Bruce M. Gans, MD
Kessler Institute for Rehabilitation
Chairman of the AMRPA Board

January 30, 2009

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RTI International
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Julie M. Stankivic
Health Insurance Specialist
Centers for Medicare and Medicaid Services
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Re: Medicare, Medicaid and SCHIP Extension Act of 2007 Report to Congress on Medicare Classification Criteria for Inpatient Rehabilitation Facilities

Dear Dr. Gage and Ms. Stankivic:

These comments are submitted in conjunction with the Town Hall Meeting held on February 2 regarding the above referenced Report to Congress. They are submitted on behalf of the American Medical Rehabilitation Providers Association (AMRPA). AMRPA is the sole national trade organization representing inpatient rehabilitation hospitals and units (IRH/Us) as well as numerous outpatient rehabilitation service providers. The vast majority if not all of our members participate in Medicare and serve over 475,000 Medicare beneficiaries and non Medicare patients a year, plus several hundred thousand outpatients a year.

AMRPA is on record as being exceptionally concerned about the existing Medicare classification criteria for IRH/Us, and particularly concerned about the criterion referred to as the "75 % rule." We appreciate this opportunity to submit these comments to RTI and the Centers for Medicare and Medicaid Services (CMS) as it embarks on formulating the Report to Congress as required by Section 115(c)of the Medicare, Medicaid SCHIP Extension Act of 2007 (MMSEA of 2007) and we look forward to working with RTI.

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The MMSEA requires the Secretary of the Department of Health and Human Services (HHS) submit to Congress within 18 months of enactment a report which includes the following:

1. An analysis of Medicare beneficiaries' access to medically necessary rehabilitation services, including the potential effect of the 75 percent rule on access care.
2. An analysis of the alternatives or refinements to the 75 percent rule policy for determining criteria for inpatient rehabilitation hospital and unit designation under the Medicare program, including alternative criteria which would consider a patient's functional status, diagnosis, co-morbidities, and other relevant factors.
3. An analysis of the conditions for which individuals are commonly admitted to inpatient rehabilitation hospitals that are not included as a condition described in the 75% rule, 42 CFR 412.23 (b)(2)(iii), to determine the appropriate settings of care, and any variation in patient outcomes and costs, across settings of care, for treatment of such conditions.

SUMMARY OF AMRPA RECOMMENDATIONS

AMRPA's complete recommendations are attached to this letter. I have summarized them here for easy reference.

I. Purpose of the Classification Criteria and the Purpose of Medical Coverage Criteria

The purpose for establishing the classification criteria for inpatient rehabilitation hospitals and units in 1982 was to distinguish them from the inpatient acute care hospitals that were about to be paid under the diagnosis based inpatient prospective payment system (IPPS) and allow them to continue to be paid on a cost basis subject to a limit under to the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA).

We believe that in order to accurately conduct this study well it is vitally important that two distinct issues be addressed. We believe there has been confusion between the purpose of the exclusion criteria and the Medicare coverage criteria. The inpatient rehabilitation hospital Medicare coverage criteria are now found both at HCFA Ruling 85-2 and the Medicare Benefit Policy Manual, (MBPM) Section 110, Inpatient Hospital Stays for Rehabilitation Care.

We recommend for purposes of this study that it be clear as to which issue is being addressed; criteria to determine eligibility of a facility for payment under the rehabilitation payment system, or benefit coverage determination for a specific patient to be treated in an IRH/U.

We recommend the following as two sets of principles for the definition of an inpatient rehabilitation hospital or unit and for making determinations for medical coverage and appropriateness.

A. Principles for the Definition of an IRF

1. The definition should be based on factors that describe facility service delivery characteristics, including:

- the programs and services offered (e.g., medical rehabilitation, physicians, nurses, rehabilitation therapists, both availability and skill levels);
- physical plant attributes (e.g., therapeutic treatment space); and
- patient care processes (e.g., plan of care, multidisciplinary team approach, quality and outcomes).

2. The definition should speak to patient care attributes as a secondary factor. For example, acute care hospitals provide care to severely ill people who require major nursing and medical or surgical care; psychiatric hospitals provide care to people with mental illnesses who require medical and nursing care; and rehabilitation hospitals and units provide care to seriously impaired and disabled people with major improvable functional deficits who require medical, rehabilitation nursing, and rehabilitation therapies.

B. Principles for Medical Coverage and Appropriateness Criteria

1. Medical coverage criteria should be based upon scientific evidence when it is available.
2. In the event the evidence base is inadequate, the criteria should be based on qualified expert medical judgment.
3. The criteria should be based upon a reasonable *prediction* that the patient needs IRH/U care rather than a retrospective review of completed patient stays
4. The criteria need to recognize the combination and interaction of a patient's needs for medical treatment (such as daily rehabilitation physician care), surveillance for complications such as venous thromboembolic events, pressure sores and active rehabilitation treatments.
5. The criteria need to incorporate the patient's needs and potential to benefit from coordinated, orchestrated intense rehabilitation therapy services that are goal directed.
   The criteria need to consider and balance the interaction between the patient's medical and functional need and overall volatility for both medical and functional change.

II. Access Issues

The MMSEA amendments made the 60% threshold and co morbidity policy permanent thereby bringing a degree of stability to the IRH/ U field. However the field remains under great pressure and is challenged by continued retrospective coverage denials by the fiscal intermediaries, Medicare Administrative Contractors and is anticipating the activity of the national RAC contractors as well. Hence we find that access to IRH/U care continues to be constrained.

III. Alternatives to the 75% Rule

AMRPA recommends that CMS and RTI move away from the diagnostic based 75% rule and move toward a non diagnostic approach to the exclusion criteria as embodied in Appendices D and E. Establishing such a new definition would be practical and should be accompanied by a new way to establish medical necessity which is discussed below.

IV. Refinements to the 75% Rule

A. If CMS does not choose to reject the diagnostic based criterion, then it may consider the use of other factors such as function, or complications and co morbidities. However the existing data to develop a realistic evidence based alternative are not robust enough for this purpose. Hence AMRPA recommends that CMS and RTI collect and analyze the CARE tool data with an eye toward using the functional data in a way to describe patients (assuming a patient oriented criterion) and convene a panel of experts to discuss any proposals to move toward using either criterion.

B. CMS may also consider using the Rehabilitation Impairment Categories except for the "Miscellaneous" category.

V. Additional Conditions for the 75% Rule

AMRPA recommends that if CMS retains the 75% rule that it broaden and enhance the condition categories to recognize the greater variety of clinical circumstances in today's world that require IRH/U care such as cardiac, pulmonary, cancer, organ transplantation and pain patients.

VI. Medical Necessity Criteria

AMRPA believes the evidence base is not adequate upon which to promulgate any new or revised criteria. Hence we believe other steps are necessary. The first is to develop or adopt tools with field credibility. Second, CMS and RTI should create new medical necessity coverage criteria through an expert consensus process that can regularly review and update criteria as they are developed.. This panel should become a permanent Rehabilitation Advisory Panel to conduct this work as part of the ongoing CMS process.

VII. Developing Standards for Other Rehabilitation Providers and Conducting Necessary Research

A large issue in the current discussion is the apparent belief that there is full substitutability for IRH/U care by skilled nursing facilities (SNFs) and other entities. AMRPA believes that there are insufficient standards and criteria for rehabilitation programs and services in other settings such as skilled nursing facilities or long term care hospitals to assure consumers that there is equivalence in the rehabilitation programs delivered and outcomes achieved. We furthermore believe that there is inadequate information collected by Medicare as to patients served, services provided and outcomes achieved to assess whether the outcomes and quality of care are acceptable.

Therefore, in concert with either approach above, be it replacing or altering the 75% rule, AMRPA recommends that CMS and RTI develop regulatory standards to define rehabilitation programs and services in other settings which protect patients and consumers and which promote consistent program quality. These efforts should also establish consistent data collection systems to assess quality and outcomes in each setting.

