Congress of the United States
Washington, DC 20515

April 15, 2013

The Honorable Kathleen Sebelius
Secretary, US Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

CC: Marilyn Tavenner, Acting Administrator, Centers for Medicare and Medicaid Services

Dear Secretary Sebelius,

We are writing because of our concern that efforts to reduce fraud and abuse in Medicare claims for prosthetics may be harming access to care for the most vulnerable Medicare beneficiaries.

We strongly support efforts to combat fraudulent payments. According the GAO, for Fiscal Year 2011, the estimated improper payments within Medicare cost approximately $65 billion. Finding and stopping these fraudulent payments is a critical task, however, we are seriously concerned about the unintended consequences of current efforts that may reduce patient access to care and harm upstanding small businesses. It has been brought to our attention that audits conducted by the Centers for Medicare and Medicaid Services (CMS) contractors concerning claims for prosthetics are jeopardizing the economic viability of these critical health care providers.

As we see it there are two issues. The first is challenges to physician documentation for prosthetics. Auditors are now using a standard that CMS contractors, without the benefit of any rulemaking processes, generated in an August 2011 "Dear Physician" letter that is based on a flawed 2011 Office of Inspector General Report. Second, according to the industry, the number and scope of audits are continuing to increase dramatically. Furthermore, these claims are being appealed, with some adverse decisions by CMS contractor auditors being overturned at the administrative law judge (ALJ) level.

Consequently, CMS's current policies are resulting in contractor audits challenging legitimate payments for prosthetic care to the degree that these critical health providers are facing terminal cash flow deficiencies. In addition to jeopardizing the jobs and economic growth added by providers of orthotic and prosthetic devices and services, many of which are small businesses, the inability of these providers to serve patients, including vulnerable Medicare beneficiaries, creates an unnecessary barrier to access.

The American Orthotic and Prosthetic Association (AOPA), representing facilities that provide orthotic and prosthetic services, recently completed a survey of its members' encounters with such audits. The survey found that 77 percent of AOPA's facilities have been subject to one or more recovery audit contractor (RAC) audits relating to physician documentation, with many facilities having been subjected to more than 20 such audits in the 11 months preceding the survey. At the facility level, these and other similar audits have led to many small businesses being stretched to their breaking points financially, hindering economic growth and costing

precious jobs. Taken collectively, the strain on the industry undermines critical patient access to orthotic and prosthetic services.

It is imperative that we find a way to develop policies that allow CMS to eliminate true fraud and abuse, while not slowing payment to providers so significantly that they cannot function. We believe it is possible to strike a reasonable balance that would ensure effective scrutiny and protection of taxpayer dollars while still preserving the viability of crucial orthotic and prosthetic specialists.

We understand it is not CMS' intent to harm these facilities. CMS leadership has also acknowledged significant deficiencies with the physician documentation standard (from the "Dear Physician" letter) that CMS contractors apply, frequently retroactively, to claims from before that standard was articulated. However, given that this has been the effect of anti-fraud activities, we respectfully request clarification on a few areas of concern for orthotic and prosthetic suppliers. Please respond to the following questions in writing.

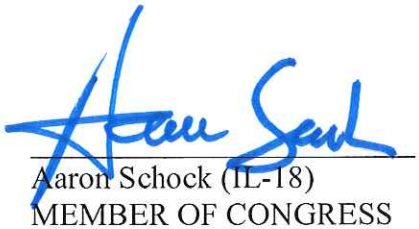
- What specifically is CMS' policy to ensure that anti-fraud activities, while necessarily rigorous, do not place undue and/or counterproductive burdens on providers?
- Does CMS believe that implementing regulations pursuant to the Benefits Improvement Protection Act of 2000 (BIPA), Transmittal 656, or other measures, including legislation, could aid in ensuring that only licensed and/or accredited providers be eligible for Medicare reimbursement, thereby reducing instances of fraud and the need for overly burdensome "pay and chase" activities?
- Given the growing number and scope of audits, and the confusion over standards that providers are subject to, are there interim steps CMS could take to maintain program integrity while not restricting provider cash flow so severely?
- In some instances, after delivery of an orthotic or prosthetic device, auditors may disagree with a single line-item amongst an otherwise wholly appropriate course of treatment, resulting in a provider's payment being entirely withheld. Would it be possible for CMS to withhold reimbursement for the specific codes or components of an artificial limb that CMS' auditors believe is inappropriate, instead of denying payment for the entire limb or service?
- Can you provide information documenting the rate at which ALJ decisions ultimately result in auditor payment denials being reversed, both in number and as a percentage of total appeals, also noting at what stage of appeal the final decision was made?

