May 27, 2005

The Honorable Mike Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, Southwest
Room 615F
Washington, D.C. 20201

Re: April 22, 2005 GAO Report – "More Specific Criteria Needed to Classify Inpatient Rehabilitation Facilities"

Dear Secretary Leavitt:

This letter pertains to your pending response to the recent Government Accountability Office (GAO) report on the inpatient rehabilitation facility (IRF) classification criterion popularly known as the "75 Percent Rule." We would like to discuss the contents of this letter with you before you issue your response to the GAO report.

The American Hospital Association, the American Medical Rehabilitation Providers Association (AMRPA), and the Federation of American Hospitals, along with many other stakeholders, are very concerned about the 75% Rule. This letter conveys our primary concerns and recommendations about future action on the 75% Rule.

GAO Recognizes Current 75% Rule is Flawed

The GAO report makes it clear that the 75% Rule in its current form is not working. This key finding of the report is highlighted in the title of the report. We concur that the rule is fundamentally flawed and therefore not adequately serving its intended purpose – which is to distinguish IRFs from general acute hospitals. Clearly, if 94 percent of facilities would not comply under the rule (even greater than the 87 percent impact estimated by CMS in the May 2004 final rule), numerous patients who are clinically appropriate for IRF-level care will be harmed due to access restrictions caused by significant staff cut-backs and facility closures.

The GAO was charged by Congress with responding to two questions:

1) Whether the current list of conditions comprising the 75% Rule represents a clinically appropriate standard for defining services provided by inpatient rehabilitation hospitals and units; and
2) If not, which additional conditions should be added to the list.

Instead of fully answering these questions, the GAO made the following recommendations to the Centers for Medicare & Medicaid Services (CMS). **The GAO recommendations are relevant to the questions posed by Congress, but do not directly and fully answer them.**

1) CMS should conduct more routine, targeted medical reviews of admissions to inpatient rehabilitation hospitals and units;
2) CMS should conduct research on the effectiveness of intensive inpatient rehabilitation services and the factors that predict the need for those services; and
3) Based upon the information obtained from research and other activities and other sources, CMS should refine the rule to describe more thoroughly the subgroups of patients within a condition that are appropriate for IRFs, and consideration of other factors such as functional status.

These recommendations reflect the current challenge facing CMS, the IRF field, and other IRF stakeholders, which is the current dearth of medical literature on the effectiveness of IRF clinical outcomes relative to outcomes for other providers of intensive rehabilitation. The National Institutes of Health (NIH) and the Agency on Healthcare Quality and Research (AHRQ) recently validated this situation through an exhaustive review of the medical literature, which also identified that only extremely limited clinical research is available to aid policy makers. Fortunately, as requested by CMS, the NIH has developed a comprehensive research plan to help fill the current IRF research void. This plan, which is pending release, will provide a proper framework for CMS, the IRF field, researchers, and other partners to adopt in our collective response to the GAO's recommendations.

A panel of experts convened by the GAO also agreed with the NIH/AHRQ findings related to limited research tools available for policy development. **Importantly, the expert panel and others consulted by the GAO agreed that the current structure of the 75% Rule, which is largely based on a patient's primary condition, is insufficient to identify the types of patients who should be treated in a rehabilitation hospital or unit.** The functional status of patients was widely supported as a key clinical characteristic that should be considered for inclusion in modified IRF classification criteria.

While we understand that the GAO's report was affected by the dearth of the medical literature on IRF outcomes, it should be recognized that the questions posed by Congress remain unanswered. The report provides an assessment of the current challenges facing policy makers wishing to comprehensively modernize the 75% Rule to reflect current

medical technology and evidence-based research. **However, the GAO does not provide actionable, specific recommendations on how to correct the flaws of the 75% Rule.**

GAO Recommends Further Research

The field strongly agrees with the GAO's recommendations for further research. We recognize that the field must actively engage in developing, funding, and implementing research, studies, and clinical trials that can inform policymakers and stakeholders. This will require the field to collaborate with HHS/CMS, the NIH, the academic research community, funders, and other partners. **We welcome a dialogue with HHS to develop a meaningful research agenda.**

A key concern related to the report's research recommendations pertains to the proposal to include medical necessity review as a research mechanism for 75% Rule policy development. Another concern with the study is that the GAO consistently inter-changed the purpose of the 75% Rule, a *facility* classification criterion, with medical necessity criteria, *patient*-focused guidelines. We are very uncomfortable with the component of the GAO's research proposals since medical necessity review is conducted by CMS' Fiscal Intermediaries who, in general, lack clinical expertise specific to medical rehabilitation. Further, medical necessity review utilizes local coverage determinations (LCD). Selected inpatient rehabilitation LCDs raise serious concerns since they were developed without the benefit of a body of clinical evidence on inpatient rehabilitation, and as such, lack a sound scientific foundation. **Medical necessity review should not be viewed as an acceptable component of a 75% Rule research plan.** Furthermore, FIs should only conduct medical necessity review using the rigorous, national criteria established in Section 110 of the Medicare Benefits Policy Manual.

