

Via online submission to www.regulations.gov

June 29, 2009

Ms. Charlene Frizzera
CMS Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
CMS-1410-P, Mail Stop C4-26-05
Baltimore, MD 21244-8016

Re: Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2010; Proposed Rule

Dear Acting Administrator Frizzera:

The American Occupational Therapy Association (AOTA) represents the interests of over 140,000 occupational therapists, occupational therapy assistants, and therapy students, many of whom serve the Medicare populations in inpatient rehabilitation facilities (IRFs) and in other post-acute care settings. We appreciate the opportunity to comment on the proposed update to rates and policies affecting the IRF prospective payment system (PPS). The notice titled Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2010 (hereinafter "Proposed Rule") was published in the *Federal Register* on May 6, 2009 (74 Fed. Reg. 21052).

AOTA presents the following comments on the IRF PPS Proposed Rule.

Proposed Changes to IRF Classification Criteria and Payment Requirements

In the Proposed Rule CMS proposes to rescind HCFA Ruling 85-2-1 as outdated and no longer accurate as the standard of care in IRFs. HCFA Ruling 85-2-1 was published as a result of litigation requiring the Secretary to publish eligibility requirements for hospital-level rehabilitation services. However, AOTA understands that HCFA Ruling 85-2-1 varies somewhat from Section 110 of the Medicare Benefit Policy Manual (MBPM). AOTA is confused about the intent of HCFA Ruling 85-2-1 as compared to the medical coverage criteria set forth at Section 110 of the MBPM. AOTA requests clarification of the relationship between the Ruling and the MBPM as well as the regulatory basis for CMS to rescind HCFA Ruling 85-2-1.

Therapy Disciplines

AOTA appreciates that the new CMS criteria for IRF coverage emphasizes the patient's rehabilitation and functional needs. In the Proposed Rule, CMS states, "The patient's needs require the active and ongoing therapeutic intervention of at least two therapy disciplines (physical therapy, occupational therapy, speech-language pathology or prosthetics/orthotics therapy), one of which must be physical or

occupational therapy.”¹ AOTA strongly supports the requirement that occupational therapy be one of the two active and ongoing therapy interventions. Occupational therapy is a regulated profession and there are numerous safeguards in place, including state licensure, Medicare standards for providers and suppliers (occupational therapy has been recognized in Medicare inpatient care since the program’s inception, and in outpatient care since 1987), and the profession’s ethical and competency requirements. The profession of occupational therapy is regulated in all fifty states. AOTA applauds CMS for recognizing and continuing to support the critical value of occupational therapy to Medicare beneficiaries receiving care in an IRF setting.

AOTA supports the proposed deletion CMS made to the MBPM removing language permitting “other skilled rehabilitative modalities”² to count toward the 3-hour rule requirement. AOTA agrees that only skilled therapy as defined currently should be counted toward the 3-hour rule.

In addition, CMS is proposing to revise requirements for IRFs at § 42 CFR 412.29(a) (Excluded rehabilitation hospitals and units: Additional requirements). Under the proposal IRFs must:

(a) Provide rehabilitation nursing, physical therapy, occupational therapy, plus, as needed, speech-language pathology, social services, psychological services, and prosthetic and orthotic services that—

(1) Are ordered by a rehabilitation physician; that is, a licensed physician with specialized training and experience in rehabilitation.

(2) Require the care of skilled professionals, such as rehabilitation nurses, physical therapists, occupational therapists, speech-language pathologists, prosthetists, orthotists, and neuropsychologists.

AOTA supports the proposed requirements at 42 CFR 412.29(a). AOTA acknowledges that other stakeholders are urging CMS to add recreational therapy to the services that must be provided by an IRF. AOTA does not regard recreational therapy as having the same status under Medicare, professional regulation under state law or impact as occupational therapy. We do not believe that IRFs should be burdened by adding a requirement to provide recreational therapy. AOTA believes that IRFs should only be required to provide critical rehabilitation services.

