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Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1551-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8012

July 2, 2007

RE: Comments by the Coalition to Preserve Rehabilitation on the 75% Rule Policy

Dear Ms. Norwalk:

The undersigned members of the Coalition to Preserve Rehabilitation (CPR) submit these comments relating to the 75 Percent Rule Policy. CPR is a coalition of national consumer, clinician, and membership organizations with the goal of preserving access to appropriate rehabilitation services so that individuals with disabilities, injuries, or chronic conditions may regain and/or maintain their maximum level of independent function. The comments set out below are written from the perspective of patients, those ultimately impacted by the 75% Rule.

Our comments are organized into four sections. First, we set out the principles that guided our analysis. Second, we provide an overview of our concerns regarding the operation of the 75 Percent Rule. Third, we identify the specific policies in the current regulations implementing the 75 Percent Rule policy that create problems and that can be addressed through regulation (and do not require legislation). Finally, we set out our recommendations.

Guiding Principles

In preparing our comments, we were guided by the following principles.

First, under the Medicare program, older Americans and certain persons with disabilities are entitled to receive medically reasonable and necessary health care services. Among the health care services recognized under the Medicare program is the provision of rehabilitation services. For some patients, rehabilitation services are appropriately provided in acute care hospitals; for others, rehabilitation services are appropriately provided in outpatient settings or part of home health care or in skilled nursing facilities. For a relatively small, but distinct number of patients, medically reasonable and necessary health care services entail the provision of intensive, coordinated rehabilitation services provided by a multi-disciplinary team in inpatient rehabilitation hospitals and rehabilitation units in acute care hospitals.

Second, in order to be excluded from the acute care inpatient hospital Prospective Payment System (PPS) specified in 42 CFR § 412.1(a)(1) and instead receive enhanced payments under the Inpatient Rehabilitation Facility (IRF) PPS, it is appropriate for CMS to establish criteria/conditions that enable it to distinguish IRFs from other settings that receive lesser payments. In other words, it is crucial to Medicare to maintain criteria ensuring that only facilities providing intensive rehabilitation services are identified as IRFs. To justify the enhanced payment, IRFs must be able to demonstrate through objective criteria/conditions their uniqueness and distinctiveness because rehabilitation services in general can be delivered in a variety of other settings, such as acute care hospitals, skilled nursing facilities, outpatient or home health care. It is appropriate to adopt conditions that enable CMS to distinguish those hospitals and units which provide intensive rehabilitation services coupled with close medical supervision.

Third, in order to be admitted to an inpatient rehabilitation hospital or rehabilitation unit in an acute care hospital, it is appropriate for CMS to establish criteria—the services must be reasonable and necessary based on an assessment of each beneficiary’s individual care needs. Thus, it is appropriate for public policy to limit access to those beneficiaries who satisfy the criteria for admission. It is appropriate for CMS to limit access to patients for whom services are reasonable and necessary (in terms of efficacy, duration, frequency, and amount) for the treatment of the patient’s condition. It is also appropriate that the services must be considered reasonable and necessary to furnish the care on an inpatient basis, rather than in a less intensive setting, i.e., the patient must have one or more conditions requiring intensive and multi-disciplinary rehabilitation care, or a medical complication in addition to their primary conditions, so that the continuing availability of a physician is required to ensure safe and effective treatment.

Fourth, and most importantly, Medicare patients’ entitlement to medically reasonable and necessary health care services, including intensive inpatient rehabilitation services, must not be impeded by the operation of policies designed to classify facilities as IRFs for purposes of payment. Further, the policies designed to classify facilities must facilitate, not impede achieving our nation’s goals regarding people with disabilities.

Overview of Concerns

CPR strongly believes that the operation of the current 75 Percent Rule, which is one of six conditions a facility must satisfy in order to be considered an IRF for purposes of enhanced payment, has the effect of denying medically reasonable and necessary rehabilitation services to beneficiaries who meet strict admission criteria but who do not happen to have one of the thirteen conditions on the list included in the regulations. If the facility accepts too many patients that need intense inpatient rehabilitation services in accordance with medical necessity criteria but who do not fall within the 13 conditions, the facility will lose its certification as a rehabilitation hospital or unit and will be forced to shut down.

To avoid such an outcome, the facility is forced to turn away (and thus deny) medically reasonable and necessary services to needy Medicare patients based on the condition they have when they arrive at the hospital. Practically speaking, inpatient rehabilitation hospitals and units are being forced to establish health care quotas, i.e., they must manage/limit the mix of patients they treat based on the 75% Rule (a classification payment rule) rather than on the basis of clinical judgment or rehabilitation need.

