

114th CONGRESS
1st SESSION

H.R. _____

IN THE HOUSE OF REPRESENTATIVES

[_____] introduced the following bill; which was referred to
the Committee on

_____.

A BILL

To amend the Social Security Act with respect to the regulation of
Medicare Administrative Contractors and their use of the
Local Coverage Determination process.

1 *Be it enacted by the Senate and House of Representatives of the*
2 *United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “[_____] Act of 2015.]

5 **SEC. 2. IMPROVEMENTS IN THE MEDICARE LOCAL COVERAGE**
6 **DETERMINATION (LCD) PROCESS.**

7 (a) IN GENERAL. – Section 1862(l)(5) of the Social Security Act (42. U.S.C.
8 1395y(l)(5)) is amended by adding at the end the following subparagraph:
9 “(D) REQUIREMENTS FOR LOCAL COVERAGE DETERMINATION
10 PROCESS FOR MEDICARE ADMINISTRATIVE CONTRACTORS. –

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- 1 (i) IN GENERAL. – The Secretary shall require each
2 Medicare Administrative Contractor to establish a
3 timely process for development of local coverage
4 determinations that provides for opportunities for
5 public comment and for disclosure of information to
6 the public regarding such determinations in accord
7 with this subsection.
- 8 (ii) PROCESS. – Before releasing a new or
9 significantly revised local coverage determination, a
10 Medicare Administrative Contractor shall –
- 11 (I) Issue a proposed local coverage
12 determination and provide a period for
13 public comment of at least 45 days (or 60
14 days in the case described in clause (iii));
- 15 (II) Upon request of individuals (including
16 providers, their representatives, or
17 representatives of Medicare beneficiaries)
18 within the jurisdiction of the contractor,
19 convene an open, public meeting to review
20 the proposed local coverage determination
21 and to receive comments from attendees;
22 and

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- 1 (III) Meet upon request with individuals
2 (including providers, their representatives,
3 or representatives of Medicare beneficiaries)
4 within such jurisdiction and manufacturers
5 or sponsors of items affected by the
6 proposed local coverage determination; and
7 (IV) Provide a written rationale for the proposed
8 local coverage determination and a
9 description of all evidence relied upon and
10 considered when drafting said
11 determination.

12 (iii) PROCESS FOR LIMITATIONS. – If a Medicare
13 Administrative Contractor proposes a local
14 coverage determination that would limit or preclude
15 coverage of an item or service, the contractor shall –

- 16 (I) Convene a meeting of its Carrier Advisory
17 Committee as required under chapter 13 of
18 the Medicare Program Integrity Manual to
19 secure its advice on the proposed
20 determination. The initial and any
21 subsequent meetings of the Carrier Advisory
22 Committee shall be open to the public and a
23 record of the meeting minutes shall be

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1 maintained and posted for public review on
2 the Medicare Administrative Contractor
3 website within thirty (30) days following
4 such meeting but in no case later than five
5 (5) days before the end of the public
6 comment period set forth in subsection (II)
7 below;

8 (II) And shall provide a period for public
9 comment on the proposed determination of
10 at least 60 days.

11 (iv) RESPONDING TO COMMENTS. – A Medicare
12 Administrative Contractor shall include with any
13 public release of a final local coverage
14 determination –

15 (I) The contractor’s response to all comments
16 on the proposed local coverage
17 determination; and

18 (II) A description of the evidence the contractor
19 considered in making the determination and
20 the rationale for the policy adopted.

21 (v) LIMITS ON ADOPTING DETERMINATIONS IN
22 OTHER JURISDICTIONS. – Under no
23 circumstances shall the Secretary designate a

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1 Medicare Administrative Contractor, expressly or in
2 practice, to establish local coverage determinations
3 that apply, or have the affect of applying, outside of
4 the Medicare Administrative Contractor’s
5 designated jurisdiction or on a nationwide basis.
6 Medicare Administrative Contractors wishing to
7 adopt local coverage determinations developed in
8 other jurisdictions shall independently evaluate and
9 consider any evidence, and undertake the process as
10 described in this subsection.

