

Via online submission

August 31, 2007

The Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1282-P
P.O. Box 8016
Baltimore, MD 21244-8016

**Re: Medicare Program; Proposed Revisions to Payment Policies Under
the Physician Fee Schedule and Other Part B Payment Policies for CY
2008; Proposed Rule (CMS-1385-P)**

Dear Sir or Madam:

The American Occupational Therapy Association (AOTA) represents over 36,000 occupational therapy professionals, many of whom are reimbursed under the Medicare Physician Fee Schedule (MPFS) and are affected by Medicare Part B payment policies. We appreciate the opportunity to comment on the rule containing revisions to payment policies under the MPFS and other Part B payment policies for calendar year 2008, as published in the Federal Register on July 12, 2007 at 72 Fed. Reg. 38122. AOTA presents the following comments on the MPFS proposed rule:

I. THERAPY STANDARDS AND REQUIREMENTS

A. *Revisions to Personnel Qualification Standards for Therapy Services (72 Fed. Reg. 38230)*

AOTA is pleased to see that the Centers for Medicare and Medicaid Services (CMS) has proposed updated qualification standards for occupational therapists (OTs) and occupational therapy assistants (OTAs). For years, AOTA has been advocating for CMS to revise the regulations at 42 C.F.R. § 484.4 since these regulations have been outdated for decades. AOTA recognizes the thoughtful consideration that went into the development of the proposed personnel qualifications, but we would like to suggest that CMS consider simplifying the requirements. *We believe that the personnel qualifications should be simple and straightforward. We suggest that the personnel qualifications should first and foremost be tied to state regulation. In the case of states without state regulation or when services are being provided “incident to” a physician’s service, we respectfully request that the education and exam requirements for the occupational therapy profession apply to those individuals wishing to provide occupational therapy services.*

1. *AOTA Requests That Personnel Qualifications Be Tied to State Regulation
First and Foremost*

For more than 25 years, AOTA has worked with state occupational therapy associations to enact state regulatory laws for the occupational therapy profession. As of August 2007, 47 states, the District of Columbia, Guam and Puerto Rico license occupational therapists; 2 states (Hawaii and Michigan) have registration laws and 1 state (Colorado) has a title protection law.

The form of regulation for occupational therapy assistants is often, but not always, the same for occupational therapists in a given jurisdiction. The District of Columbia, Guam, Puerto Rico and 43 states license occupational therapy assistants; 3 states (California, Indiana and New York) have certification laws; 1 state (Michigan) has a registration law and 1 state (Virginia) has a title protection law. Colorado and Hawaii do not regulate occupational therapy assistants.

State licensure, certification, registration and trademark laws establish education, training and exam requirements to practice as occupational therapists and occupational therapy assistants. These education, training and exam requirements are consistent across the states. AOTA closely monitors proposed changes in state occupational therapy practice acts and regulations and we advocate for state laws that are consistent with the Association's *Standards of Practice, Policy on Licensure* and the *AOTA Model Practice Act*.

AOTA has a long standing policy of supporting the role and authority of state regulatory boards. State occupational therapy regulatory boards have the legal authority to discipline practitioners who violate the law and have the authority to prevent someone from practicing that does not meet the licensure requirements. Furthermore, most state occupational therapy practice acts include a continuing education requirement for licensure renewal, which we believe reinforces the continuing competence of occupational therapists and occupational therapy assistants. To date we have heard no complaints from members or other stakeholders to suggest that the state practice acts are inadequate at protecting the public from unqualified or unscrupulous practitioners.

AOTA holds full confidence in state regulatory boards. In fact, nationally recognized accreditation organizations such as the Joint Commission (JCAHO) and the Commission on Accreditation of Rehabilitation Facilities (CARF) demonstrate similar confidence in state licensure boards by requiring verification of state licensure or related requirements for personnel employed by the facilities they accredit. For example, the Joint Commission (JCAHO) has a similar standard for many facility settings (including but not limited to hospitals; home care; long term care; and critical access hospitals), which requires that the organization have a process in place to ensure that organization staff qualifications are consistent with job responsibilities. An organization can meet this JCAHO standard by verifying the staff's current state licensure, certification, or registration at the time of hire or upon expiration of the credentials.

State legislatures have historically regulated the health professions. ***We request that CMS rely on these state laws to determine who is qualified to provide services under Medicare. To ensure that there are standards in place for states without regulation, we request that 42 C.F.R. § 484.4 include the education and exam requirements that personnel must meet to practice as occupational therapists or occupational therapy assistants.*** While most states license or otherwise regulate the occupational therapy profession, there have been attempts to deregulate health professions in the name of regulatory reform and cost savings. By including the education and exam requirements in 42 C.F.R. §484.4, there will still be standards in place should a state or states unwisely decide to deregulate the occupational therapy profession.

2. *AOTA's Recommended Language Maintains the Integrity of Incident to Services*

AOTA asserts that our interpretation of AOTA's recommended language does not create a problem for the occupational therapy profession by permitting unqualified personnel to perform incident to occupational therapy services under 42 C.F.R. § 410.59. The incident to provision at 42 C.F.R. § 410.59(a)(3)(iii), requires that an individual must meet the qualifications in 42 C.F.R. § 484.4 for an occupational therapist or appropriately supervised occupational therapy assistant, except that a license to practice occupational therapy in the state is not required. As set forth in greater detail below, AOTA's recommended language for § 484.4 states that a qualified occupational therapist must meet one of two requirements: 1) be licensed or otherwise regulated as an occupational therapist by the state of practice or 2) graduate from an occupational therapist education program accredited by ACOTE and successfully complete or be eligible to take the entry-level certification examination for occupational therapists.

