AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

March 13, 2017

Patrick Conway, MD
Deputy Administrator and Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS–6012-P, P.O. Box 8013
Baltimore, MD 21244-8013

Submitted electronically via http://www.regulations.gov.

Subject: 42 CFR Part 424 [CMS–6012–P] Medicare Program; Establishment of Special Payment Provisions and Requirements for Qualified Practitioners and Qualified Suppliers of Prosthetics and Custom-Fabricated Orthotics

Dear Dr. Conway:

On behalf of the 18,000 board-certified orthopaedic surgeons who comprise the membership of the American Association of Orthopaedic Surgeons (AAOS) and on behalf of the orthopaedic groups who agreed to sign on, we are pleased to provide comments on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule with comment period on the Medicare Program's Establishment of Special Payment Provisions and Requirements for Qualified Practitioners and Qualified Suppliers of Prosthetics and Custom-Fabricated Orthotics [CMS–6012-P] published in the Federal Register [42 CFR Part 24] on January 12, 2017.

The AAOS commends the Administration's efforts to ensure that only qualified health care personnel are providing and fabricating prosthetics and orthotics. The AAOS believes it is critical for high quality patient care to have effective safeguards and protections that ensure Medicare patients have access to the best, safest, and reliable prosthetic and orthotic care. Orthopaedic surgeons are trained and expected to be able to skillfully fabricate, apply, and monitor effective prosthetic and orthotic management as part of their licensing and continuing education and are already a key part of ensuring quality and safety in this critical area.

We worked closely with medical schools, residency and fellowship programs to incorporate effective and current prosthetic and orthotic management as part of orthopaedic training and teaching. We also collectively offer up-to-date research and up-to-date continuing medical education in orthotic and prosthetic management. Further, this proposed rule obstructs the ability of occupational and physical therapists to properly use orthoses as a component of upper and lower extremity rehabilitation across the continuum of care. We, therefore, strongly believe that Medicare is best served by expanding opportunities and incentives for orthopaedic surgeons to lead the provision of orthotics and prosthetics, ably assisted by occupational and physical

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therapists. We believe the proposed rule in effect does the opposite, and makes it more difficult for surgeons to be a primary actor in providing and prescribing orthotic and prosthetic devices and we believe the proposed rule will setback patient care, not enhance or improve it. We recommend CMS make significant changes in advance of release of the final rule.

Further, we believe that, as drafted, the proposed rule would significantly increase regulatory burden for orthopaedic surgeons and will result in patients in need of orthotic and prosthetic care getting disaggregated, non-continuous, and lower quality care as they will be forced to get fitting, training, and management in multiple locations and by multiple and disconnected providers. It moves in the opposite direction from CMS' stated objectives in recent years by decreasing coordinated care and reducing alignment of incentives and regulations. This is bad for the system and bad for patients, and we believe CMS should revise the final rule to emphasize and incentivize the coordination of high quality, integrated and seamless orthotic and prosthetic management care.

The AAOS wishes to comment on the following three aspects of the proposed rule.

- **Removal of the Exemption for Qualified Professionals:** We believe the removal of the Qualified Professional exemption from licensing and standards for orthotic and prosthetic fabrication and provision is unnecessary to ensure patient quality and safety and will vastly increase regulatory burden on qualified professionals, as well as increase costs for physician practices. Furthermore, it will lead to less coordinated and integrated patient care which likely will increase costs to Medicare and make the Medicare patient experience worse not better. It will also reduce use and development of new and improved orthotics and prosthetics such as 3D printed products currently used in VA Hospitals. With the removal of the exemption veterans would lose access to this and other promising new technologies.
- **Expansion of State Licensing for Orthotics and Prosthetics:** The proposed rule, if implemented, would allow states to implement eligible professional exemptions similar to what currently exist for all Medicare providers. This would increase variation across state lines and increase disparities in costs and quality of care by state. Also, we believe this will reduce effective cost and quality control on a national basis.
- **Licensing requirements for provision and fabricating of prosthetics and orthotics:** We believe the requirement for all physicians and therapists not otherwise certified as Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) providers to receive and maintain licensing for orthotics and prosthetic devices will reduce patient access, reduce innovation and significantly increase costs, both in fiscal terms and in terms of time requirements without increasing safety and quality standards.

Removal of Exemptions from Orthotic and Prosthetic Licensing For Eligible Professionals

Orthopaedic surgeons are best able to evaluate the patient's limb alignment, deformity and biomechanics. Proper evaluation by orthopaedic surgeons allows for patient specific customization of their orthotic inserts to address each patient's biomechanical needs - either to help avoid surgery, or address residual deficits. Only orthopaedic surgeons have the combined ability and training to examine the patient's foot or hand, evaluate radiographs and understand the biomechanics required to give the patients the specific support that they would need. To illustrate this, osteointegration plays an important role in prosthetic rehabilitation, orthopaedic oncology, and reconstructive therapy and is unique in the realm of orthopaedic surgeons' training and expertise. Osteointegration has greatly advanced the science of bone and joint replacement techniques and prosthetics for amputees. This is a key area of expertise for orthopaedic surgeons specializing in trauma care, military medicine, joint replacements, spine surgery and pediatric care. Further, orthopaedic surgeons specializing in hand and upper extremity surgeries, rely on physical and occupational therapists to fabricate custom upper extremity orthoses for their patients, both post surgically and as a part of the rehabilitation and post-surgical management process. They are entrusted with highly complex patients due to their training in evaluation, skills in fabricating orthotics, knowledge of anatomy, soft tissue healing and post-surgical protocol and orthotic fabrication skills. Many of these therapists not only have graduate degrees that include instruction in orthosis fabrication, but also are certified hand therapists (CHTs) who are already credentialed through the Hand Therapy Certification Commission. The body of knowledge of appropriate orthotic intervention specific to upper extremity injury and rehabilitation is a substantial component of the credentialing examination and included in the requirements for recertification. There is no evidence in the existing literature that the orthotist and prosthetist accreditation meets the level of rigor specific to upper extremity rehabilitation and these professionals provide superior quality outcomes.