- 11 (v) TREATMENT OF REVISIONS. – A Medicare
12 Administrative Contractor may issue a revised local
13 coverage determination without regard to clauses
14 (ii), (iii), and (iv) if the determination is –
- 15 (I) A clarification that does not restrict
16 coverage;
 - 17 (II) A change for a compelling safety or
18 technical reason such as prevention of harm
19 to individuals (subject to the approval of the
20 Secretary);
 - 21 (III) A change for coding, coverage, or payment
22 updates over which the Medicare

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- 1 Administrative Contractor does not have
2 discretion;
- 3 (IV) A discretionary coding update that does not
4 restrict coverage;
- 5 (V) A change to effectuate a decision of an
6 administrative law judge on a challenge
7 under section 1869(f); or
- 8 (VI) Another type of change that the Secretary
9 may specify in regulations.”
- 10 (vii) RECONSIDERATIONS. – Any entity (“Requesting
11 Entity”) who chooses to file a local coverage
12 determination reconsideration request
13 (“Reconsideration Request”) –
- 14 (I) Shall file a written Reconsideration Request
15 with the CMS Regional office within six (6)
16 months of a local coverage determination
17 being finalized, specifying the basis of such
18 challenge.
- 19 (II) Upon receipt of the Reconsideration
20 Request, the CMS Regional Office shall
21 forward a copy to the applicable Medicare
22 Administrative Contractor within ten (10)
23 days.

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- 1 (III) The applicable Medicare Administrative
2 Contractor shall send a copy of the complete
3 record related to the local coverage
4 determination subject to the Reconsideration
5 Request to the CMS Regional Office and to
6 the Requesting Entity within thirty (30) days
7 (subject to extension for good cause shown).
- 8 (IV) Within ten (10) days of receiving a local
9 coverage determination Reconsideration
10 Request from a Requesting Entity, the CMS
11 Regional Office shall send
12 acknowledgement of receipt of such request
13 to the Requesting Entity and shall initiate a
14 review of the challenged local coverage
15 determination. Within sixty (60) days of
16 initiation of the review, the CMS Regional
17 Office shall issue a determination on the
18 validity of the local coverage determination
19 subject to the Reconsideration Request as set
20 forth in subsection (V) below.
- 21 (V) The CMS Regional Office shall either:
22 a. If the CMS Regional Office finds the
23 reconsideration request valid in full,

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1 instruct the Medicare Administrative
2 Contractor to rescind or retire the local
3 coverage determination immediately.
4 The Medicare Administrative Contractor
5 shall rescind or retire the local coverage
6 determination subject to the
7 Reconsideration Request within five (5)
8 days of receipt of such instruction from
9 the CMS Regional Office.

- 10 b. If the CMS Regional Office finds the
11 request valid in part, instruct the
12 Medicare Administrative Contractor to
13 revise the local coverage determination
14 to be either more restrictive or less
15 restrictive, in accord with the
16 instructions of the CMS Regional Office.
17 The Medicare Administrative Contractor
18 shall revise the local coverage
19 determination in accord with such
20 instructions within thirty (30) days of
21 receiving such instructions from the
22 CMS Regional Office.

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1 c. If the CMS Regional Office finds the
2 request invalid, the CMS Regional
3 Office shall include in its written
4 determination to the Requesting Entity
5 an explanation of its rationale for finding
6 the request invalid, including any
7 evidence and evidentiary standards used
8 in such review.

9 (VI) If the CMS Regional Office finds the
10 reconsideration request invalid in whole or
11 in part the Requesting Entity shall have a
12 right to appeal the provisions of the
13 Reconsideration Request that were rejected
14 to the CMS Administrator in a separate
15 process (to be determined by the Secretary).

16 (a) EFFECTIVE DATE. – The amendment made by subsection (a) shall be
17 effective with respect to local coverage determinations proposed or
18 revised on or after the date that is 90 days after the date of the enactment
19 of this Act.

20 (b) DEFINITIONS. – In this section:

21 (1) Evidence: The term “evidence” means –

22 (A) Published authoritative evidence derived from definitive
23 randomized clinical trials or other definitive studies; or

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- 1 (B) General consensus of the medical community (usually in the form
2 of a recognized standard of practice), as supported by reasonable
3 medical authority based on:
- 4 (i) Scientific data or research studies published in
5 peer-reviewed medical or scientific journals;
 - 6 (ii) Consensus of recognized medical experts; and
 - 7 (iii) Consultations with professional medical
8 societies.