AOTA's recommended language then, read together with the incident to provision at § 410.59(a)(3)(iii), would permit an individual to provide incident to occupational therapy services without a license to practice occupational therapy in the state ***only if*** the remaining AOTA recommended requirement for § 484.4 is satisfied (since licensure is not required under the incident to provision)—that the individual graduate from an occupational therapist education program accredited by ACOTE and successfully complete or be eligible to take the entry-level certification examination for occupational therapists. AOTA asserts that an individual who has completed an accredited occupational therapy education program is qualified to provide incident to therapy services. This supports an underlying principle in AOTA's recommended language that any personnel providing occupational therapy services must be officially recognized (through formal education in OT school or licensure) as an occupational therapist. ***We do not believe that these two regulatory provisions could be read together to eliminate the occupational therapist education/exam requirement and it is AOTA's intent that this education/exam requirement remain in place for individuals providing incident to services.***

AOTA RECOMMENDED LANGUAGE

42 C.F.R. § 484.4 Personnel Qualifications

Occupational Therapist.

(1) For an occupational therapist trained in the United States, a person who meets either of the following requirements:

(i) Licensed or otherwise regulated as an occupational therapist by the state in which he or she is practicing;
or

(ii)(A) 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 predecessor organizations; and (B) Successfully completed or is eligible to take the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT) or another credentialing body recognized by the American Occupational Therapy Association.

(2) For an occupational therapist trained outside the United States, a person who meets either of the following requirements:

(i) Licensed or otherwise regulated as an occupational therapist by the state in which he or she is practicing;
or

(ii)(A) 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 predecessor organizations; or graduated after successful completion of an occupational therapist education program approved by the World Federation of Occupational Therapists; and (B) Successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT) or another credentialing body recognized by the American Occupational Therapy Association.

Occupational Therapy Assistant.

(1) For an occupational therapy assistant trained in the United States, a person who meets either of the following requirements:

(i) Licensed or otherwise regulated as an occupational therapy assistant by the State in which he or she is practicing;
or

(ii) (A) Graduated after successful completion of an occupational therapy assistant education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or predecessor organizations; and (B) Successfully completed or is eligible to take the entry-level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT) or another credentialing body recognized by the American Occupational Therapy Association.

(2) For an occupational therapy assistant trained outside the United States, a person who meets either of the following requirements:

(i) Licensed or otherwise regulated as an occupational therapy assistant by the State in which he or she is practicing;
or

(ii)(A) Graduated after successful completion of an occupational therapy assistant education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA); and (B) Successfully completed the entry-level certification examination for occupational therapy assistants developed by a credentialing body recognized by the American Occupational Therapy Association.

AOTA Comments Regarding CMS Proposed Personnel Qualifications

Again, AOTA recognizes the thoughtful consideration that went into the development of the proposed personnel qualifications. With this in mind, we would like to address some of the specific concerns we have with language proposed by CMS for occupational therapists and occupational therapy assistants.

CMS Proposal:

Occupational therapist. A person who meets one of the one of the following requirements:

(1) *Requirements for individuals beginning their practice on or after January 1, 2008.* Meets all practice requirements set forth by the State in which occupational therapy services are furnished and meets one of the following educational/training requirements on or after January 1, 2008:

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

(B) Successfully completed the National Registration Examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

AOTA Comments:

- This provision establishes standards based on when an individual begins their practice after January 1, 2008. CMS should clarify how this requirement will be applied. Does this mean when someone starts to provide services under Medicare or when an individual starts to practice occupational therapy in general?
- ACOTE accredits education programs rather than curriculum.
- Language regarding ACOTE should also address predecessor organizations.
- Language regarding the exam should allow for another professionally recognized credentialing body besides NBCOT to develop or administer the entry-level examination in the event that NBCOT leaves the market or another body enters into the market to offer the entry level exam.
- This provision requires occupational therapists to pass the exam. Many states offer temporary licenses/permits to occupational therapists that have graduated from school and are eligible to take the exam. The CMS proposal would be more restrictive and have a profound negative impact on new graduates entering the workforce. We believe that the standard should be that the individual has passed the exam or is eligible to take the exam.

CMS Proposal:

(ii) If educated outside the United States, or trained by the United States military—

(A) Graduated after successful completion of an occupational therapist curriculum accredited by the World Federation of Occupational Therapists, (WFOT));

(B) Is deemed eligible to test as a result of completing the NBCOT International Occupational Therapy Eligibility Determination (IOTED) review; and

(C) Successfully completed the National Registration Examination developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT)).

AOTA Comments:

- The United States Military does not offer education programs for occupational therapist at this time. Any future military program would need to meet ACOTE standards for occupational therapy programs in the United States. The United States Department of Education recognizes ACOTE accreditation standards.
- NBCOT determines the education requirements to sit for the examination. We do not believe it is necessary to include information about the IOTED process in the regulations.
- ACOTE should be mentioned along with WFOT as a body that may accredit foreign education programs.
- Language regarding the exam should allow for another professionally recognized credentialing body besides NBCOT to develop or administer the entry-level examination in the event that NBCOT leaves the market or another body enters into the market to offer the entry level exam.
- Consistent with regulations from the Department of Homeland Security (8 CFR Part 212.15(f)(1)(iv)), foreign trained occupational therapists should be required to pass the entry-level certification exam.

CMS Proposal:

(2) Requirements for individuals beginning their practice after December 31, 1977 and before January 1, 2008.

Meets the one following requirements after December 31, 1977 and before January 1, 2008:

(i) Is a graduate of an occupational therapy curriculum accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association. (ii) Is eligible for the National Registration Examination of the American Occupational Therapy Association.

(3) Requirements for individuals beginning their practice on or before December 31, 1977. (i) Has 2 years of appropriate experience as an occupational therapist; and (ii) Has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service on or before December 31, 1977.