It is very important that comprehensive research on the types of patients who are appropriate for inclusion in the 75% Rule is conducted in a timely fashion to have a sufficient IRF patient population to study. If the rule remains in its current form, the number and types of diagnoses presenting in IRFs will be reduced, thereby diminishing the opportunity for sound, comprehensive research on clinical efficacy since the field will be forced to continue dramatically downsizing in response to the 75% Rule changes. As such, the 75% Rule changes are destroying the natural laboratory needed for research on how to improve the current structure of the 75% Rule – this process will be accelerated at the 60 percent and higher threshold levels. **The existing laboratory must be preserved in order to fairly and objectively execute the NIH-recommended research plan and complementary research endeavors.**

Several field-initiated research efforts are already underway. The American Academy of Physical Medicine & Research held a national summit in April to establish an inpatient rehabilitation research agenda and has convened a task force to address IRF medical necessity issues. And the AMRPA is developing a study looking at IRF payment and comparing rehabilitation outcomes across sites of care. In addition, the AMRPA recently convened a separate national group to take a fresh look at the definition of an IRF. Also,

several NIH panelists are considering forming a consortium to conduct research on the effectiveness of IRF level of care as opposed to others levels for new and emerging technologies.

75% Rule Impact is Significantly Exceeding CMS' Projections

The 75% Rule changes implemented by CMS in its May 2004 final rule are producing an impact that substantially exceeds CMS' projections on patient access to rehabilitation and on Medicare spending. Using two comprehensive data sources[1], we estimate that in the first year under the new 75% Rule changes and the temporary 50 percent threshold, the impact on patients and providers is significantly exceeding CMS' stated intentions. We are highly concerned that beyond the approximately 1,800 patients CMS estimated would not receive IRF care in the first year under the 75% Rule, an additional 40,000 will also be denied care. We project that the actual fiscal impact for this first year will be a Medicare reduction of more than $200 million, which dramatically surpasses CMS' estimated reduction of $10 million. The Medicare reduction of $200 million is joined by a reduction of $80 million from other payers since the remaining inpatient rehabilitation infrastructure will not be adequate to treat the current level of non-Medicare patients. As a result, Medicare beneficiaries will not receive care that is medically necessary and many providers are being forced to take drastic operational measures.

These emerging patient trends and resulting concerns have been shared with CMS leaders and we would like to discuss these dynamics further with you and your staff. The dramatic nature of these trends raises significant concerns that Medicare beneficiaries will not receive care that is clinically justifiable due to the 75% Rule and that facilities will be harmed on a scale that far exceeds the impact estimates. This problem will be further compounded if the rule's percentage threshold increases to the 60 percent level.

Recommendations

Given the concerns discussed above we recommend the following:

1. To permit adequate time to pursue the GAO recommendations pertaining to research, comprehensive oversight of IRFs should be maintained by extending the 50 percent threshold and basing IRF medical necessity review on the national guidelines.
2. Research should be sponsored by HHS, in collaboration with the inpatient rehabilitation field and other stakeholders, to identify patients who are medically necessary of IRF-level care and other levels of rehabilitation utilizing the pending NIH research plan as a main component of this collaborative effort.
3. HHS should establish a panel of experts to reexamine and rewrite the current criteria defining inpatient rehabilitation facilities to distinguish them from general acute hospitals. This panel could be a joint government and field enterprise.

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[1] These impact estimates are based on data and analyses provided by the Uniform Data System for Medical Rehabilitation and eRehabData™ and can be distributed and discussed at our upcoming meeting.

The fact that the 75% Rule changes are having an impact that is far exceeding what was projected by CMS, is in our view, sufficient justification to extend the current threshold of 50 percent. The GAO recommendations to study and refine the rule further justify such an adjustment to the current policy.

We appreciate your consideration of our response to the GAO report and our resulting concerns. We welcome a discussion with you and your staff to assess the current and future impact of the 75% Rule, both upon Medicare beneficiaries inpatient rehabilitation units and hospitals. If you have any questions about the comments expressed in this letter, please contact Jayne Hart Chambers at 202-624-1300, Martie Kendrick at 202-457-6520, or Rochelle Archuleta at 202-626-2320. Thank you.

Respectfully Submitted,

The American Hospital Association
The American Medical Rehabilitation Providers Association
The Federation of American Hospitals