[Discussion Draft]

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.

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

SECTION 1. SHORT TITLE.

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

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

(a) IN GENERAL. – Section 1862(l)(5) of the Social Security Act (42. U.S.C. 1395y(l)(5)) is amended by adding at the end the following subparagraph:

"(D) REQUIREMENTS FOR LOCAL COVERAGE DETERMINATION PROCESS FOR MEDICARE ADMINISTRATIVE CONTRACTORS. –

(i) IN GENERAL. – The Secretary shall require each Medicare Administrative Contractor to establish a timely process for development of local coverage determinations that provides for opportunities for public comment and for disclosure of information to the public regarding such determinations in accord with this subsection.

(ii) PROCESS. – Before releasing a new or significantly revised local coverage determination, a Medicare Administrative Contractor shall –

(I) Issue a proposed local coverage determination and provide a period for public comment of at least 45 days (or 60 days in the case described in clause (iii));

(II) Upon request of individuals (including providers, their representatives, or representatives of Medicare beneficiaries) within the jurisdiction of the contractor, convene an open, public meeting to review the proposed local coverage determination and to receive comments from attendees; and

(III) Meet upon request with individuals (including providers, their representatives, or representatives of Medicare beneficiaries) within such jurisdiction and manufacturers or sponsors of items affected by the proposed local coverage determination; and

(IV) Provide a written rationale for the proposed local coverage determination and a description of all evidence relied upon and considered when drafting said determination.

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

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

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

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

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

(I) The contractor's response to all comments on the proposed local coverage determination; and

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

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

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

(v) TREATMENT OF REVISIONS. – A Medicare Administrative Contractor may issue a revised local coverage determination without regard to clauses (ii), (iii), and (iv) if the determination is –

(I) A clarification that does not restrict coverage;

(II) A change for a compelling safety or technical reason such as prevention of harm to individuals (subject to the approval of the Secretary);

(III) A change for coding, coverage, or payment updates over which the Medicare

Administrative Contractor does not have discretion;

(IV) A discretionary coding update that does not restrict coverage;

(V) A change to effectuate a decision of an administrative law judge on a challenge under section 1869(f); or

(VI) Another type of change that the Secretary may specify in regulations."

(vii) RECONSIDERATIONS. – Any entity ("Requesting Entity") who chooses to file a local coverage determination reconsideration request ("Reconsideration Request") –

(I) Shall file a written Reconsideration Request with the CMS Regional office within six (6) months of a local coverage determination being finalized, specifying the basis of such challenge.

(II) Upon receipt of the Reconsideration Request, the CMS Regional Office shall forward a copy to the applicable Medicare Administrative Contractor within ten (10) days.

(III) The applicable Medicare Administrative Contractor shall send a copy of the complete record related to the local coverage determination subject to the Reconsideration Request to the CMS Regional Office and to the Requesting Entity within thirty (30) days (subject to extension for good cause shown).

(IV) Within ten (10) days of receiving a local coverage determination Reconsideration Request from a Requesting Entity, the CMS Regional Office shall send acknowledgement of receipt of such request to the Requesting Entity and shall initiate a review of the challenged local coverage determination. Within sixty (60) days of initiation of the review, the CMS Regional Office shall issue a determination on the validity of the local coverage determination subject to the Reconsideration Request as set forth in subsection (V) below.

(V) The CMS Regional Office shall either:

a. If the CMS Regional Office finds the reconsideration request valid in full,

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

b. If the CMS Regional Office finds the request valid in part, instruct the Medicare Administrative Contractor to revise the local coverage determination to be either more restrictive or less restrictive, in accord with the instructions of the CMS Regional Office. The Medicare Administrative Contractor shall revise the local coverage determination in accord with such instructions within thirty (30) days of receiving such instructions from the CMS Regional Office.

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

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

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

(b) DEFINITIONS. – In this section:

(1) Evidence: The term "evidence" means –

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

(B) General consensus of the medical community (usually in the form of a recognized standard of practice), as supported by reasonable medical authority based on:

(i) Scientific data or research studies published in peer-reviewed medical or scientific journals;

(ii) Consensus of recognized medical experts; and

(iii) Consultations with professional medical societies.