Submitted Electronically Via Regulations.gov

March 13, 2017

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-6012-P
P.O. Box 8013,
Baltimore, MD 21244-8013

Re: CMS-6102-P: Medicare Program; Establishment of Special Payment Provisions and Requirements for Qualified Practitioners and Qualified Suppliers of Prosthetics and Custom-Fabricated Orthotics

Dear Centers for Medicare and Medicaid Services (CMS),

We are writing to provide comments on the proposed rule entitled: *CMS-6102-P: Medicare Program; Establishment of Special Payment Provisions and Requirements for Qualified Practitioners and Qualified Suppliers of Prosthetics and Custom-Fabricated Orthotics.* This rule was published in the *Federal Register* on January 12, 2017.

The American Orthotic & Prosthetic Association (AOPA), founded in 1917, is the largest national orthotic and prosthetic trade association with a membership that draws from all segments of the field of artificial limbs and customized bracing for the benefit of patients who have experienced limb loss, or mobility impairment resulting from a trauma, chronic disease or health condition. AOPA's membership includes patient care facilities, manufacturers and distributors of prostheses, orthoses and related products, and educational and research institutions.

AOPA's comments are presented in summary below and are followed by specific comments relative to specific provisions of the proposed rule.

Overview and Summary Observations and Comments

AOPA would like to commend CMS for issuing this proposed rule. AOPA believes that the need for this rule is still as important and evident today as it was when the legislation which led to the rule was passed in 2000. We appreciate CMS responding to the many congressional requests over multiple congresses for BIPA section 427 to be implemented. Our belief in the need for such a rule had led us to seek legislation most recently in the 114th Congress (S.829/HR1530) to ensure that a rule would be proposed and implemented in a timely manner. This rule would fairly take into account the appropriate roles for the range of licensed or certified qualified providers who have traditionally been involved in managing treatment for patients with limb loss, chronic limb-impairment, or other conditions that require orthopedic bracing. We believe that the enactment of this legislation would

add greater clarity on key issues, and would serve to make the final BIPA 427 regulations better, fairer, and stronger; ultimately improving quality patient care.

Core Responsibility: Patient Protection and the Public Trust.

The statutory language in section 427 of BIPA instructed CMS to take the necessary regulatory steps to ensure that Medicare beneficiaries receive prostheses and custom fabricated orthoses from qualified providers and suppliers, that is, the protection of the patient. Additionally, AOPA and all commenters must recognize the CMS has an overarching responsibility to also protect the Medicare Trust Fund, assuring fairness, that public resources are soundly deployed, and that fraud and abuse are eliminated to the greatest extent possible. Our comments which follow recognize these two pre-eminent CMS responsibilities.

AOPA strongly believes the provision of prostheses and custom fabricated orthoses to Medicare beneficiaries must be limited to individuals or entities that are truly qualified to do so. The publication of the proposed rule is the long awaited first step toward accomplishing the statutory goal of BIPA section 427 to ensure that only qualified providers and suppliers provide prostheses and custom fabricated orthoses to Medicare beneficiaries.

In the 17 years that have elapsed since the passage of BIPA 2000, Medicare has changed, as has the practice of providing prostheses and custom fabricated orthoses. Recognizing that passage of time while staying true to the original intent of the statute, there are a number of areas within the proposed rule that need to be revised and/or clarified.

The proposed regulation, as drafted, is overly broad. Many will underscore that it goes beyond the intent and authority stated in Section 427 of BIPA 2000. As an example, the proposed rule would require certification of physicians, and of those meeting the statutory definition of “qualified OTs and PTs.”

