

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5074

MINORITY (202) 225-5051

<http://oversight.house.gov>

April 28, 2016

The Honorable Sylvia Mathews Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Dear Madam Secretary:

In the absence of a Medicare coverage policy, the Centers for Medicare & Medicaid Services (CMS) can defer to Medicare administrative contractors (MACs) to develop policies to provide Medicare coverage for specific items and services by way of a local coverage determination (LCD).¹ Medicare provides services and devices for 150,000 of the nearly two million amputees in the United States.² A new policy for lower limb prostheses, however, has been criticized as relying on outdated data to limit access to clinically appropriate and medically necessary prosthetic care for Medicare beneficiaries. We are concerned that this draft LCD would deny access to advanced and higher quality prosthetics that improve mobility, function, and independence of those beneficiaries.

The four Durable Medical Equipment Medicare Administrative Contractors (DME MACs) proposed the new policy on July 16, 2015.³ The draft policy carries broader implications beyond Medicare beneficiaries since the Veterans Administration and commercial insurance companies commonly rely on Medicare policies to guide development of their own respective coverage policies. As the *Wall Street Journal* reported, commercial insurance companies began adjusting their coverage policies in response to the draft LCD even though it has not been finalized.⁴ For example, UnitedHealth Group Inc. no longer covers a vacuum-suspension system

¹ Centers for Medicare & Medicaid Services website, "Medicare Coverage Determination Process," available at <https://www.cms.gov/Medicare/Coverage/DeterminationProcess/index.html>.

² Advanced Amputee solutions LLC website, "Amputee Statistics You Ought to Know," available at <http://www.advancedamputees.com/amputee-statistics-you-ought-know>.

³ "Local Coverage Determination (LCD): Lower Limb Prostheses" (DL33787) (July 16, 2015). The four jurisdictional MACs are (A) NHIC, Inc, (B) National Government Services, Inc., (C) CGS Administrators, LLC, and (D) Noridian Healthcare Solutions, LLC.

⁴ Stephanie Armour, *Medicare's Proposed Changes on Prosthetics Stirs a Fight*, WALL ST. J., Sep. 20, 2015.

used to improve gait and prosthetic fit.⁵ Former Nebraska Senator Bob Kerrey, who was first fit with a wooden prosthetic leg in 1969 after serving in the Vietnam War, expressed the concerns of many who rely on advanced prosthetic care in noting that the draft LCD ignores the individual, unique needs of amputees, and intended or not, this proposal “really is a case of the government creating a problem rather than solving it.”⁶

On November 2, 2015, CMS announced that the DME MACs will not finalize the draft LCD “at this time.”⁷ This announcement conflicts with statements from the DME MACs that the finalization of these proposed changes have merely been delayed. Adding to the confusion, the draft LCD remains posted on the CMS and DME MAC websites⁸ and the proposed “multidisciplinary Lower Limb Prostheses Interagency Workgroup” has yet to examine the LCD and produce a consensus statement.⁹

DME MACs are required to review Medicare coverage policy in a transparent manner with adequate opportunities for stakeholder consultation. CMS spends more than \$900 million annually on ongoing operations,¹⁰ which includes MAC activities. As such CMS must oversee these activities and ensure accountability.

To help the Committee understand the draft LCD and CMS’s oversight of DME MACs, please provide the following documents and information as soon as possible, but by no later than 5:00 p.m. on May 12, 2016:

1. Documents sufficient to determine CMS’s justification and process for deferring to LCDs rather than national coverage determinations (NCDs).
2. Documents sufficient to show CMS requirements and guidance on the development and finalization of LCDs by DME MACs including, but not limited to:
 - a. Clinical and scientific basis for LCDs;

⁵ Letter from Ronald Wiesinger, M.D., Nat’l Medical Dir., to Susan Stout, President and CEO, Amputee Coalition and Alliance, re: Medical Policy on Prosthetics and Vacuum Assisted Suspension Systems (Oct. 5, 2015), *available at* <http://www.amputee-coalition.org/content/documents/medicare-alert-2015/united-healthcare-response.pdf>

⁶ Letter from Sen. Bob Kerrey to Hon. Sylvia Mathews Burwell, Sec’y, U.S. Dep’t of Health and Human Services (Aug. 11, 2015), *available at* <http://www.naaop.org/assets/pdf/Sylvia-Mathews-Burwell-CMS-PROSTHETIC-LETTER.pdf>.

⁷ Centers for Medicare and Medicaid Services website, *available at* https://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/LLP_IAWG_Announcement.pdf.

⁸ Proposed Draft Local Coverage Determination (LCD): Lower Limb Prostheses (DL33787). *Available at* <http://www.medicarehlc.com/viewdoc.aspx?id=3109>.

⁹ Centers for Medicare and Medicaid Services website, “LLP IAWG Announcement” (Nov. 2, 2015), *available at* https://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/LLP_IAWG_Announcement.pdf.

¹⁰ Centers for Medicare and Medicaid Services website, “Justification of Estimates for Appropriations Committees: Fiscal Year 2017” at 41, *available at* <https://www.cms.gov/About-CMS/Agency-Information/PerformanceBudget/Downloads/FY2017-CJ-Final.pdf>.