Use of Aides

AOTA has heard anecdotally that the services of aides may in some instances be inappropriately counted toward the 3-hour requirement in IRFs. We note that in the newly proposed policy in skilled nursing facilities, CMS makes a clear statement about the use of aides services, specifically stating, “Therapy aides are expected to provide support services to the therapists and cannot be used to provided (*sic*) skilled therapy services.”³

Thus, in other settings, CMS does not support the services of aides being provided as skilled therapy; aides are expected to provide support services to therapists. AOTA agrees with CMS’s statement on the role of aides. AOTA’s official document, *Guidelines for Supervision, Roles, and Responsibilities During the Delivery of Occupational Therapy Services (2009)*, states:

¹ 74 Fed. Reg. 21080 (proposed regulatory text at 42 CFR 412.29(b)(i)).

² Medicare Benefit Policy Manual (MBPM) Chapter 1, Section 110.4.3, Relatively Intense Level of Rehabilitation Services.

³ Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2010; Minimum Data Set, Version 3.0 for Skilled Nursing Facilities and Medicaid Nursing Facilities, 74 Fed. Reg. 22222. (May 12, 2009)

An *aide*, as used in occupational therapy practice, is an individual who provides supportive services to the occupational therapist and the occupational therapy assistant. Aides do not provide skilled occupational therapy services.⁴

Most state laws do not permit use of aides to provide skilled services. AOTA urges CMS to remind providers that state law supersedes Medicare policy with respect to the role of aides. We believe that all therapeutic time spent with a patient that counts toward the 3-hour rule must be skilled therapy.

Group Therapy

In the Proposed Rule, CMS states the belief that therapies provided in a group mode have a role in patient care in an IRF, but that they should be used in IRFs primarily as an adjunct to one-on-one therapy services, not as the main source of therapy services provided to IRF patients because group therapy is of a lower intensity than the therapy required in the IRF setting. CMS solicits comments as to “the types of patients for which group therapy may be appropriate, and the specific amounts of group instead of one-on-one therapies that may be beneficial for these types of patients.”⁵

AOTA believes that the combination of treatment modalities appropriate for any individual patient in an IRF should be determined based on individual need and as a result of the clinical evaluation, reasoning and judgment of the attending therapist. AOTA and its practitioners in IRFs believe that group therapy can be as intense as individual therapy and may be more effective in yielding outcomes in some circumstances. Thus, group therapy can be used in combination with individual therapy in certain cases; evaluations and re-evaluations are always individual. All occupational therapy provided as a skilled service by qualified professionals should count toward to 3-hour rule. See our comments elsewhere in this letter on what therapies should be counted toward the 3-hour rule.

With regard to CMS’ concerns regarding the value of group therapy, AOTA argues that occupational therapy provided to patients in a group can be of benefit with specified goals individualized to the patient. Some occupational therapy groups will have clients with similar diagnoses (for example, an exercise group for cardiac patients might be closely monitored through use of Holter monitors while they are working on functional and endurance activities), while others will mix patients with varying diagnoses to provide a richer experience (for example, a cooking group where one person sits and cuts with an adapted cutting board while another works on kitchen mobility gathering items and a third person works on endurance washing the dishes at the end).

In fact, in certain cases, group therapy can be exceedingly intense for a patient and can be the preferred form of occupational therapy for certain patients because patients share experiences and educate each other about how to accomplish a task more efficiently, build social relationships and interact collaboratively (especially since patients can often become socially isolated and depressed with complex medical conditions), build confidence, and can learn to work as a unit to accomplish a task. For example, one individual may not have enough skill to cook something alone, but feels a great sense of accomplishment to say he/she was part of the group that cooked together successfully.

⁴ To be published and copyrighted in 2009 by the American Occupational Therapy Association in the *American Journal of Occupational Therapy*, 63(November/December).

⁵ 74 Fed. Reg. 21070.

Moreover, in the Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2010; Minimum Data Set, Version 3.0 for Skilled Nursing Facilities and Medicaid Nursing Facilities published in the *Federal Register* on May 12, 2009, CMS authors specifically stated that, “In a group setting, the patients are performing similar activities. By interacting with one another, the patients observe and learn from each other. They then apply this new information into their own therapy program to progress and, thus, benefit from the group setting.”⁶ At the same time, AOTA believes that group therapy should never be the only type of therapy that a patient receives in the IRF setting. AOTA strongly values the importance of individualized 1:1 therapy and believes there is a place for both types of therapies for appropriate patients to meet their treatment goals. Professional judgment based on individual cases must guide these decisions, not arbitrary constructs based on simple diagnosis rather than the full picture of the patient.