We propose that the final rule should include exceptions that would bring the implementation of Section 427 of BIPA in line with the legislation’s intent while still operating within the framework of the proposed rule. We also believe that another CMS proposed rule relevant to off the shelf orthoses, published July 2, 2014, offers valuable framework. Although it was never finalized, it offers guidance on key issues related to the provision of custom fabricated orthoses. The proposed rule also raises significant concerns in the following areas:

(1) Enforcement Mechanisms. The statute says Medicare should not pay unlicensed/unaccredited parties. The proposed rule largely ignores this and focuses only on revocation of Medicare privileges AFTER Medicare has improperly paid. This seems to ignore the intent of the law which was to prevent Medicare from paying unqualified providers in the first place.
(2) Compliance with the ‘equivalency to American Board for Certification in Orthotics, Prosthetics, and Pedorthics (ABC) or Board of Certification (BOC) standards’. It must be recognized that the presence of an ABC or BOC certified O&P professional on their team equates to equivalency for purposes of accreditation orthotic and prosthetic suppliers. Each and every one of the deemed accrediting organizations must maintain standards for

O&P that are substantially equivalent to those of ABC or BOC. The presence of an ABC or BOC certified O&P professional on the team of such other accrediting organization must be ***in addition to*** the accrediting organization's requirement to meet the statutory prerequisite of equivalency of their O&P standards with those of ABC or BOC, and ***not in lieu of standards equivalency***.

(3) Regulation of fabrication of O&P devices. AOPA believes that CMS in this proposed rule has overlooked a critically important distinction when it comes to fabrication facilities

a) Fabrication in the same facility/physical location where patient care/treatment occurs—this is sum and substance of patient care, and CMS is not authorized to regulate how care is delivered by certified/licensed health professionals in a patient care facility.

b) Fabrication in a facility physically distinct from a site where patient care is delivered. CMS needs to defer to the certification bodies on this. CMS has not been given authority by Congress (who delegated to the Food and Drug Administration (FDA) on such matters) or any other entity to mandate a list of requirements as are set forth in the proposal, and these should be dropped.

The proposed rule needs to be modified to underscore that fabrication which occurs **at** a facility where patient care is delivered is exempt from CMS rules, similar to patient care in offices of physicians and other health care professionals. With respect to fabrication at facilities that are not the site for delivery of patient care, CMS needs to revise this proposal; (a) noting the independent accrediting bodies and their existing standards as defining the scope of requirements; and (b) withdrawing that portion of the proposed rule that prescribes extensive and exacting descriptions of purported specific new regulatory requirements in recognition of the fact that as to any direct federal government prescriptions for stand alone. i.e., physically distinct fabrication facility, any relevant authority Congress has delegated flows to FDA, not to CMS.

In addition to its general comments regarding the proposed rule, AOPA would like to offer the following comments that address specific provisions and language in the proposed rule.

The following list is illustrative of codes which have high usage by non-O&P providers, and requires CMS to address, assuring continued appropriate and high quality multi-specialist patient care.

Procedure Code	OT %	PT %	MD %	DPM %	DME %	Pharmacy %	Total Medicare $$ - All Provider Categories	$$ Paid to O&P	O&P %
L3808	20.50%	8.30%	61.70%	0.10%	0.50%	2.70%	$5,477,475	$200,721	3.66%
L3906	20.10%	7.40%	64.60%	0.30%	1.10%	1.10%	$4,730,537	$216,492	4.58%
L3913	22.00%	9.60%	63.70%	0.20%	0.20%	2.30%	$3,991,781	$30,295	0.76%
L3933	25.01%	8.40%	61.52%	0.11%	0.23%	2.52%	$1,809,373	$24,127	1.30%
L3906	20.10%	7.40%	64.60%	0.30%	1.10%	1.10%	$4,730,537	$216,492	4.58%
L3919	26.29%	10.35%	60.20%	0.01%	0.29%	0.56%	$474,383	$6,003	1.27%
L3702	12.29%	7.36%	67.63%	0.33%	2.29%	2.24%	$387,418	$24,192	6.24%
L3935	35.33%	6.79%	49.14%	1.13%	0.19%	0.33%	$116,302	$7,792	6.70%
L1844	0.00%	0.60%	59.30%	0.03%	17.70%	0.10%	$9,278,289	$1,987,594	21.42%
L1846	0.03%	0.90%	23.00%	0.10%	11.70%	0.90%	$7,071,557	$4,404,186	62.28%
L3763	15.32%	7.67%	69.12%	1.24%	0.14%	2.46%	$1,011,392	$40,015	3.96%
L1940	0.04%	0.03%	4.80%	42.20%	3.00%	0.30%	$16,058,351	$7,572,629	47.16%
L1970	0.00%	0.03%	1.66%	22.20%	2.37%	0.29%	$21,504,884	$14,003,010	65.12%
L3010	0.00%	0.67%	29.44%	25.88%	7.97%	0.33%	$750,643	$218,802	29.15%
L3020	0.72%	0.23%	16.57%	39.38%	3.55%	1.14%	$2,752,165	$1,043,323	37.91%
L3030	0.08%	1.19%	15.70%	36.51%	12.08%	11.41%	$278,781	$14,174	5.08%
L3000	0.30%	0.00%	11.90%	73.40%	2.30%	0.80%	$5,472,643	$565,635	10.34%

