September 2, 2014

Marilyn Tavenner  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
ATTN: CMS-1614-P  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, D.C.  20201

Re: CMS-1614-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies 79 Federal Register 40207 (July 11, 2014)

Dear Administrator Tavenner:

The National Athletic Trainers’ Association (NATA) appreciates the opportunity to provide comments on the proposed rule on End Stage Renal Disease (ESRD) Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (79 Federal Register 40207). Specifically, NATA is providing detailed comments on the definition of “specialized training” under the Minimum Self-Adjustment section of the proposed rule. This section identifies those health professionals who have the “specialized training” needed to provide custom fitting services if providers are not certified orthotists.

NATA is a professional organization serving more than 38,000 certified athletic trainers, students of athletic training, and other healthcare professionals. The organization’s mission is to enhance the quality of healthcare provided by certified athletic trainers and to advance the athletic training profession. As the leading organization representing athletic trainers, NATA has very serious concerns that the proposed rule would exclude athletic trainers from performing services for which they are qualified and have extensive experience.

These services are a core element of the role of athletic trainers as healthcare professionals who collaborate with physicians to provide preventative services, emergency care, clinical diagnosis, therapeutic intervention, and rehabilitation of injuries. NATA believes athletic trainers meet the necessary requirements under the proposed rule to be included among the healthcare professionals with “specialized training.” Therefore, athletic trainers should not be excluded from performing services that are directly related to their clinical expertise, education, training, and experience.
Background on the Athletic Training Profession

The athletic training profession began early in the 20th century, but the statutory title of “athletic trainer” is somewhat of a misnomer, derived from the profession’s historical roots. Athletic trainers provide medical services to all types of people and of all ages not just athletes participating in sports and are not personal or fitness trainers.

Athletic trainers have a long history of providing care for patients with orthotic device needs. In fact, athletic trainers have been directly involved in the creation and development of specific orthotic devices and equipment. For example, a bracing and orthotic product used by millions of patients every day was created by athletic trainer Moose Detty. The Duke Wyre shoulder brace, designed to keep the shoulder joint in place, was created by the athletic trainer that bears its name. Finally, the Extension Deceleration Orthotic for the knee was invented by Jim Whitesel, an athletic trainer.

Athletic trainers are highly qualified, multi-skilled healthcare professionals, and are included under the allied health professions category as defined by the Department of Health and Human Services and are assigned National Provider Identifier numbers. In addition to employment by sports and athletic organizations, athletic trainers are also employed by hospitals, clinics, occupational health departments, wellness facilities, the military, and in a number of other healthcare settings.

The following information is meant to provide the Agency with specific information and data about the education, training, licensure, certification, experience, knowledge, skills, and abilities that proves athletic trainers are more than qualified to be included in the list of health professionals permitted to perform these services.

VIII. Definition of Minimal Self-Adjustment of Orthotics under Competitive Bidding

NATA believes the proposed rule does not take into account the current role athletic trainers play in the delivery of these services related to orthotic devices. This will have a potentially negative impact on the Medicare beneficiaries we serve every day. Currently, all individuals fitting orthotics within a physician’s practice setting are considered to be under the direct supervision of a physician. The proposed rule would add restrictions that would not allow physicians to supervise individuals to provide custom fitting of these items.

The proposed rule could also require patients suffering from injuries that limit mobility to travel burdensome and unnecessary distances to obtain care. Instead of receiving and having their orthotics custom fitted while visiting their physician, they may need to visit another office for care and return to the physician’s offices again if they have questions or concerns with the fitting. This would result in avoidable and expensive referrals to
independent orthotists and other practitioners who meet the proposed definition of “specialized training” but are not under the supervision of a physician, thus disrupting the continuum of care.

Patients treated by athletic trainers benefit from their ability to have access to medical records, direct communication with the prescribing provider, and KX modifier compliance. Additionally, Athletic trainers practice in a broad range of other settings beyond the physician offices, orthopedic clinics, and hospitals. Athletic trainers work for manufacturers, DME suppliers, and other related vendors and their roles in these settings are important to Medicare patients. Medicare beneficiaries deserve the highest standard of care and when considering custom fitted orthotic devices, athletic trainers are healthcare professionals with the specialized skills, education, training, and experience equal to a certified orthotist.

The rule could also prevent athletic trainers from practicing to the full extent of their scope of practice under their state licensure. CMS is overtaking the role of state licensure boards while never indicating that patient care has ever been compromised due to differing state licensing policies. States have very strong licensure standards and qualifications for providers to perform these services. In fact, in some states athletic trainers are included by statute to provide custom orthotic fitting.

