November 3, 2003

The Honorable Thomas Scully
Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
Room 309-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicare Program; Changes to the Criteria for Being Classified as an Inpatient Rehabilitation Facility (68 Fed. Reg. 53266, September 9, 2003)

Dear Administrator Scully:

Congress established the Office of Advocacy (Advocacy) under Pub. L. 94-305 to represent the views of small business before Federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA), so the views expressed by Advocacy do not necessarily reflect the views of the SBA or of the Administration. Section 612 of the Regulatory Flexibility Act (RFA) also requires Advocacy to monitor agency compliance with the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act.[1]

On August 13, 2002, President George W. Bush signed Executive Order 13272, requiring Federal agencies to implement policies protecting small businesses when writing new rules and regulations.[2] Executive Order 13272 instructs Advocacy to provide comment on draft rules to the agency that has proposed a rule, as well as to the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget.[3] Executive Order 13272 also requires agencies to give every appropriate consideration to any comments provided by Advocacy. Under the Executive Order, the agency must include, in any explanation or discussion accompanying publication in the *Federal Register* of a final rule, the agency's response to any written comments submitted by Advocacy on the proposed rule, unless the agency certifies that the public interest is not served by doing so.[4]

On September 9, 2003, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule in the Federal Register entitled, "Changes to the Criteria for Being Classified as an Inpatient Rehabilitation Facility."[5] The proposed rule sees to change the criteria Medicare uses

[1] Pub. L. No. 96-354, 94 Stat. 1164 (1981) (codified at 5 U.S.C. §§ 601-612) amended by Subtitle II of the Contract with America Advancement Act, Pub. L. No. 104-121, 110 Stat.857 (1996). 5 U.S.C. §612(a).
[2] Exec. Order No. 13,272 § 1, 67 Fed. Reg. 53,461 (Aug. 13, 2002).
[3] E.O. 13272, at § 2(c), 67 Fed. Reg. at 53,461.
[4] Id. at § 3(c), 67 Fed. Reg. at 53,461.
[5] 68 Fed. Reg. 53266 (September 9, 2003).

for classifying a hospital, or unit of a hospital, as an inpatient rehabilitation facility (IRF). The criteria used for the IRF designation is more commonly referred to as the "75 Percent Rule."[6] The rule requires that 75 percent of an IRF's total patient population must require intensive rehabilitation services for treatment of one or more of ten medical conditions to be eligible for Medicare payment during its most recent cost reporting period.

Advocacy commends CMS for appreciating that the proposed rule is going to have a significant economic impact on a substantial number of small entities, and for preparing an initial regulatory flexibility analysis (IRFA) in conformance with the RFA. Advocacy agrees with CMS' assessment of the rule's likely impact on small businesses. Advocacy encourages CMS to use its regulatory authority to minimize the rule's impact on small entities while accomplishing its policy goals.

Advocacy recommends CMS reduce the IRF patient threshold to 50 percent for the three-year period identified in the proposed rule.

Section 603(c) of the RFA requires Federal agencies to include in their IRFA a description of any significant alternatives to the proposed rule which accomplishes the regulatory objectives of applicable statutes and which minimizes any significant economic impact of the proposed rule on small entities.

The American Hospital Association recently released results of a survey that was sent to all rehabilitation hospitals and units.[7] More than 300 hospitals, 25% of the field, responded to the survey. If CMS implements the rule as proposed, the survey results show that: (a) 94% of facilities would have to turn away patients; (b) 50% of patients would lose access to vital rehabilitation services; (c) 87% of rehabilitation facilities would lose their rehabilitation certification by 2007; (d) nearly ¼ of rehabilitation units would be expected to close; and (e) the remaining facilities would reduce staff by 69%, reduce the number of beds by 56%, and cutback services by 54%.

Advocacy appreciates that CMS has agreed to reduce the IRF threshold to 65% for three years while it gathers compliance data and that CMS has raised the qualifying conditions from ten to twelve. While these actions would appear to benefit IRFs, the benefits gained by reducing the threshold to 65 percent are offset by the fact that CMS' proposal actually narrows the definition of polyarthritis as a qualifying condition. As a result, the proposal will likely reduce the IRFs' patient population because fewer patients receive treatment under the twelve conditions proposed than under the ten conditions in the current 75 Percent Rule. A smaller patient population will adversely impact the economic viability of small IRFs. Advocacy encourages CMS to consider adopting a less burdensome regulatory alternative by lowering the threshold to 50% for the three years that CMS is studying the 75 Percent Rule. This alternative better assures that IRFs can continue to operate while CMS researches potential long-term solutions.