Total 2015 Medicare Allowed Amount for All Orthoses, All Provider Categories= $890,218,876

Total Medicare Allowed Amount for All Custom Fabricated Orthoses, All Provider Categories= $122,459,962

Table 1: Orthotic Base Code Allowed Services

Category	2015 Allowed Services	Percentage	
Certified O&P Personnel	1,369,929	25%	25%
Medical Supply	1,194,882	22%	75%
Other	285,406	5%	
Pharmacy	504,594	9%	
Physician	2,184,475	39%	
Grand Total	5,539,286	100%	

Table 2: Custom Fabricated & Fitted Orthotic Base Code Allowed Services

Category	2015 Allowed Services	Percentage	
Certified O&P Personnel	490,161	34%	34%
Medical Supply	198,251	14%	66%
Other	84,475	6%	
Pharmacy	115,784	8%	
Physician	545,962	38%	
Grand Total	1,434,633	100%	

General Overview

Definition of Providers and Suppliers

AOPA believes it is important to define and clarify the difference between Medicare providers and suppliers for purposes of the proposed rule. While the terms are often used interchangeably, there is a significant difference between the terms within the Social Security Act. Clarification of this difference within the proposed rule will help affected parties clearly understand the requirements that must be met to be considered qualified providers and/or qualified suppliers of prostheses and custom fabricated orthoses to Medicare beneficiaries.

Definition of Orthotics and Prosthetics

AOPA supports the use of the definition of the terms prosthetics and orthotics stipulated in section 1861(s)(9) of the Social Security Act for purposes of the proposed rule.

Legislative History

AOPA believes the summary of legislation that led to the publication of the proposed rule is crucial to understanding the individual provisions of the proposed rule. The proposed rule outlines the legislative history of the issue of provision of prostheses and custom fabricated orthoses starting with BIPA 2000, followed by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), and the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA). Each of these pieces of legislation has had an impact on the development of the proposed rule and is important in understanding the specific stipulations of the proposed rule. As discussed below, AOPA has concerns regarding CMS' proposal to remove specific exemptions from accreditation for certain providers and suppliers that were legislated as part of MIPPA 2008.

Provisions of the Proposed Regulations

Removal of the Exemption from Quality Standards and Accreditation

While AOPA fully supports compliance with Medicare Quality Standards relative to the provision of prostheses and custom fabricated orthoses, AOPA believes that the proposed rule goes beyond the intent of the original legislation (BIPA 427) and subsequent legislation (MIPPA) by completely removing the exemption from mandatory accreditation for those professionals who, through defined scope of practice, were identified as "qualified practitioners" in the original statute. AOPA supports the continued ability of recognized healthcare professionals such as physicians, physical therapists, and occupational therapists who are operating within their specific scope of practice to remain exempt from compliance with CMS quality standards through mandatory facility accreditation. AOPA believes existing licensure and scope of practice guidelines for these provider specialties will ensure they are providing quality care to Medicare beneficiaries.