AOTA Comments:

- These provisions reference archaic standards for the exam and occupational therapy education programs. AOTA and AMA collaborated on standards for occupational therapy education programs from 1935-1993; ACOTE became operational as an accrediting agency independent of CAHEA/AMA on January 1, 1994. The national registration exam for occupational therapists was initially offered by AOTA, then the American Occupational Therapy Certification Board (AOTCB) which is now known as the National Board for Certification in Occupational Therapy. NBCOT was formed in 1986 as AOTCB and retains the historical record for anyone that has taken the entry-level exam. AOTA has urged CMS to update these standards for many years.
- State laws define education, training and exam requirements. State regulatory bodies have already “grandfathered in” occupational therapists that met the old standards.
- If CMS retains this provision, the language should be amended to recognize the appropriate education and examination entities for both US trained and internationally trained occupational therapists.

CMS Proposal:

Occupational therapy assistant. A person who meets one of the following requirements:

(1) *Requirements for individuals beginning their practice on or after January 1, 2008.* Provides certain occupational therapy services under the supervision of a qualified occupational therapist, continues to meet all practice requirements set forth by the State in which occupational therapy services are furnished, and meets one of the educational/training requirements if his or her professional practice begins on or after January 1, 2008:

(i)(A) Graduated after successful completion of coursework and clinical field work from an occupational therapy assistant curriculum accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA); and (B) Successfully completed the certification examination for Certified Occupational Therapy Assistant developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

AOTA Comments:

- The proposed standards for occupational therapy assistants include provisions regarding supervision. While we agree that occupational therapy assistants must practice under the supervision of an occupational therapist, that issue might be best addressed in separate regulations or in CMS Medicare Manuals, as is done under the current 42 CFR §484.4. Currently the qualification standards for occupational therapy assistants do not reference supervision. AOTA also supports the role of state occupational therapy practice acts and regulations to address supervision of issues. In fact, many state laws are based upon AOTA professional standards regarding supervision and role delineation.
- This provision establishes standards based on when an individual begins their practice after January 1, 2008. CMS should clarify how this requirement will be applied. Does this mean when someone starts to provide services under Medicare or when they start to practice occupational therapy in general?
- ACOTE accredits education programs rather than curriculum.
- This provision includes a requirement that occupational therapy assistants complete coursework and clinical fieldwork. Fieldwork is part of the education program, so this provision could be simplified to require that the person complete an accredited education program.
- Language regarding ACOTE should also address predecessor organizations.
- Language regarding the exam should allow for another professionally recognized credentialing body besides NBCOT to develop or administer the entry-level examination in the event that NBCOT leaves the market or another body enters into the market to offer the entry-level exam.
- This provision requires occupational therapy assistants to pass the exam. Many states offer temporary licenses/permits to occupational therapists that have graduated from school and are eligible to take the exam. The CMS proposal would be more restrictive and have a profound negative impact on new graduates entering the workforce. We believe that the standard should be that the individual has passed the exam or is eligible to take the exam.

CMS Proposal:

(ii) If educated outside the United States or trained in the United States military, graduated after successful completion of an occupational therapy assistant curriculum that by credentials evaluation conducted or approved by the American Occupational Therapy Association is determined to be comparable, with respect to occupational therapy assistant entry level education in the United States.

AOTA Comments:

- There is one occupational therapy assistant program offered by the United States Military--the Army Medical Department Center and School at Fort Sam Houston in Texas. The program is accredited by ACOTE. Any future military program would need to meet ACOTE standards for occupational therapy assistant programs in the United States. The United States Department of Education recognizes ACOTE accreditation standards.
- There are a number of occupational therapy assistant programs in Canada, but those programs are not accredited by ACOTE or approved by WFOT. It is our understanding that NBCOT does not allow foreign trained occupational therapy assistants to take the examination as they do not meet the education requirements.
- AOTA encourages CMS to establish requirements for occupational therapy assistants trained outside of the United States. AOTA recommends the following requirements:
 - Graduation after successful completion of an occupational therapy assistant education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA);
 - Successfully completion of the entry-level certification examination for occupational therapy assistants developed by a credentialing body recognized by the American Occupational Therapy Association.

CMS Proposal:

(2) *Requirements for individuals beginning their practice after December 31, 1977 and before January 1, 2008.* Meets the requirements for certification as an occupational therapy assistant established by the American Occupational Therapy Association after December 31, 1977 and before January 1, 2008.

(3) *Requirements for individuals beginning their practice on or before December 31, 1977.* Has 2 years of appropriate experience as an occupational therapy assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service on or before December 31, 1977

AOTA Comments:

- These provisions reference archaic standards for the exam and occupational therapy education programs. In 1958, AOTA assumed responsibility for approval of educational programs for the occupational therapy assistant. In 1990, AOTA petitioned the Committee on Allied Health Education and Accreditation (CAHEA) to include the accreditation of the occupational therapy assistant programs in the CAHEA system. Following approval of the change by the AMA Council on Medical Education, CAHEA petitioned both COPA and the U.S.

Department of Education (USDE) for recognition as the accrediting body for occupational therapy assistant education. In 1991, occupational therapy assistant programs with approval status from the AOTA Accreditation Committee became accredited by CAHEA/AMA in collaboration with the AOTA Accreditation Committee. ACOTE became operational as an accrediting agency for OT and OTA programs independent of CAHEA/AMA on January 1, 1994. The national certification exam for occupational therapy assistants was initially offered by AOTA in 1977, then the American Occupational Therapy Certification Board which is now known as the National Board for Certification in Occupational Therapy. NBCOT was formed in 1986 as AOTCB and retains the historical record for anyone that has taken the entry-level exam. AOTA has urged CMS to update these standards for many years.

- State laws define education, training and exam requirements. State regulatory bodies have already “grandfathered in” occupational therapy assistants that met the old standards.
- If CMS retains this provision, the language should be amended to recognize the appropriate education and examination entities for both US trained and internationally trained occupational therapy assistants.

