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*Testimony of
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*U.S. House of Representatives
Committee on Small Business*

Date: April 10, 2002
Time: 10:00 A.M.
Location: 2360 Rayburn House Office Building
Topic: Can Improved CMS Compliance with the Regulatory Flexibility Act Resuscitate Small Healthcare Providers?

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Chairman Manzullo and Members of the Committee, good morning and thank you for the opportunity to appear before you today to discuss the issue of whether improved Centers for Medicare and Medicaid Services (CMS) compliance with the Regulatory Flexibility Act can be expected to resuscitate small healthcare providers.

For the last twenty-five years the Office of Advocacy has been monitoring federal agencies' compliance with the Regulatory Flexibility Act, commonly referred to as the RFA. The RFA requires federal agencies to determine whether a proposed rule will have a disproportionate effect on small entities, and, if so, to explore alternative regulatory solutions. As I testified before this committee on March 6, 2002, and as I indicated in our recently released annual report on RFA compliance, not all agencies comply fully with the RFA. Advocacy has historically had difficulty impressing upon some federal agencies the benefits that can be derived by complying with the provisions and spirit of the RFA. The benefits flow not only to small businesses, but also to the agencies themselves, as their compliance with the RFA helps to lessen legal challenges and legislative criticism of their regulations.

Your invitation to appear before this Committee today asked me to address the adequacy of CMS's compliance with the RFA. Advocacy appreciates the complicated public policy objectives undertaken by CMS and the enormous pressure the agency is under to promulgate regulations on payment schedules in a timely manner. We also appreciate the effect these regulations have on small healthcare providers, including the portable x-ray and EKG providers, ninety percent of whom are small entities as defined by SBA size standards.

It is our goal that CMS more fully consider the consequences of their regulatory actions on small employers prior to finalizing their rules. This is, after all, the primary tenet of the RFA.

Generally speaking, we believe that CMS should do a better job of following administrative procedures that require public notice and comment. CMS should also

consider less burdensome regulatory alternatives that would still allow the agency to meet its statutory requirements. Of particular concern is CMS's practice of promulgating direct final and interim final regulations. Procedurally this methodology allows the agency to bypass notice and comment requirements of the Administrative Procedure Act (APA) and the RFA. The APA does not afford an agency the latitude to issue direct final or interim final rules unless the agency, for good cause, finds that notice and public procedure thereon are impracticable, unnecessary or contrary to the public interest. 5 U.S.C. § 553(b)(3)(B). In one of our comment letters to CMS, Advocacy pointed out that in a 10-month period during 1998, CMS published twenty-four rules in the Federal Register. Of that total, fourteen of the rules were interim or direct final rules. We are concerned that by relying on direct final rulemaking, CMS is losing out on the benefit of public comment and the agency's ability to appreciate the rule's effect on small business is unfortunately minimized.

Two recent rulemakings serve to highlight Advocacy's ongoing concerns with CMS' lack of compliance with the RFA: The Use of Restraint and Seclusion in Psychiatric Residential Treatment Facilities Providing Psychiatric Services to Individuals Under Age 21; and the rule announcing Revisions to the Payment Policies and Five-Year Review of the Relative Value Units Under the Physicians Fee Schedule for Calendar Year 2002.

I. The Use of Restraint and Seclusion in Psychiatric Residential Treatment Facilities Providing Psychiatric Services to Individuals Under Age 21.

In July 1999, CMS's predecessor, the Health Care Financing Administration (HCFA) issued an interim final rule entitled, "Medicare and Medicaid Programs; Conditions of Participation: Patients' Rights." The rule contained standards for the use of patient restraints in hospitals. U.S. Representative Saxby Chambliss asked Advocacy to review the Patients' Rights rule to determine if HCFA had complied with the RFA. After reviewing the rule Advocacy concluded that the one-hour restriction on the use of restraints was particularly burdensome on rural hospitals primarily because it called for the treating physician to make a face to face assessment of the patient within one hour of

initiating restraint or seclusion. Advocacy commented that HCFA failed to analyze the impact of the one-hour provision in the rule and that no serious alternatives were considered. Interestingly, the rule became the subject of a lawsuit filed in the District Court of the District of Columbia. In September 2000, the court upheld the rule, but because the agency failed to comply with the RFA, the court remanded the rule back to the agency for the completion of a final regulatory flexibility analysis. The court's decision, with regard to the RFA requirement for agencies to describe their efforts to minimize their impact on small business, reads: "The Secretary [the named defendant was Donna Shalala, then Secretary of the Department of Health and Human Services] did not obtain data or analyze available data on the impact of the final rule on small entities, nor did she properly assess the impact the final rule would have on small entities." National Ass'n of Psychiatric Health Systems, et al., v. Donna Shalala, Secretary, Dep't of Health and Human Services, 120 F.Supp.2d 33, 42, (D.D.C. 2000). The court concluded that, " the fact of the matter is that she has totally failed to comply with section (5) of § 604(a) of the FRFA [§ 604 contains the elements of a Final Regulatory Flexibility Analysis (FRFA) under the RFA]. Id. at 44.