- b. Transparency requirements including providing stakeholders the opportunity to comment on draft LCDs and making comments available to the public;
 - c. CMS's oversight and authority over DME MACs publishing draft and final LCDs; and
 - d. Posting and rescinding draft and final LCDs and related documents and the extent of CMS authority related to such rescissions.
3. All documents and communications referring or related to CMS's review and approval of the document entitled "Local Coverage Determination (LCD): Lower Limb Prostheses (DL33787)," as well as comments filed by members of the public in response to the draft LCD.
4. All contracts and related documents between CMS and DME MACs since January 2015 regarding prosthetics, and the point of contact for the four jurisdictional DME MACs that issued the LCD draft and compensation for the DME MACs.
5. The following documents and information relating to the Lower Limb Prostheses Interagency Workgroup:
 - a. Documents relating to goals and objectives of the working group, with particular attention to its consensus statement being less about the LCD and more about best practices in the care of Medicare amputee beneficiaries;
 - b. Documents relating to composition and qualifications of working group members, including agency or organization representation and expertise, and the extent of participation of stakeholder groups such as the amputee community and orthotic and prosthetic practitioners; and
 - c. Documents relating to opportunities for stakeholders to provide consultation.

When producing documents to the Committee, please deliver production sets to the Majority staff in Room 2157 of the Rayburn House Office Building and the Minority staff in Room 2471 of the Rayburn House Office Building. The Committee prefers, if possible, to receive all documents in electronic format. An attachment to this letter provides additional information about responding to the Committee's request.

The Committee on Oversight and Government Reform is the principal oversight committee of the House of Representatives and may at "any time" investigate "any matter" set forth in House Rule X.

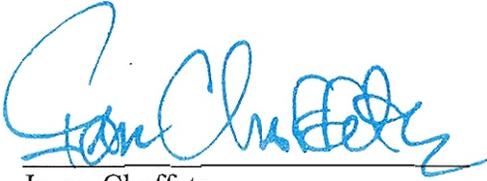
The Honorable Sylvia Mathews Burwell

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Please contact Sarah Vance of the Chairman's staff at (202) 225-5074 or Christy Gamble of the Ranking Member's staff with any questions about this request. Thank you for your attention to this matter.

Sincerely,



Jason Chaffetz
Chairman



Elijah E. Cummings
Ranking Member



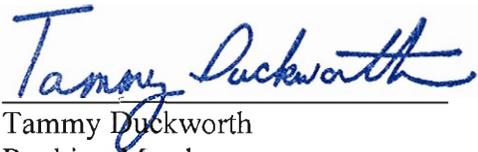
Jim Jordan
Chairman
Subcommittee on Health Care,
Benefits and Administrative Rules



Matthew Cartwright
Ranking Member
Subcommittee on Health Care,
Benefits, and Administrative Rules



Earl L. "Buddy" Carter
Member of Congress



Tammy Duckworth
Ranking Member
Subcommittee on Transportation
and Public Assets

Enclosure

Responding to Committee Document Requests

1. In complying with this request, you are required to produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. You should also produce documents that you have a legal right to obtain, that you have a right to copy or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party. Requested records, documents, data or information should not be destroyed, modified, removed, transferred or otherwise made inaccessible to the Committee.
2. In the event that any entity, organization or individual denoted in this request has been, or is also known by any other name than that herein denoted, the request shall be read also to include that alternative identification.
3. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, or thumb drive) in lieu of paper productions.
4. Documents produced in electronic format should also be organized, identified, and indexed electronically.
5. Electronic document productions should be prepared according to the following standards:
 - (a) The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.
 - (b) Document numbers in the load file should match document Bates numbers and TIF file names.
 - (c) If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.
 - (d) All electronic documents produced to the Committee should include the following fields of metadata specific to each document:

BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH,
PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE,
SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM,
CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE,
DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD,
INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION,
BEGATTACH.
6. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, box or folder is produced, each CD, hard drive, memory stick, thumb drive, box or folder should contain an index describing its contents.

7. Documents produced in response to this request shall be produced together with copies of file labels, dividers or identifying markers with which they were associated when the request was served.
8. When you produce documents, you should identify the paragraph in the Committee's schedule to which the documents respond.
9. It shall not be a basis for refusal to produce documents that any other person or entity also possesses non-identical or identical copies of the same documents.
10. If any of the requested information is only reasonably available in machine-readable form (such as on a computer server, hard drive, or computer backup tape), you should consult with the Committee staff to determine the appropriate format in which to produce the information.
11. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.
12. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) the privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author and addressee; and (e) the relationship of the author and addressee to each other.
13. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (stating its date, author, subject and recipients) and explain the circumstances under which the document ceased to be in your possession, custody, or control.
14. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, you are required to produce all documents which would be responsive as if the date or other descriptive detail were correct.
15. Unless otherwise specified, the time period covered by this request is from January 1, 2009 to the present.
16. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data or information, not produced because it has not been located or discovered by the return date, shall be produced immediately upon subsequent location or discovery.
17. All documents shall be Bates-stamped sequentially and produced sequentially.
18. Two sets of documents shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2471 of the Rayburn House Office Building.

19. Upon completion of the document production, you should submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control which reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Definitions

1. The term “document” means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, inter-office and intra-office communications, electronic mail (e-mail), contracts, cables, notations of any type of conversation, telephone call, meeting or other communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.
2. The term “communication” means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, email (desktop or mobile device), text message, instant message, MMS or SMS message, regular mail, telexes, releases, or otherwise.
3. The terms “and” and “or” shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information which might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neuter genders.
4. The terms “person” or “persons” mean natural persons, firms, partnerships, associations, corporations, subsidiaries, divisions, departments, joint ventures, proprietorships, syndicates, or other legal, business or government entities, and all subsidiaries, affiliates, divisions, departments, branches, or other units thereof.

5. The term “identify,” when used in a question about individuals, means to provide the following information: (a) the individual's complete name and title; and (b) the individual's business address and phone number.
6. The term “referring or relating,” with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with or is pertinent to that subject in any manner whatsoever.
7. The term “employee” means agent, borrowed employee, casual employee, consultant, contractor, de facto employee, independent contractor, joint adventurer, loaned employee, part-time employee, permanent employee, provisional employee, subcontractor, or any other type of service provider.