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An Open Letter to the O&P Community on H.R. 1958, the Medicare Orthotics and Prosthetics Improvement Act of 2011

Dear Member of the O&P Community:

The undersigned organizations write this letter to announce our support for passage of important federal legislation that, we believe, will positively impact the orthotic and prosthetic profession.

We support passage of H.R. 1958, the Medicare Orthotics and Prosthetics Improvement Act of 2011, bipartisan legislation that was introduced on May 24, 2011 by Congresswoman Shelley Berkley (D-NV) and Glenn Thompson (R-PA) and is expected to be introduced soon in the U.S. Senate.

The American Orthotic and Prosthetic Association (AOPA) worked to have this legislation introduced and has invested significant resources to move it forward. Each of the organizations signing this letter came to independent judgments after extensive deliberations that, on balance, the bill is worthy of support and that enactment of this legislation would benefit O&P patients and the providers and suppliers who serve them. This letter seeks to explain the rationale for supporting this bill.

I. Background

There is long history that necessitates the introduction of this legislation. It begins with an HHS Office of Inspector General (OIG) Report in 1997 entitled, *Medicare Orthotics*, OEI-02-95-00380 (October 1997) that determined that DME suppliers were more likely than orthotists to supply questionable orthotics. As a result, the OIG recommended that CMS (then known as "HCFA"), "Consider stricter standards for who is allowed to bill for orthotics, such as requiring professional credentials for orthotic suppliers."

A follow-up OIG report entitled, *Medicare Payments for Orthotics; Inappropriate Payments*, OEI-02-99-00120 (March 2000), rendered a similar conclusion. This report stated:

> "We also recommend that HCFA require standards for suppliers of custom molded and custom fabricated orthotic devices. Suppliers of these devices must be skilled in fitting and crafting an orthosis to the individual measurements of the patient. We believe that establishing standards

would help to ensure that suppliers providing custom molded and fabricated devices have such skills and that the devices they supply are appropriate. The HCFA may want to consider establishing their own standards for orthotic suppliers or using already established industry certification."

These recommendations formed the basis of the statutory language that was included in the Benefits Improvement and Protection Act of 2000, Section 427 ("BIPA 427"). This federal law established restrictions on Medicare reimbursement for certain orthotic and prosthetic (O&P) services to specific healthcare professionals. Of overriding significance in BIPA 427 is the requirement that a "qualified practitioner" or a "qualified supplier" must provide the designated O&P services in order for them to be eligible for reimbursement by Medicare.

BIPA 427 recognizes more than one category of individuals who are considered "qualified" to provide O&P services, including:

- Physicians
- Qualified Physical Therapists
- Qualified Occupational Therapists
- Individuals licensed by their State to provide O&P services
- Individuals credentialed by one of two O&P accrediting bodies[1], ABC or BOC, and who are specifically trained and educated to provide customized O&P services.

BIPA Section 427 called for the establishment of a "negotiated rulemaking" committee that was supposed to come to consensus on outstanding aspects of the law so that CMS could write regulations and implement the statute within one year of enactment. However, the negotiated rulemaking committee could not agree on a number of major points, including the level of education and training that physical therapists and occupational therapists would have to demonstrate in order to be considered "qualified" to provide comprehensive O&P care. In the end, the negotiated rulemaking committee failed and CMS never, to this day, implemented this statute through the issuance of regulations. This is the key reason we support H.R. 1958 which essentially compels CMS to finally implement this 11-year old law.

In 2003, Section 302 of the Medicare Modernization Act of 2003 (MMA) was enacted which requires the establishment and implementation of quality standards for suppliers of durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS"). It also requires accreditation of many DMEPOS suppliers. There are general quality standards that apply to the broad range of DMEPOS suppliers, as well as additional standards that apply to specific supplier types. Orthotic and prosthetic suppliers are among those to whom additional supplier-specific quality standards apply, contained in Appendix C of the DMEPOS quality standards.

Unfortunately, when CMS implemented the DMEPOS Quality Standards and accreditation requirements, they did so without considering Section 427 of the BIPA law, which required accreditation of O&P suppliers by ABC, BOC or other "equivalent" accreditation organizations as deemed by the HHS Secretary. Under DMEPOS accreditation, CMS selected nine accreditation organizations to accredit DMEPOS suppliers, with no specific recognition of the BIPA law for O&P

[1] American Board for Certification in Orthotics, Prosthetics, and Pedorthics; Board for Certification/Accreditation, International.

providers. The bottom line is that a flood of new accreditation organizations with little or no experience with the O&P profession were permitted to accredit O&P suppliers.