B. Cross-References to Personnel Qualifications (72 Fed. Reg. 38231)

AOTA concurs with CMS that therapy personnel qualifications should be required according to the same standards and policies in all settings to the extent possible, consistent with statute. AOTA supports revised regulations which cross-reference the personnel qualifications for occupational therapists and occupational therapy assistants in 42 C.F.R. §484.4 in these settings:

- Inpatient Hospital Services and Inpatient Critical Access Hospital Services
- Posthospital SNF Care
- Partial hospitalization services
- Outpatient occupational therapy services
- Hospice
- Rehabilitation Services
- Comprehensive Outpatient Rehabilitation Facilities
- Clinics, Rehabilitation Agencies, and Public Health Agencies

C. Application of Consistent Therapy Standards (72 Fed. Reg. 38193)

1. Standards Must Not Impede Access to Occupational Therapy

While AOTA supports the general intent of consistent standards and appreciates the helpful recognition that occupational therapy services can only be furnished by qualified occupational therapists (OTs) and occupational therapy assistants (OTAs), AOTA is gravely concerned that the same standards can not be applied across all therapy settings without negative impact in some settings. The MPFS proposed rule would require that inpatient hospital therapy services require a treatment plan consistent with that

established in a Medicare outpatient setting through new proposed regulation 42 C.F.R. § 409.17. Specifically, the new regulation would require establishment of a treatment plan before treatment begins and that any changes in the plan be incorporated immediately in writing and signed by a treating practitioner. Hospital inpatient practice is often done quickly and the timing of physician approval of the treatment plan may take 24 hours, delaying provision of ordered care. A physician order in the chart should be sufficient to begin treatment. Any changes to the inpatient hospital requirements should enhance patient care and expedite the delivery of medically necessary therapy services. ***AOTA asserts that changes to inpatient hospital documentation requirements should not impede or delay access to therapy unnecessarily in an inpatient setting.***

2. *Service Delivery Distinctions Exist Across Settings*

The manner in which occupational therapy services are furnished to acutely ill beneficiaries in an inpatient setting differs significantly from how the same services are furnished and paid for in the typical Part B outpatient setting. In the typical Part B setting, beneficiaries are seen by scheduled appointment, with both the payment and scheduling taking into account the therapists' time spent providing services as well as documenting every minute of treatment and evaluation in the record. However, in the inpatient hospital, beneficiaries often are furnished occupational therapy services at the bedside, with their availability subject to a myriad of procedures and tests performed by other hospital personnel related to their acute condition. A therapist may only have an hour with a patient on one day and the same patient may be suddenly discharged by the physician only days later.

While both inpatient and outpatient settings require an occupational therapy plan of treatment, in the inpatient hospital setting, the patient's acuity and a number of other factors significantly impact the feasibility of implementing that plan of care and how far into the future a plan goes. A hospital inpatient plan of treatment may only go to the point of discharge and not toward regaining pre-morbid levels of function—those are likely to be addressed in subsequent or outpatient care. ***AOTA asserts that time frames are more limited and unpredictable in inpatient hospitals than in Part B outpatient settings, and new proposed regulation 42 C.F.R. § 409.17 should allow for such differences, while still assuring proper documentation.***

AOTA is also concerned that the proposed rule brings back part of CMS' Transmittal 65 that was issued earlier this year, but then rescinded. Transmittal 65 would have required that local Medicare contractors apply Part B outpatient payment policies to acute care hospitals, inpatient rehabilitation facilities, psychiatric hospitals and units, long term acute care hospitals, and critical access hospitals. ***AOTA urges CMS to avoid requiring Medicare Part B outpatient therapy policies in Part A inpatient settings if they result in undue burden to therapists in those facilities.***

3. *Changes to Plan of Treatment Cannot Always be Incorporated Immediately in Inpatient Hospital Settings*

One problem in requiring a plan of treatment where any changes to the plan must be “made in writing, incorporated immediately, and signed” by the treating practitioner in all inpatient hospital settings will be that often hospital inpatients are discharged from the hospital prior to the completion of the therapy plan of care, which often precludes incorporating all relevant changes in the treatment plan or the completion of a therapy discharge plan. Another example is the use of dictation in smaller hospitals; sometimes a dictation backlog occurs making it more difficult to meet the requirement in the proposed rule to immediately incorporate in writing and sign any changes to the treatment plan. The “incorporated immediately” requirement is unclear. ***AOTA respectfully request that CMS revise proposed 42 C.F.R. § 409.17(d) “content of plan” to require that any change to the plan be incorporated into the medical record “as soon as possible” and to eliminate the requirement that changes be “incorporated immediately” in light of the unpredictable circumstances in which hospital inpatient occupational therapists practice.***

4. *Proposed Rule Increases Therapy Documentation Burden*

In depth documentation in the acute inpatient hospital setting would be quite time consuming and costly, with limited benefit in terms of assuring appropriate payment. Proper documentation under Part B is critical to determine if the therapy is necessary and appropriate, and thus reimbursable. Inpatient care is part of an overall treatment protocol paid for in toto; necessary and appropriate payment for therapy services is determined within the scope of the larger treatment plan. In addition, such an increased requirement may have the unintended consequence of hospitals electing to forgo identifying therapy services as skilled and not reporting them as therapy in order to avoid the time and cost of meeting these enhanced documentation requirements. We see this as a particular problem in acute hospitals. AOTA also questions the relation of these new requirements to the Paperwork Reduction Act (44 U.S.C. §3501). ***AOTA respectfully requests that CMS reconsider requiring increased documentation in the inpatient hospital setting, particularly in acute care hospitals.***

