January 31, 2001

Robert A. Berenson
Acting Administrator
Health Care Financing Administration
Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re:	Interim Final Rule on the Use of Restraint and Seclusion in Psychiatric Residential Treatment Facilities Providing Psychiatric Services to Individuals Under Age 21; 66 Fed. Reg. 7148 (January 22, 2001).

Dear Acting Administrator Berenson:

The Office of Advocacy of the U.S. Small Business Administration (SBA) was established by Congress pursuant to Pub. L. No. 94-305 to advocate the views of small business before federal agencies and Congress. Advocacy is required by section 612(a) of the Regulatory Flexibility Act (RFA)[1] to monitor agency compliance with the RFA. In addition, the Chief Counsel of Advocacy is authorized to appear as *amicus curiae* in regulatory appeals from final agency actions, and is allowed to present views with respect to compliance with the RFA, the adequacy of the rulemaking record with respect to small entities, and the effect of the rule on small entities.[2] On March 28, 1996, the Small Business Regulatory Enforcement Fairness Act (SBREFA)[3] was signed into law making a number of significant changes to the RFA, including the provision to allow judicial review of agencies' compliance with the RFA.[4]

This letter represents a second attempt to convey to HCFA Advocacy's concerns about the above-referenced regulation. HCFA officials provided Advocacy an advance copy of the interim final rule during the OMB review process. On January 11, 2001, the same day the rule was provided to Advocacy, our office submitted comments to both HCFA and OMB outlining areas where the rule fell short in minimizing small business burdens, including a discussion of viable regulatory alternatives. Inasmuch as none of the recommendations outlined in the comments were incorporated or discussed in the published interim final rule, Advocacy reiterates its concerns below.

In July 1999, per the request of Rep. Saxby Chambliss, Advocacy submitted comments to the agency on the interim final rule that dealt with Medicare conditions of participation, including standards for the use of patient restraints in hospitals. Rep. Chambliss specifically requested Advocacy's opinion as to whether the agency had complied with the RFA in issuing the hospital restraint rule. Advocacy concluded that the one-hour

[1] 5 U.S.C. § 601 et seq.
[2] *Id.*
[3] Pub. L. No. 104-121, 110 Stat. 857 (1996).
[4] 5 U.SC. § 611.

restriction on the use of restraints could be burdensome for rural hospitals in particular. The agency had not specifically discussed the one-hour standard in the proposed rule. Moreover, the agency did not analyze the impact of the provision in the interim final rule. No serious alternatives were presented that might have allowed the agency to reduce burden. On the same date that Advocacy sent its comments to Rep. Chambliss, September 14, 2000, a court decision was rendered in the case of *National Association of Psychiatric Health Systems v. Shalala*,[5] in which the court essentially upheld the hospital restraint rule, but remanded the rule to the agency for completion of a compliant final regulatory flexibility analysis pursuant to the requirements of the RFA.

The one-hour requirement in the residential treatment facility rule seems to be less burdensome because it allows a registered nurse to make the assessment of whether there is continued need for restraint rather than require a doctor to make a face-to-face assessment. Although the one-hour provisions of the instant regulation appear to be more flexible, there are other requirements that have not been analyzed adequately.

For instance, the regulation sets maximum time limits for a restraint order based on a resident's age: no more than 4 hours for those ages 18-21, 2 hours for those ages 9-17 and 1 hour for those under age 9. These limits were consistent with the time limits presented in the July 1999 hospital interim final rule, but there does not seem to be a factual basis for these particular limits. In other words, they seem somewhat arbitrary. Is there any research that says 9-year-olds suffer more injuries if they are secluded for 2 hours as opposed to 1? In the case of "time-outs", the agency felt that the duration of time-outs could be based on professional judgement alone. Although time-outs are inherently less invasive than physical restraints, it would seem reasonable that some degree of professional judgement should also be incorporated into the duration requirements for restraint.