Definition and Accreditation Requirements for Qualified Suppliers

With the exception of the suppliers discussed, above, who have been previously exempted through the MIPPA legislation, AOPA generally supports the proposed definition of the term qualified supplier as one who is "enrolled in Medicare as a DMEPOS supplier; and accredited by one of the CMS approved accreditation organizations (AO) that meet the proposed requirements that an AO must meet to accredit qualified suppliers of prostheses and custom fabricated orthoses" with the exception of those suppliers discussed above who have been previously exempted through the MIPPA legislation. AOPA has long been a proponent of the use of accreditation as a means to ensure that Medicare beneficiaries are receiving O&P devices that are appropriate for their medical needs. Since Medicare payments for DMEPOS are made to entities rather than individuals, the most efficient manner to ensure that prostheses and custom fabricated orthoses are being fabricated and fit by properly certified and/or licensed health care professionals is to require the supplier to become accredited by a CMS approved AO. AOPA also supports the stipulation in the proposed rule that accredited suppliers must notify the AO of any change in conditions, practices, or operations that may affect the supplier's ability to remain a qualified supplier.

Another pathway to ensuring that custom fabricated orthoses and prostheses are furnished by qualified providers is through the reporting of individual National Provider Identifier (NPI) on Medicare claims that can be used to identify the identity and credentials of the healthcare professional responsible for the actual provision of the custom fabricated item. Adopting inclusion of the individual provider NPI number in addition to the supplier number as a condition for payment for

custom orthotics and prosthetics would offer the same benefits to CMS. This will help ensure patient care by qualified providers and eliminate unnecessary reimbursement to unqualified providers at the individual claim level. Current Medicare regulations only require the reporting of the NPI that is assigned to the supplier that is billing for the service and offers no ability to determine the credentials of the individual providing the actual service. Requiring the reporting of individual NPIs in addition to the supplier NPI is an effective method of ensuring that the provision of custom fabricated orthoses and prostheses are limited to those qualified to do so.

Definition of Custom Fabricated Orthotics

AOPA generally supports the definitions of the terms "positive model of the patient" and "custom fabricated" as indicated in the proposed rule but believes there must be accommodation in the final rule to include the addition of other current custom fabrication techniques and evolving technologies for making custom prostheses and/or custom fabricated orthoses in the future. As technology continues to advance, the final rule must be flexible enough to accommodate alternate techniques for custom fabrication. A current technology that is rapidly advancing to commercial application in the O&P industry is additive manufacturing, also known as 3-D printing. While this technology is fairly new to the O&P industry, it is quickly becoming a viable means of fabricating some custom made devices. In the additive manufacturing process, a positive model of the patient is not used in fabrication, yet the end result is truly a custom fabricated device. AOPA believes the final rule must acknowledge continuing advancements in technology by creating a sub-regulatory process for identifying alternate methods of creating prostheses and custom fabricated orthoses.