The proposed rule's removal of exemptions for physicians and therapists, if implemented, would require these providers, who are already experts in prosthetic and orthotic fabrication and management, to obtain licensing in prosthetic and orthotic management unless the provider is already a registered Durable Medicare Equipment (DME) provider or if their state provides additional exemptions. This regulatory requirement for licensing is costly, both in time and money, for providers who have obtained and maintained this training through residency, fellowship, and regular practice and without any basis in peer-reviewed evidence. It would take providers away from patient care, and additional licensing has not been proven to be effective in improving patient quality. Thus, limiting patient access to the professions who have the skills, knowledge and expertise to appropriately treat them will put surgical repairs and the functional outcomes of beneficiaries in jeopardy. We believe CMS can best incentivize innovative, coordinated and integrated orthotic and prosthetic provision by maintaining the current set of exemptions that allow physicians and therapists to provide orthotic and prosthetic management and fabrication in integrated offices where patients receive the rest of their musculoskeletal care.

We recommend CMS maintain the exemptions as currently in the law and regulations and revise the final rule in accordance with this.

State based Exemptions from Licensing for Orthotics and Prosthetics

Under the proposed rule, states would be allowed to set and maintain standards and exemptions in the area of prosthetic and orthotic fabricating, fitting and management. While we generally support the use of states to experiment with variations in healthcare regulations in order to test and measure different standards, in this case we believe having varying requirements across states would be counterproductive and increase variation in health care costs and quality for Medicare patients. It also could result in practices, facilities and physicians licensed to practice in multiple states to have to seek, obtain and maintain varying licenses in different states. This could excessively costly and inefficient. It also would lead to variations in access to physician and therapy based orthotic and prosthetic care by state which would be unfair to patients in different geographic areas.

We recommend maintaining a single national exemption for physicians and therapists as currently exists and reversing the proposed removal of exemption.

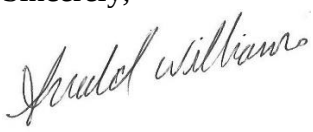
Requirement to Obtain and Maintain Licensing and Accreditation for Eligible Professionals

In the proposed rule CMS states they wish to require licensing and accreditation for providers of orthotics and prosthetics. While CMS rightly wants to maintain the highest quality standards for patients requiring orthotics and prosthetics, would actually drive patients to licensed prosthetists and orthotists who would be providing just one part of the patient care and doing so without coordination with the patient or therapists providing the face-to-face patient care. Additional licensing requirements will not improve quality and will decrease patient satisfaction and convenience. Therefore, maintaining the current exemptions for physicians and therapists will both ensure high quality standards as well as coordinated, integrated and one-stop patient management which results in higher patient satisfaction and higher overall quality of care.

We recommend CMS not require additional licensing and accreditation for physicians and therapists beyond what is required to maintain their current licenses. Physicians and therapists are fully trained and qualified to fabricate, fit, apply, and shape prosthetics and orthotics through their current training and should not be subject to another regulatory requirement for licensing, particularly when that training would not be additive to their already current training.

In conclusion, AAOS and the co-signing orthopaedic groups appreciate your efforts to ensure orthotic and prosthetic safety and high quality care. However, we believe the proposed rule will decrease quality, safety, and patient satisfaction, decrease product and device innovation, and increase regulatory burdens and costs for musculoskeletal practices. We recommend amending the proposed rule and issuing a final rule maintaining current exemptions. We are thankful for the opportunity to comment on this proposed rule and if you have any additional questions on our comments, please do not hesitate to contact AAOS Medical Director, William O. Shaffer, MD at shaffer@aaos.org.

Sincerely,



Gerald R. Williams Jr., MD
President, American Academy of Orthopaedic Surgeons (AAOS)

This letter has received sign-on from the following orthopaedic societies:

American Association for Hand Surgery (AAHS)
American Association of Hip and Knee Surgeons (AAHKS)
American Association of Orthopaedic Executives (AAOE)
American Orthopaedic Foot and Ankle Society (AOFAS)
American Orthopaedic Society for Sports Medicine (AOSSM)
American Shoulder and Elbow Surgeons (ASES)
Arthroscopy Association of North America (AANA)
Cervical Spine Research Society (CSRS)
J. Robert Gladden Orthopaedic Society (JRGOS)
Orthopaedic Rehabilitation Association (ORA)
Orthopaedic Trauma Association (OTA)
Pediatric Orthopaedic Society of North America (POSNA)
The Hip Society (HIP)
The Knee Society (KNEE)
OrthoForum
Alabama Orthopaedic Society
Colorado Orthopaedic Society
Connecticut Orthopaedic Society
Delaware Orthopaedic Association

Florida Orthopaedic Society
Louisiana Orthopaedic Association
Maryland Orthopaedic Association
Massachusetts Orthopaedic Association
Michigan Orthopaedic Society
Minnesota Orthopaedic Society
Nevada Orthopaedic Society
New York State Orthopaedic Society
South Carolina Orthopaedic Association
Tennessee Orthopaedic Society
Texas Orthopaedic Association
Utah Orthopaedic Society
Virginia Orthopaedic Society

CC: Karen Hackett, FACHE, CAE, AAOS Chief Executive Officer
William O. Shaffer, MD, AAOS Medical Director