQUESTS FOR LOCAL COV-
5 ERAGE DETERMINATIONS.—

6 “(i) IN GENERAL.—The Secretary
7 shall require each Medicare administrative
8 contractor that receives a formal reconsid-
9 eration request on or after the date that is
10 90 days after the date of enactment of this
11 subparagraph to determine whether such
12 request is a complete request or an incom-
13 plete request not later than 60 days after
14 such contractor receives such request.

15 “(ii) NOTIFICATION WITH RESPECT
16 TO INCOMPLETE REQUESTS.—In the case
17 that a Medicare administrative contractor
18 makes a determination described in clause
19 (i) with respect to a formal reconsideration
20 request that such request is incomplete,
21 such contractor shall, not later than 60
22 days after the date on which such con-
23 tractor received such request, transmit to
24 the entity that submitted such request a
25 written notification of such determination

1 that includes a specification of each item
2 of additional information needed to make
3 such request complete.

4 “(iii) DECISION TIMELINE FOR COM-
5 PLETE REQUESTS.—In the case that a
6 Medicare administrative contractor makes
7 a determination described in clause (i) with
8 respect to a formal reconsideration request
9 that such request is complete, such con-
10 tractor shall, not later than 1 year after
11 the date on which such contractor received
12 such request, take the actions described in
13 clauses (i) and (ii) of subparagraph (D).

14 “(iv) DEFINITIONS.—In this subpara-
15 graph:

16 “(I) FORMAL RECONSIDERATION
17 REQUEST.—The term ‘formal recon-
18 sideration request’ means, with re-
19 spect to a Medicare administrative
20 contractor, a document that—

21 “(aa) identifies itself as a
22 formal request for reconsider-
23 ation of part or all of a finalized
24 local coverage determination

6

1 made by such contractor with re-
2 spect to a geographic area; and

3 “(bb) is submitted by an in-
4 terested party.

5 “(II) INTERESTED PARTY.—The
6 term ‘interested party’ means, with
7 respect to a local coverage determina-
8 tion made by a Medicare administra-
9 tive contractor with respect to a geo-
10 graphic area—

11 “(aa) an individual entitled
12 to benefits under part A or en-
13 rolled under part B who resides
14 in, or receives items or services
15 in, such area;

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

21 “(cc) any entity that the
22 Secretary determines to be an in-
23 terested party in such area.

24 “(G) AGENCY REVIEW OF RECONSIDER-
25 ATION DECISION.—Upon the request of an in-

1 terested party (as defined in subparagraph
2 (F)(iv)), the Secretary shall review the final de-
3 termination (as defined in subparagraph
4 (D)(ii)) made by a Medicare administrative con-
5 tractor following a complete formal reconsider-
6 ation request made under subparagraph (F).
7 Such review shall include an analysis of wheth-
8 er—

9 “(i) the determination did not apply,
10 or inaccurately interpreted, qualifying evi-
11 dence (as defined in subparagraph (D)(iv))
12 relevant to such determination;

13 “(ii) the determination used language
14 that exceeded the scope of the intended
15 purpose of the determination;

16 “(iii) the determination was incorrect
17 in its determination of whether such item
18 or service is reasonable and necessary for
19 the diagnosis or treatment of illness or in-
20 jury under section 1862(a)(1)(A);

21 “(iv) the determination failed to de-
22 scribe, with respect to such an item or
23 service, the clinical conditions to be used
24 for purposes of determining whether such
25 item or service is reasonable and necessary

1 for the diagnosis or treatment of illness or
2 injury under section 1862(a)(1)(A);

3 “(v) the determination does not apply
4 with respect to items or services to which
5 it was intended to apply; or

6 “(vi) the determination conflicts with
7 any other law, rule, regulation, or national
8 coverage determination, as determined by
9 the Secretary.”.

10 (c) DEVELOPMENT PROCESS FOR SPECIFIED
11 LCDs.—Section 1862(l)(5)(D) of the Social Security Act
12 (42 U.S.C. 1395y(l)(5)(D)) is amended to read as follows:

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

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

22 “(I) Publish on the public Inter-
23 net website of the Centers for Medi-
24 care & Medicaid Services commonly
25 referred to as the ‘Medicare Coverage

1 Database’ (or a successor website)
2 and on the public Internet website of
3 the Medicare administrative con-
4 tractor a proposed version of the spec-
5 ified local coverage determination (in
6 this subparagraph referred to as a
7 ‘draft determination’), any related
8 coding or billing information, a writ-
9 ten rationale for the draft determina-
10 tion, and a description of all evidence
11 relied upon and considered by the con-
12 tractor in the development of the
13 draft determination.