Finally, on August 19, 2005, CMS issued Transmittal 656 (CR 3959). This Transmittal stated that CMS would only pay O&P suppliers who were appropriately licensed in those states that have O&P licensure. This Transmittal was reissued in 2010 (CR6566) as well as condensed to regulations in that same year (75 Fed. Reg. 52,629, [pin cite] (August 27, 2010).

The problem is that CMS has, to our knowledge, never implemented the required claim edits at the DMAC level to make sure that only licensed O&P suppliers' claims are being paid by Medicare in those states that have O&P licensure. We have analyzed the Medicare claims data and can demonstrate CMS's lack of compliance with their own rules on this matter. In fact, the fraud and abuse in Miami, Florida that was detailed on the *60 Minutes* report last year, as well as more recent fraudulent activity in Texas associated with limb prosthetics could not have occurred if CMS was enforcing its own rules. Both Florida and Texas are O&P licensure states.

It appears that O&P claims are allowed to pass through the Medicare billing system, regardless of the type of supplier submitting the claim, and be paid. For example, once enrolled as a DMEPOS supplier, an oxygen supplier could arguably bill for a lower limb prostheses, even though it lacks the licensed/certified and qualified staff to provide prosthetic services, and does not hold the proper accreditation to provide prosthetic services. As a result of this lack of claim edits, once a supplier has been granted Medicare DMEPOS billing privileges, it is largely free to submit claims for any type of DMEPOS service, including many of those for which it is not licensed or certified, or does not meet the definition of "qualified."

CMS has O&P-specific tools in place that it can use to prevent fraud and abuse and improve the quality of care in the O&P Medicare benefit, but instead, they tend to rely on regulatory options that are more appropriate for DME suppliers. For instance, the HHS Office of Inspector General just recently issued a report entitled, *Questionable Billing by Suppliers of Lower Limb Prostheses*, OEI-02-10-00170 (August 2011). The report made a number of recommendations similar to what the OIG routinely has recommended for DME suppliers such as face-to-face physician visits before an order is written, as well as stricter supplier standards and more aggressive claims review. What the OIG failed to examine was the licensure and accreditation status of those providers and suppliers submitting the claims.

We believe that a failure to segregate claims by the qualifications of the supplier has contributed to the OIG's negative findings in its report, and caused the OIG to unfairly characterize the billing practices of legitimate and qualified providers of O&P services as "questionable." We would further suggest that this study highlights the flaws in the current system in that the supplier enrollment process does not ensure that claims are being submitted by qualified suppliers. This could be easily accomplished by simply enforcing existing law and having CMS create a claim edit based on the appropriateness of the qualifications of the supplier to the type of service billed.

II. Why Is New Legislation Necessary?

The O&P Alliance has been actively pressing CMS to fully implement the laws described above for its entire existence (the past five years), and the individual members of the Alliance as well as other organizations have been working to implement these laws for years before that. While there are

positive signs that CMS may be beginning to embrace our preferred approach, the fact is that BIPA Section 427 has been federal law for eleven years and it is still not implemented in a meaningful way.

The undersigned organizations came to the conclusion that we simply must act. We will continue to work actively and cooperatively with CMS and, in fact, we have recently briefed CMS on the intent of H.R. 1958 and asked them to join us in supporting it. But we must engage Congress to keep pressure on CMS to follow through.

III. What Would H.R. 1958 Accomplish?

The Medicare O&P Improvement Act (H.R. 1958) would accomplish three primary objectives that CMS, to date, has not fully implemented despite the fact that the existing laws and regulations clearly give them authority to do so:

1. *Modifies O&P Accreditation Organizations*: For purposes of applying quality standards to suppliers of O&P care, the legislation would refine the organizations eligible to accredit Medicare suppliers of O&P services. The existing accreditation organizations will no longer be able to accredit O&P suppliers and the HHS Secretary will be required to newly designate one or more accrediting organizations that meet the requirements of BIPA Section 427 to perform this accrediting function, effective in 2013. This will require the Secretary to establish accrediting standards for O&P suppliers that are at least as high as ABC and BOC standards. (By 2013, ABC's and BOC's educational standards will be more consistent.)

