American Therapeutic Recreation Association

July 29, 2004

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Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, D.C. 20201

VIA FACSIMILE: (202) 690-6262

Re: CMS Program Transmittal # 221 for Inpatient Rehabilitation

Dear Dr. McClellan:

On June 25, 2004, the Centers for Medicare and Medicaid Services ("CMS") issued Transmittal No. 221 (Change Request No. 3334), which pertains to the implementation of the so-called "75% Rule" (referred to herein as the "75% Rule" or the "Rule") applicable to inpatient rehabilitation hospitals and units. The undersigned organizations have reviewed Transmittal 221, and would like to express several of our initial concerns regarding these implementation guidelines of the Transmittal.

Transmittal 221 substantially modifies the Medicare Claims Processing Manual in a manner that we believe is, in part, inconsistent with the language of the final 75% Rule issued on May 7, 2004 (69 Fed. Reg. 25,752). Some of its provisions also are inconsistent with long-standing, established CMS policies governing the process of determining whether inpatient rehabilitation care and services are medically necessary and appropriate.

I. Overly Restrictive Standard of "Appropriate, Aggressive, and Sustained" Course of Therapy:

As you are aware, when CMS issued the final 75% Rule, it eliminated the term "polyarthritis" which was one of the ten (10) conditions or medical diagnoses that was used to determine compliance with the Rule prior to July 1. The term "polyarthritis" was replaced with four (4) new conditions or diagnoses, as follows:

1) Active, polyarticular rheumatoid arthritis, psoriatic arthritis, and seronegative arthropathies resulting in significant functional impairment of ambulation and other activities of daily living that have not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission, or that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.

2) Systemic vasculidities with joint inflammation, resulting in significant functional impairment of ambulation and other activities of daily living that have not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission, or that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.

3) Severe or advanced osteoarthritis (osteoarthrosis or degenerative joint disease) involving two or more major weight bearing joints (elbow, shoulders, hips, or knees, but not counting a joint with a prosthesis) with joint deformity and substantial loss of range of motion, atrophy of muscles surrounding the joint, significant functional impairment of ambulation and other activities of daily living that have not improved after the patient has participated in an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission but have the potential to improve with more intensive rehabilitation. (A joint replaced by a prosthesis no longer is considered to have osteoarthritis, or other arthritis, even though this condition was the reason for the joint replacement.)

4) Knee or hip joint replacement, or both, during an acute hospitalization immediately preceding the inpatient rehabilitation stay and also meet one or more of the following specific criteria:

(a) The patient underwent bilateral knee or bilateral hip joint replacement surgery during the acute hospital admission immediately preceding the IRF admission.

(b) The patient is extremely obese with a Body Mass Index of at least 50 at the time of admission to the IRF.

(c) The patient is age 85 or older at the time of admission to the IRF.

69 Fed. Reg. 25,775-76 (codified at 42 C.F.R. §412.23(b)(2)(iii)).

In contrast, the language of Transmittal 221 requires that for conditions 1, 2 and 3 above, a patient may be counted in an inpatient rehabilitation hospital's or units inpatient count for purposes of satisfying the Rule's threshold requirements only after receiving "at least 3 weeks

minimum duration with at least two individual (non-group) therapy sessions" of outpatient rehabilitation therapy. Additionally, the Transmittal also requires that weekly therapy sessions must "target[] all clinically impaired joints supported by documentation in the medical record." Finally these services must be delivered "within 20 calendar days of an acute hospitalization preceding immediately an IRF stay, or 20 calendar days immediately preceding and IRF admission." This language interpreting what constitutes "an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive settings" for conditions 1, 2, and 3 is overly restrictive; will cause undue hardships for Medicare beneficiaries who need inpatient rehabilitation services; and should not be included in the Claims Processing Manual.