CPR believes that the administration of the 75 Percent Rule is inconsistent with and is thwarting efforts to achieve the goals of disability policy articulated in the Americans with Disabilities Act, the Rehabilitation Act of 1973, as amended, and Executive Order No. 13217 (42 U.S.C. 12131 note; relating to community-based alternatives for individuals with disabilities issued by President Bush).

The goals of the ADA include:

- Equality of opportunity (treat people as individuals based on facts, not arbitrary and pernicious categories and provide effective services and supports in the most integrated setting appropriate);
- Full participation (empower people to make informed choices)
- Independent living, not dependency and isolation; and
- Economic self-sufficiency.

The administration of the 75% Rule by CMS is inconsistent with each and every principle articulated in the Americans with Disabilities Act and the Rehabilitation Act of 1973, as amended.

Equal opportunity:

- Medicare rules are supposed to facilitate the ability of every individual beneficiary to receive medically reasonable and necessary inpatient rehabilitation services to which he or she is entitled based on an individualized assessment of need, consistent with medical necessity criteria.
- A beneficiary who satisfies the criteria for admission to an inpatient rehabilitation facility (based on facts applicable to that individual) should not be denied admission simply because he or she fails to fall within an arbitrary list of 13 conditions promulgated by CMS. And yet, this is precisely what is happening because of the operation of the 75% Rule.
- Persons denied admission to inpatient rehabilitation hospitals and units are being forced into other settings. They are being denied access to comprehensive, coordinated inpatient rehabilitation services provided by a multidisciplinary team that will enable them to be reintegrated into their community and return to their own homes and jobs (whenever feasible) with the maximum ability to function independently.

Full Participation

- Medicare rules are supposed to provide beneficiaries with the ability to access inpatient rehabilitation services that will enable them to return to their homes after experiencing medical interventions. This access is not absolute—a beneficiary must meet strict medical necessity criteria promulgated by CMS to be admitted into an inpatient rehabilitation facility.
- Access of a beneficiary who meets criteria for admission to an inpatient rehabilitation facility should never be negated by the operation of an arbitrary, inflexible rule for classifying hospitals and units. And yet, the 75% Rule is having the effect of forcing inpatient rehabilitation hospitals and units to turn away needy beneficiaries to retain their certification, *i.e.*, the rule is having the effect of denying beneficiaries the right to receive safe and effective treatment.

Independent Living and Economic Self-sufficiency

- For some beneficiaries who require intense, comprehensive, coordinated inpatient rehabilitation services provided by a multidisciplinary team, access to inpatient rehabilitation hospitals and units is the lifeline from treatment to independent living in one's own home rather than in a nursing home and return to work, to the extent feasible. And yet, the operation of the 75% Rule is having the effect of denying certain beneficiaries the outcome of independent living and potential employment.

Implementation of the 75% Rule is also threatening the overall stability of the rehabilitation hospital system, thereby threatening access to intensive inpatient rehabilitative care for all individuals in need of this care, including Medicare beneficiaries and individuals with disabilities who are not beneficiaries. If the rule continues to be implemented as planned over the next two years, many rehabilitation hospitals and units will be unable to meet the criteria mandated by the rule, and upon losing their certification, will likely close or dramatically shrink their rehabilitation programs. This would have a devastating impact on all individuals with disabilities and chronic conditions, not just Medicare patients, who depend on inpatient rehabilitative care to restore their health status, function, and independence in their home and community. This reduced capacity in the rehabilitation field comes at the very time that demographics suggest an increased need for inpatient rehabilitation in future years across the country.

Specific Concerns with the Current Regulations and Recommendations: Comorbidities

Consistent with authority granted to the Secretary of HHS by Section 1886 (j) of the Social Security Act, CMS has established criteria for classifying a hospital or unit of a hospital as an "inpatient rehabilitation hospital." One key criterion specifies that a minimum percentage of a facility's total inpatient population must require intensive rehabilitation services for the treatment of at least one of 13 medical conditions listed in §412.23(b) (2) (iii) in order for the facility to be classified as an IRF. In addition, for cost reporting periods beginning on or after July 1, 2004, and before July 1, 2008, a patient with a comorbidity, as defined at §412.602, may be included in the inpatient population that counts toward the required applicable percentage if certain requirements are met. The minimum percentage is commonly referred to as the "compliance threshold."