If you have any questions, please do not hesitate to contact Kalina Bakalov in the office Representative Tammy Duckworth at 202-225-3711, or Megan Spindel in the office of Representative Brett Guthrie at 202-225-3501.

Sincerely,

Tammy Duckworth (IL-08)
MEMBER OF CONGRESS

Brett Guthrie (KY-02)
MEMBER OF CONGRESS



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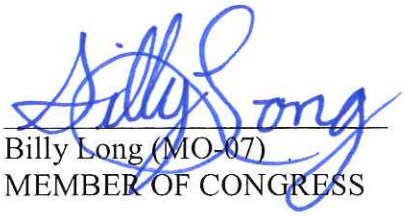

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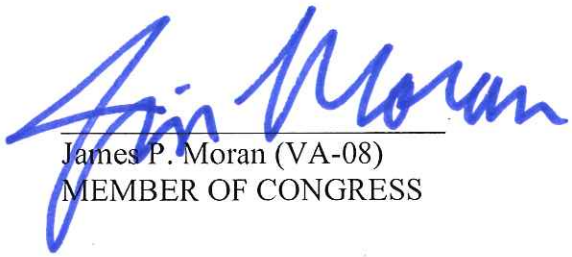

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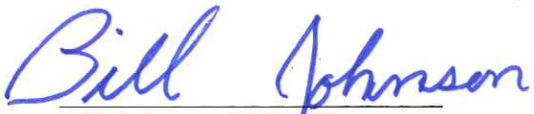

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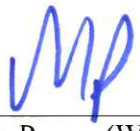

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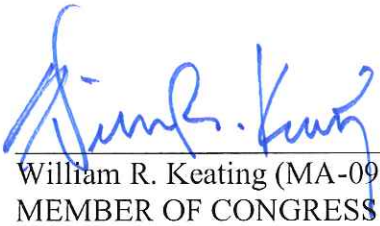

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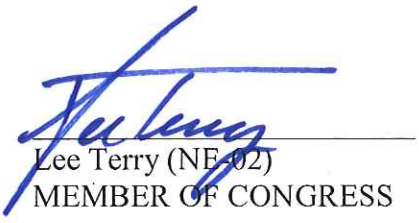

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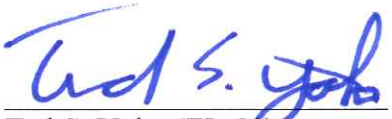

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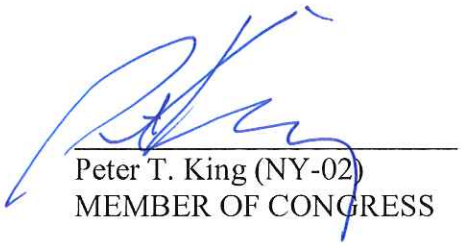

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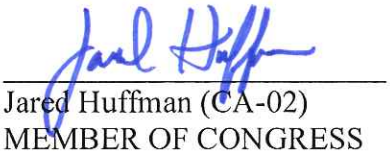

