American Hospital Association

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January 7, 2005

Sidney Hayes, M.D.
Medicare Medical Director
Arkansas Medicare Services
PO Box 1418
Little Rock, AR 72203

Re: Draft Local Coverage Determination (Local Medical Review Policy) on Inpatient Rehabilitation Medical Necessity.

Dear Dr. Hayes:

On behalf of our nearly 5,000 member hospitals, health care systems, networks and other providers of care, including nearly 1,000 inpatient rehabilitation facilities, the American Hospital Association (AHA) appreciates the opportunity to comment on the draft local coverage determination (LCD) concerning inpatient rehabilitation medical necessity, which was issued by Arkansas Medicare Services (AMS) in November 2003.

The AHA feels that the existing, national medical necessity criteria established in the Medicare Benefits Policy Manual (MBPM) serve as a rigorous standard to determine which patients are clinically appropriate for admission into an inpatient rehabilitation facility (IRF). As such, several provisions in the draft LCD raise substantial concerns because they would impose additional, inappropriate and unsupported criteria, which would restrict national policy. Of particular concern are the absence of a sound clinical rationale for the draft LCD and the use of diagnosis-based criteria.

The AHA continues to call for a delay in all policymaking related to inpatient rehabilitation, including this proposal, so that a multi-disciplinary panel of clinical and research experts can be convened to establish a clinical consensus on how to medically distinguish patients more appropriately treated in IRFs versus other medical rehabilitation settings. This clinical consensus will provide a needed framework for medically sound and consistent national policymaking regarding inpatient rehabilitation medical necessity criteria and facility criteria.

The opposite scenario exists now with substantial uncertainty in the field as a result of incomplete and inconsistent provisions in the 75% Rule issued by the Centers for Medicare & Medicaid Services (CMS) in May 2003, and equally confusing operating instructions to the fiscal intermediaries (FI) in Transmittals 221 and 347. Because LCDs must be consistent with federal statutes, regulations and guidelines, all FIs should wait for conclusive action on the 75% Rule before implementing revisions to local coverage policies for inpatient rehabilitation.

We suggest that AMS consider several key principles in the LCD implemented by FI AdminaStar on July 1, 2004. The AHA supports the following AdminaStar principles that offer a more effective approach to determining inpatient rehabilitation medical necessity:

- A patient's need for inpatient rehabilitation should be based on the patient's ability to regain function lost due to an injury or illness, and not solely on diagnosis. The AdminaStar proposal forgoes diagnosis-based limitations and is, therefore, consistent with the federal guidelines.
- Cases should not be deemed clinically inappropriate for IRF care based on screening criteria. Rather, cases that fail an initial screen by an FI auditor should be referred to a physician with experience in medical rehabilitation for an individualized review based on clinical expertise, experience and other resources.

We urge AMS to review the AdminaStar proposal and give strong consideration to incorporating these key elements.

Current Medical Necessity Standards are Effective

CMS' inpatient rehabilitation medical necessity standards are found in Chapter 1, Section 110 of the Medicare Benefit Policy Manual (MBPM), which replaced the CMS Hospital Manual Section 211 on October 1, 2003. These standards are based on inpatient rehabilitation medical necessity and appropriateness of admission criteria finalized in 1980 by theAmerican Academy of Physical Medicine and Rehabilitation (AAPM&R) and theAmerican Congress of Rehabilitation Medicine (ACRM). The standards have been validated by CMS and widely accepted by the field**. Until the findings and recommendations of a clinical panel of experts become available, the continued use of Section 110, in its entirety (Attachment A), is a stringent but fair standard for inpatient rehabilitation medical necessity.** The AHA and other national organizations sent a letter to the CMS Office of General Counsel outlining our concerns about the inappropriate restriction of the national inpatient rehabilitation medical necessity guidelines being proposed in the draft LCDs issued by various FIs during the past 16 months. These concerns were discussed with staff from the CMS Program Integrity Group in Baltimore on December 1, 2004 (Attachment B).

The existing rigorous standards for IRF admission have resulted in the vast majority – 98 percent – of acute discharges being referred to settings other than an IRF for follow-up rehabilitation (AHA Analysis of 2002 MedPAR data). **Clearly, in most cases, these criteria are already effectively distinguishing patients requiring intensive,**

multidisciplinary rehabilitation care from those who are would benefit from a less intensive rehabilitation setting.

CMS will further modify Section 110 of the MBPM to ensure that it is consistent with related policies. This will also require modifications to related LCDs, CMS FI manuals and other affected guidelines. Therefore, AMS and other FIs should treat the new Section 110 guidelines as a work in progress rather than final policy.

LCD Must Preserve Physicians' Decision-making Role

The AMS proposal appropriately acknowledges the overseeing physician's leadership and decision-making role in guiding the IRF's multidisciplinary team to develop and execute an individualized care plan for each patient. However, the diagnosis-specific parameters in the "Indications" section of the proposal would wrongly diminish these roles by focusing on pre-set guidelines that restrict the referring and receiving rehabilitation physician's ability to make case-by-case determinations on the appropriate course of care for each patient. Since aspects of these criteria are inconsistent with both prevailing medical practice and the medical literature, AMS should omit these criteria. Doing so would reinforce the role of physicians' expert clinical judgment in determining which patients are clinically appropriate for inpatient rehabilitation within the parameters set by the MBPM.

Section 110.4 Screening Criteria Should be Fully Cited

The medical necessity standard put forth in Section 110 requires that:

> *1) inpatient rehabilitation care be medically necessary for the patient's condition, and*
> *2) inpatient level care – rather than less intensive rehabilitation care provided in another setting – be medically necessary.*

If both of these criteria are met, then an assessment is conducted using the pre-set screening criteria established in Section 110.4 and referred to in the "LCD Description" and "General Indications" sections of the draft LCD, to determine if the patient meets the criteria for an IRF admission. For any patient who fails to satisfy the screening criteria, the case should be referred to a physician with experience in medical rehabilitation to determine, on a case-by-case basis using individual clinical expertise, experience, and other resources, whether the patient is clinically appropriate for an IRF admission.

While it is appropriate for the draft LCD to provide clarification of the existing national medical necessity standards, it is inappropriate to contradict the existing standards, the medical literature, or prevailing clinical practice. An example of a provision that exceeds the proper role for an LCD is the proposed medical necessity standard of returning the patient to "self-care to live alone." This provision improperly surpasses the acknowledged and appropriate clinical goal of returning a patient to the highest possible level of function. A clinically appropriate goal for many inpatient rehabilitation patients is to restore lost functionality and return the patient to the community, which may fall short of regaining independent self-care, as proposed by AMS, yet is still justifiable and

reimbursable, and more important, of substantial value to the patient. All such provisions in the AMS draft LCD should be removed since they are inconsistent with accepted medical practice and are not supported in the medical literature.

The condensed version of the screening criteria noted in the "LCD Description" and "General Indications" sections of the draft LCD inappropriately paraphrase the screening criteria, as established in Section 110. The missing provisions provide substantive clarification and understanding for providers and should not be omitted.

For all references to the patient screening process, the LCD should explicitly refer the case reviewer to a fully articulated version of the screening criteria, which should be included in complete form within the LCD text. In addition, the LCD should note that the fully articulated requirements should be used during initial patient assessments to establish whether inpatient rehabilitation care is medically necessary for a patient on a case-by-case basis. Furthermore, the LCD should clarify that these criteria are not an absolute threshold since, as an exception, certain patients may be appropriately deemed medically eligible for inpatient rehabilitation by an admitting IRF physician even if they do not meet all of the criteria listed. Finally, it also should be clarified that screening criteria, in full or abbreviated form, should not limit physician review of a patient's individual needs. Instead, the physician should draw upon individual medical expertise and clinical experience to determine each patient's individual rehabilitation care needs.

Draft LCD is Inconsistent with Program Integrity Manual
Chapter 13 of the CMS Medicare Program Integrity Manual requires all FIs to involve inpatient rehabilitation providers in the development of LCDs, which did not occur during the development of this AMS LCD. In addition, Chapter 13 states that LCDs are an "administrative and educational tool" that may not "restrict or conflict with . . . coverage provisions in interpretive manuals," such as the Benefit Policy Manual. However, **rather than serving solely as an "administrative and educational tool," some components of the diagnosis-specific section of the draft LCD would restrict Medicare coverage of IRF services and deny beneficiaries access to care in the most appropriate setting without the clinical literature to substantiate the draft policy**.

"Reasons for Denial" Section Would Diminish Role of Physician Judgment
The "Reasons for Denial" section of the proposal should be removed since it contradicts the individualized medical necessity determination required by the admitting physician of an IRF. A denial should not be based on a checklist such as that presented in this section, but should be based on an individualized case review by a physician with experience in rehabilitation on behalf of the FI. **If AMS is to keep this section however, we recommend modifying the language as outlined in Attachment C.**

Proposal Cites Weak Scientific Sources
Chapter 13 also requires FIs to base LCDs "on the strongest evidence available" and states that:
"In order of preference, the LCDs should be based on:

- *published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and*
- *general acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:*
  - *Scientific data or research studies published in peer-reviewed medical journals;*
  - *Consensus of expert medical opinion (i.e., recognized authorities in the field); or*
  - *Medical opinion derived from consultations with medical associations or other health care experts."*

Chapter 13 also states, "the extent and quality of supporting evidence is key to defending challenges to LCDs," and a "broad range of available evidence must be considered and its quality must be evaluated before a conclusion is reached."