Prior to the May 7, 2004 final rule, §412.23 (b) (2) stipulated that the compliance threshold was 75%. Therefore, the compliance threshold was commonly referred to as the "75% Rule." In addition, prior to May 7, 2004, the regulation specified 10 medical conditions. In the May 7, 2004 final rule, the number of total conditions was increased to 13 [§412.23 (b) (2) (iii)] but the new conditions replaced a much broader orthopedic condition, resulting in fewer orthopedic patients being admitted to inpatient rehabilitation hospitals or units. The final rule also temporarily lowered the compliance threshold while at the same time specified a transition period at the end of which IRFs would once again have to meet a compliance threshold of 75%. Also, the final rule specified that during the compliance threshold transition period a patient's *comorbidity* (listed in the regulations) could be used to determine if a provider met the compliance threshold provided certain applicable requirements were met.

In §421.602, a comorbidity is defined as a specific patient condition that is secondary to the patient's principal diagnosis. A patient's principal diagnosis is the primary reason for the patient being admitted to an IRF and this diagnosis is used to determine if the patient had a medical condition that can be counted towards meeting the compliance threshold. In order for an inpatient with a

comorbidity to be included in the inpatient population that counts toward the applicable percentage, the following criteria must be met [§412.23 (b) (2) (i)]:

- The patient is admitted for inpatient rehabilitation for a condition that is not one of the 13 listed conditions;
- The patient also has a comorbidity that falls within one of the 13 listed conditions;
- The comorbidity has caused a significant decline in the functional ability of the individual such that, even in the absence of the admitting condition, the individual would require the intensive rehabilitation treatment that is unique to inpatient rehabilitation facilities paid under the IFR PPS and that cannot be appropriately performed in another setting.

In accordance with the May 7, 2004 final rule, IRFs would have to meet a compliance threshold of 75% for cost reporting period starting on or after July 1, 2007. However, Section 5005 of the Deficit Reduction Act of 2005 (Public Law 109-171) modified the applicable time periods when the various compliance thresholds must be met. Due to the DRA, the transition period was extended to include cost reporting periods starting on or after July 1, 2004 and before July 1, 2008. The regulations were revised to reflect the new compliance thresholds during the transition period and the new end date of the transition (July 1, 2008). In addition, during this transition period, CMS permitted a comorbidity that meets the criteria described above for the cost reporting periods beginning before July 1, 2008 instead of July 1, 2007.

However, after this phase-in period (i.e., for cost reporting periods beginning on or after July 1, 2008) comorbidities will **not** be eligible for inclusion in the calculations used to determine if the provider meets the 75% compliance threshold.

CPR Position on the 75% Rule and Comorbidities:

CPR strongly opposes the inclusion of any compliance threshold (e.g., 13 conditions in the current regulations) under the 75 Percent Rule as a means to help distinguish/classify IRFs from other facilities for purposes of payment. CPR believes that medical and rehabilitation need alone i.e., the patient's overall function, should determine access to inpatient rehabilitation, not arbitrary compliance thresholds that are used as a means to classify/define what constitutes a rehabilitation hospital or unit. However, we recognize that legislation, not regulation, is necessary to fix the compliance threshold issue.

CPR recognizes that CMS has the authority to modify the list of 13 conditions included in the regulations as well as to modify the comorbidity policy. Our comments regarding the comorbidity provision are set out below.

CPR believes that the current comorbidity provision is far too narrow in its scope and that CMS should substantially modify and make permanent the comorbidity policy. Our proposed approach is guided by the following criteria: First, the revised provision must be consistent with and reflect the same policy rationale originally used to adopt the 13 conditions. Second, the provision must rely on objective data readily available to the agency. Third, the specific parameters of the revised provision should reflect input from expert opinions from the types of groups originally consulted by the agency.

In explaining the policy rationale for the inclusion of a compliance threshold consisting of the 13 listed conditions, CMS explained that a defining feature of an inpatient rehabilitation facility is the

proportion of patients treated for conditions that “**typically**” require intensive inpatient rehabilitation. The intent of the 75% Rule is to ensure that these facilities are “unique” compared to other facilities in that they provide “intensive” rehabilitative services in an inpatient setting. The “uniqueness” of these facilities is the justification for paying them under a separate payment system. In other words, CMS explained that it is “imperative to identify conditions that would typically require intensive inpatient rehabilitation services because rehabilitation in general can be delivered in a variety of settings, such as acute care hospitals, skilled nursing homes, and outpatient settings.” Also, CMS explained that requiring an IRF to treat a patient population that has a high concentration of the conditions listed in the regulations is one of the means chosen to ensure that the treatment setting is appropriately classified to justify payment of the level of services furnished. [69 Fed. Reg. 25753, 25755, 25759-25770-25771 (May 7, 2004)]

In sum, the 75% Rule is used as an objective standard to justify the higher payment standard and requiring IRFs to treat a patient population that has a high concentration of conditions listed is one means chosen to ensure that the treatment setting is appropriate. Consistent with this policy objective, the current regulations include the 13 listed conditions and then restate the same list as secondary conditions (comorbidities).

