

TO: American Orthotic and Prosthetic Association

FROM: Alston & Bird LLP

DATE: July 3, 2014

RE: DMEPOS Proposed Rule Provision on "Minimal Self-Adjustment"

On July 2, 2014, the Centers for Medicare & Medicaid Services (“CMS”) released a rule that proposes to “update the definition of minimal self-adjustment regarding what specialized training is needed by suppliers to provide custom fitting services if they are not certified orthotists.”¹ Comments will be accepted on the proposed rule through September 1, 2014.

Section 1847(a)(1)(A) of the Social Security Act² mandates the implementation of competitive bidding programs for awarding contracts for furnishing competitively priced items and services, including off-the-shelf (“OTS”) orthotics that require minimal self-adjustment for appropriate use and that do not otherwise require expertise in trimming, bending, molding, assembling, or customizing to fit an individual. Currently “minimal self-adjustment” is defined as “an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual who is certified by either the American Board of Certification in Orthotics and Prosthetics, Inc., or the Board of Orthotist/Prosthetist Certification) or an individual who has specialized training.”³

CMS says that since the finalization of the definition in 2007, there have been some “concerns raised by the industry and other stakeholders regarding who is considered an individual with specialized training,” and that the term “minimal self-adjustment” is ambiguous. To clarify the difference between OTS orthotics and those that require more than minimal self-adjustment, CMS proposes to identify the credentials and training a supplier needs in order to be considered a supplier with expertise in custom fitting and to clarify the term “individual with specialized training.” CMS says this also would “help to prevent any supplier without expertise in custom fitting orthotics from potentially circumventing the competitive bidding process by furnishing custom fitting [services] they are not qualified to provide in the event that they are not

¹ Medicare Program; End Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Proposed Rule, *available at*: <https://s3.amazonaws.com/public-inspection.federalregister.gov/2014-15840.pdf>. The proposed rule is scheduled to be published in the Federal Register on July 11, 2014, after which it will be available here: <http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR&browsePath=2014%2F07&isCollapsed=false&leafLevelBrowse=false&ycord=0>.

² 42 U.S.C. § 1395w-3(a)(1)(A).

³ 42 C.F.R. § 414.402.

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awarded a contract for furnishing OTS orthotics in their service area, as the custom fitted devices are not included in the competitive bidding program.”

The proposed rule mentions the HCPCS codes, effective on January 1, 2014, that CMS says it developed to help distinguish orthotics that do not need adjustment from those that do. The codes describe items CMS says are never furnished as OTS, that are always furnished as OTS, and that may be furnished either way (depending on whether more than minimal fitting and adjustment of a particular device by an expert is necessary for a particular patient). For this last category of items, CMS developed separate codes to describe the items when they are furnished OTS and when they have been custom-fitted.⁴ Following the publication of this list, one of the DME MACs (Noridian) published an article entitled “Correct Coding – Definitions Used for Off-the-Shelf versus Custom-Fitted Prefabricated Orthotics – Revised” that in part sought to clarify what kinds of practitioners could be considered “individuals with specialized training” that could provide adjustment of OTS orthotics.⁵

CMS believes that physicians, treating practitioners, occupational therapists, and physical therapists are considered “individuals with specialized training” that possess training equivalent to a certified orthotists for the provision of custom fitted orthotic devices through their individual degree programs and continuing education requirements; they also possess equivalent or higher educational degrees, continuing education requirements, licensing, and certification and/or registration requirements. Clinical providers such as assistants, fitters, and manufacturer representatives that work under the supervision of the individual with specialized training must do so as required under their governing body Code of Ethics and supervision standards, as well as state licensure requirements. These individuals are not considered to have specialized training for the purposes of providing custom fitting; therefore, orthotics they adjust still would be considered OTS.

CMS proposes to update the definition of “minimal self-adjustment” at 42 C.F.R. § 414.402 this way:

Minimal self-adjustment means an adjustment the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification), or a physician as defined in 1861(r) of the Act, a treating practitioner which means a physician assistant, nurse practitioner, or clinical nurse specialist as defined in section 1861(aa)(5) of the Act, an occupational therapist as defined in § 484.4 of this chapter, or physical therapist as defined in §

⁴ The HCPCS codes may be accessed here: http://www.cms.gov/Medicare/Medicare-Fee-For-Service-Payment/DMEPOSFeeSched/OTS_Orthotics.html.

⁵ The article may be accessed here:

https://www.noridianmedicare.com/dme/news/docs/2014/03_mar/correct_coding_definitions_used_for_off_the_shelf_versus_custom_fitted_prefabricated_orthotics_braces_revised.html.

484.4 of this chapter who are in compliance with all applicable Federal and State licensure and regulatory requirements.