To do so would require supporting and conducting comparative effectiveness research to determine the best setting for specific clinical conditions among the various rehabilitation

provider types and incorporating the results as they become available from that research into the medical necessity criteria.

AMRPA appreciates the opportunity to work with RTI and CMS as it seeks to meet the requirements of the MMSEA 75% rule Report to Congress. Please feel free to call me at 973 - 324-3658, or at bgans@kessler-rehab.org or Carolyn Zollar at AMRPA at 202 223 1920, czollar@amrpa.org if you have any questions.

Sincerely,

Bruce M. Gans, M.D.
Chair
AMRPA

Executive Vice President
Chief Medical Officer
Kessler Institute for Rehabilitation

American Medical Rehabilitation Providers Association

AMRPA COMMENTS ON THE CMS 75% RULE STUDY TOWN HALL MEETING FEBRUARY 2, 2009

I. PURPOSE OF THE CLASSIFICATION CRITERIA FOR INPATIENT REHABILITATION FACILITIES

The purpose for establishing the classification criteria for inpatient rehabilitation hospitals and units in 1982 was to distinguish them from the inpatient acute care hospitals that were about to be paid under the diagnosis based inpatient prospective payment system (IPPS) and allow them to continue to be paid on a cost basis subject to a limit under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA).

We believe that in order to accurately conduct this study well it is vitally important that two distinct issues be addressed. We believe there has been confusion between the purpose of the exclusion criteria and the Medicare coverage criteria. The inpatient rehabilitation hospital Medicare coverage criteria are now found both at HCFA Ruling 85-2 and the Medicare Benefit Policy Manual, (MBPM) Section 110, Inpatient Hospital Stays for Rehabilitation Care.

The purpose of the exclusion criteria are to define an entity providing care similar to a long term care hospital (LTCH) or other IPPS excluded entity. The sole focus was to define entities as different from acute care hospitals *for payment purposes*. The purpose of the Medicare coverage criteria are to assure that services provided are reasonable and necessary pursuant to Section 1862 of the Medicare Act.

We recommend for purposes of this study that it be clear as to which issue is being addressed: criteria to determine eligibility of a facility for payment under the inpatient rehabilitation facility prospective payment system, or benefit coverage determination for a specific patient to be treated in an IRH/U.

We recommend the following as two sets of principles for the definition of an inpatient rehabilitation hospital or unit and for making determinations for medical coverage and appropriateness.

A. Principles for the Definition of an IRF

1. The definition should be based on factors that describe facility service delivery characteristics, including:

- the programs and services offered (e.g., medical rehabilitation, physicians, nurses, rehabilitation therapists, both availability and skill levels);
- physical plant attributes (e.g., therapeutic treatment space); and
- patient care processes (e.g., plan of care, multidisciplinary team approach, quality and outcomes).

2. The definition should speak to patient care attributes as a secondary factor. For example, acute care hospitals provide care to severely ill people who require major nursing and medical or surgical care; psychiatric hospitals provide care to people with mental illnesses who require medical and nursing care; and rehabilitation hospitals and units provide care to seriously impaired and disabled people with major improvable functional deficits who require medical, rehabilitation nursing, and rehabilitation therapies.

B. Principles for Medical Coverage and Appropriateness Criteria

1. Medical coverage criteria should be based upon scientific evidence when it is available.
2. In the event the evidence base is inadequate, the criteria should be based on qualified expert medical judgment.
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5. The criteria need to incorporate the patient's needs and potential to benefit from coordinated, orchestrated intense rehabilitation therapy services that are goal directed.
6. The criteria need to consider and balance the interaction between the patient's medical and functional need and overall volatility for both medical and functional change.

II. HISTORY OF THE CLASSIFICATION CRITERIA FOR IRFS

The purpose of the classification criteria (hereinafter exclusion criteria) was to distinguish rehabilitation hospitals and rehabilitation units from acute care hospitals based on the changes made by the Social Security Amendments of 1983 (P.L. 98-21). Sections 1886(d)(1)(B) and d(1)(B)(ii) excluded rehabilitation hospitals and units from the IPPS and gave the Secretary authority to define each entity. CMS's predecessor, the Health Care Financing Administration, (HCFA) issued proposed regulations on September 1, 1983, and final rules on January 3, 1984. The criteria are now found at 42 CFR 412.23 (b) (ii). In that initial proposal CMS stated that it included the75% Rule as a defining feature of a rehabilitation hospital because it believed "that examining the types of conditions for which a hospital's patients are treated and the proportion of patients treated for conditions that typically require intensive inpatient rehabilitation, will help distinguish those hospitals in which the provisions of rehabilitation services is a primary, rather than a secondary, goal." (48 FR 39756)

CMS published various changes to the rules from 1985 to 2002 pertaining to compliance by new facilities, new rehabilitation units and for other reasons, but did not change the original 10 conditions that were part of the rule published in January 1984.

On May 16, 2003, CMS published the Inpatient Rehabilitation Facility Prospective Payment System (IRF-PPS) Proposed Rule for FY 2004. In that document CMS discussed extensively the 75% rule, the results of its survey of fiscal intermediaries and a study it had commissioned from the RAND Corporation to examine compliance with the rule based on a definition CMS provided. It later published another proposed rule on September 9, 2003. A final rule extensively revising the rule was published on May 7, 2004. The rule changed the list of conditions from 10 to 13 and dramatically revised those applicable to arthritis and related joint replacement cases, added a co-morbidity policy for purposes of compliance with the rule and provided a phased in compliance percentage threshold over 4 years starting with cost reporting periods beginning on or after July 1, 2004. The latter two aspects of the rule were subsequently amended by statute, with the last amendments being found in Section 115(a) and (b) of the MMSEA of 2007. See Appendix A for a more detailed history of the rule.

IV. COMMENTS ON MMSEA STATUTORY REQUIREMENTS FOR THE REPORT

A. Medicare Beneficiaries' Access to Medically Necessary Rehabilitation Services, Including Potential Effects of the 75% Rule

AMRPA has been tracking access to inpatient medical rehabilitation services since the inception of its primary database, eRehabData® in 2002. Prior to that, it utilized its predecessor data base, PF2K, for tracking data from approximately 2000. We have observed that in the third quarter of 2004, access to IRH/U services started to be constrained. Admissions to IRH/Us have declined an average of 9.4% from 2004 to 2007 annually.

At the same time that CMS started evaluating compliance with the rule in 2002, CMS issued a transmittal to the Fiscal Intermediaries (FI) stating that responsibility for medical reviews for inpatient rehabilitation facilities (and some other providers) was being transferred to the FIs. In order to implement this new responsibility, many of them drafted proposed Local Coverage Determinations (LCDs) for Inpatient Rehabilitation. These FIs included Riverbend, TN; Cahaba, AL; Blue Cross and Blue Shield of Georgia; Administar Federal; Mutual of Omaha; Trispan; First Coast and AHS. In addition and without regard to the LCDs, many of these FIs, as well as others, started to conduct both pre-payment and post-payment medical necessity reviews, with what appeared to be a specific focus on orthopedic and arthritis cases. By 2007 these reviews were occurring in at least 33 states. A third prong to the medical review activities was the Recovery Audit Contractor (RAC) demonstration program which was mandated by the Deficit Reduction Act of 2005. The RAC contractor in California was particularly severe in conducting these audits. AMRPA believes that these activities coupled with the IRF's efforts to come into compliance with the 75% Rule percentage thresholds each year have and are resulting in decreased access to IRF services. AMRPA does not anticipate that there will be a dramatic change in these trends in the immediate future.