The AMS draft LCD cites the same 35 sources used by several FIs[1] that issued identical draft LCDs on inpatient rehabilitation in August 2003. As noted in correspondence to these FIs, these resources fail to satisfy the Chapter 13 requirements for LCD development. This failure combined with the currently limited body of clinical research on which to base significant changes to the existing, national medical necessity standards reinforce our recommendation to stop local rulemaking on inpatient rehabilitation and allow a panel of rehabilitation experts to be convened to develop a clinical consensus on which to base a fair and reasonable policy.

In addition, the AMS draft LCD lacks appropriate clinical support to substantiate the proposed limitations on inpatient rehabilitation medical necessity. The AHA concurs with the Rehabilitation Institute of Chicago's (RIC) Center for Rehabilitation Outcomes Research, which commented to CMS on October 28, 2003, on the inability of these 35 sources to support the August 2003 draft LCDs, which are almost identical to the AMS draft LCD.

> *"The failure of the authors to meet accepted standards of review methodology and the evidence provided by the literature cited in these draft recommendations is often of such poor quality (omissions, exclusions, and poor design) that it is unclear that the reviewers could have come to any conclusions, let alone the ones they did. The quality of the studies is often poor, any effects found are generally small, the populations studied are extremely heterogeneous, and there are multiple plausible competing explanations of the observed effects."*
>
> *"**Given the literature cited, there is simply not enough evidence provided to draw the conclusions that the authors did about the circumstances and conditions under which inpatient rehabilitation is medically necessary or unnecessary..."***

Given the RIC's status as one of the premier medical rehabilitation research organizations in the nation, their assessment of the sources used in the August 2003 LCDs and the AMS LCD must not be overlooked. **These findings raise fundamental and grave questions about the medical legitimacy of the LCDs.**

[1] Cahaba (Alabama and Georgia), Riverbend (New Jersey and Tennessee), and Veritus (Pennsylvania).

The AAPM&R also conducted a thorough analysis of the reference materials cited in the proposed LCDs and like the RIC, found an extremely weak relationship between the cited articles and the proposed LCDs. **Of the articles cited in the LCD, only seven were found to be directly relevant to the proposal, and of those, only two were supportive of provisions in the proposal.**

Noted researcher, Dr. Margaret Stineman, whose work includes two articles cited in the August 2003 LCDs and the AMS LCD, echoes similar critiques of the reference material in her comments. In her October 29 letter to CMS, Stineman states, "It is unclear to me why the authors of the LCDs would cite my work, which does not affirm the LCDs, and in the case of the "*Prospective Payment, Prospective Challenge"* article, actually counters the provisions in the proposals." She further writes, "The proposed LCDs are poorly developed and as such should not be implemented. **CMS should intervene to ensure that policies promulgated under the auspices of the agency are based on science and reason, which is clearly not the case with the proposed LCDs**."

It appears that AMS was not diligent in complying with the standard set forth in the CMS Program Integrity Manual, which requires LCDs to be based on published, authoritative evidence and standards of practice in the medical community. Not only do the LCDs cite medical literature that fails to support the proposal, they also fail to incorporate the findings of other articles that are relevant to inpatient rehabilitation medical necessity. A group of rehabilitation experts developed the attached list of research articles not utilized by the LCD authors, but which should be considered by CMS and its FIs when designing policy on inpatient rehabilitation (Attachment D).

Given these highly critical assessments of the medical foundation of the August 2003 and the AMS LCDs, it appears these FIs completely disregarded the Chapter 13 guidance that "the extent and quality of supporting evidence is key to defending challenges to LCDs." Further, the requirement to base LCDs on the "strongest evidence available" was completely overlooked. AMS and the other FIs also fell far short of Chapter 13 by failing to consider a "broad range of available evidence" and ensure the quality of such evidence prior to reaching a conclusion on the merits of the proposed policy changes.

For future work on inpatient rehabilitation policy, **we encourage AMS to consider the journal articles noted in Attachment D.** This list was developed by a group of rehabilitation experts and should be considered by CMS and its FIs when designing policy on inpatient rehabilitation.

LCD Overemphasizes Diagnosis and Other Fixed Criteria

The draft LCD states the intention to use functional loss as the guiding factor in determining medical necessity, but contradicts itself by also establishing the importance of the specific diagnosis in admission decisions. The proposal's disease-specific parameters seem to be based on the cited Milliman and Robertson Clinical Guidelines, which were not designed for Medicare patients, are not evidence-based, and are not used by the majority of the field due to these shortcomings. Chapter 13 of the Program

Integrity Manual explicitly prohibits such pre-set "rules of thumb." The diagnosis specific provisions undermine the significance of patient functionality and role of the physician in using clinical judgment during the admission of a patient and discourage the application of individual case analysis. In addition, the diagnosis-specific guidelines fail to recognize the role of IRFs in providing care that integrates the treatment of each patient's medical *and* functional needs.

An IRF admission is made if a patient's function has been affected by an impairment and there is a medical basis for an intense program of rehabilitation services, supervised by physicians and nurses with specialized training in medical rehabilitation, that is likely to result in meaningful functional improvement in a reasonable period of time. Chapter 110 supports this comprehensive and medically rational foundation for assessing inpatient rehabilitation medical necessity. IRFs appropriately treat patients in the context of their overall medical condition when they meet the clinical thresholds for medical necessity established in Chapter 110. Depending on the individual, secondary diagnoses may appropriately influence the medical decision to admit a patient into an IRF due to the added complexity of the treatment plan that is required to restore function. The AHA is concerned that case reviewers using the AMS guidelines may inappropriately use the diagnosis-specific guidelines as short cuts that substitute for the review of the entire medical record and assessment of the whole patient. **Therefore, the AHA asks that all diagnosis-specific guidelines be deleted from the draft LCD.**

LCD Coding Provisions Would Create Inconsistencies and Confusion

The draft LCD proposes coding provisions that are unclear and appear to be inconsistent with the Official Coding Guidelines validated by the four cooperating parties, including CMS; implementing these provisions in their current form would create confusion for FIs and providers alike. **AMS should address the following concerns about the draft LCD's coding provisions:**

- For certain coding provisions, the draft LCD refers to the UB92 claim form, and at other points the draft seems to refer to the IRF-patient assessment instrument (PAI) diagnoses codes. This creates confusion for providers because each of these has its own coding conventions and instructions. The LCD needs to clarify whether these two coding processes, with their distinct codes, will be used jointly, and if so, how. To date, all other LCDs solely utilize the UB92 claims data.
- Since IRFs utilize both the UB92 and IRF-PAI processes, which are often a source of confusion, we encourage AMS to utilize chart reviews to the greatest extent possible to determine medical necessity of a claim, rather than solely relying on codes.
- The LCD fails to recognize that under the Official Coding Guidelines, IRFs may use the V57 code for a primary diagnosis. An exception to the principal diagnosis coding rules allows reporting of V57 code as the principal diagnosis for "care involving use of rehabilitation procedures."
- The LCD's definition of "secondary diagnoses" also is inconsistent with the established definition published in the Official Coding Guidelines and fails to capture many allowable secondary conditions. Under the Official Coding Guidelines, "secondary diagnoses" include conditions "requiring clinical evaluation; therapeutic

treatment; diagnostic procedures; extended length of hospital stay; or increased nursing care and/or monitoring." Allowed secondary diagnoses include a broad list of conditions and comorbidities that coexist at the time of admission, develop subsequently, or affect the treatment received and/or the length of stay.

- The LCD coding provisions also would be inconsistent with the Health Insurance Portability and Accountability Act (HIPAA), which references use of the Official Coding Guidelines as part of its electronic billing standards on transactions and clinical coding.
- At no point should the draft LCD utilize any CPT/HCPCS codes, which are the HIPAA designated standard code set for *outpatient* services, while ICD-9-CM is for hospital inpatient procedures.

LCDs Would Create a Burden on the Entire Health Care System

This LCD would not only substantially limit access to clinically appropriate care for Medicare beneficiaries, it also could cause an overall reduction in services by inpatient rehabilitation providers. Such cutbacks in IRF services would have a broader negative effect. A reduction in IRF access would be particularly burdensome in rural communities and communities with acute hospitals that are already challenged with capacity limitations.

Given our substantial concerns with the proposed LCD – in particular, the problems related to the diagnosis-specific parameters – we strongly recommend that the proposal be delayed, so that a national panel of inpatient rehabilitation experts can establish a clinical consensus on whether and how to expand upon the national standards set forth in Section 110 of the MBPM to ensure appropriate access to care for Medicare beneficiaries. Until such a panel can develop recommendations, AMS should convene local inpatient rehabilitation providers and referring physicians to facilitate a dialogue on the development of a more effective and appropriate LCD.