To require that patients seeking inpatient rehabilitation services for conditions 1, 2, or 3 above "must" undergo "at least 3 weeks minimum duration with at least two individual (non-group) therapy sessions" of outpatient rehabilitation therapy before they can be included within a hospital's or unit's inpatient count for purposes of satisfying the Rule's threshold requirements will be a very burdensome, if not impossible, standard for many patients to satisfy. Consequently, this interpretation stands to substantially erode access to inpatient rehabilitation services for patients who need it.

By shifting services from Medicare Part A (inpatient) to Part B (outpatient), beneficiaries will be forced to incur co-payments for services that previously would have been covered entirely by Medicare under Part A. This will create a substantial cost-shift to beneficiaries in need of rehabilitation services that will be, for some, a major disincentive to seek these services on a timely basis. It is reasonable to assume that many of those beneficiaries who will be deterred initially from seeking needed care by this cost-shift that, at some point, ultimately will seek such care when their medical condition has deteriorated, leading to an increase in the cost of providing that care. While the future is uncertain, if the therapy cap is reinstated in calendar 2006, patients may face another hurdle in receiving outpatient therapy services.

In addition, we are not aware of any clinical or medical evidence or other findings which would support such an arbitrary standard for purposes of determining whether services provided in outpatient settings or other less intensive settings are "appropriate, aggressive, and sustained."

Further, the requirement that weekly therapy sessions must "target all clinically impaired joints supported by documentation in the medical record," combined with the requirement that at least two individual therapy sessions occur, is inappropriately proscriptive and impedes upon the ability of physicians and therapists to direct the post-acute health care needs of their patients. It also impedes upon the ability of physicians to apply the expert clinical and medical judgment needed to direct the post-acute health care needs of their patient.

These requirements also will create unnecessary administrative burdens for inpatient rehabilitation hospitals and units as well as less intensive setting providers. Contracts between hospitals or units, outpatient therapy settings and practitioners and other less intensive setting providers will have to be entered into in order to avoid potential HIPAA violations. The requirements also will impact the quality of inpatient rehabilitation services received by a

Medicare beneficiary. The extent, quality, and scope of the documentation maintained by the less intensive setting provider will affect subsequent medical decisions made by the beneficiary's treating physician at an inpatient rehabilitation hospital or unit. It is not clear how this process will work, and we see a range of potential administrative problems that undoubtedly will arise out of this framework.

We recognize that Transmittal 221 provides fiscal intermediaries ("FIs") with discretion in determining whether the Transmittal's interpretation of an "appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive settings" would be appropriately applied to a particular patient based upon their specific rehabilitative needs. We believe this discretion is warranted in clinically appropriate circumstances, and should be based upon the judgment of the patient's physician, which is consistent with established criteria and guidelines of the Medicare Benefit Policy Manual that are used to determine the appropriateness and necessity of inpatient rehabilitation services. However, we are concerned that FIs will simply adopt the standard as enumerated by CMS, or a standard similar to it. If the FI has the discretion to determine what constitutes an "appropriate, aggressive, and sustained" course of outpatient therapy, then attempting to define it with an overly restrictive standard such as that included in the Transmittal is wholly unnecessary and should not be included in the Medicare Claims Processing Manual.

Finally we ask CMS to clarify what is intended with respect to "within 20 days of an acute hospitalization." We also find that this standard and the exacting requirement that the services be delivered exactly 20 calendar days immediately preceding an IRF admission to be unclear if not difficult. Patients may participate in a course of outpatient therapy. They may then consult with their physicians shortly thereafter or they may wait awhile. All these non-controllable human factors may not occur within this exact time frame and the patient may need to be admitted over a longer or short period of time.