5. *Clarify “Content of Plan” requirement in Proposed 42 C.F.R. § 409.17(c)*

Another issue involves goal setting. Not all services provided in acute care involve interventions intended to change a person's functional status. Some services are purely diagnostic/evaluative (e.g., bedside swallow evaluation), case management (e.g., discharge planning, procurement of equipment, referrals), or preventative (e.g., splinting to prevent decubiti, ROM to prevent contractures). These are occupational therapy services that are medically necessary, but goal setting and treatment planning may not fit the mold of what's typically required by CMS in outpatient settings -- i.e., functional restoration. ***Thus, AOTA asserts that the section for "content of plan" needs further clarification to reflect OT services that are skilled and medically necessary in a manner appropriate for inpatient settings.***

6. *AOTA Agrees that Recertification Requirements Need Not Apply in Inpatient Hospitals and Requests Deletion of Reference to Certification*

AOTA agrees with CMS' rationale regarding the decision not to apply recertification requirements to inpatient hospitals because the physician's review and certification of the treatment plan is implied by the review and approval of a facility plan that includes therapy services. The decision appears to appropriately consider occupational therapy practice needs and patterns in facility settings. CMS clarifies in the preamble language that certification requirements will not apply in inpatient hospitals and that review of the plan of treatment should occur as the patient's condition requires in inpatient hospitals. AOTA agrees with this rationale, but finds the reference to certification in the last phrase of 42 C.F.R. § 409.17(e) to be inconsistent with the CMS preamble rationale. ***Thus, AOTA requests that CMS delete the last phase of proposed regulation 42 C.F.R. § 409.17(e), which states, "but at least prior to certification."***

D. Outpatient Therapy Certification Requirements (72 Fed. Reg. 38193)

AOTA has previously advocated for and strongly supports the MPFS rule proposal, in proposed regulation 42 C.F.R. § 424.24, to permit a plan of care to cover therapy services for up to 90 days and that recertification would be required for therapy services provided beyond 90 days. This positive change to the certification and recertification timing allows for variation among patients' needs and puts decision-making back in the hands of treating practitioners.

While AOTA agrees that there may be public policy reasons to ensure that physicians (or other appropriate practitioners) review the therapy plan of care and attest to a continuing medical need for therapy services, the length of time for recertification at 30 days was arbitrary and not based upon any data about the need for recertification. AOTA also strongly supports CMS' rationale for changing the certification requirement because many other means of ensuring appropriate utilization exist, including CCI edits, recent edits required by the Deficit Reduction Act, local coverage determination policies and related local contractor and CMS claims review mechanisms, to name a few.

Physicians rely on close communication with the therapist to track the progress and effectiveness of therapy and will choose to see the beneficiary again based on their consultation with the therapist. The proposed 90 day recertification requirement puts medical decision making squarely where it belongs, back into the hands of the treating physician, in coordination with the occupational therapy practitioner. ***AOTA strongly supports CMS' action in the MPFS proposed rule to leave it up to the physician's discretion to determine when and how often it is necessary for each beneficiary under his or her care who is receiving occupational therapy services to be reassessed.***

II. TRHCA—SECTION 201: THERAPY CAPS (72 Fed. Reg. 38205)

AOTA continues to oppose the underlying policy to apply a financial cap on therapy services. AOTA asserts the therapy cap is an arbitrary and inappropriate solution to assure correct utilization of therapy services. As CMS stated itself in the preamble of the proposed rule with respect to changes in therapy certification timing, **CMS has**

instituted many other means of ensuring appropriate utilization of therapy services. Some of these means include: CCI edits, edits required by the Deficit Reduction Act, local coverage determination policies and related local contractor claims review mechanisms, and Transmittal 63 setting forth greater documentation and evaluation requirements, among others.

Although AOTA recognizes that current law allowing for the exceptions process will expire on December 31, 2007, AOTA continues to advocate that Congress take action to extend the exceptions process. AOTA asserts that the exceptions process is effectively achieving its original objective to assure appropriate therapy service utilization and create savings for the Medicare program. The feedback that AOTA has heard from occupational therapists regarding the cap exceptions process has been overwhelmingly positive with regard to the diagnoses (ICD-9 codes) that are acceptable for automatic exceptions. At the same time, Preliminary Part B carrier data suggests a large decrease in Medicare expenditures for outpatient therapy services. The exceptions process has only been in effect for two years, and there is certainly room for improvement and further tightening of the system. AOTA is happy to assist with any endeavors to improve the cap exceptions process. In addition, AOTA has been working closely with CMS and Congress on appropriate alternatives to the therapy cap and will continue to offer feedback needed by CMS. ***In conclusion, AOTA asserts that the therapy cap is arbitrary CMS policy and AOTA continues to strenuously advocate to Congress to extend the cap exceptions process because it is effectively achieving its objective to assure appropriate utilization.***

III. COMPREHENSIVE OUTPATIENT REHABILITATION FACILITY (CORF) ISSUES

A. *Social and Psychological Services (72 Fed. Reg. 38174)*

With regard to the change in the definition of social and psychological services in CORFs, AOTA is concerned with the underlying premise that mental illness falls outside of the purpose of CORFs stated as “rehabilitation of injured, disabled or sick patients.” While AOTA appreciates CMS’ intent to interpret the underlying purpose of CORFs and prevent inappropriate use of CORFs, we urge caution in using the arguments CMS presents that mental illnesses do not make patients “disabled or sick” and that rehabilitation cannot or should not be provided to those with mental illnesses. AOTA recognizes that there are other Medicare benefits that specifically meet the needs of individuals with mental illnesses; for example, partial hospitalization, which includes occupational therapy, is available for patients with specific mental illness diagnoses. However, we urge CMS to be cautious about separating mental illness rehabilitation from physical illness rehabilitation. While CMS may choose to limit the diagnoses that are reimbursable in a CORF rehabilitation plan, AOTA wants to emphasize that care should be taken in making these distinctions overall. CMS states that social and psychological services should “include only those services that address the patient’s response and adjustment to the treatment plan” and other items related to the “rehabilitation goals.” AOTA notes that “rehabilitation goals” can in some contexts be related only to a mental illness rehabilitation plan that contains occupational therapy. While AOTA is not aware

of any CORFs providing occupational therapy services solely to provide rehabilitation for mental illness, occupational therapy provided in other contexts does address mental illness.