Thank you for considering our remarks on the proposed LCD. If you have any questions about our comments, please feel free to contact me or Rochelle Archuleta, senior associate director for policy, at (202) 626-2320.

Sincerely,

Rick Pollack
Executive Vice President

Attachments

Attachment A

Medicare Benefit Policy Manual
Chapter 1; Section 110
Inpatient Rehabilitation Screening Criteria
(Effective 10-1-2003)

Special Note on Pending Changes to Section 110: The current medical necessity guidelines in section 110 of the online Medicare Benefit Policy Manual replaced Section 211 of the Hospital Manual in October 2003; however it should be noted that additional modifications to the new guidelines are pending. To ensure consistency with other related policies, conforming changes will also be required for related LMRPs/LCDs, FI manuals and other affected guidelines. The field has noted that in converting the screening criteria from the Hospital Manual to the Benefit Policy Manual, substantive changes were made in the screening criteria that did not undergo the scrutiny of public hearing or comments, and as such, these changes must be revisited by CMS. Therefore Palmetto and other FIs should treat the new section 110 guidelines as a work in progress rather than a finalized policy.

110.4 - Rehabilitation Hospital Screening Criteria
(Rev. 1, 10-01-03)
A3-3101.11.D, HO-211.D
Rehabilitative care in a hospital, rather than in a SNF or on an outpatient basis, is reasonable and necessary for a patient who requires a more coordinated, intensive program of multiple services than is generally found out of a hospital. A patient probably requires a hospital level of care if they have either one or more conditions requiring intensive and multi-disciplinary rehabilitation care, or a medical complication in addition to their primary condition, so that the continuing availability of a physician is required to ensure safe and effective treatment.

The QIOs will review rehabilitation services if they are rendered at the inpatient facility as part of that particular admission.

The CMS has developed a set of screening criteria to assist the QIOs in applying this level-of-care requirement. The criteria (which are listed below) are designed to enable the QIOs to identify those cases that clearly involve a hospital level of rehabilitative care. The QIOs are expected to use these criteria in performing their screens of rehabilitative hospital claims. Thus, if a case satisfies each of the criteria, the QIO may approve the claim at the initial screening level. However, the fact that a case fails to satisfy the criteria does not mean that the QIO denies the claim. Rather, it only means that the QIO refers the case to a physician reviewer for a determination as to the medical necessity of the

patient's hospitalization.

These criteria set forth below are intended to be applied only at the initial screening level (which is typically conducted by the QIO's nurse reviewer). The criteria do not apply to cases referred to a QIO's physician reviewer. For determinatio ns about reasonableness, medical necessity, and appropriateness of setting, the QIO's physician reviewer is expected to make a determination on the basis of their knowledge, expertise and experience, and upon an assessment of each beneficiary's individual care needs rather than on fixed criteria.

At the initial screening, a QIO determines that the patient requires a rehabilitative hospital level of care if all of the following screening criteria are met.

110.4.1 - Close Medical Supervision by a Physician With Specialized Training or Experience in Rehabilitation

(Rev. 1, 10-01-03)
A3-3101.11.D.1, HO-211.D.1
A patient's condition must require the 24-hour availability of a physician with special training or experience in the field of rehabilitation. This need should be verifiable by entries in the patient's medical record that reflect frequent and direct, and medically necessary physician involvement in the patient's care; i.e., at least every two to three days during the patient's stay. This degree of physician involvement which is greater than is normally rendered to a patient in a SNF is an indicator of a patient's need for services generally available only in a hospital setting.

110.4.2 - Twenty-Four Hour Rehabilitation Nursing

(Rev. 1, 10-01-03)
A3-3101.11.D.2, HO-211.D.2
The patient requires the 24-hour availability of a registered nurse with specialized training or experience in rehabilitation.

110.4.3 - Relatively Intense Level of Rehabilitation Services

(Rev. 1, 10-01-03)
A3-3101.11.D.3, HO-211.D.3
The general threshold for establishing the need for inpatient hospital rehabilitation services is that the patient must require and receive at least three hours a day of physical and/or occupational therapy. (The furnishing of services no less than five days a week satisfies the requirement for "daily" services.) While most patients requiring an inpatient stay for rehabilitation need and receive at least three hours a day of physical and/or occupational therapy, there can be exceptions because individual patient's needs vary. In some instances, patients who require inpatient hospital rehabilitation services may need, on a priority basis, other skilled rehabilitative modalities such as speech-language pathology services, or prosthetic-orthotic services and their stage of recovery makes the concurrent receipt of intensive physical therapy or occupational therapy services

inappropriate. In such cases, the 3- hour a day requirement can be met by a combination of these other therapeutic services instead of or in addition to physical therapy and/or occupational therapy.

An inpatient stay for rehabilitation care can also be covered even though the patient has a secondary diagnosis or medical complication that prevents participation in a program consisting of three hours of therapy a day. Inpatient hospital care in these cases may be the only reasonable means by which even a low intensity rehabilitation program may be carried out. The intermediary secures documentation of the existence and extent of complicating conditions affecting the carrying out of a rehabilitation program to ensure that inpatient hospital care for less than intensive rehabilitation care is actually needed.

110.4.4 - Multi-Disciplinary Team Approach to Delivery of Program

(Rev. 1, 10-01-03)
A3-3101.11.D.4, HO-211.D.4
A multidisciplinary team usually includes a physician, rehabilitation nurse, social worker and/or psychologist, and those therapists involved in the patient's care. At a minimum, a team must include a physician, rehabilitation nurse, and one therapist.

110.4.5 - Coordinated Program of Care

(Rev. 1, 10-01-03)
A3-3101.11.D.5, HO-211.D.5
The patient's records must reflect evidence of a coordinated program, i.e., documentation that periodic team conferences were held with a regularity of at least every two weeks to:

- Assess the individual's progress or the problems impeding progress;
- Consider possible resolutions to such problems; and
- Reassess the validity of the rehabilitation goals initially established.

A team conference may be formal or informal; however, a review by the various team members of each other's notes does not constitute a team conference. The decisions made during such conferences, such as those concerning discharge planning and the need for any adjustment in goals or in the prescribed treatment program, must be recorded in the clinical record.

110.4.6 - Significant Practical Improvement

(Rev. 1, 10-01-03)
A3-3101.11.D.6, HO-211.D.6
Hospitalization after the pre-admission screening is covered only in those cases where the pre-admission screening results in a conclusion by the rehabilitation team that a significant practical improvement can be expected in a reasonable period of time. It is not necessary that there be an expectation of complete independence in the activities of daily living, but there must be a reasonable expectation of improvement that is of practical value to the patient, measured against the patient's condition at the start of the rehabilitation program. For example, a multiple sclerosis patient's condition may have

deteriorated as a result of a secondary illness. To be restored to a level of function before the secondary illness, the patient may require an intensive inpatient hospital rehabilitation program. While such a program does not restore the level of function before multiple sclerosis developed, a return to pre-secondary illness level is considered to be a "significant practical improvement" in the condition. In addition, a beneficiary must classify into one of the CMG's payable by Medicare under the IRF PPS.

110.4.7 - Realistic Goals

(Rev. 1, 10-01-03)
A3-3101.11.D.7, HO-211.D.7
While there may be instances where an intense rehabilitation program may enable a Medicare patient to return to the labor market, vocational rehabilitation is generally not considered a realistic goal for most aged or severely disabled individuals. The most realistic rehabilitation goal for most Medicare beneficiaries is self-care or independence in the activities of daily living; i.e., self-sufficiency in bathing, ambulation, eating, dressing, homemaking, etc., or sufficient improvement to allow a patient to live at home with family assistance rather than in an institution. Thus, the aim of the treatment is achieving the maximum level of function possible.

110.5 - Length of Rehabilitation Program

(Rev. 1, 10-01-03)
A3-3101.11.E, HO-211.E
Coverage stops when further progress toward the established rehabilitation goal is unlikely or when further progress can be achieved in a less intens ive setting. In deciding whether further care can be carried out in a less intensive setting, both the degree of improvement that has occurred and the type of program required to achieve further improvement must be considered. In some cases, an individual may be expected to continue to improve under an outpatient program. There are other situations where further improvement in the individual's ability to function relatively independently in the activities of daily living can be expected only if a multidisciplinary team effort is continued.

While occasional home visits and other trips into the community are factors in determining whether continued stay in the hospital is necessary, such excursions alone are not a basis for concluding that further hospital care is not required. Planned home visits and trips to the community are frequently used to test the individual's ability to function outside the institutional setting and assist in discharge planning for the individual.

It is also important to consider how close the patient may be to the planned end of the rehabilitation hospital stay when further progress becomes unlikely. If a patient is within a few days of discharge, transfer to a less intensive setting in another facility would be inappropriate even though further progress in the hospital setting is unlikely. However, it

could be appropriate to utilize a "swing bed" arrangement, if it exists in the same facility, for rendering necessary services to the patient pending discharge. When discharge or transfer to another facility is appropriate, the cut-off point for coverage should not be the last day on which improvement actually occurred. Rather, coverage should continue through the time it would have been reasonable for the physician, in consultation with the rehabilitation team, to have concluded that further improvement would not occur and to initiate the patient's discharge.