Educational Requirements and Standards for Athletic Trainers

All certified athletic trainers must have a bachelor’s or master’s degree from an accredited college or university and pass a comprehensive examination administered by the Board of Certification, Inc. (BOC). To retain certification, Certified Athletic Trainer (ATC®) credential holders must demonstrate completion of a prescribed number of medically related continuing education credits every two years and adhere to the BOC Standards of Professional Practice1, including the following:

- Prevention measures to educate patients and manage risk
- Clinical examination and diagnosis
- Immediate and acute care of injury and illness, especially in emergencies
- Treatment, rehabilitation and reconditioning
- Therapeutic intervention
- Psychosocial strategies and referral
- Healthcare administration
- Ethical and legal practice, cultural competence
- Professionalism and patient-centered approach

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Athletic training education programs, requiring a degree in Athletic Training, are accredited by the Commission on Accreditation of Athletic Training Education (CAATE).

The CAATE sets forth rigorous standards for the preparation of athletic training graduates that include a strong scientific base, as well as didactic and clinical education that addresses the continuum of care that would prepare a student to function in a variety of settings with patients engaged in a range of activities.

The curriculum of an accredited program is similar to that of our peers in healthcare and must include a comprehensive basic and applied science background. Education leading to the professional degree in Athletic Training uses a competency-based approach in both the classroom and clinical settings. Using a medical-based education model, athletic training students are provided the skills to serve in the role of physician extenders with an emphasis on clinical reasoning skills. Educational content must incorporate current knowledge and skills that represent best practices. Students must receive formal instruction in the following subject matter areas:

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<th>Foundational Courses²</th>
<th>Professional Courses³</th>
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<td>Human anatomy</td>
<td>Risk management and injury/illness prevention</td>
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<td>Human physiology</td>
<td>Pathology of injury/illness</td>
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<td>Exercise physiology</td>
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<td>Kinesiology/biomechanics</td>
<td>General medical conditions and disabilities</td>
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<td>Nutrition</td>
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<td>Strength training and reconditioning</td>
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<td>Acute care of injury and illness</td>
<td>Weight management and body composition</td>
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<td>Psychosocial intervention and referral</td>
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<td>Pharmacology</td>
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<td>Professional development and responsibilities</td>
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Students are required to participate in a minimum of two years of academic and clinical education. A segment of the clinical education experience must be directed toward a patient population having general medical ailments (e.g., cardiorespiratory, metabolic). Using an outcomes-based approach, students are instructed and evaluated by preceptors, including physicians, in clinics and hospitals.

Athletic Training graduates must have an extensive supervised clinical education that provides authentic, real-time opportunities to practice and integrate knowledge, skills,

³ Ibid.
and clinical abilities, including decision-making and professional behaviors required of the profession. Clinical education is required across a variety of settings with patients engaged in a range of activities across the continuum of care.

**Licensure and Certification of Athletic Trainers**

Upon completion of their academic program, graduates become eligible to take the Board of Certification (BOC) exam. Athletic trainers who pass the exam are awarded the ATC® credential. The credibility of the BOC program and the ATC® credential it awards are supported by three pillars: the BOC certification examination; BOC Standards of Practice and Disciplinary Process; and continuing competence requirements. BOC Certification is recognized by the National Commission for Certifying Agencies and is the only accredited certification program for athletic trainers.

The BOC traditionally conducts annual examination development meetings during which certified athletic trainers and recognized experts in the science of athletic training develop, review, and validate examination items and problems. The knowledge, skills, and abilities required for competent performance as an entry-level athletic trainer fall into three categories: (1) Understanding, applying, and analyzing; (2) Knowledge and decision-making; and (3) Special performance abilities.

In 49 states and the District of Columbia, athletic trainers are licensed or otherwise statutorily regulated. In states that license athletic trainers, the statutes may require the individual represent themselves with a designation other than the trademarked ATC®.

**Athletic Trainers Knowledge, Skills and Abilities**

All athletic training graduates must have knowledge and skills in concepts of body movement, including normal osteokinematics and arthrokinematics as well as the influence of pathomechanics on function. The NATA’s professional competencies document contains a section specific to “Protective Equipment and Prophylactic Procedures” and it specifically references the fabrication, modification, and appropriate application or use of orthotics and other dynamic and static splints.

The following is a list of the relevant professional competencies that athletic trainers are required to possess.

*Prevention and Health Promotion*

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• Summarize the basic principles associated with the design, construction, fit, maintenance, and reconditioning of protective equipment, including the rules and regulations established by the associations that govern its use;
• Summarize the principles and concepts related to the fabrication, modification, and appropriate application or use of orthotics and other dynamic and static splints;
• Fit standard protective equipment following manufacturers’ guidelines; and
• Apply preventive taping and wrapping procedures, splints, braces, and other special protective devices.