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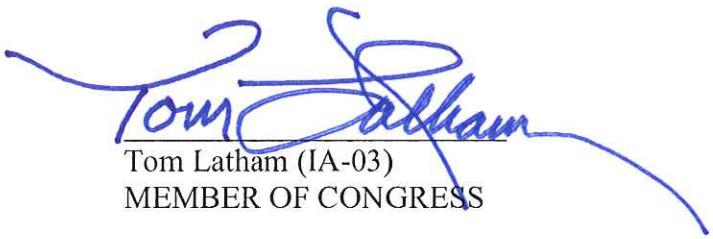

Tom Latham (IA-03)
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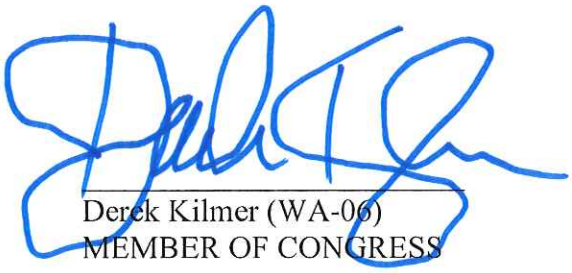

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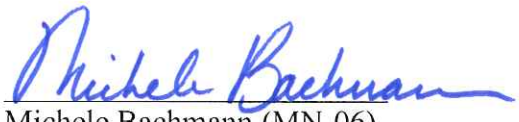

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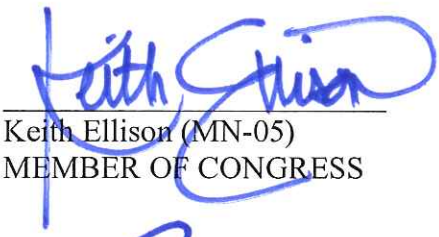
André Carson (IN-07)
MEMBER OF CONGRESS

Steve Chabot (OH-01)
MEMBER OF CONGRESS



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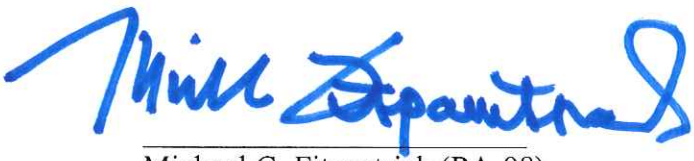

Michael G. Fitzpatrick (PA-08)
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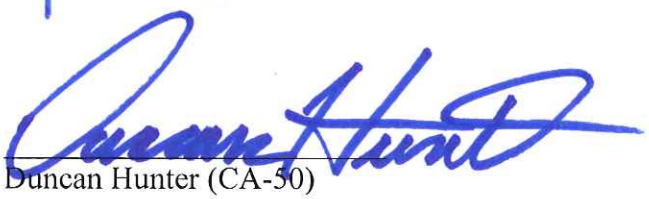

Duncan Hunter (CA-50)
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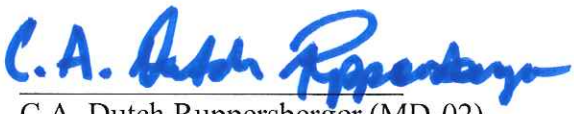

C.A. Dutch Ruppersberger (MD-02)
MEMBER OF CONGRESS

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

July 16, 2013

The Honorable Brett Guthrie
U.S. House of Representatives
Washington, DC 20515

Dear Representative Guthrie:

Thank you for your letter expressing concern about the Medicare procedures for ensuring proper claims payment for prosthetics. I share your commitment to ensuring that Medicare beneficiaries have adequate access to necessary medical care and items, including prosthetics.

In 2011, the Department of Health and Human Services Office of the Inspector General released a report that found Medicare claims for lower limb prosthetics had a high improper payment rate. The Centers for Medicare & Medicaid Services (CMS) is working to educate providers and suppliers on Medicare coverage and documentation requirements for lower limb prosthetics to reduce the improper payment rate. For example, CMS offers a range of educational resources through online manuals and websites to assist prosthetists with understanding Medicare policies, billing procedures, and required supporting documentation requirements. The documentation is critical for Medicare coverage purposes since it is the primary source of information to support the medical necessity of the item. Be assured that CMS is committed to continually working with the physician and prosthetist communities to reduce improper payments without imposing unnecessary burdens on providers or beneficiaries.

