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Congress of the United States

House of Representatives

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May 3, 2012

Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Ms. Tavenner:

The Committee on Oversight and Government Reform is conducting oversight of the Centers for Medicare and Medicaid Services' (CMS) National Coverage Determination (NCD) process.¹ As part of this oversight, I am writing to request documents and information relating to recent CMS actions related to coverage of medical devices that address pain management.

NCDs were created to expand the ability of Medicare beneficiaries to access cutting edge medical products. As CMS guidance states, "NCDs help ensure that access to advances in health technologies that may result in improved health care are available to Medicare beneficiaries when those items and services are reasonable and necessary."² (Emphasis added). To help ascertain whether an NCD is appropriate, CMS created the coverage with evidence development (CED) process.³ Specifically, CEDs were developed to help CMS ensure that federal funds are spent on NCDs which have the necessary evidence to confirm the clinical benefit of newly emerging technologies for Medicare beneficiaries.⁴

¹ See generally, Centers for Medicare & Medicaid Services, "National Coverage Determinations (NCDs) Alphabetical Index, viewed April 16, 2012. Available at <http://www.cms.gov/medicare-coverage-database/indexes/ncd-alphabetical-index.aspx?bc=BAAAAAAAAAAAAA>.

² Centers for Medicare and Medicaid Services, Guidance for the Public, Industry, and CMS Staff. National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development, July 12, 2006. Available at <https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/ced.pdf>.

³ See generally, *Id.*

⁴ Centers for Medicare and Medicaid Services, "National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development," November 7, 2011. Available at <http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=8&McdName=National+Coverage+Determinations+with+Data+Collection+as+a+Condition+of+Coverage%253A+Coverage+with+Evidence+Development&mcdtypename=Guidance+Documents&MCDIndexType=1&bc=BAIAAAAAAAAA&>.

CMS's recent Federal Register⁵ notice announcing the intent to utilize a CED policy for transcutaneous electric nerve stimulation (TENS) treatments, however, appears to turn the original intent of the CED process on its head by limiting patient access rather than expanding it and leaving patients with fewer options rather than more. It is my understanding that the use of the CED process to revoke long-standing coverage of a treatment is unprecedented.

CMS made this decision despite the fact TENS has long been recognized by CMS as an effective treatment for Medicare beneficiaries with low back pain, and its costs have long been covered by Medicare when prescribed by physicians who have actively monitored its use and effectiveness in individual patients.⁶ Currently, low back pain is one of the costliest and most common, reoccurring problem among Medicare beneficiaries.⁷ Several studies show TENS is a cost effective treatment for this common Medicare beneficiary issue, as well as the least expensive of all treatments for low back pain – with the same level of efficacy in treatment.⁸ Thus, CMS's decision regarding TENS appears likely to result in many Medicare beneficiaries being forced to seek more expensive treatments for low back pain that was already being adequately treated with TENS.

At the same time that CMS is proposing to halt its long-standing coverage of TENS treatment, CMS is proposing to change the entire CED process itself. CMS has asked interested parties to gather on May 16, 2012, in Baltimore, Maryland to discuss CED changes. Instead of depriving current Medicare beneficiaries from its physician-verified benefits by placing a long-covered, successful treatment – such as TENS – in a CED process that CMS plans to significantly change in the near future, it would seem more appropriate to determine first the future of the CED process.

I am concerned about the unprecedented use and timing of the CED process as it relates to TENS, particularly given the uncertainty surrounding the CED process itself at this time. To assist the Committee in its oversight, please provide the following information:

1. CMS's rationale for moving TENS into the CED process despite long-standing coverage.
2. CMS's rationale for conducting the TENS CED process at the same time CMS is reevaluating the CED process.

⁵ Centers for Medicare and Medicaid Services, "National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development," November 7, 2011. Available at <http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=8&McdName=National+Coverage+Determinations+with+Data+Collection+as+a+Condition+of+Coverage%253A+Coverage+with+Evidence+Development&mcdtypename=Guidance+Documents&MCDIndexType=I&bc=BAAIAAAAAAAAA&>

⁶ See generally, Centers for Medicare & Medicaid Services, Medicare National Coverage Determinations Manual, Chapter 1, Part 4 (Sections 200 – 310.1) Coverage Determinations, Table of Contents. Available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1_Part4.pdf. See also, Melissa Martinson, MS, Phd and Michael Johnson, "Cost-effectiveness of Treatments for Low Back Pain."

⁷ *Id.*

⁸ *Id.*

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3. CMS' annual average reimbursement per beneficiary for lower back pain, as well as CMS' annual average reimbursement per beneficiary for TENS treatment.
4. All Alternative low back pain treatments approved by CMS for coverage, including annual average reimbursement per beneficiary.

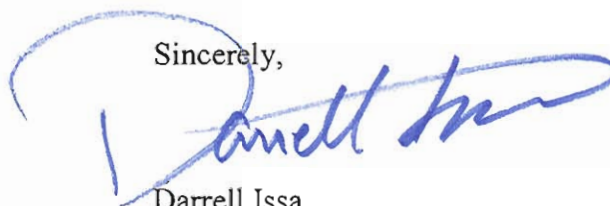
In addition, I request your office brief Committee Staff on CMS's CED process and CMS's intent to place TENS treatment in the CED process on or before May 17, 2012.

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" as set forth in House Rule X.

We request that you provide the requested documents and information as soon as possible, but no later than 5:00 p.m. on May 17, 2012. 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.

Should you have any questions or concerns, please contact Sery Kim of the Committee staff at (202)225-5074.

Sincerely,



Darrell Issa
Chairman

cc: The Honorable Elijah E. Cummings, Ranking Minority Member