Clinical Examination and Diagnosis

Athletic trainers must possess strong clinical examination skills in order to accurately diagnose and effectively treat their patients. The clinical examination is an on-going process, repeated to some extent each time the patient is treated. The development of these skills requires a thorough understanding of anatomy, physiology, and biomechanics. Athletic trainers must also apply clinical-reasoning skills throughout the physical examination process in order to assimilate data, select the appropriate assessment tests, and formulate a differential diagnosis.

The clinical examination process is comprehensive and may include a review of the systems and regions identified below based on the patient’s behavioral and cognitive status and history:

• Describe the normal structures and interrelated functions of the body systems.
• Describe the principles and concepts of body movement, including normal osteokinematics and arthrokinematics.
• Describe the influence of pathomechanics on function.
• Identify the patient’s participation restrictions (disabilities) and activity limitations (functional limitations) to determine the impact of the condition on the patient’s life.
• Explain the role and importance of functional outcome measures in clinical practice and patient health-related quality of life.
• Identify functional and patient-centered quality of life outcome measures appropriate for use in athletic training practice.
• Determine criteria and make decisions regarding return to activity and/or sports participation based on the patient’s current status.
• Assess and interpret findings from a physical examination that is based on the patient’s clinical presentation.

Therapeutic Interventions
Athletic trainers assess the patient’s status using clinician- and patient-oriented outcome measures. Based on this assessment and with consideration of the stage of healing and goals, a therapeutic intervention is designed to maximize the patient’s participation and health-related quality of life. Therapeutic interventions include:

- Techniques to reduce pain;
- Techniques to restore joint mobility;
- Techniques to restore muscle extensibility;
- Techniques to restore neuromuscular function;
- Activities to improve balance, neuromuscular control, coordination, and agility;
- Exercises to improve gait, posture, and body mechanics;
- Therapeutic modalities such as the following:
  - Superficial thermal agents;
  - Electrical stimulation;
  - Therapeutic ultrasound;
  - Diathermy;
  - Therapeutic low-level laser and light therapy;
  - Mechanical modalities;
  - Traction;
  - Intermittent compression; and
  - Continuous passive motion.

**Physical Rehabilitation and Therapeutic Modalities**

- Analyze the impact of immobilization, inactivity, and mobilization on the body systems and injury response.
- Describe common surgical techniques, including the interpretation of operative reports, and any resulting precautions, contraindications, and comorbidities that impact the selection and progression of a therapeutic intervention program.
- Describe the use of joint mobilization in pain reduction and restoration of joint mobility.
- Perform joint mobilization techniques as indicated by examination findings.
- Fabricate and apply taping, wrapping, supportive, and protective devices to facilitate return to function.
- Analyze gait and select appropriate instruction and correction strategies to facilitate safe progression to functional gait pattern.
- Explain the relationship between posture, biomechanics, and ergodynamics and the need to address these components in a therapeutic intervention.
- Identify manufacturer, institutional, state, and/or federal standards that influence approval, operation, inspection, maintenance and safe application of therapeutic modalities, and rehabilitation equipment.
- Inspect therapeutic equipment and the treatment environment for potential safety hazards.
Clinical Integration Proficiencies

- Select, apply, evaluate, and modify appropriate standard protective equipment, taping, wrapping, bracing, padding, and other custom devices for the client/patient in order to prevent and/or minimize the risk of injury to the head, torso, spine, and extremities for safe participation in sport or other physical activity.
- Perform a comprehensive clinical examination of a patient with an upper extremity, lower extremity, head, neck, thorax, and/or spine injury or condition. This exam should incorporate clinical reasoning in the selection of assessment procedures and interpretation of findings in order to formulate a differential diagnosis, determine underlying impairments, and identify activity limitations and participation restrictions. Based on the assessment data and consideration of the patient’s goals, provide the appropriate initial care and establish overall treatment goals.
- Create and implement a therapeutic intervention that targets these treatment goals to include, as appropriate, therapeutic modalities, medications (with physician involvement as necessary), and rehabilitative techniques and procedures. Integrate and interpret various forms of standardized documentation including both patient-oriented and clinician-oriented outcomes measures to recommend activity level, make return to play decisions, and maximize patient outcomes and progress in the treatment plan.

Athletic trainers are highly educated, credentialed, licensed, trained, and qualified to be among the health professionals that can provide custom fitting of orthotics to Medicare beneficiaries. Preventing this group of qualified healthcare professionals from providing these services is a mistake that will negatively impact the quality of care received by Medicare patients.

Thank you for the opportunity to share the National Athletic Trainers’ Association’s comments on the Minimum Self-Adjustment rule. Should you have any questions, please do not hesitate to contact Amy Callender, Director of Government Affairs, at amyc@nata.org or (972) 532-8853.

Sincerely,

Jim Thornton, MS, ATC, CES

NATA President