14 “(II) Not later than 60 days
15 after the date on which the Medicare
16 administrative contractor publishes
17 the draft determination in accordance
18 with subclause (I)—

19 “(aa) convene one or more
20 open, public meetings to review
21 the draft determination, and,
22 with respect to each such meet-
23 ing, make available means for the
24 public to attend such meeting re-
25 motely, and make the planned

1 agenda for such meeting publicly
2 accessible at least 14 days in ad-
3 vance;

4 “(bb) receive comments with
5 respect to the draft determina-
6 tion; and

7 “(cc) secure the advice of an
8 expert panel, which shall in-
9 clude—

10 “(AA) 1 or more physi-
11 cians;

12 “(BB) 1 or more mem-
13 bers of the Contractor Advi-
14 sory Committee (as de-
15 scribed in chapter 13 of the
16 Medicare Program Integrity
17 Manual, as in effect on Feb-
18 ruary 12, 2019); and

19 “(CC) 1 or more enti-
20 ties advocating on behalf of
21 one or more individuals enti-
22 tled to benefits under part A
23 or enrolled under part B.

24 “(III) With respect to each meet-
25 ing convened pursuant to subclause

1 (II)(aa), post on the public Internet
2 website of the contractor, not later
3 than 14 days after such meeting is
4 convened, a record of such meeting,
5 which may include a video or audio
6 recording of the meeting.

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

15 “(ii) FINALIZING A SPECIFIED LOCAL
16 COVERAGE DETERMINATION.—

17 “(I) IN GENERAL.—Subject to
18 subclause (II), a Medicare administra-
19 tive contractor that has entered into a
20 contract with the Secretary under sec-
21 tion 1874A shall, before a specified
22 local coverage determination (in this
23 subparagraph referred to as the ‘final
24 determination’) takes effect, post on
25 the Medicare Coverage Database and

1 the public Internet website of the con-
2 tractor the following information:

3 “(aa) A response to public
4 comments received and the rel-
5 evant issues raised at meetings
6 convened pursuant to clause
7 (i)(II)(aa) with respect to the
8 draft determination.

9 “(bb) The full text of all
10 such public comments received.

11 “(cc) The rationale for the
12 final determination.

13 “(dd) In the case that the
14 Medicare administrative con-
15 tractor considered qualifying evi-
16 dence (as defined in clause (iv))
17 in the development of the deter-
18 mination that was not described
19 in the written notice provided
20 pursuant to clause (i)(I), a de-
21 scription of such qualifying evi-
22 dence.

23 “(ee) An effective date for
24 the final determination that is
25 not less than 45 days after the

1 date on which such determination
2 is so posted.

3 “(II) LOGICAL OUTGROWTH RE-
4 QUIREMENT.—Notwithstanding sub-
5 clause (I), a final determination may
6 not take effect unless such determina-
7 tion is a logical outgrowth of the draft
8 determination published under clause
9 (i).

10 “(iii) SPECIFIED LOCAL COVERAGE
11 DETERMINATION DEFINED.—For purposes
12 of this subparagraph, the term ‘specified
13 local coverage determination’ means, with
14 respect to the relevant geographic area—

15 “(I) a new local coverage deter-
16 mination;

17 “(II) a revised local coverage de-
18 termination that makes a substantive
19 revision to one or more existing local
20 coverage determinations (such as by
21 imposing new requirements with re-
22 spect to coverage of the relevant item
23 or service or by changing any coding
24 or billing information related to such
25 determination); or

1 “(III) any other local coverage
2 determination specified by the Sec-
3 retary pursuant to regulations.

4 “(iv) QUALIFYING EVIDENCE DE-
5 FINED.—For purposes of this subpara-
6 graph, the term ‘qualifying evidence’
7 means publicly available evidence of gen-
8 eral acceptance by the medical community,
9 such as published original research in peer-
10 reviewed medical journals, systematic re-
11 views and meta-analyses, evidence-based
12 consensus statements, and clinical guide-
13 lines.”.

14 (d) EFFECTIVE DATE.—This section, and the amend-
15 ments made by this section, shall apply beginning on the
16 date that is 1 year after the date of the enactment of this
17 section.