Since discharge planning is an integral part of any rehabilitation program and should begin upon the patient's admittance to the facility, an extended period of time for discharge action would not be reasonable after established goals have been reached, or a determination made that further progress is unlikely, or that care in a less intensive setting would be appropriate.

Attachment B

POWERS PYLES SUTTER & VERVILLE PC
ATTORNEYS AT LAW

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MEMORANDUM

To: Robert P. Jaye, Acting Associate General Counsel
Centers for Medicare and Medicaid Services

From: Peter W. Thomas, Esq. and Justin R. Hunter, Esq.
Powers, Pyles, Sutter & Verville, P.C., on behalf of the:

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

Date: September 20, 2004

Re: **Analysis of Medicare Fiscal Intermediaries' Use of the "Less Intensive Setting" Concept in Local Coverage Determinations for Inpatient Rehabilitation**

I. Statement Of The Problem

Medicare fiscal intermediaries ("FIs") are developing local coverage determinations ("LCDs") on inpatient rehabilitation which are inconsistent with the

longstanding policy of the Centers for Medicare and Medicaid Services ("CMS"). Although LCDs are required to be consistent with law, regulations and CMS national policy, and although these inpatient rehabilitation LCDs purport to follow CMS national policy as set forth in the Medicare Benefits Policy Manual ("MBPM"), many of them depart significantly from CMS national policy by adding what amounts to a new requirement for assessing the medical necessity of inpatient rehabilitation. Under the new criterion, inpatient rehabilitation will be denied if the FI determines that the care could have been provided in a "less intensive setting" even when the inpatient admission meets all of the requirements for inpatient rehabilitation facility (IRF) care set forth in the CMS Manual.

The addition of this new requirement is inappropriate and problematic for a number of reasons. First, it circumvents longstanding published CMS standards for the medical necessity of inpatient rehabilitation. Second, it permits FIs or other contractors to deny inpatient rehabilitation without clearly articulating a clinical basis for the denial. Third, it creates confusion and uncertainty among physicians and IRFs as to whether an inpatient admission will be covered—the exact opposite of what an LCD is supposed to do. Fourth, it could delay or deny some Medicare beneficiaries of their right to medically necessary inpatient rehabilitation in a manner that may negatively impact functional outcomes.

In adopting this new criterion, the FIs implicitly reject that the medical necessity of inpatient rehabilitation is established by meeting the eight existing CMS criteria. For the reasons stated below, we believe that the FIs should refrain from implementing LCDs for inpatient rehabilitation that impose this new criterion and, instead, reaffirm that satisfaction of the eight criteria described in Chapter 1, Sec. 110.4 of the MBPM is the proper standard for determining the medical necessity of inpatient rehabilitation services.

II. Legal Background

In order to properly understand the legal issues surrounding the fiscal intermediaries' use of the less intensive setting standard in the LCD's for inpatient rehabilitation, it is important to understand the relevant legal and regulatory frameworks that govern inpatient rehabilitation services under Medicare.

A. Hospital Inpatient Prospective Payment System

Under the Medicare statute, a Medicare beneficiary is entitled to reasonable and necessary inpatient hospital care, including inpatient rehabilitative care. *See* §§1812(a)(1), 1862(a)(1)(A) of the Social Security Act ("the Act"). In 1983, Congress established a system of payment for the operating costs of acute care hospital inpatient stays covered by Medicare Part A based on prospectively set rates. *See* §1886(d) of the Act. Under the inpatient prospective payment system ("IPPS"), payment for an inpatient stay is based on "diagnosis-related groups," or "DRGs," which are specific rates for each hospital discharge.

B. Exclusion Of Rehabilitation Hospitals And Units From The Inpatient Prospective Payment System

Under IPPS, rehabilitation hospitals and units were excluded from the DRG-based payment system and were paid based on reasonable cost reimbursement subject to hospital-specific annual limits. *See* §1886(d)(1)(B) of the Act. Congress gave the Secretary of HHS the authority to define, through regulation, an excluded rehabilitation hospital or unit. Regulations, promulgated by the Secretary under this authority, specify a number of criteria that must be met for a provider to be classified as a rehabilitation hospital or unit exempt from IPPS. See 42 C.F.R. §§412.23(b), 412.25, and 412.29. They include:

- that 75% of the facility's inpatient population require rehabilitation services for treatment of specific medical conditions set forth in the regulation (the "75% rule"); [2]
- that the facility have a preadmission screening procedure;
- that the facility ensure that patients receive close medical supervision and that the facility furnish, through qualified personnel, rehabilitation nursing, physical and occupational therapy plus, as needed, speech therapy, social or psychological services, and orthotic and prosthetic services;
- that there be a physician medical director of rehabilitation with specialized training in rehabilitation; and
- that the facility use a coordinated multidisciplinary team approach with team conferences at least every two weeks to note the patient's status in relationship to his or her rehabilitation goals.

42 C.F.R. §412.23.

C. Prospective Payment System For IRFs

[2] This rule was recently amended to increase the number of qualifying medical conditions to 13 rather than 10 and to lower the 75% threshold to 50% beginning July 1, 2004. However, while the number of medical conditions was increased, the final rule imposes a number of new restrictions on these conditions, including that a patient must undergo and fail an aggressive course of outpatient therapy services prior to being included in the hospital's or unit's patient count to satisfy the Rule. These new restrictions will have the net effect of reducing the number of patient cases that hospitals and units will be permitted to count for purposes of compliance with the Rule. The 2004 percentage will be increased incrementally until 2007 when it will once again become 75%.

In the Balanced Budget Act of 1997 ("BBA"), Congress established an inpatient prospective payment system for rehabilitation hospitals and units ("IRF PPS"). *See* §1886(j) of the Act. The IRF PPS covers the inpatient and capital costs of furnishing covered intensive rehabilitation services, and its payments are made on a per discharge basis through the use of a patient classification system which assigns patients to case-mix groups ("CMGs"). An IRF must meet the definition of a rehabilitation hospital or unit, described above, in order to be paid under the IRF PPS. Payment based on the IRF PPS was fully implemented for cost reporting periods beginning on or after October 1, 2002.

D. Establishment Of Specific Coverage Criteria For Inpatient Rehabilitation

In 1985, CMS (then HCFA) issued HCFA Ruling 85-2. *See* 50 F.R. 31040 (July 31, 1985) (setting forth the agency's criteria for Medicare coverage of inpatient hospital rehabilitation services). That Ruling states that there are two basic requirements which must be met for inpatient hospital stays for rehabilitation care to be covered:

> 1. The services must be reasonable and necessary (in terms of efficacy, duration, frequency, and amount) for the treatment of the patient's condition; and
>
> 2. It must be reasonable and necessary to furnish the care on an inpatient hospital basis, rather than in a less intensive facility, such as a SNF, or on an outpatient basis.

The Ruling then sets forth eight criteria which, if satisfied, indicate the patient meets the above two requirements for inpatient rehabilitation. Each criterion includes a detailed discussion of how it should be applied. HCFA Ruling 85-2 was subsequently incorporated into the Medicare Hospital Manual (HCFA Pub. 10) §211 with some additional language. (HCFA Hospital Manual Revision Transmittal 582, February 1990). One addition is a statement that the criteria are to assist PROs (now QIOs) in applying the "level-of-care" requirement (i.e., the requirement that it be reasonable and necessary to furnish the care in an IRF rather than a less intensive setting). [3] However, the basic criteria were not changed when the HCFA Ruling was incorporated into the CMS Manuals.

The applicability of these criteria was most recently reconfirmed by CMS in 2003 when §211 of the Hospital Manual was cross-walked to Chapter 1, § 110.1 *et seq.,* of the new CMS "Internet Only Manual" ("IOM") – the Medicare Benefits Policy Manual.

[3] The medical review function for inpatient rehabilitation has since been transferred to the fiscal intermediaries. See CMS Transmittal No. 21 (February 21, 2002).

These eight criteria, which have remained essentially unchanged since 1985, address the following areas:

1. Close medical supervision by a physician with specialized training or experience in rehabilitation;

2. Twenty-four hour rehabilitation nursing;

3. Relatively intense level of rehabilitation services;

4. Multi-disciplinary team approach to delivery of program;

5. Coordinated program of care;

6. Significant practical improvement;

7. Realistic goals; and

8. Length of rehabilitation program.

These eight criteria, if met, establish the medical necessity of inpatient rehabilitation. However, the fact that a particular rehabilitation case does not satisfy these eight criteria does not necessarily mean that the patient does not qualify to be treated at the inpatient level of care. Rather, under CMS Policy, the medical review entity (previously QIOs, but now the FIs as of April 1, 2002) are instructed to refer the case to a physician reviewer to determine whether an inpatient level of care is medically necessary. At this stage of review, the eight criteria do not apply and the physician is to review the case based upon his or her knowledge, expertise and experience, and upon an assessment of the beneficiary's individual care needs rather than on fixed criteria. MBPM, ch. 1, §110.4. As noted above, although the MBPM refers to QIOs as the medical review entity, the responsibility for medical review was recently transferred to the fiscal intermediaries.