AMRPA observed that facilities started to amend their admission practices with the initial proposed rule in May 2003. The decrease in admissions increased dramatically starting in the period from July 2004 to July 2005 as compared to July 2003. We believe that these early years

were driven almost entirely by efforts to comply with the rule and the continued drops reflect the dynamic of the two factors mentioned above. Our eRehabData® quarterly updates show that as of the 4th quarter in 2008 we observed an overall decline in Medicare patients of over 148,141 patients. This figure represents a drop in Medicare patients of 31.58% compared to July 1, 2003 to June 30, 2004, a Percentage of Discharges by Payer. See Appendix B, *Patient Reductions in Inpatient Rehabilitation Facilities Required to Meet May 7, 2004 75% Rule Compared to July 1, 2003 – June 30, 2004, As a Percentage of Discharges by Payer, Updated January 26, 2009.*

Other studies also reflect similar trends. The Moran Company tracked the impact of the rule for several years and reported similar volume of drops. MedPAC has also tracked the impact of these serious changes on IRFs initially through a RAND study, *"Comparison of Medicare Spending and Outcomes for Beneficiaries with Lower Extremity Joint Replacements"*, June 2005. RAND found that ultimately, in order to fully assess the impact of the 75 percent rule, "we would need three additional types of information. First we would ideally measure real resource use across sites of care rather than measuring only Medicare payments. Second, we would need a method for evaluating the trade-off between better outcomes and higher costs. Finally, we would need better measures of outcomes, including a measure of functional status that was captured consistently across all discharge settings. "

Starting the next year, 2006, MedPAC began assessing payment adequacy for IRFs. In doing so each year it has taken a close look at the issue of access to facilities and each year has noted that accurately assessing access is difficult. MedPAC has carefully noted each year, including the staff presentations in January of this year, that the volume of admissions continues to drop and that the entire IRF infrastructure is shrinking dramatically.

On one hand the MMSEA provision setting the compliance percentage threshold at 60% has brought a degree of stability to the field with respect to the rule alone and it also provides flexibility in the cases that may be admitted. However AMRPA believes the result of the rule and the interplay with the current and anticipated medical reviews create an ongoing problem. AMRPA estimates that before the industry stabilizes itself, over 4,000 beds will be lost. As noted in our January 26 analysis of trends in admissions, the increases are occurring in the non Medicare population. We find that IRFs are managing to the 60% rule for their Medicare patients at a compliance rate of 61%. Their non Medicare patients trend to be more compliant at approximately 73%, for an overall average for all patients of 67%. With the passage of the MMSEA amendments we anticipated an uptick in the Medicare admissions. However, that has not, to date, proven to be true. The rate of decrease has slowed but on an annual quarter to quarter comparison (to even out seasonal variation) it continues to drop. For example, from Q4 07 to Q4 08, Medicare patients dropped 3.02% and all payers increased slightly by 0.09%.

B. Alternatives and Refinements to the 75% Rule Including Alternative Criteria Which Would Consider Functional Status, Diagnosis, Comorbidities and Other Factors

1. Alternatives to the 75% Rule

The MMSEA study requirements give CMS an excellent opportunity to reconsider the 75% rule and the IRF exclusion criteria. To that end AMRPA recommends that CMS focus on alternatives to the criteria and specifically delete it from the exclusion criteria.

Using diagnostic based criteria is not uniquely or sufficiently representative of the true needs, nor of the value of inpatient rehabilitation to the patients. Furthermore, inpatient rehabilitation facilities are uniquely subject to these criteria. Diagnostic categories are not used to define an acute care, hospital, a skilled nursing facility, an outpatient facility or a home health agency. If an acute care hospital provides services that fall under one of the multiple MS DRGs, it is paid for the DRG. Payment is not limited by a requirement that a certain percentage of the hospital's cases must fall within a limited list of specific DRGs. It does not make sense to require an acute care hospital to have 75% of its cases fall into 10 or 13 conditions in order to be paid.

It is telling that a key document that forms part of the historical basis for the rule, the PSRO Technical Assistant Document Number 24 was drafted initially for a totally different purpose. It was intended provide guidance to the PSROs for purpose of admission criteria for clinically appropriate patients, not to provide a basis for distinguishing an IRF from an acute care hospital. Furthermore a diagnostic based system is insensitive to the special needs of individual patients. CMS has recognized this most recently in changing from the diagnosis related groups (DRGs) to the Medicare Severity DRGs (MS DRGs). Part of the debate over the 75% rule centers on the fact that the rule has moved away from its original purpose and is confused with the issues of medical necessity noted above. The rule is being used as a crude measure of medical necessity. As Med PAC noted in testimony before the House Ways and Means Committee Subcommittee on Health and in its comment letter on the FY 2008 IRF PPS proposed rule, the 75% rule is a blunt instrument.

AMRPA has undergone an comprehensive evaluation of state law and regulation to determine if any states define inpatient rehabilitation hospitals and, if so, whether the definitions include diagnostic criteria. While the analysis has not yet been completed, we have found that a number of states include inpatient rehabilitation hospitals (and therefore units) in the state's definition of a hospital. Other states include more comprehensive standards, but do not include a diagnostic standard. For example, the Pennsylvania Department of Health law sets forth requirements for organization, staffing, facilities, equipment plan of care and patient medical records. However, the requirements do not include a diagnostic standard. In a similar manner, the New Jersey Administrative Code includes a Manual of Standards for Licensure of Rehabilitation Hospitals, but does not utilize a diagnostic based criterion. See Appendix B, State Codes and Regulations.

Therefore AMRPA recommends that CMS move away from the 75% rule and focus on a larger framework that embraces the principles set forth above. To that end, AMRPA convened a work group to develop an alternative definition that meets these principles. It proposed to remove the 75% rule and revise the other exclusion criteria. The proposal and draft implementing regulations are attached at Appendices D and E. AMRPA recommends that CMS adopt this definition and include it in its Report to Congress. To do so would clarify the purpose of a rehabilitation hospital and unit and further clarify the discussion regarding medical appropriateness.

AMRPA recommends that CMS and RTI move away from the diagnostic based 75% rule and move toward a non diagnostic approach to the exclusion criteria as embodied in Appendix D and E.

2. Alternative Approach to Measuring Compliance with the 75% Rule

In lieu of replacing the rule or refining it, CMS may also consider an alternative to its current enforcement methodology. Currently, CMS uses a presumptive methodological approach to determine compliance. If 50% of a provider's patients are Medicare Part A beneficiaries and are representative of the total patient population, CMS allows the use of the presumptive method which is based on existing IRF PAI data. If the IRF PAI data as reported by CMS's contractor show the provider does not meet the 60% level, then the fiscal intermediary will conduct a record review of all patients to determine compliance. If the provider does not meet the threshold based on that review, it generally loses its exclusion status.

Several AMRPA members have suggested another step be considered prior to loss of the exclusion status. Under this option, the fiscal intermediary would convene a panel of three experts, to have experts survey the facility and determine if it is truly providing rehabilitation pursuant to all the other criteria. If so, it would be allowed to keep its exclusion. For example if a rural rehabilitation hospital had a high load of cancer patients and was the only facility suited to provide appropriate care and rehabilitation, the panel may find that it is truly providing a comprehensive medical rehabilitation program because the vast majority of the patients participate in the program.

3. Refinement of the 75% Rule

In the event CMS wishes to retain an exclusion criteria that focuses on patients' characteristics and simultaneously move away for a diagnosis based approach, AMRPA offers the suggestions below.

a. Functional Status

A patient's functional status is one of the key factors in determining whether the person is a viable patient for a rehabilitation hospital or unit. However, there are many other critical factors to consider, including medical status, living situation and others. When the IRF PPS was first implemented one thought was to consider including for purposes of the rule specific CMGs and not others. We reject that approach as discriminatory against specific patients needing care. Another proposed approach would be to consider patients within a specific functional range to be compliant with the rule. However upon a close inspection of the CMG "cut points" for function, it would again be too easy to inadvertently exclude certain patients. For example, it is universally agreed that severe traumatic brain injury patients with a motor functional score on admission of less than 22.5 (See CMG 0207) need rehabilitation care. However, under the CMG "cut points" proposal, these patients could be perversely excluded from treatment. Additionally the current measures of functional status imbedded in the IRF PAI have been found to have some weaknesses

in measurement. These include floor and ceiling effects. Furthermore, certain measures are non-existent, limited or weak.

