DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Office of the Administrator
Washington, DC 20201

NOV 18 2004

The Honorable Charles E. Grassley
Chairman
Committee on Finance
U.S. Senate
Washington, DC 20510-6200

Dear Mr. Chairman:

Thank you for your letter concerning the requirements for a hospital to be classified as an inpatient rehabilitation facility (IRF), more commonly known as the "75 percent rule." On May 7, 2004, the Centers for Medicare & Medicaid Services (CMS) published a final rule that modernized this longstanding requirement in a way that supports appropriate access to intensive rehabilitation services for Medicare beneficiaries, more flexibility for providers, and prudent fiscal stewardship of the program. We are already implementing the revised rules through our Medicare contractors to ensure appropriate access to rehabilitation services for Medicare beneficiaries, fair and consistent application of the new requirements, and that the large number of facilities that were out of compliance in recent years gradually come back into compliance with the requirements.

CMS is committed to ensuring that beneficiaries in need of intensive inpatient rehabilitation services have access to appropriate care. At the same time, we are committed to ensuring that the Medicare program, which pays substantially higher amounts to IRFs than to other providers of rehabilitation care, properly classifies these facilities for Medicare payment purposes. Based on extensive public comments and expert analysis, the final rule takes important steps to achieve both goals. First, by providing clear definitions of the clinical conditions included under the policy, the rule will facilitate greater transparency in the policy and support effective enforcement and compliance. Second, the rule expands the list of conditions to include specific orthopedic conditions requiring intensive rehabilitation that were not previously included under the rule. Finally, by lowering the compliance threshold to 50 percent during the first year that the regulation is effective and then only gradually phasing the threshold back up to 75 percent over four years, the rule allows time to assure that IRFs can achieve compliance, while patients receive the rehabilitation services they need.

With that by way of background, let me respond to your specific questions. First, with regard to your concern that the 75 percent rule may cause patients who need rehabilitative care to be denied access to that care, we have initiated several activities to ensure that the rule is applied correctly. The most important is that the final regulation gives clear guidance to our contractors and to hospitals as to what the requirements of the regulation are. For example, the final regulation replaces the term "polyarthritis"—a term that many commenters agreed had limited clinical significance—with more precise orthopedic conditions. Therefore, we believe that the plain language of the final regulation will ensure that providers have clear guidance as to what medical conditions count toward the compliance threshold. In addition, on June 25, 2004, CMS

issued instructions to the CMS Regional Offices (ROs) and Medicare fiscal intermediaries (FIs) regarding how verification of compliance policies in the final rule will be performed. In August 2004, CMS held training/learning sessions with the CMS ROs and FIs, including the Medical Directors involved in the compliance process, to discuss the instructions regarding the implementation of the policies in the final rule. We believe that the CMS ROs and the FI staff responsible for implementing the operational procedures specified in the instructions are fully prepared to do so.

In addition, in August 2004, we surveyed the ten CMS ROs regarding: (1) the existence of IRFs having problems meeting the 50 percent threshold, (2) the existence of IRFs having to deny access to beneficiaries, and (3) concerns expressed regarding local coverage determinations (LCDs). In response, only one RO responded in a manner that reflected concerns expressed by a local IRF trade association. We are continuing to monitor whether any facilities in this local area are experiencing problems. Also, in August 2004, we surveyed the FIs about these same issues. We received no affirmative responses related to the above issues. We expect to continue to survey the CMS ROs and FIs periodically and to begin a provider outreach program to address industry questions and concerns with the requirements.

Second, we appreciate and support your comments regarding the importance of patients being directed to the most appropriate site to receive rehabilitation care, given that Medicare covers such care in a variety of settings. We believe it is important to maintain policies that avoid creating perverse financial incentives to steer less complicated patients toward inpatient services when this level of care may not be warranted. Our goal is to use the new IRF requirements to support access to IRF services for those patients that truly require the specialized and intensive inpatient rehabilitation care provided in an IRF, in contrast to care that can be appropriately provided at a lower cost in some of these other settings. CMS expects that beneficiaries that need inpatient services will continue to receive those services, as will beneficiaries that require alternative rehabilitation services.

There is no doubt that strong financial incentives exist for IRFs to admit patients who may require rehabilitative services that could be provided at a lower cost in other settings. For example, Medicare may pay $11,000 for rehabilitation of a joint replacement case in an IRF. Payment for a comparable case in an acute care hospital, skilled nursing facility, or under home health care may be $9,000, $6,600, and $5,100, respectively. In many areas of the country, the vast majority, if not all patients, undergoing rehabilitation for joint replacement receive rehabilitation services in these alternative settings.