Furthermore, in CORFs, occupational therapy may be provided for an individual who has had a stroke but who also has mental illness such as schizophrenia. Attention to the schizophrenia related to rehabilitation for the stroke would be central to an occupational therapist's approach to the treatment plan. AOTA does not want to see the CMS proposed change to the definitions of social services and psychological services to be too broadly interpreted as meaning that mental illness would be a valid reason for denial of CORF eligibility. Nor does AOTA want to have the proposal implemented in ways that have a chilling effect on or limit the full and appropriate scope of occupational therapy. It is intrinsic to the profession of occupational therapy to consider the functioning of the whole person in occupational therapy evaluations—and this includes social and psychological aspects of performance. The Occupational Therapy Framework, the profession's guiding practice document, describes social participation as an area of occupation including activities associated with organized patterns of behavior that are characteristic and expected of an individual or an individual interacting with others within a given social system. Social and psychological issues are critical constructs to address in any rehabilitation plan of occupational therapy.

Thus, while we see the intent of CMS, we urge caution in separating mental and physical illnesses and their rehabilitation. *AOTA urges CMS to further refine its arguments about the appropriate use of CORFs to provide rehabilitation for mental illnesses and to assure that any interpretation of policy does not restrict the provision of needed occupational therapy to address the psychosocial aspects of a beneficiary's function.*

B. Clarification and Payment Updates for Other CORF Services (72 Fed. Reg. 38175)

1. AOTA Supports CMS Clarification Regarding Therapy Provided in the Beneficiary's Home

The MPFS proposes to clarify at § 410.105(b)(3) that no fixed location requirement exists, permitting CORF therapy services, including occupational therapy, to be furnished in a beneficiary's home when payment for those services are not otherwise covered under the Medicare home health benefit. *AOTA supports the CMS clarification regarding therapy provided in the beneficiary's home.*

2. Home Environment Evaluation Presence Requirement Needs Clarification

In addition, the proposed rule would clarify that the beneficiary must be present in their home, *as appropriate*, for coverage of the home environment evaluation described in proposed § 410.100(k). CMS believes beneficiary presence is necessary to fully evaluate the potential impact of the home situation on the rehabilitation goals. AOTA asserts that

requiring the beneficiary to be present in the home following discharge from certain settings, such as skilled nursing facilities (SNFs), is not always beneficial for an occupational therapist to perform her work. It is the occupational therapist's role to evaluate the entire environment to assess whether it is most conducive to current beneficiary function upon discharge from a setting like a SNF; sometimes a therapist determines that this evaluation is best performed without the beneficiary present. *AOTA respectfully requests that CMS clarify the meaning of the language "as appropriate" in the context of proposed § 410.100(k)(2) to permit therapists to use their clinical judgment in situations where it may be inappropriate to have the patient present during the home environment evaluation.*

IV. TRHCA – SECTION 101(B): PHYSICIAN QUALITY REPORTING INITIATIVE (PQRI)

A. Requirements for Measures Included in the 2008 PQRI (72 Fed. Reg. 38196)

AOTA supports CMS in requiring that a consensus based process must be used for developing measures. AOTA also supports the process of requiring National Quality Forum (NQF) or AQA Alliance (AQA) endorsement of measures. AOTA would also support CMS considering other valid national endorsement bodies for purposes of reviewing and adopting PQRI quality measures. Furthermore, CMS should assure that initial development of measures is done in an open process emphasizing participation by all appropriate professional associations.

B. Categories of Proposed 2008 PQRI Quality Measures (72 Fed. Reg. 38199)

1. Table 16- 2007 PQRI Measures

AOTA requests that CMS consider expanding the possible eligible providers for certain current 2007 measures to include occupational therapists beginning on January 1, 2008. Previously, AOTA prepared detailed specifications and submitted a formal request to CMS and the American Medical Association that occupational therapists be deemed eligible to apply the following measures in the 2007 PQRI¹:

- Screening for Future Fall Risk
- Plan of Care for Urinary Incontinence in Woman Aged 65 Years and Older
- Osteoporosis: Communication with the Physician Managing Ongoing Care Post Fracture
- Stroke and Stroke Rehabilitation: Screening for Dysphagia
- Cataracts: Assessment of Visual Functional Status

AOTA was granted only one of the above measures for 2007, Screening for Future Fall Risk. While AOTA understands that the statute does not allow refinements or modifications to the detailed specifications for 2007 PQRI quality measures, there does

¹ AOTA will provide a copy of its proposed 2007 specifications for CMS review upon request.

not appear to be a restriction on revising the 2007 quality measure specifications for use in the 2008 PQRI. ***AOTA respectfully requests that CMS create a process to give consideration to including occupational therapists as eligible to apply the 2007 measures cited above in the 2008 PQRI.***

2. *Table 18- Non-Physician Measures Currently Under Development*

AOTA greatly appreciates the opportunity to be involved with the PQRI and to help identify occupational therapists to assist Quality Insights of Pennsylvania (QIP) to develop relevant non-physician measures. AOTA has been working closely with QIP since measure development was initiated in 2007. Occupational therapists are eligible professionals for and continue to be closely involved with QIP's 2008 measure development and beta testing for the following measures:

- Documentation Of Current Medications In The Medical Record
- Patient Co-Development Of Plan Of Care
- Pain Assessment Prior To Initiation Of Patient Treatment