AOTA urges CMS to explore these issues in greater depth and to conduct research regarding outcomes of individual therapy v. group therapy before proposing IRF group therapy policy changes. One option is to use the Post Acute Care (PAC) Payment Reform Demonstration CARE instrument to collect data to further study the effectiveness of different modes of therapy delivery. In addition, a review of IRF patient discharge information, namely discharge destination, might be of assistance to CMS in getting at the outcomes and quality of the various modes of therapy delivery. Defining rules for therapy approaches outside the context of achieving appropriate outcomes is not good policy.

The patient’s functional status is a critical consideration when a therapist is evaluating including a patient in an occupational therapy group. A patient’s rehabilitation needs can change during the IRF stay. As the patient becomes stronger and increases their endurance, group therapy may become more dominant for some patients. It is highly unlikely that a patient would be placed into group occupational therapy upon IRF admission. Individual therapy should be used in combination with appropriate group therapy during the course of treatment in an IRF based on the occupational therapist’s clinical judgment and the patient’s changing needs. For instance, group therapy may be used more heavily at the end of an IRF stay as the patient achieves his or her goals.

AOTA asserts that groups play a vital role in the IRF therapeutic environment and should not be restricted from the 3-hour rule. Ultimately the decision as to whether group therapy is appropriate for a given patient should be left up to the occupational therapist’s clinical judgment. Accordingly, AOTA respectfully requests that CMS revise the language below as it appears in the proposed MBPM with regard to group therapy (additions are in italics; ~~denotes deletion~~):

The intensity of therapy services typically required to meet the needs of a beneficiary requiring an IRF level of care is expected to exceed the intensity of therapy services provided in a SNF. For this reason, therapy services provided in an IRF must generally exceed the SNF therapy requirements. This means that an IRF patient’s daily therapy requirements *can be met by a combination of one-on-one therapy and group therapy as appropriate for the individual* and as documented in the patient’s

⁶ 74 Fed. Reg. 22223

medical record. ~~Group therapies are to be used in IRFs primarily as an adjunct to one-on-one therapy services.~~⁷

Medical Stability

In the Proposed Rule, CMS would require that patients be medically stable upon admission to the IRF. AOTA supports this important distinction and believes that the proposal will lead to the availability of medically necessary therapy for patients who would benefit from 3 or more hours of therapy per day. However, AOTA respectfully requests that CMS add additional language to both the regulatory text and the MBPM language to better define medical stability because the proposal can be interpreted to mean that the need for all acute issues must be resolved prior to consideration for IRF admission. A patient may have acute medical issues that are being managed by the IRF team with the primary focus being on rehabilitation, such as occupational therapy, to improve the patient's functional status. The concept of medical management in the IRF setting should include the reasonable management of acute medical issues as well as management of a patient's medical status in the context of functional recovery.

Pre-Admission Screening

AOTA supports the regulatory language proposed in connection with the pre-admission screening, however, we request that CMS allow for an exception to modify the within 48-hour time frame in those cases where IRF admission is delayed. AOTA suggests including an addendum to the admission paperwork to provide an update to those cases in which IRF admission was delayed. This would document the fact that the pre-admission screening has occurred greater than 48 hours prior to IRF admission.

Individualized Overall Plan of Care

AOTA supports the plan of care requirement, but requests that CMS clarify the time frame requirement that the individualized overall plan of care be developed "within 72 hours of the patient's admission to the IRF."⁸ For example, if a patient is not admitted to the IRF until Friday night and is unable to obtain therapy services until the following Monday, the therapist would be unintentionally out of compliance with the 72-hour rule. AOTA urges CMS to make the individualized overall plan of care requirement consistent with the IRF patient assessment instrument (PAI) requirement (plan of care must be completed by day 4 of the IRF stay)⁹ to avoid confusion and the additional unnecessary administrative burden of requiring therapists to begin counting hours from the point of admission to assure compliance.