II. "Appropriate, Aggressive, and Sustained" Course of Outpatient Therapy for Knee or Hip Joint Replacements:

The final 75% Rule does not require that patients receiving a knee or hip joint replacement must undergo a prior regimen of "appropriate, aggressive, and sustained" outpatient therapy services before being admitted to an inpatient rehabilitation hospital or unit. However, §140.1.1 of the Transmittal, particularly the paragraph immediately following paragraph "C., 13., c.," can be interpreted in a fashion that would impose such a requirement for knee or hip joint replacement cases. It is our understanding that CMS has informally clarified and confirmed that knee or hip joint replacement cases will not require pre-admission outpatient therapy and that §140.1.1., C., 13, c. should not be read in that fashion. We request CMS to modify the Manual appropriately in order to eliminate the possibility of any inaccurate interpretation by rehabilitation hospitals, units or FIs.

III. No Surgical Preparation:

The Transmittal's establishment of a policy that a course of outpatient therapy "should have the goal of completing the rehabilitation, not preparing a patient for surgery," like the standard described above in paragraph I., is arbitrary; ignores the particular rehabilitative needs of Medicare beneficiaries; and is inconsistent with well-established policies used to determine the medical necessity and appropriateness for such surgery and subsequent inpatient rehabilitation services.

Outpatient rehabilitation services often are necessary for patients who will undergo surgery, whether to prepare them for a surgical procedure or to prepare them for their post-surgery rehabilitative needs. In many instances, it is medically necessary to provide pre-surgical outpatient therapy services, both to prepare patients for surgery *and* for other treatment modalities, including post-surgical rehabilitation, the latter of which often involves inpatient rehabilitation care. Although these purposes can be distinct, they often are clinically and medically interrelated. However, Transmittal 221 leaves no room for examining the clinical or medical rationale of pre-surgical outpatient therapy services to determine whether, based upon the particular needs of an individual patient, those services were provided to prepare for surgery or for other treatment modalities (or both), including any post-surgical rehabilitative needs that may be present.

Instead, the Transmittal implicitly states that outpatient rehabilitation services received by a patient to prepare for surgery should not be counted for purposes of satisfying the 75% Rule's "three week" threshold requirement. Prohibiting rehabilitation hospitals and units from counting a patient who receives outpatient rehabilitation services to prepare for surgery will place additional constraints on their ability to satisfy the Rule. Ultimately, these constraints will cause many patients, who have a legitimate medical need to receive inpatient rehabilitation services following a surgical procedure, to nonetheless be denied access to those services. We believe this aspect of the Transmittal represents an overly proscriptive framework for purposes of determining the appropriate medical course of action that should be taken in providing rehabilitation care and services to Medicare beneficiaries and diminishes the importance of the clinical and medical expertise and judgment of treating physicians. These kinds of decisions often are critical to the overall well-being of a patient, and are best left to the discretion and capabilities of the referring and treating physician.

This kind of approach also is inconsistent with well-established policies that historically have been used to determine the necessity and appropriateness of inpatient rehabilitation services, particularly Chapter 1, §110 of the Medicare Benefit Policy Manual. This section of the Manual envisions that a patient's surgical needs may be a direct factor in making a determination as to whether inpatient rehabilitation services are necessary and appropriate. *See generally,* Medicare Benefit Policy Manual, §110.1, stating that:

> Physicians generally agree on the circumstances that justify a medical or surgical patient's hospitalization. In addition, in some cases an admission to a rehabilitation hospital or to the rehabilitation service of a short-term hospital can be justified on essentially the same medical or surgical grounds. In other cases, however, a patient's medical or surgical needs alone may not warrant inpatient hospital care, but

hospitalization may nevertheless be necessary because of the patient's need for rehabilitative services.

Clearly, inpatient rehabilitation services are considered to share a medical corollary with surgery for many patients by longstanding policies established by CMS that have been used for inpatient rehabilitation coverage matters under the Medicare program.

We are also concerned that CMS would seek to impose this kind of restrictive policy within the context of a Program Transmittal. As you are aware, CMS issued multiple proposed rules for the 75% Rule, on May 16, 2003 (68 Fed. Reg. 26,791) and September 9, 2003 (68 Fed. Reg. 53,266), and issued the final Rule on May 7, 2004 (69 Fed. Reg. 25,752). Nowhere within any of these proposed rules or their preamble discussions, or within the final Rule or its preamble discussion, did CMS undertake any analysis or discussion relating to whether patients who receive outpatient therapy services to prepare them for surgery (irrespective of whether the sole or partial clinical or medical rationale for those services would be to prepare them for surgery) should be included within a hospital's or unit's patient count for purposes of compliance with the Rule.