   Analysis: This provision would reset the clock on Medicare accreditation of suppliers of O&P care and separate it from accreditation of DME suppliers. This provision would finally implement key portions of BIPA Section 427 and raise the bar on qualifications to bill Medicare for O&P services.

2. *Licensure and Accreditation Standards Enforced*: The legislation would ensure that existing O&P licensure and accreditation standards are fully implemented at CMS. Suppliers of prosthetics and custom-fabricated and custom -fitted orthotics would not be eligible for Medicare payment unless they are in compliance with state licensure and accreditation standards.

   Analysis: These laws are already on the books but CMS has simply failed to fully enforce them for years. This section of the new law operates as a mandate for CMS to finally do so. The new language also expands these protections from custom-fabricated to custom-fitted orthotics as well. It would prompt CMS to establish claim edits that deny payment to suppliers who submit claims for O&P services in the future who are not in compliance with state O&P licensure and O&P accreditation requirements. Recent, high-profile Medicare fraud and abuse cases demonstrate that this provision alone could save many millions of dollars in fraudulent and abusive Medicare O&P claims, and would have the added benefit of helping to ensure that Medicare-covered O&P care is being provided by qualified suppliers.

3. *Linking the Complexity of O&P Care with Practitioner Qualifications*: The legislation takes what the O&P Alliance organizations have been recommending to CMS for years and

seeks to codify it in statute. This part of the bill establishes five categories of O&P services and links requirements for education, training, and accreditation to these categories in order to receive payment from Medicare, effective in 2013. The five categories are:

a. Custom Fabricated Limb Prosthetics;
b. Custom Fabricated Orthotics;
c. Custom Fitted High Orthotics;
d. Custom Fitted Low Orthotics; and
e. Off-the-shelf Orthotics.

For the first three categories, the bill establishes specific requirements for O&P education, clinical residency, and accreditation. A less stringent standard is used for Custom Fitted Low Orthotics, as these are devices and related services that are deemed to involve a low level of complexity and low clinical risk. The bill does not regulate suppliers of off-the-shelf orthotics. In order to avoid major political opposition from physicians, physical therapists, and occupational therapists, these groups of providers are exempted from the bill's requirements.

Analysis: Full implementation of this section of the legislation would truly protect patients from suppliers with little or no education and training to provide comprehensive O&P services. But it also recognizes that certain orthotics are routinely provided by suppliers without extensive education and training in orthotics and prosthetics. By exempting physicians, qualified PTs and qualified OTs from the bill, a key issue that has derailed progress on this entire set of issues is hopefully removed from the calculus. While these exemptions were difficult to ultimately accept, on balance, it is an acceptable compromise if the remainder of the legislation is fully implemented.

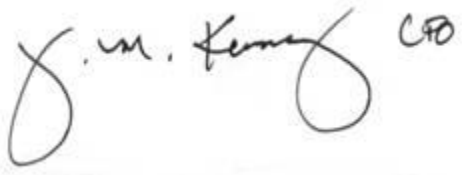
This bill does not seek to protect the O&P profession's "turf." It fully acknowledges the rights of suppliers of lower level orthotics as well as off-the-shelf orthotics. It acknowledges that physicians and therapists are already qualified providers from Medicare's perspective and relies on their own state licensure for accountability. The bill does not seek to modify payment amounts based on complexity of care, only the right to receive payment from Medicare based on one's qualifications. In this manner, it is expected to save the Medicare program millions of dollars over the next several years. And it finally implements BIPA Section 427, which was designed in the first place to protect patients, improve the quality of care, and reduce fraud and abuse.

The undersigned organizations will continue to make the case for H.R. 1958 and encourage the entire O&P community to consider the legislation, ask questions, and ultimately, strongly support the legislation.

To get this bill enacted, we will need the active and engaged support of the entire O&P profession. Thank you for your consideration.

Sincerely,

Paul E. Prusakowski, CPO, FAAOP
President
National Association for the
Advancement of Orthotics and Prosthetics



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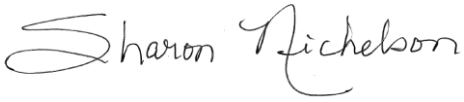

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