In fact, evidence suggests that some IRFs may have been taking advantage of the requirements in effect prior to the final rule. Data indicate that some IRFs have recently been admitting orthopedic patients with relatively moderate rehabilitation needs in order to boost profits under the new IRF prospective payment system (PPS) that went into effect on January 1, 2002. While this may make good business sense for hospitals, it does not comport with longstanding Medicare rules or the interest of taxpayers and beneficiaries in receiving high quality care in the most efficient setting possible.

Third, the rehabilitation community had asked for a delay in issuing LCDs until the regulation was published, so that any clinical policy related to coverage might be informed by the regulation on IRF classification. CMS agreed to do so. With the issuance of the regulation, contractors are now permitted to follow the required process in developing and issuing local coverage policy related to IRFs. This is, by design, an open process that involves public notice and comment, with the goal of developing transparent coverage policies that work most effectively. Some LCDs have already gone through this process and have been implemented. These LCDs are important tools to provide education and guidance to providers as to what is covered, while also serving as a guide when conducting medical review.

Fourth, you can be assured that the final rule was developed only after conducting a careful and thorough review of the approximately 9,800 comments received in response to the proposed rule (published on September 9, 2003). We also conducted a Town Hall meeting and other public forums where we received additional information on the proposed rule. In addition, the final rule reflects the input received from knowledgeable professionals who have experience treating rehabilitation patients, and managing rehabilitation hospitals and facilities. Further, we solicited input from experts working in commercial insurance, academic medicine, and other segments of the rehabilitation industry. These individuals reviewed and commented on the clinical approach and potential effect on patient access to intensive rehabilitation services.

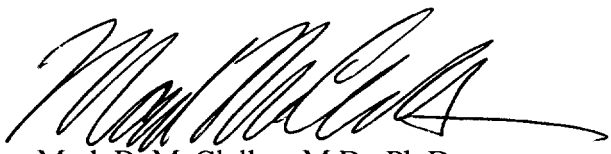
The final rule also reflects the need for a focused research program to generate the data required to continue assessing the efficacy of rehabilitation services in various settings. CMS will conduct additional applied research and analysis to provide for potential enhancements in the next several years, as the rule is phased in. We have contracted with the Agency for Healthcare Research and Quality at the Department of Health and Human Services to perform a review of current medical literature on certain conditions and patient characteristics that require intensive inpatient rehabilitation services (rather than care in alternative therapy settings) to achieve an optimal outcome. In addition, we are working with the National Center for Medical Rehabilitation Research at the National Institutes of Health to facilitate a panel of experts in the rehabilitation field. This panel will address the most appropriate clinical conditions for care in IRFs, based on evidence available through the literature review, and formulate a research agenda to assist in developing scientific studies to examine the efficacy of rehabilitation services in various settings.

Finally, in response to your question on financial performance of IRFs, the available data also support a determination that IRFs continue to show strong financial performance under the Medicare payment system, which accounts for a significant majority of their revenues. For example, the Pennsylvania Health Care Cost Containment Council released a report in August 2004 with information from a study that showed Pennsylvania IRFs experienced "unprecedented growth" last year. The report found the average total margin (the ratio of all income to all expenses) for IRFs increased to 10.9 percent in fiscal 2003, from 1.8 percent the previous year, suggesting that the difference between payments and actual patient costs has been increasing. In addition, CMS has contracted with the RAND Corporation to review the most current IRF data available to determine the impact of implementing the IRF PPS. Preliminary data estimates show that the average IRF PPS payment exceeds the average IRF cost by 17 percent. Medicare

expenditure data in this area also indicate an increase in aggregate payments of 30 percent in 2002, the most recent year for which comparison data are available.

We hope this letter has been helpful in addressing your questions. Our goal, like yours, remains to ensure that patients receive the proper quality rehabilitation care in the appropriate setting. We believe this new rule makes that important, patient-centered distinction. Further, we are committed to continued and careful monitoring of patient access to rehabilitation care and remain open to input from consumers and the rehabilitation industry to address any issues arising from implementation of the final regulation. Thank you for your interest in this important Medicare issue.

Sincerely,



Mark B. McClellan, M.D., Ph.D.