We note further our disagreement with the recommendations in the 2005General Accountability Office (GAO) report, "*More Specific Criteria Needed to Classify Inpatient Rehabilitation Facilities.*" The report recommended using function to describe subgroups within the existing 13 conditions. AMRPA does not support that approach in that it would further restrict the patients considered within the scope of the rule and further jeopardize access.

The Post Acute Care Payment Reform Demonstration Program (PAC-PRD) CARE tool expands upon the functional data and measures in the IRF PAI. **Hence AMRPA recommends that CMS and RTI collect and analyze the CARE tool data with an eye toward using the functional data in a way to describe rehabilitation patients and convene a panel of experts, including national trade association representatives to discuss any proposals to move to a functionally based criterion.**

In summary, CMS and RTI might consider utilizing function alone as a criterion or consider adding it to any expanded conditions to be included in the list of conditions. In any case, the decision must be based on additional, more robust data.

b. Co-morbidities and Complications

Another non diagnostic patient factor is the presence or lack of complications or co morbidities. A large number of rehabilitation patients present on admission with numerous complications and co morbidities. Some of these are apparent during preadmission assessments, while some occur shortly after admission or during the stay. The IRF PAI captures some highly limited information on co morbidities for purposes of payment in item 24, Comorbid Conditions. Some providers complete additional information in item 47 on the form "Complications". However we are concerned that the co morbidities allowed for in the IRF PPS are too limited for purposes of a given criteria and do not necessarily give a complete picture of all the co morbidities. Given that the majority of IRF patients are Medicare beneficiaries, it is not surprising to see multiple complications and co morbidities such as cardiac conditions, diabetes and obesity in one patient.

If CMS and RTI were to consider such a criterion, AMRPA cautions that the data on the IRF PAI may be too limited or undependable. Other data sources would need to be examined such as claims data for the ICD 9 codes to match against the IRF PAI data. In addition, the PAC PRD CARE data should also be considered. **Once this data review is completed, AMRPA recommends that CMS and RTI convene a broad based panel of experts from the rehabilitation field, including from the trade organizations, to consider the data and any potential recommendations for amending the rule**.

c. Utilizing the Rehabilitation Impairment Categories

Another approach to refining the rule is to replace the current conditions with the Rehabilitation Impairment Categories (RICs), with the exception of the 'Miscellaneous' category. Patients within each of the currently excluded RICs require the intensive, multidisciplinary care provided by IRFs.

In summary, AMRPA recommends that if CMS wishes to continue with a patient specific oriented criterion that it do the following:

(i) If CMS and RTI consider the use of functional status and/or complications and co morbidities as the basis of a criterion:

- **I. More data should be gathered beyond what is available from the IRF PAI such as the CARE tool; and**
- **II. CMS and RTI should meet with a panel of medical rehabilitation experts, including representatives of the national trade organizations, to come to develop a consensus on the use of specific functional or other approaches.**

(ii) CMS and RTI may also want to include all the Rehabilitation Impairment Categories (RICs) except the 'Miscellaneous' RIC for purposes of compliance with the rule.

B. Analysis of Conditions Outside of those Currently Allowed to Determine Appropriate Settings of Care, Variation in Outcomes and Costs Across Settings

The current 13 conditions do not include numerous cases that have historically been treated in IRFs. These include cardiac, pulmonary, cancer, pain, and burns. Prior to implementation of the revised 75% rule, treatment of these conditions within IRFs were increasing but have been decreasing since implementation of the revised rule. At the same time, more people are surviving these conditions because of medical advances. However, these survivors need inpatient medical rehabilitation to fully recover from complicated surgery or the effects of radical treatment such as chemotherapy. A ready example is patients who are recovering from surgery for left ventricular assistive devices. Intuitively we do not believe the more medically and functionally complicated cases can be adequately treated with beneficial outcomes outside the IRF space. Yet, comprehensive, high level research has not been performed to determine if this is the case.

Therefore AMRPA recommends that CMS broaden and enhance the conditions to recognize the greater variety of clinical circumstanced in today's world that require IRH/U care, specifically cardiac, pulmonary, cancer, transplant and pain patients.

V. LITERATURE REVIEW

In the scope of work for this study, CMS asked RTI to review the relevant literature and policy materials related to the focus of the study. In preparing for the Town Hall Meeting, AMRPA conducted a brief literature review. We examined the literature found with respect to its methodology, database, comparative effectiveness of care across sites, whether it addressed the definition of a facility, and other issues relating to medical appropriateness.

The issue of research in the medical rehabilitation field and comparative effectiveness is an ongoing one. The Agency for Healthcare Quality and Research (AHRQ) performed a literature review in 2005 and came to the following conclusion:

> "We summarized 31 studies in this report. There are only 17 Category I or II comparative studies relevant to the conditions of interest. Only 1 RCT compared rehabilitation programs at an inpatient rehabilitation facility and an outpatient setting. Overall, studies were heterogeneous in terms of the research question, condition of interest, type of rehabilitation facilities, country of origin, interventions, follow-up duration, and outcomes assessed. There is a paucity of comparative studies for each of the conditions of interest. Very few studies were conducted in the US within the past 10 years. Even though it is not the intent of this report, it would be difficult to draw reliable conclusions about the beneficial effects of different rehabilitation settings. Current data is insufficient, mostly outdated or irrelevant to inform clinical practice in the US. Many more high quality studies that directly compare inpatient rehabilitation with alternative rehabilitation settings for various conditions of interest are needed on the US population. These studies should fully report the characteristics of the rehabilitation setting and the protocols. These studies should also be adequately powered and follow patients for at least 6 months report not only physiologic and clinical outcomes, but functional status and rate of return to the community as well."
>
> *An assessment of medical literature evaluating inpatient rehabilitation facility programs on conditions of interest, AHRQ, March 7, 2005.*

Subsequent to this study AMRPA funded six studies on medical rehabilitation and sponsored a symposium in February 2007, in which Dr. Gage participated. The results of the symposium were subsequently published in the Archives of Physical Medicine and Rehabilitation, November, 2007.

We have also reviewed other literature sources, including the *Cost Effectiveness Bibliography* created by the American Academy of Physical Medicine and Rehabilitation and AMRPA which is also attached. See Appendix F. We are continuing our review.

In performing this review, we discovered that, overall, there is still a dearth of well done, extensive cross-site literature on matched patients, the process of care in each site, the amount of services, costs, payments, measures of outcomes and variation in provider cost across settings, In fact the PAC PRD demonstration program is the most current study underway that may allow glimpses into these factors.

VI. MEDICAL COVERAGE AND APPROPRIATENESS CRITERIA

The issues pertaining to the 75% rule and medical coverage and appropriateness criteria have been intertwined as noted above. AMRPA believes that there should be a separate discussion regarding medical coverage and appropriateness criteria. Furthermore we believe that any such discussion and formulation of revisions, amendments or replacement of the existing Medicare coverage criteria should meet the principles articulated above.

Our review of the literature shows that "gold standard" scientific evidence such as randomized clinical trials for medical rehabilitation patients and sites are limited. They also raise certain

ethical issues regarding denial of care. Additional studies can be done prospectively and further information may be forth coming from the PAC PRD program and others which can inform this discussion.

However, AMRPA believes the evidence base is not adequate upon which to promulgate any new or revised criteria, hence other steps are necessary. The first is to develop tools or adopt existing tools with field credibility. The second is to develop a consensus methodology utilizing a panel of experts from the field of medical rehabilitation.

The recommendations of this panel should then be field tested and the panel should become a standing Rehabilitation Advisory Panel to conduct this work as part of the CMS process. The panel may also have a future role for purposes of coverage decisions for medical rehabilitation in several post-acute care settings. The same standardization should also be required for other settings, specifically skilled nursing facilities and long term care hospitals. Standards should be established for the rehabilitation services offered by these other providers that define the attributes of that setting. AMRPA believes that there are insufficient standards and criteria for rehabilitation programs and services in SNFs or LTCHs to assure consumers that there is equivalence, and there is inadequate information collected by Medicare as to patients served, services provided, and outcomes achieved to assess whether outcomes and quality of care (as well as true cost) is acceptable.