Definition of Fabrication Facility

AOPA acknowledges the statutory language at 1834(h)(1)(F) of the Social Security Act that requires that "no payment can be made for prosthetics or custom fabricated orthotics unless the item is fabricated by a qualified practitioner or a qualified supplier at a facility that meets such criteria as the Secretary determines appropriate." AOPA is concerned the proposed rule, as it is currently written, does not recognize any difference between a stand-alone fabrication facility, referred to as a central fabrication facility that is integrated within the physical location of the enrolled DMEPOS supplier, which we previously indicated, is generally exempt from CMS prescriptions and requirements. Central fabrication facilities traditionally are not part of the patient care process involved with fitting and delivering prostheses and custom fabricated orthoses. A comparable example would be a dental lab that makes teeth and implants that are sent to the dentist's office where patient care is provided. The central fabrication facilities receive information from the O&P patient care facility, often a modified positive model of the patient's limb or other body part, a digital scan of the body part, or detailed measurements. This information is used to fabricate a device which is then returned to the O&P patient care facility for additional modification and delivery to the patient. The requirements for a fabrication facility that are detailed in the proposed rule may be somewhat consistent with what is typically found in a fabrication facility housed within an O&P practice but, as discussed above, the proposed requirements vastly exceed what is typically found in a central fabrication facility. AOPA recommends that the final rule acknowledge the difference between "in house" fabrication facilities and "central" fabrication facilities. As noted above, AOPA believes that: (a) the final rule should acknowledge and recognize the separate accreditation requirements that have been established by both the American Board for Certification in Orthotics, Prosthetics, and Pedorthics (ABC) and the Board of Certification/Accreditation (BOC); and (b) defer to these as the controlling guidelines for

central fabrication facilities, those that are physically distinct from fabrication facilities that are integrated within a facility where patient care is regularly rendered by certified and/or licensed health professionals. Both of these organizations are deemed Accrediting Organizations (AOs) by CMS, and both have separate and unique accreditation standards for in house fabrication facilities and central fabrication facilities. As discussed in its general comments above, AOPA has significant concerns regarding CMS' authority to create specific standards for fabrication facilities as part of this proposed rule. Rather than creating a new set of requirements that may be in conflict with the established standards of deemed AOs such as ABC and BOC, and potentially beyond the scope and authority of CMS, AOPA believes that the final rule should make reference to the existing standards established by ABC and BOC for central fabrication facilities. Adoption of these established standards in the final rule will maintain consistency with current requirements while ensuring that prostheses and custom fabricated orthoses are fabricated in an appropriate environment to meet the clinical needs of Medicare beneficiaries. Adoption of these standards will also ensure that AOs will maintain the ability to accredit or renew the accreditation of qualified suppliers with minimal interruption as stated in the proposed rule.

Definition of Qualified Practitioner

Occupational Therapist

AOPA has no objection to the use of the definition of the term occupational therapist housed at § 424.57 (a) for purposes of the proposed rule. The proposed rule requests specific comments regarding the proposed qualifications for an occupational therapist to furnish/fabricate prostheses and custom fabricated orthoses. AOPA supports the continued exemption from mandatory accreditation for occupational therapists operating within their defined scope of practice as it relates to the provision of **custom fabricated upper extremity** orthoses.

Ocularist

AOPA has no objection to the use of the definition of the term ocularist as defined in the proposed rule. The proposed rule requests specific comments regarding the proposed qualifications for an ocularist to furnish/fabricate prosthetics and custom fabricated orthotics. AOPA believes that only the fabrication and furnishing of ocular prostheses is within the defined scope of practice of an ocularist and therefore believes that their ability to provide services to Medicare beneficiaries should remain limited to ocular prostheses.

Orthotist

AOPA has several concerns regarding the definition in the proposed rule that will be used to determine the qualifications of an orthotist. The definition of the term orthotist in the proposed rule discusses a requirement that the individual has successfully completed a training program that is jointly recognized by the American Council on Education (ACE) and ABC. The proposed rule makes no mention of training programs that are recognized by BOC which could inadvertently cause a significant segment of current certified orthotists to not qualify as such under the definition in the proposed rule. In addition, the proposed rule makes no mention of training programs recognized by the Council on Accreditation of Allied Health Education Programs (CAAHEP). Since the passage of the BIPA legislation in 2000, CAAHEP has emerged as the primary accrediting organization for university based education programs in orthotics and prosthetics and currently accredits all of the

master's level education programs in orthotics and prosthetics. AOPA recommends that the final rule include CAAHEP recognized training programs when discussing qualifications of orthotists as qualified practitioners. Finally, AOPA recommends that the final rule include ABC and BOC certified orthotists who have achieved certification prior to implementation of the current educational requirements. Failure to recognize these individuals as qualified orthotists in the final rule may result in their inability to be defined as qualified orthotists solely because they were certified prior to the current education requirements for certification.