IRF Classification and Payment Requirements

AOTA applauds the work of CMS to revise coverage policies in the IRF setting that are patient-centered and transparent in nature, as required under a Congressionally-mandated study being performed by Research Triangle Institute (RTI) to examine alternatives to IRF classifications and payment

⁷ MBPM, chapter 1, Section 110.2.1, Intensive Level of Rehabilitation Services (proposed section). Note that AOTA recommends deleting the last sentence in this section that states, "Group therapies are to be used in IRFs primarily as an adjunct to one-on-one therapy services."

⁸ 74 Fed. Reg. 21081.

⁹ MBPM, Chapter 1, Section 110.3, Inpatient Assessment of Individual's Status and Potential for Rehabilitation.

requirements. However, AOTA requests that CMS address in the IRF PPS final rule our concern with the continuation of the “75% rule” (currently set at 60%) to classify IRFs. Occupational therapists and occupational therapy assistants provide key intensive rehabilitation services in IRFs. Consequently, occupational therapy practitioners are well aware that the “75% rule” fails to accurately reflect the increasing need for patients with diagnoses outside of the existing 13 conditions to have access to inpatient rehabilitation hospital care.

According to occupational therapy practitioners working in IRFs, many patients fall outside the 13 CMS conditions that might require and benefit from IRF services, including: orthopedic, joint/limb replacement, post-transplant patients, patients with chronic pulmonary and cardiac conditions, and medically complex patients. The decision of where services are best obtained for a patient must be based on the individual’s total needs as assessed by a physician, clinician, and discharge planner and not based on arbitrary categorizations.

Using the “75% rule” as a proxy for IRF admission prevents patients from receiving appropriate intensive, multidisciplinary rehabilitation services by setting impossibly narrow medical necessity criteria. Such narrow criteria are contrary to the purpose of IRFs. The “75% rule” is unnecessary and interferes with sound clinical decision making and, consequently, with patient access to medically necessary and appropriate services. The need to better clarify existing medical necessity criteria is of the utmost importance for the RTI project. The focus on diagnosis alone is not founded in any scientific research or sound medical judgment. In addition, the “75% rule” fails to account for changes in medical technology and advances in rehabilitation made in the last 2 decades. Unlike in other areas of medical care, the need for IRF services is *not* driven by the presence or absence of a specific diagnosis. IRF medical necessity is multi-factorial and involves in-depth assessment of functional abilities (mobility, cognition, social participation etc.), potential for improvement, co-morbidities, and care personnel skill set among other factors, must be considered when determining an individual’s need for intensive inpatient rehabilitation services.

Additionally, according to anecdotal information from occupational therapy practitioners, a number of States over the past several years have seen a decrease in patient access to medically necessary inpatient rehabilitation services because of interpretations made by regional Medicare entities. According to our members, the recent problems in patient access to IRFs in California have been caused by the inappropriate application of existing medical necessity criteria, as outlined in Section 110 of the MBPM, by Medicare reviewers. Though the vast majority of the claims in question are upheld in subsequent review (typically Administrative Law Judge), the expensive and time-consuming appeal process has led many facilities to limit admissions of certain patients they believe may be subject to review. The impact of the “75% rule”, combined with the impact of arbitrary claims review and denials (e.g., Recovery Audit Contractors and/or Medicare Administrative Contractors) taken together can inappropriately restrict patient admission decisions and affect patient outcomes. CMS acknowledged in the Proposed Rule the inconsistent application of medical necessity criteria by Recovery Audit Contractors. AOTA supports a repeal or modification to the “75% rule” that reflects patient need for intensive rehabilitation services.

Finally, AOTA recommends that RTI and CMS compile a group of experts from among the professionals on the IRF care team to discuss new IRF coverage criteria. This group of experts should be permanently established as an advisory group that can continue to reconvene as CMS considers future changes to IRF

policies. Additional research must be done regarding comparative effectiveness and outcomes in the various post-acute care settings.

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AOTA requests that due consideration be given to these comments. Thank you, again, for the opportunity to comment on the Inpatient Rehabilitation Facility PPS 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, flowing style.

Sharmila Sandhu, Esq.
Regulatory Counsel