AMRPA recommends that CMS convene a broad panel of experts to discuss and develop medical necessity criteria. The panel should consist of medical rehabilitation physicians, rehabilitation hospital and unit administrators, therapists, other clinicians and practitioners in IRH/Us and representatives of national rehabilitation trade organizations. Furthermore AMRPA recommends that CMS convene additional panels to develop standards defining the attributes of SNF and LTCH providers and the attributes of patients treated in those settings as well as outcomes achieved to assess whether outcomes and the quality of care (as well as cost) are acceptable.

VII. CONCLUSION

AMRPA appreciates the opportunity to work with RTI and CMS as it seeks to meet the requirements of the MMSEA 75% rule Report to Congress. Should you have any questions, please feel free to contact me at 973-324-3658 or bgans@kessler-rehab.org, or Carolyn Zollar at 202- 223-1920 or czollar@amrpa.org.

Sincerely,

Bruce M. Gans, M.D.
Chair

AMRPA

Executive Vice President
Chief Medical Officer
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Cc:
Laurence Wilson, CMS
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APPENDICES

Appendix A History of the 75% Rule

Appendix B Patient Reductions in Inpatient Rehabilitation Facilities Required to Meet the May 7th 2005 75% Rule Compared to July 1, 2004-June 30,2004 as Percentage of Discharges by Payer, Updated January 26, 2009

Appendix C State Codes and Regulations

Appendix D Proposed Definition of an Inpatient Rehabilitation Hospital/Unit (IRH/U)

Appendix E Proposed Regulations for the Revised Definition of an IRH/U

Appendix F Cost Effectiveness Bibliography

Appendix A

History of the 75% Rule's Interpretation and Enforcement

1. Social Security Act Amendments of 1983

The Social Security Act Amendments of 1983 (P.L. 98-21) created the IPPS, which applies to most inpatient hospitals participating in the Medicare program. However, the law excluded from the IPPS certain specialty hospitals and units of general acute care hospitals, such as long-term care, children's, cancer, rehabilitation, and psychiatric hospitals and rehabilitation and psychiatric units.

While the law defined psychiatric, long-term care and children's hospitals,[1] no statutory definition of a rehabilitation hospital or unit existed when Congress chose to exclude these facilities from the IPPS. Recognizing this, Congress authorized the Secretary of Health and Human Services (HHS) to define rehabilitation hospitals and units for purposes of IPPS exclusion. While the statutory language offers no guidance as to how rehabilitation hospitals and units should be defined for this purpose, report language accompanying the legislation acknowledged existing standards in the rehabilitation field and instructed the Secretary to consult with national accrediting bodies in developing the definitions. *See* H.R. Rep. No. 98025, 98th Cong., 1st Sess. 147 (1983).

The Health Care Financing Administration (HCFA), now CMS, followed Congress' advice and consulted with the national accrediting bodies to develop criteria determining which facilities would be excluded from the IPPS. In addition to the criteria recommended by the accrediting bodies, HCFA also added several additional exclusion criteria, including the 75% Rule, in an interim final rule (48 FR 171) published on September 1, 1983.

In developing the interim final rule, HCFA relied heavily on an earlier industry-developed document entitled "Sample Screening Criteria for Review of Admissions to Comprehensive Medical Rehabilitation Hospitals/Units." *See* HCFA Technical Assistance Document No. 24 (May 1981). This document was jointly developed by the Committee on Rehabilitation Criteria for Peer Standards Review Organizations (PSROs) of the American Academy of Physical Medicine and Rehabilitation ("the Academy") and the American Congress of Rehabilitation Medicine (ACRM).

Although the Technical Assistance Document relied on by HCFA was dated just two years before the interim final rule's publication, it was actually based on criteria developed using data

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[1] *See* 42 U.S.C. §1395ww(d)(1)(B) (defining long-term care and children's hospitals); 42 U.S.C. 1395x(f) (defining the term "psychiatric hospital").

from as early as 1971, when the Academy first established an Ad hoc Committee on Peer Review. The Ad hoc Committee published several monographs that formed the basis of professional standards for physical medicine and rehabilitation and sample screening criteria for review of admissions to comprehensive medical rehabilitation hospitals and units.[2]

In 1975, the Academy, under subcontract to the American Medical Association (AMA), developed for HCFA sample screening criteria for inpatient rehabilitation admissions that were based on the work of the Ad hoc Committee. The HCFA/Academy/AMA project was intended primarily to provide a basis for reviewing the medical necessity of admission to and continued stay in these hospitals and units and for assessing the quality of care furnished in them. The medical conditions for which sample screening criteria were developed by the project were believed to account for approximately 75% of the admissions to comprehensive medical rehabilitation hospitals and units.

These HCFA/Academy/AMA screening criteria later formed the basis of a monograph published in September 1978 by the ACRM and the Academy's Committee on Rehabilitation Criteria for PSROs as its report to HCFA. Dr. Leon Rhinestein, Chair of the Committee at the time, has described the process used to determine the original list of conditions meriting inpatient rehabilitation care:

> As Chair of the Committee, I asked the members . . . to identify the most common diagnoses or rehabilitation inpatients as examples of conditions to which the criteria might apply. As they call out eight diagnoses, I write them on the blackboard – not a very scientific method. I present our report to HCFA in a dingy makeshift building on Dogwood Road down the street. Subsequently, in 1984, two more diagnoses are added to the list. These ten diagnoses become the basis for defining the required patient population of an inpatient rehabilitation facility.

Statement of Leon Rhinestein, M.D. at CMS IRF-PPS Town Hall Meeting (May 19, 2003), CMS Transcription dated May 20, 2003 at 8 .

The eight medical conditions (first identified in the 1975 project and carried forward into the 1981 Technical Assistance Document[3]) were:

- Stroke
- Dorsal or lumber spinal cord injury with paraparesis/paraplegia;
- Cervical spinal cord injury with quadriparesis/quadriplegia;

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[2] In October 1977, the Ad hoc Committee published a monograph summarizing its recommendations entitled "Criteria for Inpatient Review at Comprehensive Medical Rehabilitation Hospitals."

[3] The Technical Assistance Document is compatible with Medicare coverage guidelines for inpatient stays at comprehensive medical rehabilitation hospitals and units set forth in Section 3101.11 of the Medicare Intermediary Manual and Section 211 of the Hospital Manual. Thus, in the view of some, the screening criteria formed the basis for the current coverage criteria.

- Congenital deformity;
- Amputation of the leg or lower limb;
- Polyarthritis, rheumatoid, or acquired deformity of the leg or lower limb;
- Fracture of femur; or
- Head Injury.

On January 3, 1984, HCFA published a final rule implementing the IPPS (49 FR 336).[4] The 75% Rule was modified in the final rule to add two conditions: neurological disorders and burns. The final rule required each rehabilitation hospital or unit seeking exemption to "show that during its most recent 12 month cost reporting period it served an inpatient population of whom at least 75% required intensive rehabilitation services for the treatment of one or more of the following conditions:"

- Stroke
- Spinal Cord Injury
- Congenital Deformity
- Amputation
- Major Multiple Trauma
- Fracture of Femur (hip fracture)
- Brain Injury
- Burns
- Polyarthritis, including rheumatoid arthritis
- Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease

In developing the IPPS final rule, HCFA considered, but did not include, pain or pulmonary/cardiac disorders. 69 FR 240. . The rule and its list of ten conditions stood unchanged for almost two decades, as if frozen in time.

After issuing the IPPS final rule, HCFA released a stream of guidance in the form of program memoranda, policy transmittals, and manual issuances. For example, compliance with the 75% Rule is discussed in Section 3104 *et. seq* of the *State Operations Manual* and Section 2260 of the *Fiscal Intermediary Manual*.