The proposed rule states that in order to be defined as an Orthotist or Prosthetist, individuals must be licensed (if a state requires it), **and** must complete a training program that is jointly recognized by ABC and ACE, **and** must be eligible to take either the BOC or ABC certification exam. The original statute does not stipulate that all of these requirements must be met. It is an "or" situation rather than an "and" situation, and the proposed regulations should be modified to confirm the "or" iteration. Additionally, the rule references the American Council on Education (ACE) as an accrediting body for orthotic and prosthetic education. This is not accurate. The Commission on Accreditation of Allied Health Education Programs (CAAHEP) overseen by the Council on Higher Education Accreditation (CHEA) is the primary accrediting organization for university-based education programs in orthotics and prosthetics. CAAHEP currently accredits all of the graduate level educational programs in orthotics and prosthetics, while the National Commission on Orthotic and Prosthetic Education (NCOPE) currently accredits all clinical residency programs as required for certification in orthotics and prosthetics. CAAHEP should replace the ACE in the final rule.

Pedorthist

AOPA has no objection to the use of the definition of the term pedorthist as defined in the proposed rule. The proposed rule requests specific comments regarding the proposed qualifications for a pedorthist to furnish/fabricate prosthetics and custom fabricated orthotics. AOPA believes that pedorthists who are accredited by a CMS approved AO should be able to fabricate and furnish prostheses and custom fabricated orthoses that are within their scope of practice as established by the Pedorthic Footcare Association.

Physical Therapist

AOPA has no objection to the use of the definition of the term physical therapist housed at § 484.4 for purposes of the proposed rule. The proposed rule requests specific comments regarding the proposed qualifications for a physical therapist to furnish/fabricate prosthetics and custom fabricated orthotics. AOPA supports the continued exemption from mandatory accreditation for physical therapists operating within their defined scope of practice as it strictly relates to the provision of certain custom fabricated orthoses.

Physician

AOPA has no objection to the use of the definition of the term physician housed at § 484.4 for purposes of the proposed rule. The proposed rule also discusses a unique requirement that "for the purposes of furnishing or fabricating prosthetics and custom fabricated orthotics, a physician must be specifically educated, certified or trained in the area of prosthetics and custom fabricated orthotics. The physician must be knowledgeable and competent (as evidenced by education and experience) in the assessment, furnishing, fabrication, care, and follow up needs of the patient as specifically

delineated in the DMEPOS quality standards." While AOPA understands the desire of CMS to ensure that prostheses and custom fabricated orthoses are only provided by individuals who have the knowledge, training, education, and experience to do so, we are also sensitive to the view of many that the proposed rule is unnecessarily restrictive, and needs to be modified to restore consistency with the original statutory language in Section 427 of BIPA 2000. AOPA supports the original statutory language of BIPA 2000 that defines physicians, in general, as qualified practitioners.

Doctors of Dental Surgery or Dental Medicine, Doctors of Optometry, Psychiatrists, and Chiropractors

AOPA supports the CMS decision to not propose requirements for these and other physician groups that do not typically provide prostheses and custom fabricated orthoses.