Rehabilitation hospitals and units have been given no notice of CMS's apparent intention to prohibit these patients from being included within a hospital or unit's patient count for purposes of complying with the Rule. Therefore, this policy should not be implemented until additional study and analysis can be conducted to determine the efficacy and appropriateness of prohibiting hospitals and units from including surgery patients in their patient counts, and to ascertain the extent to which this policy may reduce access to inpatient rehabilitation services for patients who undergo a surgical procedure and need post-surgical inpatient rehabilitation care.

IV. 'Administrative Presumption':

In the preamble to the final 75% Rule, CMS observed that commenters suggested that if a rehabilitation hospitals or unit's Medicare population meets the compliance threshold of the Rule, then the Agency should "administratively presume" that its total patient population satisfies the compliance threshold of the Rule. However, if the hospital or unit's Medicare population does not meet the threshold, then its total patient population should be used to determine whether the Rule's threshold requirements have been satisfied. 69 Fed. Reg. at 25,759-60.

In responding to this suggestion, CMS agreed with the notion of administratively presuming that a hospital or unit satisfies the Rule's threshold requirement based upon its Medicare patient numbers, with the caveat that a majority of its overall patient population should be comprised of Medicare patients. Specifically, CMS stated that it "will instruct the FIs that if an IRF's Medicare population does not represent at least a majority of the facility's total patient population, the FI is to verify if the compliance threshold was met *using only the facility's total patient population*." *Id.* at 25,760 (emphasis added).
However, the Transmittal at §140.1.4 B.2.a.states that:

> The FI must use the IRF's total patient population to verify that the IRF has met the requirements specified above in §140.1.1B if:
> ...
> ...In the case where [1] the Medicare admissions comprise less than 50 percent of the IRF inpatient population, or [2] the FI otherwise determines that the Medicare admissions are not representative of the overall IRF inpatient population, or [3] the FI is unable to generate a valid report using the IRF-PAI methodology, the presumptive determination is that the IRF did not meet the requirements specified above in §140.1.1B.

This language is inconsistent with the first sentence of §140.1.4, B., 2., a., which states that the FI is to use an IRF's total patient population if certain requirements are not met. However, the language above states that the FI will "presume" that the Rule's threshold requirements would not be met if [1], [2] or [3] are not satisfied, including those instances where a hospital or unit's Medicare admissions are less than 50% of its inpatient population.

Our understanding of an FI's ability to use "administrative presumption," both according to the preamble discussion of it in the final 75% Rule as well as in Transmittal 221, is that such a presumption may be used positively in favor of a hospital or unit if its total inpatient population is comprised of a majority (i.e., '50% plus one') of Medicare patients. If it is not so comprised, then the FI is to examine a hospital or unit's total inpatient population, Medicare and non-Medicare. However, §140.1.4, B., 2., a. does not appear to comport with this analysis. Put another way, it would appear to permit FIs to use administrative presumption *negatively* against hospitals and units, apparently without the FI affording the hospital or unit with a complete examination of its total patient population data.

We believe this may be a drafting error on the part of CMS, and request that §140.1.4, B., 2., a. be appropriately revised to alleviate the possibility of misinterpretation on the part of FIs. To the extent that our concern with §140.1.4,B., 2., a. accurately reflects CMS's intended policy to be used by FIs when applying its administrative presumption authority, such a framework is inconsistent with the position taken by CMS in the preamble to the final 75% Rule and does not reflect the position that inpatient rehabilitation hospitals and other providers have advocated throughout the rulemaking process.