Each of the relevant terms, in turn, are defined this way in the Social Security Act:

“The term ‘**physician**’, when used in connection with the performance of any function or action, means

(1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action (including a physician within the meaning of section 1301 (a)(7) of this title),

(2) a doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the State in which he performs such function and who is acting within the scope of his license when he performs such functions,

(3) a doctor of podiatric medicine for the purposes of subsections (k), (m), (p)(1), and (s) of this section and sections 1395f (a), 1395k (a)(2)(F)(ii), and 1395n of this title but only with respect to functions which he is legally authorized to perform as such by the State in which he performs them,

(4) a doctor of optometry, but only for purposes of subsection (p)(1) of this section and with respect to the provision of items or services described in subsection (s) of this section which he is legally authorized to perform as a doctor of optometry by the State in which he performs them, or

(5) a chiropractor who is licensed as such by the State (or in a State which does not license chiropractors as such, is legally authorized to perform the services of a chiropractor in the jurisdiction in which he performs such services), and who meets uniform minimum standards promulgated by the Secretary, but only for the purpose of subsections (s)(1) and (s)(2)(A) of this section and only with respect to treatment by means of manual manipulation of the spine (to correct a subluxation) which he is legally authorized to perform by the State or jurisdiction in which such treatment is provided. For the purposes of section 1395y (a)(4) of this title and subject to the limitations and conditions provided in the previous sentence, such term includes a doctor of one of the arts, specified in such previous sentence, legally authorized to practice such art in the country in which the inpatient hospital services (referred to in such section 1395y (a)(4) of this title) are furnished.”⁶

“(A) The term ‘**physician assistant**’ and the term ‘**nurse practitioner**’ mean, for purposes of this subchapter, a physician assistant or nurse practitioner who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations.

⁶ 42 U.S.C. § 1395x(r).

(B) The term ‘**clinical nurse specialist**’ means, for purposes of this subchapter, an individual who—

(i) is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed; and

(ii) holds a master’s degree in a defined clinical area of nursing from an accredited educational institution.”⁷

“**Occupational therapist.** A person who—

(a) (1) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing, unless licensure does not apply;

(2) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA), or successor organizations of ACOTE; and

(3) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(b) On or before December 31, 2009—

(1) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing; or

(2) When licensure or other regulation does not apply—

(i) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or successor organizations of ACOTE; and

(ii) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc., (NBCOT).

(c) On or before January 1, 2008—

(1) Graduated after successful completion of an occupational therapy program accredited jointly by the committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or

⁷ 42 U.S.C. § 1395x(aa)(5).

(2) Is eligible for the National Registration Examination of the American Occupational Therapy Association or the National Board for Certification in Occupational Therapy.

(d) On or before December 31, 1977—

(1) Had 2 years of appropriate experience as an occupational therapist; and

(2) Had achieved a satisfactory grade on an occupational therapist proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(e) If educated outside the United States, must meet all of the following:

(1) Graduated after successful completion of an occupational therapist education program accredited as substantially equivalent to occupational therapist entry level education in the United States by one of the following:

(i) The Accreditation Council for Occupational Therapy Education (ACOTE).

(ii) Successor organizations of ACOTE.

(iii) The World Federation of Occupational Therapists.

(iv) A credentialing body approved by the American Occupational Therapy Association.

(2) Successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(3) On or before December 31, 2009, is licensed or otherwise regulated, if applicable, as an occupational therapist by the State in which practicing.”⁸

“Physical therapist. A person who is licensed, if applicable, by the State in which practicing, unless licensure does not apply and meets one of the following requirements:

(a) (1) Graduated after successful completion of a physical therapist education program approved by one of the following:

(i) The Commission on Accreditation in Physical Therapy Education (CAPTE).

(ii) Successor organizations of CAPTE.

(iii) An education program outside the United States determined to be substantially equivalent to physical therapist entry-level education in the United States by a credentials evaluation organization approved by the

⁸ 42 C.F.R. § 484.4.

American Physical Therapy Association or an organization identified in 8 CFR 212.15(e) as it relates to physical therapists; and

(2) Passed an examination for physical therapists approved by the State in which physical therapy services are provided.

(b) On or before December 31, 2009—

(1) Graduated after successful completion of a physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE); or

(2) Meets both of the following:

(i) Graduated after successful completion of an education program determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified in 8 CFR 212.15(e) as it relates to physical therapists.

(ii) Passed an examination for physical therapists approved by the State in which physical therapy services are provided.

(c) Before January 1, 2008—

(1) Graduated from a physical therapy curriculum approved by one of the following:

(i) The American Physical Therapy Association.

(ii) The Committee on Allied Health Education and Accreditation of the American Medical Association.

(iii) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association.

(d) On or before December 31, 1977 was licensed or qualified as a physical therapist and meets both of the following:

(1) Has 2 years of appropriate experience as a physical therapist.

(2) Has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(e) Before January 1, 1966—

(1) Was admitted to membership by the American Physical Therapy Association; or

(2) Was admitted to registration by the American Registry of Physical Therapists; or

(3) Has graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education.

(f) Before January 1, 1966 was licensed or registered, and before January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy.

(g) If trained outside the United States before January 1, 2008, meets the following requirements:

(1) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.

(2) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.”⁹

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We hope you have found this summary to be helpful. Please let us know if you have any questions.

⁹ 42 C.F.R. § 484.4.