Prosthetist

AOPA has several concerns regarding the definition in the proposed rule that will be used to determine the qualifications of a prosthetist. The definition of the term prosthetist in the proposed rule discusses a requirement that the individual has successfully completed a training program that is jointly recognized by the American Council on Education (ACE) and ABC. The proposed rule makes no mention of training programs that are recognized by BOC which could inadvertently cause a significant segment of current certified prosthetists to not qualify as such under the definition in the proposed rule. In addition, the proposed rule makes no mention of training programs recognized by the Council on Accreditation of Allied Health Education Programs (CAAHEP). As we have previously stated, since the passage of the BIPA legislation in 2000, CAAHEP has emerged as the primary accrediting organization for university based education programs in orthotics and prosthetics and currently accredits all of the master's level education programs in orthotics and prosthestics. AOPA recommends that the final rule include CAAHEP recognized training programs when discussing qualifications of prosthetists as qualified practitioners. Finally, AOPA recommends that the final rule include ABC and BOC certified prosthetists who have achieved certification prior to implementation of the current educational requirements. Failure to recognize these individuals as qualified prosthetists in the final rule may result in their inability to be defined as qualified prosthetists solely because they were certified prior to the current education requirements for certification.

Training, Licensure, and Certification Requirements for Qualified Practitioners

AOPA generally supports the provisions in the proposed rule regarding training, licensure, and certification requirements for qualified practitioners providing prostheses and custom fabricated orthoses to Medicare beneficiaries. Again, we need to reiterate what we stated above with respect to the definition of "orthotist" and the importance of modifying the proposed rule so that it clearly and unequivocally recognizes that the statute requires a qualified O&P practitioner to be either licensed by the state (where a licensure statute exists), OR accredited.

Proper licensure and/or certification is crucial to ensure that Medicare beneficiaries receive O&P care from individuals who are properly trained and educated in the provision of prostheses and custom fabricated orthoses. AOPA remains concerned, as indicated earlier in our comments, that the proposed rule, as currently written, may impose unnecessary requirements on providers who have been historically exempt from mandatory accreditation and or certification. AOPA believes that licensed and/or certified providers who are operating within the defined scope of practice for their respective professions should not be required to also meet specific licensure and/or certification

requirements specific to orthotics and prosthetics in order to provide these services to Medicare beneficiaries.

Claims for Prosthetics and Custom Fabricated Orthotics

AOPA believes that the provisions in the proposed rule that authorize the revocation of a qualified supplier's enrollment from Medicare as a result of failure to comply with the requirements of the proposed rule are at least somewhat misdirected and reflect an improper prioritization of the proper enforcement mechanism for the statute. The intent of the original statute was to prevent unqualified suppliers from billing Medicare for prostheses and custom fabricated orthoses. The sole enforcement mechanism mentioned in the proposed regulation is revocation of supplier billing privileges, which would only occur AFTER improper payments have already been made by Medicare. In effect, this is a "pay and chase" mechanism. While the intent is to weed out bad operators, this may catch some legitimate providers in untenable situations as well. The power to revoke billing privileges is ripe for misapplication with significant impact on business continuity in cases where billing privileges were revoked inappropriately.

AOPA believes that there are better methods of enforcing the requirements of the proposed rule than revocation of a supplier's billing privileges and would like to offer three viable options that would work to help fix these issues:

1. Implementation of appropriate claim edits that would reject claims from unqualified providers;
2. Implementation of a requirement that all qualified suppliers submit their individual NPIs along with supplier numbers when submitting claims; and
3. Implementation of increased screening during the initial provider enrollment process and subsequent re-enrollment periods.

The statute says Medicare should not pay unlicensed/unaccredited providers, yet there is no enforcement mechanism to proactively limit such improper payments. The implementation of simple claim edits would serve to reject claims from unqualified providers at submission.

As noted above, the inclusion of the supplier's individual NPI, in addition to the supplier's billing number, as a condition for payment for custom orthotics and prosthetics, is a preferable approach that would offer the same benefits to CMS in assuring proper patient care by qualified providers and eliminating unnecessary reimbursement to unqualified providers at the individual claim level.

Also, increased screening during the initial provider enrollment process and subsequent re-enrollment periods should prevent most unqualified suppliers from entering or remaining in the system. In the unlikely event that an unqualified supplier is improperly enrolled, existing audit processes should be considered a reliable pathway to preventing or recouping payment from unqualified providers.