V. Burdensome Recordkeeping and Document Production Requirements:

A. Recordkeeping:

The Transmittal states that CMS:

> expect[s] that the IRF will obtain copies of the therapy notes from the outpatient or therapy in another less intensive setting and place it in the patient's inpatient chart (in a section for prior records). We believe that these records will be primarily used by therapists and others caring for the inpatient in the IRF, but will also be available for FIs who review the medical records for compliance with the requirements of [the 75% Rule].

Transmittal 221 / §140.1.1.

We strongly agree that rehabilitation hospitals and units should maintain adequate and appropriate medical records for the patients they serve. However, in many instances it is unrealistic to require them to obtain the previous medical records of their patients. Despite the best efforts of inpatient rehabilitation hospitals and units, physicians, and other professionals, often these providers are simply unable to gain access to a patient's medical records for services that were provided previously by other providers, whether because the patient is unable or unwilling to have his or her medical records disclosed and forwarded, or due to the uncooperativeness or disorganization of a previous service provider.

The administrative challenges associated with gathering all of a particular patient's medical records should be recognized by FIs as weighing strongly against any adverse or negative outcome that would be applied to inpatient rehabilitation hospitals and units for purposes of determining whether they have complied with the 75% Rule. This is particularly important in those instances where the FI seeks to determine whether a patient has undergone "an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings."

We also note that the medical exigencies of a particular patient's case may be such that to delay the provision of inpatient rehabilitation services until her prior medical records are received could adversely affect one's overall health care needs, and could expose practitioners and/or rehabilitation hospitals or units to potential legal liability for failure to provide medically necessary services on a timely basis.

For these reasons, we request CMS to clarify to the FIs that a failure on the part of an inpatient rehabilitation hospital or unit to maintain or produce a complete set of medical records for a given patient, particularly in those circumstances where a portion of the records were prepared by other previous providers or practitioners, is not a sufficient reason to determine that the hospital or unit has failed to meet the requirements of the 75% Rule.

B. Document Production:

The Transmittal discusses a number of the patient data-gathering and submission procedures that will be used for purposes of determining whether a hospital or unit has complied with the Rule. *See* §140.1.4, B., 2., b. The Transmittal also states that if a rehabilitation hospital or unit "fail[s] to provide the FI with the information in accordance with the requirements" specified in paragraph (b), such a failure "will result in a determination by the [CMS Regional Office] that the [hospital or unit] has not met the requirements" of the Rule. §140.1.4, B. 2., d. The Transmittal also states that a regional office "will notify the IRF that failure to send the FI the list within an additional 10 calendar days will result in a determination by the RO that the IRF has not met" the requirements of the 75% Rule. §140.1.4, B.

We appreciate the need for rehabilitation hospitals and units to provide FIs with sufficient information in a timely fashion for purposes of determining whether they are in compliance with

the 75% Rule. However, we believe it is arbitrary that failure on the part of a hospital or unit to provide patient information to its FI precisely in accordance with a particular format or within a narrow timeframe (i.e., 10 days) will be treated as a failure to satisfy the requirements of the Rule. Given the history of the 75% Rule and the fact that CMS is only now beginning to enforce it, there undoubtedly will be some initial administrative and technical problems in this process, both on the part of providers and on the part of CMS and its contractors.

Accordingly, we request that this language be modified to ensure that FIs are prohibited from concluding that a hospital or unit has not satisfied the threshold requirements of the 75% Rule simply because it fails to submit data in a format that may not precisely follow that enumerated in the Transmittal, or because the data was not received within 10 calendar days of the FI's request.

Thank you for your time and consideration of our views. If you have any questions about this letter, please contact Justin Hunter, Washington counsel to the American Academy of Physical Medicine and Rehabilitation, at (202) 466-6550.

Sincerely yours,

American Academy of Neurology
American Academy of Physical Medicine and Rehabilitation
American Hospital Association
American Medical Rehabilitation Providers Association
American Occupational Therapy Association
American Therapeutic Recreation Association
Federation of American Hospitals
New Jersey Hospital Association