HCFA gave FIs responsibility for assuring compliance with the criteria but stated that if the FI did not conduct reviews, the state health agency would do so. The state health agency is responsible for assuring initial and annual compliance with all the other criteria. Under Section 2260.A.2.a of the *State Operations Manual*, the FIs are to review a sample of charts or discharge records that accurately reflects the mix of Medicare and non-Medicare admissions or discharges.

2. *Application of the Exclusion Criteria to Polyarthritis and Lower Extremity Joint Replacement Cases Since 1984*

a. Historical Definition of "Polyarthritis"

Cases involving a joint replacement due to an arthritic condition have generally been considered polyarthritis cases for purposes of the 75% Rule and the historical pattern of admissions bears

[4] Although the 75% Rule was originally published as 42 C.F.R. 405.47(c)(2)(ii) and (c)(4)(iii)(A), it was later redesignated at 42 C.F.R. 412.23(b)(2), .29, .30(b)(2), (c).

this out. Neither HCFA nor CMS has issued a formal statement regarding the definition of the term polyarthritis, and CMS declines to do so in the NPRM.[5]

The Technical Assistance Document on which HCFA relied to develop the 75% Rule summarized the then-current understanding of "Polyarthritis, Rheumatoid and Acquired Deformities of Leg and Lower Limb" on page 23. According to John T. Melvin, M.D. of the Academy/ACRM Committee on Rehabilitation Criteria (which developed the Technical Assistance Document)

> the term 'polyarthritis' as used in Technical Document 24 was the result of earlier AAPM&R committee activity, including the AAPM&R/ACRM/HCFA funded project. Project participants used 'polyarthritis' to indicate that more than one joint demonstrated arthritic involvement, regardless of the underlying pathologic origin of the arthritis**.** Thus, it applies to joints with degenerative osteoarthritis or inflammatory changes from rheumatoid arthritis or other collagen disorders.
>
> --*Email from John T. Melvin, M.D. to Carolyn C. Zollar, AMRPA (emphasis added).*

The Technical Assistance Document's definition of "polyarthritis" thus represented a consensus definition among the participants on the committee that was intended to denote the presence of arthritis in more than one joint. This is consistent with the definition of "polyarthritis" in Dorland's and other medical dictionaries. *See, e.g., Dorland's Medical* Dictionary (defining "polyarthritis" as "an inflammation of several joints together"); Amersham *Health Medcyclopaedia* (defining "polyarthritis as "involvement of multiple joints by inflammation or arthritic changes").

b. <u>Rise and Influence of PROs on IRF Admission Patterns</u>

After the IPPS final rule became effective, Peer Review Organizations (PROs) succeeded Peer Review Standards Organizations. PROs were responsible for reviewing cases admitted to hospitals, including rehabilitation hospitals and units, to determine both the appropriateness of the site of care and which cases fell within the 10 categories listed in the 75% Rule.

In the mid-1980s, questions arose regarding the treatment of hip fracture and hip procedure cases for IRF admission and 75% Rule purposes. AMRPA's predecessor organization met with the national staff of the PRO program to discuss these issues. The national staff took the position that, if a patient had arthritis and underwent hip replacement, the patient should be considered a polyarthritis patient for purposes of the 75% Rule. The reasoning was that, if the medical condition of arthritis resulted in a surgical intervention, the underlying medical condition would be the determining factor for purposes of the 75% Rule. Most PROs used the 1981 Technical Assistance Document cited above in making determinations regarding Medicare admissions to IPPS-excluded rehabilitation hospitals and units.

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[5] One CMS official did discuss the definition of the term "polyarthritis" in a conference call with providers, but CMS did not subsequently publish or formally acknowledge the definition. *See discussion infra* at pages 11-12.

In the late 1980s, AMRPA's predecessor surveyed the various PROs to determine how they were treating hip procedure cases for purposes of admission to rehabilitation hospitals and units and application of the 75% Rule. AMRPA found that in California, the PRO generally took the position that "simple" hip procedure cases would not be admitted to inpatient rehabilitation hospitals or units, but "complex" cases could be.[6]

The AMRPA survey revealed that most PROs generally allowed admission of hip procedure cases in rehabilitation hospitals and units. The pattern of admissions of hip procedure cases (and hip fracture cases) across the country bears out the geographical differences identified by the AMRPA survey and CMS' survey of 75% Rule compliance. Hence rehabilitation facilities generally admitted joint replacement cases with an underlying arthritis diagnosis, except for facilities operating under the restriction imposed by the California PRO.

The IRF-PPS was implemented on January 1, 2002. To facilitate patient categorization into RICs and CMGs for payment purposes, an excluded rehabilitation hospital or rehabilitation unit must complete a patient assessment instrument, known as the IRF-PAI. The patient assessment instrument provides data to classify each Medicare patient into an Impairment Group Code, then a RIC and then into a Case-Mix Group (CMG).

As noted above, once the IRF-PPS was implemented, facilities continued to operate under the prior PRO directions regarding treatment of arthritis patients who undergo joint replacements. As under past practice, it was assumed that such cases would continue to be counted as polyarthritis cases for purposes of determining 75% Rule compliance**.** Even CMS, in press releases announcing the implementation of (and subsequent update to) the IRF-PPS, described inpatient rehabilitation facilities as "hospitals that care for Medicare beneficiaries recovering from strokes, joint replacements or other conditions requiring rehabilitation."[7]

However, the coding guidelines in the IRF-PAI Training Manual state that, if a patient has arthritis and undergoes joint replacement, the patient should be placed into Impairment Group Code 08.51, 08.52, 08.61, 08.62, 08.71 or 08.72, which then places the case in Rehabilitation Impairment Code 08, Replacement of Lower Extremity Joint under the IRF-PPS.

These coding directions therefore change how these patients are readily recognized. *See* IRF-PAI Training Manual, p. B-9, Arthritis (06) NOTE and p. B-11 Orthopedic Disorders (08) NOTE. Rather than being categorized according to their underlying condition (arthritis), they

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[6] Complex cases were defined as those in which the patient had additional conditions requiring rehabilitation or medical conditions such as diabetes, cardiac conditions or chronic obstructive pulmonary disease that required close medical management while the rehabilitation services program was delivered.

[7] *See* CMS Office of Public Affairs press release entitled "Medicare to Establish New Payment System for Rehabilitation Hospitals" (Nov. 2, 2000) (emphasis added); *see also* CMS Office of Public Affairs press release entitled "Medicare Establishes New Payment System for Rehabilitation Hospitals" (July 31, 2001); CMS Office of Public Affairs press release entitled "Rehabilitation Hospitals Get 3 Percent Increase in Medicare Payment Rates in FY 2003" (July 31, 2002). Although this sentence appeared in three consecutive CMS press releases regarding the IRF-PPS, CMS chose to remove it in this year's press release, instead describing IRFs as "hospitals that care for Medicare beneficiaries recovering from strokes, spinal cord injury or other conditions requiring extensive therapy." CMS Office of Public Affairs press release entitled "CMS Proposes 3.3 Percent Increase in Medicare Payment Rates in FY 2004 for Rehabilitation Hospitals" (May 8, 2003).

instead are categorized by the treatment they receive (joint replacement). Thus, for purposes of applying the 75% Rule, joint replacement cases which previously would have been considered polyarthritis cases for 75% Rule purposes may no longer be counted as such.