AOPA recommends that the final rule either remove the authority of CMS and its contractors to revoke the billing privileges of suppliers that it deems unqualified, or place substantial due process protections in place as protection. The authority to revoke a supplier's billing privileges based on unconfirmed information may lead to devastating consequences for legitimate suppliers. Just as important, the proper and primary enforcement mechanism under this rule MUST reflect the intent of

the statute that Medicare should use claim edits and such processes **so that Medicare does not pay** claims requested by unlicensed or unaccredited providers in the first place.

Requirements for Accreditation Organizations

AOPA supports the proposed continued designation of ABC and BOC as deemed AOs for suppliers who wish to bill Medicare for prostheses and custom fabricated orthoses. AOPA acknowledges the need for flexibility in the final rule to allow for the future deeming of AOs who maintain standards equivalent to ABC or BOC and as we stated in the Overview above. AOPA supports clearer, stronger provisions to this effect than have been provided in the proposed rule. The statement in the proposed rule-- that AOPA cannot support-- concerns the proposed definition of "a DMEPOS accreditation organization that has standards equivalent to ABC or BOC." The proposed rule indicates that "in order to meet this definition, an AO must only employ or contract with an orthotist, prosthetist, occupational therapist, or physical therapist who meets the qualified practitioner definition at § 424.57(a) and who is utilized for the purpose of surveying the supplier for compliance, and has the authority to approve or deny accreditation of qualified suppliers." AOPA believes this definition is overly broad and recommends that the final rule be amended to state that in order to be deemed equivalent to ABC or BOC for accreditation purposes, an AO must, first and foremost, and as a prerequisite, maintain standards that are equivalent, if not identical to those maintained by ABC or BOC.

Effective Date for Compliance with New Quality Standards

AOPA believes that the final rule must better define the effective date for compliance with the quality standards that are addressed in the proposed rule. The proposed rule indicates that suppliers of prostheses and custom fabricated orthoses must be in full compliance with the quality standards within one year after the final posting of the quality standards or at the time of the supplier's next re-accreditation cycle, whichever is later. The current accreditation cycle for O&P suppliers is three years. AOPA recommends that the final rule require all O&P suppliers to be compliant with the Quality Standards within 18 months of their final publication. This will allow appropriate time for compliance but will also protect the Medicare program from potential fraud and abuse.

List of Prosthetics and Certain Custom Fabricated Orthotics

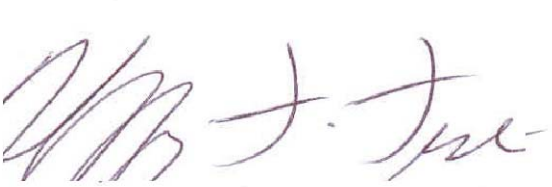
AOPA supports the indication in the proposed rule that CMS will continue to consult with industry groups in order to maintain a current list of prosthetic and custom fabricated orthotic HCPCS codes that are subject to the proposed rule. AOPA has always been and remains committed to assisting CMS in such matters and in any way possible. AOPA's concern regarding the definitions of the terms positive model of the patient and custom fabricated have been expressed previously. AOPA requests that CMS consider the implications of future developments and improvements in fabrication techniques for prostheses and custom fabricated orthoses when considering updates to the list of HCPCS codes subject to the provisions of the proposed rule.

Conclusion

As stated in our general comments, AOPA is generally pleased that CMS has finally published this proposed rule and we concur with some of its provisions. However, as we have indicated above, there are multiple aspects in which the proposed rule needs revision. After 17 years, the publication

of the proposed rule is the first step toward reducing inferior care and risk to patients by unqualified providers as well as fraud and abuse by bad operators. AOPA looks forward to working with CMS to ensure that the final rule makes the necessary improvements and corrections, so that it ultimately protects the health of Medicare beneficiaries while ensuring that access to quality care from qualified O&P providers remains available.

Very truly yours,



Michael H. Oros, CPO, President

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