F. Role Of Medicare Fiscal Intermediaries

CMS' authority to enter into contracts for the administration of the Medicare program, including the making of payments, is set forth in §1874A of the Act. Implementing regulations at 42 CFR § 421.100 *et seq*., describe the coverage functions of fiscal intermediaries. They include ensuring that payments are made only for services covered under Medicare. Additional guidance on FI medical review functions is set forth in Chapter 1, §1.1 of the Program Integrity Manual.

G. Establishment Of LCDs By Medicare Contractors

The term "local coverage determination" was created by §522 of the Benefits Improvement and Protection Act ("BIPA") of 2000. An "LCD" is defined as "a determination by a fiscal intermediary or a carrier under Part A or Part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary or carrier-wide basis under such parts, in accordance with section 1862(a)(1)(A)." §1869(f)(2)(B) of the Act. Prior to the enactment of BIPA, local coverage policies were referred to as "local medical review policies" ("LMRPs") and contained coverage, coding and payment information. The difference between an LMRP and an LCD is that an LCD contains only "reasonable and necessary" information and an LMRP may also contain benefit category, coding, and statutory exclusion provisions. Effective December 7, 2003, intermediaries are to issue only LCDs and have two years to convert existing LMRPs into LCDs.

BIPA §522 provides for appeals of LCDs and sets forth appeal procedures. Prior to BIPA, a challenge to an FI's coverage policy could only be brought in the context of the denial of a claim. Under §522 of BIPA, an aggrieved party (limited to Medicare beneficiaries) may appeal an LCD to an Administrative Law Judge ("ALJ") and the ALJ must review the LCD based upon "reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary." §1869(f)(2)(A)(i)(III) of the Act. Thus, an ALJ is not bound by an LCD. CMS published regulations implementing BIPA §522 on November 11, 2003. Those regulations, set forth at 42 CFR §426.300 *et seq*., establish procedures for challenging LCDs. They provide that in applying the "reasonableness" standard, "the ALJ must follow all applicable laws, regulations, rulings, and NCDs." 42 C.F.R. §426.431.

CMS policies governing the development of LCDs are set forth in the Program Integrity Manual ("PIM") at §13.1.3 et seq. The PMI states that LCDs are "administrative and educational tools to assist providers in submitting correct claims for payment" and should "specify under what clinical circumstances a service is considered to be reasonable and necessary." PIM § 13.1.3. In addition, LCDs may not conflict with CMS policies. The PIM states the following:

> The contractor shall ensure that LCDs are consistent with all statutes, rulings, regulations, and national coverage, payment and coding policies. (PIM §13.1.3); and
>
> The LCD shall . . . not restrict or conflict with NCDs or coverage provisions in interpretative manuals. . . (PIM §13.5).

III. Discussion

A. Overview

Medicare has contracts with more than twenty fiscal intermediaries for administration of the Medicare program. Many of these FIs are developing, or have

already developed, LCDs for inpatient rehabilitation. Although the language varies, these LCDs have as a common thread a requirement, as a new condition of coverage in addition to the screening criteria set forth in the CMS Policy, that the services could not have been provided in a "less intensive setting." Although the LCDs purport to adopt the eight medical necessity criteria set forth in the MBPM for inpatient rehabilitation, they then proceed to thwart the purpose and intent of these criteria by requiring that the provider also demonstrate that care could not have been provided in a less intensive setting.

Some examples of LCDs with this new requirement are as follows:

- The Cahaba GBA's proposed LCD would require a showing that rehabilitation could not be provided in a less intensive setting due to "required rehabilitation services at such an intensity, frequency and duration as to make it impractical for the patient to receive such rehabilitation services in a less intensive setting" and would also exclude coverage if the required services are available in a less intensive setting (outpatient or SNF) and the patient is medically appropriate for such a setting. (Emphasis added).

- The AdminaStar GBA final LCD denies payment for "failure to meet the coverage requirements for inpatient rehabilitation as stated above – i.e. the services are available in a less intensive setting (outpatient or SNF) and the patient is medically appropriate for such a setting." (Emphasis added).

- The LCD proposed by Riverbend GBA would cover inpatient rehabilitation only if the care "cannot be provided in a less intensive setting."

It is not disputed that FIs have the right to review an admission to determine whether it was necessary to furnish the care on an inpatient rehabilitation hospital basis rather than in a less intensive setting. However, this determination must be made by reference to the eight criteria in the MBPM. The eight criteria are interpretations of the two basic requirements for coverage of inpatient rehabilitation set forth in the MBPM, ch. 1, §110.1: 1) that it be reasonable and necessary for treatment of the patient's condition; and 2) that it be reasonable and necessary to furnish the care in an IRF rather than in a less intensive setting. By definition, patients who meet the eight MBPM criteria have met the two basic coverage requirements and, consequently, have established that they could not receive care in a "less intensive setting."

LCDs which require the provider to prove the negative (i.e., that it was not appropriate to provide care in a less intensive setting) when the provider has already established the positive (i.e., that the patient met the eight criteria and thus needed an inpatient level of care) are illogical and reflect a fundamental misunderstanding of CMS

policy. They also permit FIs to override longstanding Medicare criteria and will result in arbitrary, subjective, and inappropriate denials of inpatient rehabilitation.

Our concern is not merely speculative. We are aware of numerous denials of inpatient rehabilitation by FIs in recent months based solely on a finding that care could have been provided in a less intensive setting without reference to any of the eight CMS criteria or the individual clinical conditions which caused the FI to make its determination.[4] We believe that the FIs have been given tacit approval by CMS central to use this new paradigm, permitting FIs to retroactively deny payment for claims without adhering to the more time consuming and exacting process of applying the eight criteria to the patient's clinical condition.

B. An LCD May Not Add A New Criterion For Medical Necessity Of Inpatient Rehabilitation

1. Addition of a new criterion related to whether care can be provided in a less intensive setting is inconsistent with CMS Policy

As already stated, CMS, through the MBPM, has identified two basic requirements that must be met for an inpatient rehabilitation stay to be covered for a particular Medicare patient:

1. The services must be reasonable and necessary (in terms of efficacy, duration, frequency, and amount) for the treatment of the patient's condition; and

2. It must be reasonable and necessary to furnish the care on an inpatient hospital basis, rather than in a less intensive facility such as a SNF, or an outpatient basis. MBPM, ch. 1, §110.1.

As discussed above, CMS has established eight specific screening criteria to be used in determining whether the above two requirements are met. CMS policy is clear that the medical reviewer "determines that the patient requires a rehabilitative hospital level of care if all of the [eight] screening criteria are met." MBPM, ch. 1, §110.4. Thus, if an inpatient admission satisfies these criteria, inpatient rehabilitation is considered to be reasonable and necessary and is, therefore, covered by Medicare.[5] No additional requirements need be met.

Guidelines and examples of how these eight criteria should be applied are described in detail in the MBPM, ch. 1, §§110.4.1 - 110.4.7. All of these criteria address some aspect of the issue of appropriate level of care. The MBPM is clear that if the

[4] For example, one large chain of IRFs recently had nearly one hundred inpatient stays denied on the grounds that the services in question could have been provided in a less intensive setting.

[5] These standards have been in place since at least 1985, when they were issued in the form of a HCFA Ruling (Ruling No. 85-2, 50 Fed. Reg. 31,040 (July 31, 1985)).

patient satisfies these criteria then the admission satisfies the two basic requirements for the coverage of inpatient rehabilitation.

Among the eight criteria, the first three are especially important in defining the need for inpatient rehabilitation. The first criterion is that the patient requires close medical supervision from a physician with special training or experience in the field of rehabilitation. CMS notes that "this degree of physician involvement which is greater than is normally rendered to a patient in a SNF is an indicator of a patient's need for services generally available only in a hospital setting." MBPM, ch. 1, §110.4.1.

The second criterion is that the patient requires 24-hour availability of a registered nurse with specialized training or experience in rehabilitation. MBPM, ch. 1, §110.4.2. Although a SNF may have an RN available on a 24-hour basis, it is unlikely that the RN would have specialized training in rehabilitation.

The third criterion is the need for a "relatively intense level of rehabilitation," and relates directly to the issue of whether a particular case for rehabilitative care is appropriate and medically necessary for treatment at an inpatient level of care. CMS policy specifically states that the need for a relatively intense level of rehabilitation is met if the patient needs and receives three hours of skilled rehabilitation services per day (for five days out of a week) -- what is known as the "Three Hour Rule" -- (or is exempt from the three hour requirement due to medical complications).

Thus, if a provider documents that a patient meets the Three Hour Rule, needs 24-hour rehabilitation nursing care and close medical supervision by a rehabilitation physician, and the remaining criteria are otherwise met, the provider has established that the patient needs a level of care that is provided in an inpatient rehabilitation hospital and, *by definition*, not in a less intensive setting.