AOTA supports CMS inclusion of the above measures because development will be completed in a timely manner for the 2008 PQRI, the measures consider critical policy goals, these measures act to augment the recognition of services provided by occupational therapists beyond the one measure currently available, and these measures fill a need in the Medicare program for consistency in documenting the current medications taken by a patient, assessing the level of pain and considering the patient's objectives in developing the plan of care. ***Since occupational therapists were directly involved in developing these measures, AOTA also asserts that occupational therapists should be deemed eligible providers for the three measures cited above.***

However, under Table 18, QIP non-physician measures on Federal Register pages 38201-38202, there are several listed measures that we understand currently do not apply to occupational therapists. AOTA asserts that the following additional Table 18 measures should apply to occupational therapists as eligible professionals because these measures fit squarely within the occupational therapy scope of practice and meet the important policy goals set forth by CMS in the proposed rule:

- *Universal Weight Screening (BMI)*
- *Screening for Clinical Depression*
- *Screening for Cognitive Impairment*
- *Patient Co-Development of Treatment Plan*

Universal Weight Screening (BMI) fits within the scope of occupational therapy practice. AOTA believes that inquiry into a patient's weight should be a quality consideration asked by every health care professional upon initial Medicare evaluation. A number of studies have demonstrated that obesity appears correlated with increased risk of both acute and chronic diseases, including type II diabetes, sleep apnea, chronic low back pain, hypertension, breast cancer, prostate cancer, colon cancer, cardiovascular

disease, stroke, gall bladder disease, joint problems, activity limitations, reduced generalized health ratings, psychological issues, discrimination, and an increased mortality rate. Occupational therapy is a health care profession that is qualified to provide interventions with individuals, groups, and society to effect change to promote optimum health

Occupational therapy services are often used directly and indirectly to influence weight management and related health concerns through attention to lifestyle and engagement in fulfilling activities. According to AOTA's Obesity and Occupational Therapy Position Paper, occupational therapy interventions in the area of obesity may include, but are not limited to: community programs of health promotion through lifestyle change; education programs; facilitating the development of new habits and routines; recommendation of home modifications; adaptations/equipment; compensatory training in ADL and IADL; wellness programs for adults; patient handling programs in hospitals and skilled nursing facilities; and post-surgical acute care interventions. Occupational therapy practitioners apply their knowledge about engagement in occupation—that is, “everyday life activity”—to help clients who may be experiencing disease, impairment, disability, dissatisfaction, or adverse circumstances to participate in their daily life in a manner that supports their health and well-being.

Screening for Clinical Depression fits within the scope of occupational therapy practice. AOTA believes that inquiry into a patient's mental health should be a quality consideration asked by occupational therapists upon initial Medicare evaluation. Occupational therapy practitioners are skilled in helping people deal with stress, depression, and other emotional issues. Practitioners also offer clients wellness techniques that may prevent injury and disease. People with clinical depression may have difficulty completing tasks at work, managing a household, participating in leisure activities, and maintaining healthy relationships with family and friends. Occupational therapists can help people with clinical depression to regain their ability to function in their daily lives at work and at home through the following skills: evaluating a person's ability to take care of himself or herself; identifying treatment goals that are meaningful to the person such as establishing a personal care routine, managing money, communicating effectively with family/caregivers, and setting realistic short-term and long-term goals; adapting activities and the environment so that the person can participate in tasks that are meaningful to them; monitoring a person's response to medication used for treating clinical depression; and educating family members and caregivers about clinical depression, and collaborating with them on treatment goals.

With regard to ***Screening for Cognitive Impairment***, we understand that QIP supports including occupational therapists as eligible professionals able to apply this measure. AOTA believes that inquiry into a patient's cognitive abilities should be a quality consideration asked by occupational therapists upon initial Medicare evaluation. During AOTA's recent collaboration with QIP, occupational therapists serving on an expert work group for QIP mentioned that they were interested in developing a measure related to screening for cognitive impairment because it is a relevant quality issue that most therapists consider in the initial evaluation of a Medicare beneficiary. AOTA was

informed by QIP that, even though this measure was developed for use by social workers and psychologists, QIP would make a request for occupational therapists to be added to the eligible professional listing. QIP also has provided AOTA with the opportunity to comment on potential changes to the measure language to assure it is written in a way that is conducive to application by an occupational therapist. AOTA appreciates and supports QIP's consideration of the applicability of measures to the scope of practice of additional professionals.

With regard to the measure *Patient Co-Development of Treatment Plan*, AOTA requests clarification regarding the difference between this measure and Patient Co-Development of the Plan of Care, both listed in Table 18. For a practicing occupational therapist, the treatment plan and plan of care are referred to synonymously and interchangeably. For this reason, we are interested in knowing how CMS defines both treatment plan and plan of care. AOTA also seeks clarification as to which professionals the Patient Co-Development of the Treatment Plan applies and how these professionals differ from those to which Patient Co-Development of the Plan of Care applies. In recent AOTA discussions with QIP, we were informed that it is QIP's understanding that CMS plans to merge these two separate measures into one measure for 2008 as a result of similar confusion voiced from other stakeholders. AOTA supports the merging of these two measures by CMS because no clear difference is apparent.

3. *Table 19- QIP Structural Measures*

AOTA believes that these structural measures provide a valuable opportunity to enhance the efficiency and quality of patient recordkeeping and data recording through electronic means. Occupational therapists are watching many of their colleagues move in the direction of electronic health records and e-prescribing. AOTA supports CMS approval of the QIP structural quality measures to assure quality care continues to be provided to patients. AOTA also supports CMS moving forward in the arena of electronic health records (EHR). AOTA requests further clarification, however, of how the structural measures might work in practice. For example, could an occupational therapist be rewarded under the PQRI program for having the electronic infrastructure in place to receive some form of an electronic referral from a physician for therapy services? Further clarification of these measures in the final rule will assist AOTA to understand how therapists may participate in PQRI using these measures.