In spring 2002, CMS surveyed FIs to determine what methods they were using to determine 75% Rule compliance. After analyzing the resulting survey data, CMS concluded that "inconsistent methods were being used" to evaluate 75% Rule compliance, and that "some IRFs were not being reviewed" for compliance. 68 FR 26791. The agency therefore suspended 75% Rule enforcement on June 7, 2002 to enable it to conduct "a careful examination of this area and determine whether changes were needed to the regulation." *Id.*

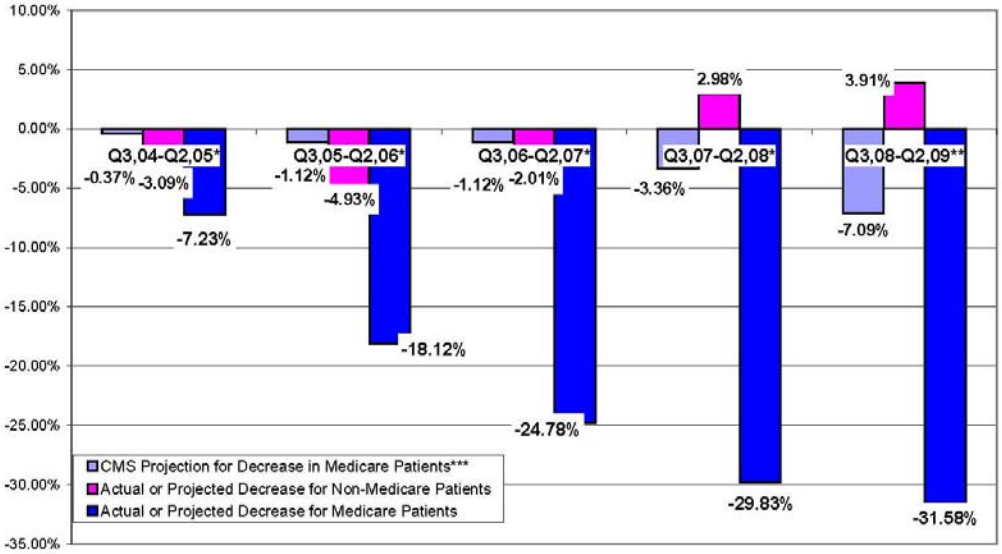
On May 16, 2003, CMS published the NPRM, summarizing the results of its enforcement review and announcing its intent to instruct FIs to "reinstitute appropriate enforcement action" for 75% Rule violations for cost reporting periods beginning on or after October 1, 2003. 68 FR 26794. Although the NPRM does not propose any textual changes to the regulations setting forth the 75% Rule, it discusses CMS's new criteria for determining compliance with the rule and invites comments on (1) "any conditions that necessitate the intensive, multidisciplinary care that IRFs are required to provide" and (b) "any potential negative effect on patient access to rehabilitative care" resulting from CMS' proposal to reinstate enforcement of the existing 75% Rule. 68 FR 26794-95. CMS then published a subsequent proposed rule (NPRM) on September 9, 2003 (68 FR 53265 which added three new arthritis conditions, proposed several comorbidity policy methodologies and proposed lowering the percentage threshold to 65% for three years.

The current final rule was published on May 7, 2004. (69 FR 25752).

Appendix B

erehabdata.com

Patient Reductions in Inpatient Rehabilitation Facilities Required to Meet May 7th 2004 75% Rule Compared to July 1, 2003 - June 30, 2004 as Percentage of Discharges by Payer
Updated January 26, 2009



*Actual patient volume calculated from data supplied by UDSmr and eRehabData for 70% of patients.
**Projection of patients (both Medicare and Non-Medicare) accessing IRFs based on actual patient volume for 132 IRFs (20% of discharges nationally) in eRehabData for Q4 2008
***CMS projections based on May 7th, 2004 Federal Register page 25772 by dividing total estimated savings by the projected per discharge savings of $5,710

Appendix C

EXAMPLES OF STATE CODES OR REGULATIONS DEFINING A REHABILITATION HOSPITAL

Many states, such as California, include rehabilitation hospitals in the definition of a hospital. Others such as New Jersey, and Texas provide a separate definition. A third approach is taken by Pennsylvania and New York wherein the a rehabilitation hospital is included in the definition of a hospital but if a hospital offers rehabilitation services as a freestanding hospital or for a rehabilitation unit it must meet specific standards. The New Jersey, Texas and New York definitions are provided herein. The Pennsylvania citation is 28 PA Code Section 131 with regulations from the Pennsylvania Department of Health, Rule and Regulations for Hospitals, Bureau of Facility Licensure and Certification, Division of Acute and Ambulatory Care. It appears to draw its authority from sections of the Pennsylvania Code. Note that none of these approaches include a diagnostic based criterion as part of the definitions.

New Jersey:

"Rehabilitation hospital" means a facility licensed by the New Jersey State Department of Health and Senior Services to provide comprehensive rehabilitation services to patients for the alleviation or amelioration of the disabling effects of illness. Comprehensive rehabilitation services are characterized by the coordinated delivery of interdisciplinary care intended to achieve the goal of maximizing the independence of the patient. A rehabilitation hospital is a facility licensed to provide only comprehensive rehabilitation services or is a distinct unit providing only comprehensive rehabilitation services located in a licensed health care facility.

Reference: From Licensing Standards for Rehabilitation Hospitals N.J.A.C. TITLE 8, CHAPTER 43H. State of New Jersey

Texas:

(10) Comprehensive medical rehabilitation hospital--A general hospital that specializes in providing comprehensive medical rehabilitation services, including surgery and related ancillary services.

(11) Comprehensive medical rehabilitation unit--An identifiable part of a hospital which provides comprehensive medical rehabilitation services to patients admitted to the unit.

Reference: This is located in the Texas Administrative Code: TITLE 25, Part 1, Chapter 133, Subchapter A, Rule 133.2

New York

Section 405.18 Rehabilitation services: The hospital shall make available rehabilitation services consistent with the needs of the patients, which shall be designed to provide individualized, goal-

oriented, comprehensive and coordinated services to minimize the effects of physical, mental, social, and vocational disadvantages and to effect a realization of the patient's potential for useful and productive activity while ensuring the health and safety of the patient. Such services shall include but are not limited to audiology, occupational therapy, physical therapy and speech language pathology and shall be delivered in accordance with a written plan for treatment. Hospitals providing general rehabilitation services but not providing comprehensive inpatient physical medicine and rehabilitation programs shall meet the provisions of subdivisions (a) and (b) of this section. Hospitals which do not provide comprehensive inpatient physical medicine and rehabilitation programs shall meet the provisions of subdivisions (a) and (c) of this section. Hospitals which provide a spinal cord injury program shall meet the provisions of subdivisions (a), (c) and (d) of this section. Hospitals which provide a traumatic head injury program shall meet the provisions of subdivisions (a), (c), and (e) of this section.

Reference: New York Codes Rules and Regulations.

Appendix D

Proposed Revised Exclusion Criteria

INPATIENT REHABILITATION HOSPITAL/UNIT (IRH/U) REQUIREMENTS

Comprehensive acute rehabilitation programs are physician led, hospital-based clinical programs that are designed to meet the medical and rehabilitation needs of people challenged by functional impairments. These programs are short term in nature and designed to provide a coordinated and intense service provided by a team of professionals, who through their work with patients and families, improve health status, enhance functional abilities, and reduce dependence on others and society.

Legal and Regulatory Requirements

1. Licensure

   - Rehabilitation Hospital - licensed to operate as a rehabilitation hospital (or acute care hospital where no specific rehabilitation hospital licensure category exists).

   - Rehabilitation Unit within An Acute Care Hospital - distinct part of a hospital that is licensed to operate as an acute care hospital

2. Accreditation – The IRH/U shall be accredited as a hospital by The Joint Commission, the American Osteopathic Association (AOA), r the Commission on Accreditation of Rehabilitation Facilities (CARF), or other organizations recognized by CMS.

Program Components

1. Comprehensive rehabilitation programs are organized as physician led multidisciplinary teams that work to achieve goals that are directed towards improving a patient's health status and functional status.

2. Patients are admitted who have significant functional limitations that are determined to be likely to improve in a reasonable period of time using the intensive services and programs of the IRH/U.

3. There is a preadmission screening procedure, overseen by a physician, to determine if patient can benefit from an intensive inpatient program or assessment.