LCDs that require the provider, after determining that a specific patient meets the eight criteria, to also demonstrate that care could not have been furnished in a less intensive setting, are inconsistent with Medicare policy as published in HCFA Ruling 85-2 and the MBPM. Although the MBPM states that a requirement for coverage of inpatient rehabilitation is that it must be "reasonable and necessary to furnish the care on an inpatient hospital basis, rather than in a less intensive facility . . .," the question of whether an inpatient admission meets this requirement is answered by application of the eight criteria.

The addition of this new criterion -- that care could not have been furnished in a "less intensive setting" -- essentially permits FIs to deny coverage even where the patient meets all of the eight CMS criteria, without articulating any clinical reason or other specific basis for the denial. As such, LCDs with this kind of requirement are inconsistent with longstanding CMS policy.

2. The Three Hour Rule

The "Three Hour Rule" is characterized by the Medicare Benefits Policy Manual as the "general threshold for establishing" the need for inpatient rehabilitation. MBPM, ch.1, §110.4.3. However, the "Three Hour Rule" functions only as a screening measure when considering the medical necessity for inpatient rehabilitation services, and a patient's failure to satisfy the rule does not create an irrebuttable presumption of noncoverage of those services. Long-standing CMS policy governing the procedures used to determine the medical need for inpatient rehabilitation services specifically prohibits "denials…based on numerical utilization screens, diagnostic screens, diagnosis or specific treatment norms, *'the three hour rule,'* or any other 'rules of thumb,'" and deems denials of services based upon a patient's failure to satisfy any of these criteria or factors as "not appropriate." MBPM, ch.1, §110.1 (emphasis added).

Indeed, CMS policy explicitly recognizes that some patients may have a diagnosis or medical complication that prohibits them from satisfying the "Three Hour Rule," and in those instances inpatient hospital care "may be the only reasonable means by which even a low intensity rehabilitation program may be carried out." MBPM, ch.1, §110.4.3. In other words, while it is an important screening criteria, the "Three Hour Rule" is not an absolute requirement that all patients must satisfy, and, in fact, may be waived in those cases where the patient's medical or physical condition prohibits him or her from satisfying it.

Despite the fact that CMS policy makes it abundantly clear that the "Three Hour Rule" is only a screening criteria to be used in evaluating the medical necessity of inpatient rehabilitation services and a patient's failure to satisfy the rule may not be used as a mechanism to deny coverage of those services, CMS and its various fiscal intermediaries appear to be increasingly ignoring this aspect of the rule. In the preamble to its final rule, "Medicare Program; Changes to the Criteria for Being Classified as an Inpatient Rehabilitation Facility," (otherwise known as the 'Seventy-Five Percent Rule' / 69 Fed. Reg. 25,752, 25,766 / May 7, 2004), CMS stated that "*[a]ll* admitted patients [to inpatient rehabilitation hospitals or units] must still meet coverage requirements for IRF care and be able to actively participate in 3 hours of multidisciplinary rehabilitation…" (emphasis added). This statement is wholly inconsistent with the agency's policies regarding the "Three Hour Rule."

Fiscal intermediaries are developing LCDs containing provisions addressing the "Three Hour Rule" that stand to inappropriately deny coverage of inpatient rehabilitation services for patients whose medical conditions limit their ability to participate in an intensive therapy program. These LCDs are being crafted to limit the applicability of the exception to the "Three Hour Rule" to circumstances in which a patient's condition temporarily interrupts or decreases the ability to participate in a three-hour regiment of intensive rehabilitation therapy, and if the patient is permitted to continue receiving inpatient rehabilitation services, the delay in participating in the three-hour regiment should not be prolonged. This policy further restricts access to inpatient rehabilitation services, contrary to standards established in the Medicare Benefits Policy Manual, as

nothing in it limits a patient's inability to participate in an intense level of rehabilitation services as a temporary circumstance.

Another significant issue associated with the "Three Hour Rule" relates to the particular mix of skilled rehabilitation modalities that a patient may require, on a priority basis, to satisfy the rule. Although CMS policy identifies physical and occupational therapies as two acceptable modalities, it also recognizes that there can be "exceptions" to them. The underlying policy rationale regarding this aspect of the "Three Hour Rule" is appropriately and correctly designed with the flexibility to permit physicians and the rehabilitation team to tailor a plan of care for patients based upon their specific medical conditions and needs.

CMS policy does not deem any particular skilled rehabilitative modality as unacceptable for purposes of satisfying the rule. Instead, the MBPM mentions, in an illustrative fashion, two alternative modalities (speech-language pathology services and prosthetic-orthotic services) that are acceptable replacements to physical or occupational therapies. The policy states as follows:

> In some instances, patients who require inpatient hospital rehabilitation services may need, on a priority basis, other skilled rehabilitative modalities *such as* speech-language pathology services, or prosthetic-orthotic services and their stage of recovery makes the concurrent receipt of intensive physical therapy or occupational therapy services inappropriate. In such cases, the 3-hour a day requirement can be met by a combination of these *other* therapeutic services instead of or in addition to physical therapy and/or occupational therapy.

MBPM, ch.1, §110.4.3 (emphasis added). Use of the words "such as" and "other" in this policy make it clear that speech-language pathology and prosthetic-orthotic services are a non-exhaustive list of replacement modalities for purposes of the "Three Hour Rule."

However, CMS has provided its fiscal intermediaries in recent months via informal instructions (i.e., e-mail) that the only skilled rehabilitative modalities that will satisfy the "Three Hour Rule" are occupational and physical therapy, and occasionally speech language pathology and prosthetic-orthotic services. This is inconsistent with the agency's long-standing policies as enumerated in the MBPM. It also inappropriately impedes upon the medical judgment of the physician and the clinical judgment of the rehabilitation team by removing from their discretion the clinical decision as to the appropriate mix of rehabilitation modalities that are needed by the patient on a priority basis.

Moreover, a number of fiscal intermediaries are including provisions in LCDs being developed for inpatient rehabilitation that reflect the inconsistent position taken by CMS regarding the issue of alternative rehabilitative modalities that can satisfy the "Three Hour Rule." In addition to inappropriately limiting the range of alternative rehabilitative modalities that can satisfy the rule, fiscal intermediaries are also seeking to

require patients to receive a limited set of specific services despite the fact that the MBPM specifically permits patients to satisfy the rule by receiving those rehabilitative therapy services that are determined by the rehabilitation team to be medically appropriate.

3. LCDs must be consistent with law, regulations and CMS policy

It is a basic principle of administrative law that a government agency (including an FI administering a government program) must follow agency guidelines and not act in a manner that is inconsistent with its own rules. This principle is reflected in the Program Integrity Manual, which states that "[t]he contractor shall ensure that LCDs are consistent with all statutes, rulings, regulations, and national coverage, payment and coding policies" (PIM§ 13.1.3), and that "[t]he LCD shall . . . not restrict or conflict with NCDs or coverage provisions in interpretative manuals. . ." (PIM §13.5).

FIs that add a new medical necessity criterion for inpatient rehabilitation are in conflict with the coverage provisions for inpatient rehabilitation set forth in the MBPM and, consequently, are in violation of the PIM. The medical necessity criteria for inpatient rehabilitation were published in the Federal Register in the form of a HCFA Ruling and, as such, are binding on all CMS contractors. *See* 42 C.F.R. §401.108.[6]

Courts have not hesitated to strike down agency policies or actions that are inconsistent with the agency's own rules. In State of New York o/b/o Beatrice Stein v. Secretary of HHS, 924 F.2d. 431 (2d Cir. 1991), this principle was applied in the context of Medicare coverage policy for inpatient rehabilitation. In that case, HCFA denied coverage of inpatient rehabilitation for a Medicare beneficiary but did not base its denial on the eight criteria set forth in HCFA Ruling 85-2.

On appeal of the denial, the court held that HCFA, in reviewing the medical necessity of inpatient rehabilitation, was required to apply the specific criteria promulgated by HHS through HCFA Ruling 85-2 to the facts of the case.[7] The court stated that "[w]hen a rule sets forth specific criteria, as HCFA Ruling 85-2 does, the Secretary's determination must contain an application of the criteria to the particular facts of the case." Id. at 433. The court also noted that the Secretary, in his brief, agreed that "coverage for inpatient rehabilitative hospital care is contingent on the patient's condition meeting each of [the] eight criteria." Id.

In a similar case, the same court held that the Secretary, in reviewing the medical necessity of inpatient rehabilitation, was required to follow the criteria in HCFA Ruling

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[6] HCFA Ruling 85-2 was issued to comply with the court's order in Hooper v. Harris, ~~(D. Conn. 1985)~~ 1985 WL 56560 (D. Conn. 1985). In Hooper, the court ordered that criteria for inpatient rehabilitation must be published in the Federal Register.

[7] Those criteria are the same as those published in section 211 of the Medicare Hospital Manual and recently transferred to §110.4 of the Medicare Benefits Policy Manual.