We believe that CMS should ascertain whether a facility has a high concentration of typical conditions relying on the best available data, not solely on 13 arbitrary conditions suggested in the 1980s. The original medical conditions specified in the 75% rule was partly based upon information contained in a document entitled “Sampling Screening Criteria for Review of Admissions to Comprehensive Medical Rehabilitation Hospitals/Units,” a product of the Professional Standards Review Organization of the American Congress of Rehabilitation Medicine. In addition, CMS received input from the National Association of Rehabilitation Facilities and the American Hospital Association [69 Fed. Reg. 25753 (May 7, 2004)]. In short, the Secretary relied in part on the opinions of experts in the field.

Since that time major policy changes have occurred, including the adoption of the Prospective Payment System for IRFs. When CMS adopted PPS for IRFs, it needed to rely on the existence of patient-specific objective data. Thus, at the time a Medicare patient is admitted, the IRF must use the patient assessment instrument (PAI). Based on the IRF-PAI, a patient classification system is used to classify patients into mutually exclusive case-mix groups. These case-mix groups are identified based on the patient’s impairment, age, comorbidities, functional capabilities (motor and cognitive), and other factors that may improve the ability of the functional-related groups to estimate variations in resource use. Data from admission assessments are used to classify a Medicare patient into an appropriate case-mix group. An appropriate weight is assigned to each case-mix group that measures the relative difference in facility resource intensity among the various case-mix groups [See 42 CFR §412.602, §412.606, §412.620]. In short, objective criteria now exists that will enable CMS to ascertain a high concentration of typical conditions relying on the best available data, rather than relying solely on 13 arbitrary conditions suggested in the 1980s.

Conclusion:

We recommend that the comorbidity provision be substantially modified. CMS should convene a group of experts, including experts from the groups CMS originally relied on when it prescribed the 13 listed conditions, to determine how best to revise the comorbidity component of the 75% Rule. The group should determine how best to use data available from the IRF-PAI, including impairment, functioning, and comorbidities (all comorbidities, not comorbidities limited to the 13 listed

conditions) to objectively determine, for purposes of classification only (not medical necessity) “types of conditions that will typically require intensive inpatient rehabilitation in IRFs because rehabilitation in general can be delivered in a variety of settings” [69 Fed. Reg. 25770-25771 (May 7, 2004)]. This determination should focus on developing objective criteria that not only address levels of functioning but that also address the need for close medical supervision to stabilize medical conditions.

Quite simply, by limiting consideration of a patient’s comorbidities to a list of 13 conditions and by requiring such comorbidities to independently qualify a patient for inpatient rehabilitation, the CMS policy artificially segregates into parts the overall health and functional status of patients. The current policy utterly fails to recognize the totality of patients’ conditions on their need for inpatient rehabilitation care. At the very least, and in the absence of a better alternative, CMS should permanently recognize the impact that comorbidities have in qualifying patients under the 75% Rule or any other mechanism that purports to identify who requires an intensive level of rehabilitation care. Optimally, however, CMS would revisit the comorbidity policy and use the objective mechanisms available to it to devise a more appropriate policy that better meets the needs of seniors and people with disabilities under Medicare.

Thank you for your consideration.

Sincerely,

American Association of People with Disabilities
American Academy of Physical Medicine and Rehabilitation
American Occupational Therapy Association
American Physical Therapy Association
American Therapeutic Recreation Association
Amputee Coalition of America
Association of Academic Physiatrists
ACCSES
Brain Injury Association of America
Center for Medicare Advocacy, Inc.
Christopher and Dana Reeve Foundation
Easter Seals
National Association of Social Workers
National Association for the Advancement of Orthotics and Prosthetics
National Council for Community Behavioral Healthcare
National Council on Independent Living
National Multiple Sclerosis Society
National Spinal Cord Injury Association
Paralyzed Veterans of America
The Arc of the United States
United Cerebral Palsy
United Spinal Association