4. *Table 20- Additional AQA Starter Set Measures*

AOTA asserts that occupational therapists should be provided the opportunity to review with QIP the additional measures from AQA that were not included in the 2007 PQRI quality measures, but that remain relevant to Medicare beneficiaries. Occupational therapists were not given the opportunity to review and consider the applicability of these measures for 2007 and we are requesting that opportunity for review and potential use in the 2008 PQRI. Particularly relevant to the scope of practice of occupational therapy is the quality measure for Advising Smokers to Quit. AOTA supports the practice of all health care professionals inquiring into a patient's tobacco usage. Occupational therapy

practitioners are in a unique position to assist patients to quit smoking successfully due to the profession's focus on all aspects of a patient's function, including psychosocial, cognitive, behavioral, and physical function. AOTA has been involved with a number of projects to expand this area of practice in connection with health promotion, wellness, and prevention initiatives.²

C. *Submission of Data via Medical Registry or Electronic Health Record*
(72 Fed. Reg. 38202)

In general, AOTA supports the concept of a clinical data registry in which uniform information about a defined population can be collected and reviewed in a systematic manner. AOTA's primary concern continues to be ensuring that Medicare beneficiaries obtain necessary therapy and rehabilitation care without restriction and that the physician's and therapist's clinical judgments remain central to decision-making. AOTA also has an interest in protecting therapy patients' personal identifiable information; therefore, AOTA supports CMS' requirement that any registry developed by the agency be in compliance with HIPAA and the Consolidated Health Informatics Initiative (CHI) standards. Presently, there is no known clinical data registry for occupational therapy services. AOTA will be following CMS's movement in this area closely with regard to how the registries function and in what way such a mechanism can be designed to be most useful for collecting occupational therapy clinical data.

V. PHYSICIAN SELF-REFERRAL PROVISIONS

A. *In-Office Ancillary Services Exception* (72 Fed. Reg. 38181)

1. *Referral Relationships between Occupational Therapists and Physicians*

In the proposed rule, CMS announced that it is seeking comments on the referral relationships between physicians and occupational therapists (as well as other providers of designated health services). CMS noted its concerns that the in-office ancillary services exception to the physician anti-referral law (Stark): (1) encourages physicians to create physical and occupational therapy practices and (2) enables physicians to order and then subsequently perform ancillary services instead of making a referral to a specialist such as an occupational therapist.

Under the laws of most states, occupational therapists are not obligated to obtain a referral from a physician before evaluating and treating a client. However, authorities other than state law impact the referral relationship between occupational therapists and physicians. For example, Medicare Part B requires occupational therapists to obtain a physician signature on the therapy plan of care as prerequisite for payment. Requirements like this force the therapist to rely on the physician for a referral. Referral requirements are but one of the reasons why a number of occupational therapists forge

² American Journal of Occupational Therapy, Wellness Works: Community Service Health Promotion (Nov/Dec 1999); OT Practice, Agency for Health Care Research and Quality (AHCPR) Guidelines Support Smoking Cessation (Nov. 1999).

strong working relationships with physicians. Occupational therapists also are compelled to collaborate with physicians and other members of the care team in order to assure quality care. The Institute on Medicine has highlighted in their report "Health Professions Education: A Bridge to Quality" how collaborations among clinicians is essential to ensure patient safety and quality of care. AOTA believes individuals' rights to direct their own health care can be enhanced by the collaborative approach to rehabilitation that occupational therapists embody. Collaboration, including consultation with physicians, is critical to meet the needs of the Medicare population.

There is a broad spectrum of ways in which occupational therapists collaborate with physicians. Many occupational therapists choose to be employed by a physician practice and extol the benefits of the teamwork that such close collaboration brings. At the same time, many other occupational therapists have chosen to establish therapist owned practices and cherish their independence while maintaining strong working relationships with referring physicians. AOTA strongly supports billing for occupational therapy services under an occupational therapy private practice (OTPP) number. It is crucial that the Medicare program can assure that occupational therapy services are provided by qualified individuals, which the Medicare program can monitor when such services are billed under an OTPP number (whether reassigned or not). The same oversight over whether qualified individuals provide occupational therapy services does not exist when such services are billed as incident to the physician.

Whether CMS should make changes to the in-office ancillary services exception to the Stark law is a significant question, the answer to which would greatly impact occupational therapists. Given the diversity among occupational therapists' practice arrangements with physicians (e.g., employed by a physician and billing under their OTPP number, employed by a physician and billing incident to a physicians services, and employed by a therapist owned OTPP and independently billing Medicare Part B), there are a number of professionals whose livelihood would be impacted either way by a change. For these reasons, AOTA has encouraged its members to directly respond to CMS on this issue. *AOTA supports CMS' policy objective in the Stark law to ensure appropriate utilization and billing of Medicare outpatient services consistent with the Medicare coverage guidelines and free of improper physician self-referral.*

VI. BUDGET NEUTRALITY/FIVE-YEAR REVIEW WORK ADJUSTER (72 Fed. Reg. 38125)

As stated in earlier comments, *AOTA continues to request that CMS revise the MPFS formula to eliminate the work value adjuster in favor of an adjustment to the conversion factor (CF).* The work adjuster has created a number of problems when the RBRVS formula is used by other payers, as it affects the relativity of services. Although this adjustment is solely for Medicare budget-neutrality purposes, it has been used to inappropriately reduce payments by non-Medicare payers. It also is inconsistent with CMS' historical methodology for making budget-neutrality adjustments.

AOTA MPFS Comments
August 31, 2007

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AOTA requests that due consideration be given to these comments. Thank you, again, for the opportunity to comment on the MPFS proposed rule. AOTA looks forward to a continuing dialogue with CMS on coverage and payment policies that affect the ability of occupational therapists to provide quality care to Medicare beneficiaries.

Sincerely,

A handwritten signature in blue ink that reads "Sharmila Sandhu". The signature is written in a cursive style.

Sharmila Sandhu, Esq.
Regulatory Counsel