85-2 and that a decision to deny coverage "must contain an application of the criteria to the particular facts of the case." State of New York v. Sullivan, 927 F. 2d 57 (2d Cir. 1991). The court remanded that case to the Secretary where the Secretary and Appeals Council had failed to demonstrate a relationship between their findings and the HCFA 85-2 criteria.

LCDs which contain a blanket "less intensive setting" standard applicable after satisfaction of the eight criteria permit the FI to deny coverage based on the new criterion without reference to the criteria set forth in HCFA Ruling 85-2. This is exactly what was held to be incorrect by the courts in the cases discussed above.

IV. The LCDs Do Not Meet The "Reasonableness" Test Under Section 522 Of BIPA

Under BIPA §522[8] (42 U.S.C. §1869(f)(2)(A)), an ALJ must uphold an LCD if he or she determines that it is based on "reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law ...." *Id.* at §1869(f)(2)(A)(i)(III); *see also*, 68 Fed. Reg. 63,692, 63,703 (stating that "[i]n determining whether LCDs … are valid, the adjudicator must uphold a challenged policy … if the findings of fact, interpretations of law, and applications of fact to law by the contractor [or CMS] are reasonable …."). Regulations implementing this section of the law require the ALJ, in applying the reasonableness standard to an LCD, to "follow all applicable laws, regulations, rulings and NCDs." 42 C.F.R. §426.431.

A. An LCD That Conflicts With CMS Policy Does Not Pass The "Reasonableness" Test Under BIPA

As discussed above, the LCDs are in conflict with longstanding CMS medical necessity principles related to inpatient rehabilitation and with the PIM which requires LCDs to be consistent with CMS rulings and interpretative manuals. An ALJ, in reviewing the LCDs under the reasonableness standard, must adhere to and be guided by applicable CMS laws, regulations and other rulings. Because the LCDs are directly in conflict with CMS policy as set forth in HCFA Ruling 85-2 and the MBPM, it does not pass the reasonableness test.

B. An LCD Is Invalid If It Does Not Specify What Clinical Circumstances Will Be Considered Reasonable And Necessary

The PIM requires that LCDs specify "under what clinical circumstances a service is considered to be reasonable and necessary." PIM §13.1.3. This important principle is reiterated in §13.5.3 of the PIM in which contractors are cautioned to "clearly state what specific clinical situations would have to exist to be considered reasonable and

[8] BIPA §522 allows an "aggrieved" party to challenge LCDs, but does not permit providers or suppliers to do so. However, if an "aggrieved" party successfully challenges an LCD, it is invalid in the FI's jurisdiction.

necessary." An LCD that does not abide by this principle fails the essential purpose of an LCD. The new criterion being adopted by FIs which requires, in addition to the eight criteria set forth in the MBPM, that the care could not have been provided in a less intensive setting, causes the LCDs to fail this important test. Requiring, as a condition of coverage, proof that the patient could not have received the care in a less intensive setting, does not describe any clinical conditions. In fact, this criterion appears to relate more to the availability of other rehabilitation settings in the community than to the clinical conditions and medical needs of the Medicare beneficiary.

For example, would the provider be required to provide evidence of the lack of availability of the requisite level of rehabilitation at other sites in the geographic area? Must the patient's chart document which other sites were considered and why they were rejected? Must this be done for each type of "less intensive setting" (*e.g.* SNFs, HHAs, outpatient clinic)? How would this information or evidence differ from evidence that the patient meets the screening criteria for inpatient rehabilitation set forth in the CMS Manual? What must one demonstrate, in addition to the fact that the clinical conditions set forth in the eight criteria in the MBPM are satisfied in order to have a patient's inpatient care be considered reasonable and necessary? In essence, LCDs that employ the use of the "less intensive setting" criterion fail to educate or clarify the medical necessity requirements of inpatient rehabilitation care. As such, the less intensive setting criterion does not meet the requirement of an LCD and is arguably invalid.

C. The LCDs Do Not Pass The Reasonableness Test Because They Are Not Supported By The Record

Medicare law requires that an LCD must be evaluated based on a review of the record. The PIM sets forth specific instructions which intermediaries are expected to follow in developing a record to support an LCD. It states that "LCDs shall be based on the strongest evidence available" and sets forth, in order of preference, the types of evidence which should be used. They are:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
-
- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on
    - Scientific data or research studies in peer-reviewed medical journals;
    - Consensus of expert medical opinion (i.e. recognized authorities in the field); or
    - Medical opinion derived from consultations with medical associations or other health care experts. (PIM § 13.7.1.)

The eight screening criteria set forth in the CMS policy were developed through consultations with medical associations and experts in the field of rehabilitation and have been in place for at least twenty years. The eight criteria first published in HCFA Ruling 85-2 in 1985, were based on a 1980 document, Sample Screening Criteria for Review of Admission to Comprehensive Medical Rehabilitation Hospital/Units. This document was developed by the Committee on Rehabilitation Criteria for PSRO of the American Academy of Physical Medicine and Rehabilitation and the American Congress of Rehabilitation Medicine.[9] The document was subsequently approved by the Professional Standards Review Council whose work was funded by HCFA's Health Standards and Quality Bureau. The criteria were adopted by HCFA in a formal ruling published in 1985 and were subsequently added to the CMS Hospital and Intermediary Manuals before being cross-walked to the MBPM.

These criteria enjoy wide acceptance in the medical rehabilitation community. In contrast, the "less intensive setting" criterion being adopted by FIs through the LCD process does not have general acceptance in the medical rehabilitation community. In fact, rehabilitation professionals and inpatient rehabilitation hospitals strongly oppose this new standard. Rather than being based on "the strongest evidence available," the new LCD criterion appears to be based on no medical, clinical, or scientific evidence at all.

D. Medicare Review Criteria Used by FIs Must Be Consistent with Established CMS Criteria

The adoption of new criteria by FIs, through the LCD process, that differ from established CMS policy as set forth in HCFA Ruling 85-2 and the MBPM, will result in inconsistent denials of inpatient rehabilitation among the various FIs. This is directly at odds with CMS's goal of creating more consistency in coverage determinations. Further, affected providers will not know which set of rules will be applied to them. The purpose of an LCD is to assist providers in submitting correct claims for payment. PIM §13.1.3. LCDs that differ from CMS policy do not accomplish this purpose -- instead they are sources of confusion.

V. <u>If Inpatient Rehabilitation Is Denied Because The Provider Has Not Proved That The Care Could Not Have Been Furnished In A Less Intensive Setting, Beneficiaries Will Be Harmed As Well As The Medicare Program</u>

FIs are attempting to require that, in addition to meeting the eight CMS criteria, a provider must document that it would not have been appropriate to furnish the care in a less intensive setting. The FIs provide no guidance as to the type of documentation needed to establish that this criterion is satisfied. In essence, the FIs are requiring IRFs to prove a negative.

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[9] The American Academy of Physical Medicine and Rehabilitation is a physician specialty organization whose members are board-certified (or board-eligible) in physical medicine and rehabilitation. The American Congress of Rehabilitation Medicine is an organization whose members are professionals from various fields in rehabilitation medicine.

The practical effect of this kind of approach is that inpatient rehabilitation hospitals and units will be discouraged from admitting patients because they will be uncertain as to whether the care and services they provide will be covered. Even if a patient satisfies the eight criteria in the MBPM, care may be denied under the blanket "less intensive setting" criterion. Consequently, physicians will feel constrained to first send patients to less intensive settings to prove that those settings are not sufficiently intense before admitting them to an inpatient rehabilitation hospital or unit. This delay in appropriate rehabilitation could have a significant detrimental effect on the patient's functional improvement. In some cases, the "window of opportunity" for improvement in function could be lost. Even worse, the patient's functional status could decline irreparably.[10]

An irreparable loss of recovery of function could result in increased costs to the Medicare program for home health services and may increase the likelihood of subsequent complications resulting in acute care hospitalization. For example, patients who have had a knee replacement or stroke may develop contractures, de-conditioning, unrecognized neurological decline, or further decline of their original impairment or disease process, any one of which could require re-hospitalization in an acute care setting.

Even more serious is the case in which medical complications arise which cannot be adequately addressed within a SNF or in the home setting, resulting in death or permanent disability. For example, patients requiring anti-coagulation secondary to a medical issue, recent surgery, or neurological deficit often require more frequent medical monitoring than may be anticipated and at a level that is not provided in a SNF or other less intensive setting. Excess dosing of the patient could result in internal bleeding, while inadequate dosing could result in deep venous thrombosis or pulmonary aneurysm resulting in sudden death.

A delay or denial of in inpatient rehabilitation in favor of care in a less intensive setting may also harm the Medicare program because it may ultimately cost more to care for that patient. This could occur under a number of scenarios. For example, if a patient is first referred to a less intensive setting (*e.g.* a SNF or home health care setting), and that care is not effective, Medicare dollars would have been spent on unnecessary or inappropriate care if the patient is ultimately admitted to an inpatient rehabilitation hospital or unit. Further, the length of stay in the IRF, as a result of the delay in treatment, may be considerably longer.