4. Multidisciplinary team conferences, led by the rehabilitation physician, are held at least weekly. At those conferences, initial patient assessments, current status, goals, and progress towards goals and discharge plans are shared. The team also engages in problem solving at these meetings on behalf of the patients.

5. Functional outcomes are measured by determining functional status at admission and discharge.

6. In general, the discharge goal for the patient is to return home or to a home-like setting in the community.

Physical Space

1. The rehabilitation program has space that is safe and accessible for people with functional loss. The space will be sufficient for the numbers and kinds of patients to be treated, including:

    - Gym and other dedicated space with specialized equipment for delivery of therapy services and treatment of functional loss.

    - Dedicated space for teaching daily living activities, including a bedroom, bath, kitchen and space for mobility training

    - Inpatient beds aggregated in a designated and distinct space

Professional Staffing

1. Medical Director
    a. provides services to the hospital or unit and its inpatients on a full-time basis at least 40 hours/week for a hospital and at least 20 hours/week for a unit;
    b. Is a doctor of medicine or osteopathy;
    c. Is licensed under State law to practice medicine or surgery; and
    d. Has had, after completing a one year hospital internship, at least two years of training or experience in the medical-management of inpatients requiring rehabilitation services.

2. Rehabilitation programs are provided by a multidisciplinary team and the team will be comprised at minimum of the following:

- Constant availability of a physician with special training or experience in the field of rehabilitation medicine, frequently and directly involved in medically necessary patient care, at least 5 days per week during the patient's stay.

- Availability of physician specialists as part of an organized medical staff.

- Constant on-site availability of registered nurses with specialized training or experience in rehabilitation.

- Availability of adequate physical therapy (PT), occupational therapy (OT), and speech language pathology (SLP) services provided by licensed and registered professionals so that each patient generally receive at least 3 hours of therapy services at least 5 days a week. Therapy services are provided at the direction of a physician in the complement required by the patient to achieve team established goals

- Availability of the services of neuropsychologists, social workers, case managers, and recreation therapists provided under the direction of a physician.

- Availability of laboratory, radiology, and pharmacy services.

Quality Improvement

1. Outcome measures are used for quality improvement of patient care processes including indicators such as:

   - Mortality
   - Adverse events and safety
   - Unplanned return to acute care
   - Discharge to community
   - Functional improvement in key areas
   - Goal achievement
   - Functional and health status within 6 months following discharge

   Active input at the program level is provided by consumers and community members, and utilized by the facility to revise and adapt its programs and services.

Revised: August 6, 2007

Appendix E

Proposed Draft Regulations to Implement Proposed Revised Exclusion Criteria; Unit Regulations Would Need To Be Similarly Conformed

§412.23 Excluded hospitals: Classifications.

Hospitals that meet the requirements for the classifications set forth in this section are not reimbursed under the prospective payment systems specified in §412.1(a) (1):

(a) ……

(b) *Rehabilitation hospitals.* A rehabilitation hospital must meet the requirements stated below to be excluded from the prospective payment systems specified in § 412.l(a) (1) and to be paid under the prospective payment system specified in §412.1(a) (3) and in Subpart P of this part.

(1) General

Generally, comprehensive acute rehabilitation hospitals and units' programs are physician led, hospital – based clinical programs that are designed to meet the medical and rehabilitation needs of people challenged by disease or injury resulting in physical and cognitive disabilities. These programs are short term in nature and designed to provide coordinated and intense services provided by a team of professionals , who through their work with patients and families , improve health status, enhance functional ability and reduce dependence on others and society.

(2) Each rehabilitation hospital shall meet the following requirements:
(i) Has a provider agreement under Part 489 of this chapter to participate as a hospital.

(ii) Be accredited as a hospital by the Joint Commission on Accreditation of Hospital Organizations (JCAHO) or the American Osteopathic Association (AOA)

(iii) Program Components:

A rehabilitation hospital shall have all of the following components:

(A) A comprehensive rehabilitation program that is organized through physician led multidisciplinary teams working to achieve goals that are directed towards improving a patient's health status and functional status.
(B) Patients who have significant functional limitations that are believed to be amenable to improvement using the intensive services and programs offered by the hospital in a reasonably short period of time.
(C) Preadmission screening procedures, overseen by a physician, to determine if patient can benefit from an intensive inpatient program or assessment.
(D) Regular team communication and assessment of every patient that are documented and used in planning and coordinating patient care.
(E) Functional outcomes measurement that determines functional status at admission and discharge.

(F) In general, the discharge goal for the patient is to return home or to a home-like setting in the community whenever possible, or if not to reduce the burden of care in another setting.

(iv) Physical Space

The rehabilitation hospital shall have space that is safe and accessible for people with functional loss. The space will be sufficiently large for the number and type of patients treated, including:

(A) A gym and other dedicated space with specialized equipment for delivery of therapy services and treatment of functional loss,
(B) Space dedicated for teaching daily living activities, including a bedroom, bath, kitchen and space for mobility training,
(C) A dining area where patients are encouraged to eat to benefit from social interaction and gain independence, and

(v) A rehabilitation hospital shall meet the following staffing requirements:

(A) Have a director of rehabilitation who—
(I) provides services to the hospital and its inpatients on a full-time basis at least 40 hours/week;
(II) Is a doctor of medicine or osteopathy;
(III) Is licensed under State law to practice medicine or surgery; and
(IV) Has had, after completing a one year hospital internship, at least two years of training or experience in the medical-management of inpatients requiring rehabilitation services.

(B) The program is provided by a multidisciplinary team and will be comprised at minimum of the following:
(I) Attending physicians who are physiatrists or other physicians who by training and experience are qualified and privileged to direct comprehensive inpatient rehabilitation programs.
a. 24 hour/ 7 day a week availability of physicians to provide for medical management as needed
b. Physician patient visits of no less than five times a week to manage the medical and rehabilitation programs

(II) Rehabilitation nurses (inclusive of (CRRN) – Certified Rehabilitation Registered Nurses) and other nursing personnel are provided in a complement similar to acute hospital medical/surgical services nurse staffing levels.

(III) Physical therapy, occupational therapy and speech-language pathology services are provided by licensed and registered professionals, typically a minimum of 3 hours a day, at least 5 days a week.
(A) Therapy services are provided at the direction of a physician in the complement required by the patient to achieve established team goals.

(IV) The additional services of rehabilitation psychologists, social workers, case managers, and recreation therapists are provided under the direction of a physician.

(vi) Quality Improvement

The hospital shall have outcome measures used for quality improvement in patient care processes, which include, at least indicators related to:

(A) Mortality;
(B) Adverse events and safety;
(C) Return to acute care within the first 72 hours;

(D) Discharge to independent living;
(E) Functional improvement in key areas;
(F) Goal achievement;
(G) The success of patient and family teaching; and
(H) Re-hospitalization post discharge

(vii) Consumers and community members have a role with the facilities and their comments are utilized by the facility to revise and adapt its programs and services.

(viii) Any rehabilitation hospital of a general hospital that is accredited by CARF in Comprehensive Inpatient Rehabilitation is deemed to have met requirements (ii)-(viii) above.

(3) A hospital that seeks classification under this paragraph as a rehabilitation hospital for the first full 12-month cost reporting period that occurs after it becomes a Medicare-participating hospital may provide a written certification that the inpatient population it intends to serve meets the requirements of paragraph (b)(2) of this section, The written certification is also effective for any cost reporting period of not less than one month and not more than 11 months occurring between the date the hospital began participating in Medicare and the start of the hospital's regular 12-month cost reporting period.

(4) For cost reporting periods beginning on or after October 1 1991, if a hospital is excluded from the prospective payment systems specified in § 412.1(a) (1) or is paid under the prospective payment system specified in 412.1(a) (3) for a cost reporting period under paragraph (b)(3) of this section, we adjust payments to the hospital retroactively in accordance with the provisions in § 412.130.

Appendix F

COST-EFFECTIVENES/COST BENEFIT BIBLIOGRAPHY

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