We continue to insist that CMS complete the regulatory analysis as ordered by the court, which still has not been done. Why do the analysis after the fact? Because it creates an institutional mechanism whereby CMS can produce regulatory analyses of the rules' impacts on small healthcare entities.

II. Revisions to the Payment Policies and Five-Year Review of the Relative Value Units Under the Physicians Fee Schedule for Calendar Year 2002.

Currently, Advocacy is experiencing similar problems getting CMS to address RFA compliance issues in a rulemaking that Advocacy believes will have a detrimental effect on the portable x-ray and EKG industry, the majority of which are small businesses. On November 1, 2001, CMS published the rule regarding Revisions to the Payment Policies and Five-Year Review of the Relative Value Units under the Physicians Fee Schedule for Calendar Year 2002. Portable x-ray and EKG providers transport x-ray and EKG machines to the patient's bedside so they do not have to be transported to a

hospital or facility for the studies. Because of the nature of the industry, the majority of the portable x-ray and EKG providers' billing is derived from Medicare. The rule would reduce, among other things, the transportation component of the portable x-ray service by 5.4%. As transportation costs make up approximately 80% of the portable x-ray industries' overhead, the 5.4% reduction in the physician fee schedule rate, in addition to other reductions, will likely devastate numerous portable x-ray businesses.

On three occasions since 1998, the Office of Advocacy has filed comments with the CMS concerning the agency's determination of payment policies as they applied to the portable x-ray and EKG industry. Advocacy suggested that because portable x-ray providers were consolidated with the other physician practice groups covered by the rule, CMS was running afoul of the legislative intent behind the RFA, to eliminate "one-size-fits-all regulations." We believed that pursuant to the RFA, CMS should have analyzed the impact on this industry separately. Only then would the agency have been in a position to decide whether to certify no impact under the RFA, or whether to perform further analysis. Advocacy suggested that the preparation of a flexibility analysis would allow CMS to determine the true extent to which the rule would impact the portable x-ray industry. Advocacy also opined that because CMS failed to prepare a proper regulatory flexibility analysis, the agency was not in a position to determine whether the cost of the regulation relative to the portable x-ray industry outweighed the benefits. For example, will it ultimately cost more money for CMS to transport patients to the hospital for the x-ray and EKG services? Will the public good will be adversely impacted if elderly patients, who currently rely on the services provided by the portable industry, have to be transported to the hospital for their studies, resulting in an increased risk of infection, or transportation injuries?

Conclusion

As I stated in my testimony before this Committee on March 6, 2002, Advocacy hopes that Secretary Tommy Thompson's recently announced plan to reform the regulatory process within his agency extends to CMS. We believe that one of the ways

CMS can implement Secretary Thompson's vision is to comply with the requirements of the RFA. Another way that CMS can reform the regulatory process is to issue proposed rules which should allow for the consideration of public comment, instead of going direct final and shutting out constructive input on the rules.

Recently, the President singled out the RFA in his Small Business Plan. In a speech before the country's top woman entrepreneurs, President Bush said, "I want to make sure people understand that we're going to do everything we can to clean up the regulatory burdens on small businesses, starting with this: Every agency -- already it's under current law -- but every agency is required to analyze the impact of new regulations on small businesses before issuing them. That's an important law. The problem is, it's oftentimes being ignored. The law is on the books; the regulators don't care that the law is on the books. From this day forward, they will care that the law is on the books."

Advocacy is working to implement the President's commitment towards full agency compliance with the RFA. We applaud this renewed emphasis toward government accountability to the small employer community. We at Advocacy have learned that when regulatory agencies involve our office in the pre-proposal stage of rule promulgation, compliance with the requirements of the RFA is improved. Advocacy has been aggressively attempting outreach with regulatory agencies in an effort to highlight the benefits of RFA compliance and early consultation with Advocacy during the pre-proposal stage of rule promulgation. We've found that this early consultation works. And we are willing to work with CMS on this early consultation process.

It is my hope and desire that the Office of Advocacy and CMS will develop a working relationship that will result in better communication and action on the issues that are of concern to this Committee.