VII. Conclusion

For the reasons stated in this analysis, we urge CMS and the fiscal intermediaries to reaffirm the view that satisfaction of the eight criteria listed in §110.4 of Chapter 1 of

[10] The harmful consequences of a delay in appropriate treatment resulting from inappropriate denial of care for Medicare beneficiaries was recognized by the court in Hultzman v. Weinberger, 495 F.2d 1276 (3d Cir. 1974).

the MBPM is the proper standard for determining the medical necessity of inpatient rehabilitation services and to refrain from imposing additional inappropriate and unsupported criteria on this long-established process.

Attachment C

Reasons for Denials

If MoO retains the "Reasons for Denial" section of the proposal, which we suggest should be repealed, we suggest the following modifications.

1. **Current language:** There is no reasonable expectation of improvement in quality of life or level of functioning.
Recommendation: "There is no expectation of a significant practical improvement in a reasonable period of time, measured against his/her condition at the start of the rehabilitation program." This statement reflects language from Section 110.4.6. In addition, there are no clear guidelines for determining the improvement in quality of life at this time.

2. **Current language:** "The services are available in a less intensive setting (Outpatient or SNF)."
Recommendation: A broad statement like this gives providers and reviewers no guidance on criteria used to make such a determination. At a minimum, the rationale for such a determination should be provided in each case where this reason for denial would be applied. However, we recommend changing it to: "The services did not require 24 hour physician availability, 24 hour rehabilitation nursing, a relatively intense level of rehabilitation services, and a multidisciplinary team approach to delivery of the program." This statement reflects the language in Sections 110.4.1, 110.4.2 and 110.4.4.

3. **Current language:** "The reason for admission is due to a medical condition that is appropriately considered part of the acute inpatient stay (premature discharge)."
Recommendation: This is a very broad statement. It would give providers and reviewers no guidance on criteria used to make such a determination. Furthermore, if the reason for admission is due to a premature discharge from the acute care side, this is an acute care issue and the rehabilitation facility that admits the patient, addresses the medical condition, and improves the patient's functioning should not be penalized. The issue of premature discharge from the acute care side is addressed as a payment rule through the Medicare post acute care transfer policy, and we believe as a quality issue by the QIOs. We recommend using the following language instead: "The patient has a medical condition that precludes participation in the rehabilitation program, even a low intensity rehabilitation program.

4. **Current language:** "Some or all of the services that contributed to the 3 hour requirement were not skilled."
Recommendation: "Patient functional status showed no progress toward rehabilitation goals for the past 14 days, and no medical condition/complication has been documented to show a cause for the lack of functional progress."

5. **Current language:** "Multi-disciplinary care was not provided. (OT services did not exceed the skillset of PT as function would be expected to recover with the return of strength and ROM.)"
Our recommendation: We recommend this reason for denial be deleted as the focus is on patient's functional loss, including loss of activities of daily living skills. As noted above, the occupational therapist is an important member of the multidisciplinary team, enhancing beneficiaries' care with specialized training strategies, adaptive equipment, and other techniques to assist in achieving the multidisciplinary treatment program. Again, Section 110 specifies there is a reasonable expectation of measurable improvement that will be of practical value to the patient measured against his condition at the start of the rehabilitation program. Limiting the goals to strength and ROM is more restrictive that Section 110.

6. **Current language:** Reasons for denials listed in the draft LMRP include:

a. Services provided after a given date were not medically necessary in an inpatient environment as the patient no longer required an inpatient level of care. (Documentation does not justify LOS.)
b. Physician did not order an intensive level of care as described in this policy.
c. Coordinated multidisciplinary care was not required.
d. Facility did not provide the services ordered such that an intensive level of care was not provided for the bulk of the inpatient stay.

Recommendation: We recommend deleting these reasons for denials, as the issued are covered within the above recommendations.

Attachment D

Research Articles for Policy Development on Inpatient Rehabilitation Medical Review

Botney, Richard, Brett R. Stacey, Aaron M. Levine, Michael C. Munin, Thomas E. Rudy, Nancy W. Glynn, Lawrence S. Crossett, and Harry E. Rubash.
"Rehabilitation After Hip and Knee Arthroplasty." JAMA 1998 280: 1402-1403.

Munin, Michael C., Thomas E. Rudy, Nancy W. Glynn, Lawrence S. Crossett, and Harry E.Rubash.
"Early Inpatient Rehabilitation After Elective Hip and Knee Arthroplasty." JAMA 1998 279: 847-852. Munin's study is not exactly on pointbut it does suggest that early rehabilitation saves money and improves function faster.

Kramer, A.M., J.F. Steiner, R.E. Schlenker, T.B. Eilertsen, C.A. Hrincevich, D.A. Tropea, L.A.Ahmad, and D.G. Eckhoff.
"Outcomes and costs after hip fracture and stroke. A comparison of rehabilitation settings." JAMA 1997 277: 396-404.

American Academy of Physical Medicine and American Medical Rehabilitation Providers Association bibliography on "Cost Benefit of Rehabilitation."

Duncan, P.W., R.D. Horner, D.M. Reker, G.P. Samsa, H. Hoenig, B. Hamilton, B.J. LaClair, and T. Dudley.
"Adherence to postacute Rehabilitation Guidelines is Associated With Functional Recovery in Stroke." STROKE 2002; 33: 167-178.

Kong, K. et al.
"Functional outcomes of patients on a rehabilitation unit after open heart surgery." J Cardiopulmonary Rehabil 1996; 16:413-418.

Sansone, G. et al.
"Analysis of FIM instrument scores for patients admitted to an inpatient cardiac rehabilitation program." Arch Phys Med Rehabil 2002; 83: 506-512.

Stewart, D. et al.
"Benefits of an inpatient pulmonary rehabilitation program: A prospective analysis." Arch Phys Med Rehabil 2001; 82: 347-352.

Votto, J et al.
"Short stay comprehensive inpatient pulmonary rehabilitation for advanced chronic obstructive pulmonary disease." Arch Phys Med Rehabil 1996; 77: 1115-1118.

Lichtman, S. et al.
"Long term follow- up of extended acute (Phase 1B) inpatient medical rehabilitation for patients with cardiac disease: A multi-center trial." In press.

Munin, M. et al.
"Early inpatient rehabilitation after elective hip and knee arthroplasty." JAMA 1998; 279, No. 11: 847-852 (also referenced above).

Munin, M. et al.
"Predicting discharge outcome after elective hip and knee arthroplasty." Am JPhys Med Rehabil 1995; 74, No. 4: 294-301.

Jha, A. et al.
"Dissatisfaction with medical services among Medicare beneficiaries with disabilities." Arch Phys Med Rehabil 2002; 83: 1335-1341.

Clauser, Ph.D., Steven B. Clauserand Arlene S. Bierman, M.D.
"M.S. Significance of Functional Status Data for Payment Quality." Health Care Financing Review, Conference Proceedings Measuring Functional Status Spring 2003: Volume 24, Number 3.

Jette, Ph.D., Alan M., Stephen M. Haley, Ph.D., and Pengsheng Ni, M.P.H, M.D.
"Comparison of Functional Status Used in Post-Acute Care." Health Care Financing Review, Conference Proceedings Measuring Functional Status Spring 2003, Volume 24, Number 3.

Carter, Ph.D., Grace M., Daniel A. Relles, Ph.D., Gregory K. Ridgeway, Ph.D, and Carolyn M.Rimes, M.A.
"Measuring Function for Medicare Inpatient Rehabilitation Payment." Health Care Financing Review, Conference Proceedings Measuring Functional Status**,** Spring 2003, Volume 24, Number 3.

Buchanan, Ph.D., Joan L., Patricia L. Andres, M.S., P.T., Stephen M. Haley, Ph.D., P.T., Susan M. Paddock, Ph.D., and Alan M. Zaslavsky, Ph.D.
"An Assessment Tool Translation Study.**"** Health Care Financing Review, Conference Proceedings Measuring Functional Status Spring 2003, Volume 24, Number 3.

Iezzoni, M.D., M.Sc., Lisa I., and Marjorie S. Greenberg, M.A.
"Capturing and Classifying Functional Status Information in Administrative Databases." Health Care Financing Review, Conference Proceedings Measuring Functional Status Spring 2003, Volume 24, Number 3.

Bedirha n Somnath Chatterji, M.D., T., Nenad Kostansjek, M.Sc., and Jerome Bickenbach, Ph.D.,L.L.B.
"WHO's ICF and Functional Status Information in Health Records." Health Care Financing Review, Conference Proceedings Measuring Functional Status Spring 2003, Volume 24, Number 3.

Harris, R.N., Ph.D., Marcelline R., Alexander P. Ruggieri, M.D., and Christopher G. Chute, M.D., Dr.P.H.
"From Clinical Records to Regulatory Reporting: Formal Terminologies as Foundation." Health Care Financing Review, Conference Proceedings Measuring Functional Status Spring 2003, Volume 24, Number 3.