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[6] 42 C.F.R. § 412, *et seq*.

[7] American Hospital Association press release, October 21, 2003.

Advocacy bases its recommended alternative on the Medicare Payment Advisory Commission's (MedPAC) recommendation that CMS should lower the threshold in the 75 Percent Rule to 50 percent for a period of one year.[8] During that time, MedPAC recommends that the Secretary consult with an expert panel of clinicians to reach consensus on the diagnoses to include in the 75 Percent Rule.

Under its current proposal, CMS will put the IRFs in a position of having to make a choice between going out of business or turning away patients whose conditions will not count towards the 65 percent threshold. For example, CMS states:

> While it is difficult to predict the aggregate impact of improved compliance on provider payments, we expect IRFs …will change their behavior in a variety of ways. IRFs may change admission practices to alter their case-mix, either Medicare or total patient population, by admitting patients with more intensive rehabilitation needs that fall into the 10 conditions.
>
> On the other hand, enforcement of the 75% rule may cause some IRFs to reduce the number of beds and/or reduce the number of admissions that may result in a reduction of the facility's revenue.[9]

By using its regulatory authority to set the threshold at 50%, CMS would be minimizing the rule's potential to severely impact small inpatient rehabilitation facilities and assuring that patients continue to receive adequate rehabilitation care while CMS collects the data necessary to modernize the rule. Advocacy recommends CMS initiate another rulemaking when, and if, it decides to raise the threshold after three years. This will give the affected small entities and public an opportunity to be heard on the issue.

While CMS acknowledges that the IRF-PAI data is of limited utility to assess the adequacy of compliance with the 75 Percent Rule, CMS intends to rely on the same data in its future analysis of the 75 Percent Rule.

Advocacy agrees with CMS's policy goal of improving the IRF system and compliance with the requirements of 42 C.F.R § 412.23(b)(2). Advocacy is concerned that CMS is changing its longstanding policy on how IRFs qualify to provide their services and under what conditions they are allowed to bill Medicare for the services, without the data to support such action. Advocacy questions whether CMS can obtain the data necessary to make an informed decision about IRFs over the next three years by looking at paid claims and IRF-PAI data. This is the same data that CMS acknowledges is currently inadequate to reach conclusions about how the IRF system is currently functioning.[10] Advocacy believes that CMS should consider expanding how it intends to obtain data on IRFs and maximize industry input on the matter. This could be accomplished through the use of clinical trials or an expert panel as recommended by MedPAC. This

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[8] Letter from MedPAC Chairman, Glenn Hackbarth to CMS Administrator, Thomas Scully, dated July 7, 2003. (MedPAC letter). Advocacy believes MedPAC's recommendation to retain the ten qualifying conditions while reducing the threshold to 50 percent for one year is a significant alternative that CMS should have considered as part of its IRFA.

[9] 68 Fed. Reg. at 53269 (September 9, 2003).

[10] *Id*.

suggestion is consistent with MedPAC's recommendation that CMS should periodically revisit the list of diagnoses and clinical criteria for rehabilitation patients, with the expectation of moving away from simple diagnoses-based criteria to patient-based criteria.[11]

Advocacy can be of help in determining how many proprietary small IRFs will be impacted by the proposed rule.

CMS states that, "because we lack data on individual hospital receipts, we cannot determine the number of small proprietary IRFs."[12] Advocacy has previously been of help to CMS in its effort to determine the number of small businesses that would be negatively impact by a regulation. Advocacy extends the same offer with respect to this regulation. For example, based on informal discussions with industry contacts, Advocacy has learned that there are approximately 107 small free-standing proprietary hospitals, and approximately 143 small proprietary units within hospitals. If CMS wishes, Advocacy will work with CMS to get a better determination of how many small proprietary IRFs are in existence.

Conclusion

In conclusion, while it is clear that the IRF industry agrees with CMS that the 75 Percent Rule needs revision, the proposed rule presents a number of significant issues for small businesses. As written, CMS's proposal could result in a significant number of small IRFs going out of business. Advocacy is confident that CMS will take this into account in the drafting of the final rule.

Thank you for your attention to the above matters. If you have any questions about this correspondence, please do not hesitate to contact Linwood Rayford at (202) 401-6880.

Sincerely,

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Chief Counsel for Advocacy

Linwood L. Rayford, III
Assistant Chief Counsel for Advocacy

Cc: Dr. John D. Graham, Administrator
Office of Information and Regulatory Affairs

[11] *See* July 7, 2003, MedPAC letter.
[12] 68 Fed. Reg. at 53275 (September 9, 2003).