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

Date: July 14, 2003
Time: 2:00 P.M.
Location: Winchester Hall
12 East Church Street, First Floor Hearing Room
Frederick, Maryland 21701
Topic: The Role of Medical Professionals as Small Business Owners

Chairman Manzullo and Members of the Committee, good afternoon and thank you for giving me the opportunity to appear before you today to discuss the role of medical professionals as small business owners. Advocacy's Chief Counsel, Tom Sullivan, wanted me to convey how pleased the Office of Advocacy is to be testifying in Representative Bartlett's district and for Representative Bartlett's ongoing support of our office.

My name is Linwood Rayford and I am the Assistant Chief Counsel for Food, Drug and Health Policy at the Office of Advocacy. Please note that my office's views expressed here independently represent the views of small business and do not

necessarily reflect the views of the Administration or the U. S. Small Business Administration. The Committee asked me to discuss the Office of Advocacy's review of government regulations, and how our review of health care regulations reduces the burden on small doctor's offices.

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. Advocacy has historically had difficulty impressing upon some federal agencies the benefits that can be derived by complying with the letter 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 reduce legal challenges and legislative interventions into their regulations.

One of the agencies that Advocacy is responsible for monitoring is the Department of Health and Human Services, more commonly referred to as HHS. The primary agency within HHS that is charged with promulgating rules that govern physicians' care of patients and physician reimbursement under Medicare and Medicaid is the Centers for Medicare and Medicaid Services, CMS.

Pursuant to U. S. Small Business Administration size standards, the vast majority of practicing physicians are considered small businesses. Recent studies have shown that physicians are spending more time on administrative paperwork and less time on patient care. Therefore, it has been one of Advocacy's goals that CMS more fully consider the consequences of their regulatory actions on small health care providers prior to finalizing their rules. This is, after all, the primary tenet of the RFA.

How Does Advocacy Fulfill its Mandate under the RFA?

Historically, Advocacy monitored CMS' compliance with the RFA by reviewing rules that the agency published in the *Federal Register*, or because of a request from a small health care business or health care association that asked us to review a rule that was particularly burdensome. The problem with this method of regulatory review was that once the rule was published in the *Federal Register* or had come to the attention of industry, it was often too late for Advocacy to encourage CMS to consider less burdensome alternatives. Advocacy realized that the best way to have a meaningful effect on CMS rulemaking was to become involved in the process before the proposed rule or final rule was published in the *Federal Register*.

Three recent developments have helped Advocacy become involved in CMS rulemakings earlier. First, the President signed Executive Order 13272 which requires federal agencies to implement policies protecting small entities when writing new rules and regulations. The Executive Order ensures that regulatory agencies will work closely with Advocacy, as early as possible in the regulation writing process, to address disproportionate impacts on small entities and to reduce regulatory burden. Second, in large measure because of the influence of this Committee, CMS agreed to increase its dialogue with the Office of Advocacy during the rule development process. Third, Advocacy signed a Memorandum of Understanding with the Office of Information and Regulatory Affairs at the Office of Management (OMB). Agencies are required to submit significant rules to OMB for review before publishing the rule in the *Federal Register*. OMB and Advocacy have agreed to communicate more closely on rules that are expected to have a significant small business impact. As much as anything, these developments have allowed Advocacy to become more involved early in rulemakings expected to have an impact on small businesses. Now, when Advocacy is concerned about the impact of a regulation, we can have input on the rulemaking before the ink becomes dry. This serves to reduce the rule's impact on small entities.

Some Examples of How Advocacy has Influenced CMS Rulemaking

I. Health Insurance Portability and Accountability Act (HIPAA), Standards for Privacy of Individually Identifiable Health Information (Privacy Rule)

On April 14, 2003, the HIPAA Privacy Rule became effective. The Privacy Rule was intended to provide standards for preventing unauthorized disclosure of individually identifiable health information maintained, or transmitted electronically, by health care providers. Advocacy was intimately involved with the rule during each stage of its promulgation. While concerned with many aspects of the rule, Advocacy fought to provide an extended time period for small businesses to comply with such a complex regulation. As a result, small entities covered by the regulation have an additional year to comply with its provisions. Advocacy is aware that this regulation continues to be a source of great concern to physicians, and Advocacy is having ongoing discussions with CMS to make the provisions of the rule more easily understood by health care providers through the use of a small business compliance guide.

II. HHS Limited English Proficiency Guidelines

Executive Order 13166 was signed by the President to ensure that reasonable steps would be taken to make federally funded and conducted activities meaningfully accessible to individuals with limited English proficiency. In compliance with Executive Order 13166, HHS issued a policy guidance document that generally required health care providers to provide, on request, translation services to all patients with private insurance and fee-for-service patients. Advocacy argued that the HHS guidance document was impracticable, could prove economically devastating to small health care providers, and could force practitioners to opt out of federal programs designed to provide health care to disadvantaged individuals. Currently, Advocacy understands that HHS is reviewing its guidance document. Hopefully, Advocacy's input will result in meaningful changes that will reduce the overall burden on small health care businesses.

III. Revisions to Payment Policies under the Physicians Fee Schedule

Every year, CMS is required by law to update the prospective payment schedule (PPS) for physicians. The PPS outlines the Medicare reimbursement rates for physicians and other health care providers who provide certain services to patients. Advocacy was concerned that CMS often failed to analyze the impact of the PPS on certain health care industries like the portable x-ray and EKG providers. Because of Advocacy's concerns and those voiced by this Committee, CMS promised to do a better job of assessing the impact of the PPS on the portable x-ray industry. Advocacy's strengthened relationship with CMS has resulted in additional benefits. For example, while preparing the 2004 PPS, CMS reached out to my office to determine whether Advocacy had heard of any specific industry concerns about the 2004 PPS. This request led Advocacy to host a small business roundtable on the 2004 PPS. CMS was present at the roundtable as were numerous health care associations and providers. This dialogue will hopefully result in CMS being more sensitive to how their rules impact specific small health care businesses.

Conclusion

Advocacy is pleased with the improving relationship that it has with CMS and is working to make it even stronger. Further improvements in Advocacy's relationship with CMS will ultimately benefit health care providers like those present at this hearing today. Advocacy pledges to continue encouraging CMS to appreciate how their rules and regulations affect small health care businesses. This will hopefully result in physicians being able to dedicate more time to patient care and less time worrying about government mandates.