Please find answers to your specific questions in the enclosure. I appreciate your efforts to assist Medicare providers and suppliers in addressing issues related to audit and Medicare program integrity. Please do not hesitate to contact me if you any further thoughts or concerns. I will also provide this response to the co-signers of your letter.

Sincerely,

Kathleen Sebelius

Kathleen Sebelius

Enclosure

What specifically is CMS' policy to ensure that anti-fraud activities, while necessarily rigorous, do not place undue and/or counterproductive burdens on providers?

CMS has implemented several measures to ease provider burden and to ensure accurate decisions by Recovery Auditors, who, for the most part, review claims on a post-payment basis. First, CMS must approve areas of focus for Recovery Auditors before they can begin reviewing claims. Second, the Recovery Auditors lose their contingency fee if their decision is overturned at any level of appeal. Third, CMS has limited the number of additional documentation requests a Recovery Auditor can send to a provider. On April 3, 2013, CMS created a separate additional documentation request limit category for prosthetists/orthotists. Recovery Auditors can request a maximum of ten medical records per prosthetist/orthotist every 45 days. Before, Recovery Auditors could request up to 10 percent of their records.

Does CMS believe that implementing regulations pursuant to the [Medicare, Medicaid and SCHIP] Benefits Improvement [and Protection] Act of 2000 (BIPA), Transmittal 656, or other measures, including legislation, could aid in ensuring that only licensed and/or accredited providers be eligible for Medicare reimbursement, thereby reducing the instances of fraud and the need for overly burdensome "pay and chase" activities?

CMS continues to focus on ways to move beyond a "pay and chase" approach to one that prevents fraud. The BIPA provisions, as well as provisions contained in statutes passed subsequently (MMA and MIPPA), are important and CMS is carefully evaluating options for implementing these provisions.

Given the growing number and scope of audits, and the confusion over standards that providers are subject to, are there interim steps CMS could take to maintain program integrity while not restricting provider cash flow so severely?

CMS is developing an electronic clinical template that would allow electronic health record (EHR) vendors to incorporate prompts in to EHRs that would assist physicians when they are documenting a progress note during a visit to evaluate a beneficiary's need for a lower limb prosthetic. Physicians without an EHR may also benefit from this template. CMS welcomes input from both the physician and prosthetic communities in this effort.

In some instances, after delivery of an orthotic or prosthetic device, auditors may disagree with a single line-item amongst an otherwise wholly appropriate course of treatment, resulting in a provider's payment being entirely withheld. Would it be possible for CMS to withhold reimbursement for the specific codes or components of an artificial limb that CMS' auditors believe is inappropriate, instead of denying payment for the entire limb or service?

In 2009, the U.S. Court of Appeals issued a decision in *Hays v. Sebelius*, 589 F.3d 1279 (D.C. Cir. 2009) regarding the application of the least costly alternative policy. The Court of Appeals held that the Medicare coverage decision is binary: an item or service is either reasonable and necessary, in which case it may be covered at the statutory rate, or it is unreasonable or unnecessary, in which case it may not be covered at all. Therefore, if a supplier bills for a level 3 prosthetic but the beneficiary only qualified for a level 1 prosthetic, the review contractor cannot

simply reduce the payment to the level 1 payment amount; the review contractor must issue a full denial.

Can you provide information documenting the rate at which Administrative Law Judge (ALJ) decisions ultimately result in auditor payment denials being reversed, both in number and as a percentage of total appeals, also noting at what stage of appeal the final decision was made?

While we do not have specific ALJ data for prosthetic device appeals, general appeals statistics are available for download under "Appeal Fact Sheets" on the CMS website at:

http://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/RedeterminationbyaMedicareContractor.html