The regulation also requires that clinical staff trained in the use of emergency safety interventions be physically present, continually assessing and monitoring the resident in restraints. Video monitoring is not sufficient to meet this standard according to the requirements of the regulation. The agency is concerned that patients might go into cardiac arrest or suffer asphyxiation, and that these emergencies might go unnoticed on a video monitor. It seems that video monitoring in combination with audio and or vital sign monitors could be a workable alternative. Or, perhaps frequent bedside checks at timed intervals could suffice. To have to sit with one resident until restraint is no longer necessary may place other patients in jeopardy due to lack of available staff. What if more than one patient requires restraint? How will that affect the resident-to-staff ratio? How many staff typically work at a residential facility at any given time?

The regulation requires that there be face-to-face post-intervention debriefings within 24 hours after a resident has been restrained. The debriefings are to include the resident and the staff involved in the intervention, in addition to others (e.g., family) when appropriate. This may be impossible as a practical matter. What if the patient is incapable of comprehending the discussion or if a new emergency arises requiring a

[5] 120 F. Supp.2d 33 (D.D.C. 2000).

second restraint period within those 24 hours? There either needs to be an exception to the 24-hour rule to address these and other variables, or the agency should consider a longer period as a means to reduce burden. There is yet another requirement for a separate staff debriefing to review administrative procedures within 24 hours of the intervention. Once the immediate needs of the resident have been addressed through the initial debriefing with the patient, it seems reasonable to address administrative issues on a less frequent basis.

In terms of requirements, one final concern is that staff must demonstrate their competencies on a semi-annual basis. The agency concedes that the training and education requirements in the rule exceed the minimum requirements outlined in the Children's Health Act of 2000, however the meaning of the requirements is unclear. Does demonstrating competency mean that a supervisor or office manager must review each employee's file twice a year to determine if training requirements are up-to-date? Does it mean that employees will have to be retrained twice a year, somewhat akin to continuing education? Does it mean that in the case of CPR, for instance, that an employee will have to demonstrate his or her competency on a CPR training dummy? Does it mean that employees will be required to take some sort of written test? Does it mean that employees will have to be recertified in certain medical techniques? To assess the impact of this requirement, more explanation is necessary.

The agency has chosen to publish this rule as an interim final action. The agency claims that the framework for this rulemaking was outlined in the November 1994 proposed rule. And, to the extent that some of the new provisions are not a logical outgrowth of the proposed rule, the agency believes that children and adolescents would be in danger without the immediate changes. Advocacy has criticized HCFA on numerous occasions for unnecessarily bypassing the notice and comment provisions of the Administrative Procedure Act (APA) (e.g., competitive bidding for durable medical equipment, surety bonds for home health agencies, interim payment system for home health agencies, inherent reasonableness, etc.). As for the sudden need based on safety, it would seem that there have been safety issues in existence since the proposed rule was published over six years ago. In addition, more and more states have introduced their own safety standards for the use of restraints since that time. Advocacy opines that the more prudent course would have been to issue a proposed rule and to solicit public comment. After-the-fact comment periods seem somewhat disingenuous. In this case, the rule becomes effective on March 23, 2001 and the comment deadline is March 23, 2001. If substantial changes are made as a result of comments, greater burden could result.

As an endnote, it bears mentioning that SBA's new size standards may affect your definition of a small business. You list $5 million or less in annual receipts. This size standard is still accurate. However, Advocacy cannot determine whether residential mental retardation facilities are also included in your definition of psychiatric treatment facilities. If so, the definition of a small residential mental retardation facility is $7.5 million or less in annual receipts. Of course, hospitals are not covered under this rule, but for your information, the definition of a small psychiatric and substance abuse hospital is one with $25 million or less in annual receipts. SBA's new size standards for the health

industries may be found in the November 17, 2000 *Federal Register* (65 Fed. Reg. 69432).

No one can argue that these regulations are not good intentioned. Proper restraint techniques are required to ensure patients' rights for those most vulnerable to abuse. There is a fine line, however, in over regulating to the point that other patient care might be jeopardized. At the very least there ought to be greater flexibility to allow for professional judgement and emergency situations. Greater flexibility through reasonable regulatory alternatives could result in better patient care, better compliance and reduced economic burden.

Advocacy urges HCFA to consider the alternatives discussed throughout these comments. Thank you for your attention to this matter. Please do not hesitate to contact this office if you have any questions, 202-205-6945.

Sincerely,

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