December 28, 2001

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

Re: Medicare Program; Revisions to Payment Policies and Five-Year Review of and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 2002

Dear Administrator Scully:

The Office of the Chief Counsel for Advocacy of the U.S. Small Business Administration was created in 1976 to represent the views and interests of small businesses in Federal policy making activities.[1] The Chief Counsel participates in rulemakings and other agency actions when he/she deems it necessary to ensure proper representation of small business interests. In addition to these responsibilities, the Chief Counsel monitors agencies' compliance with the Regulatory Flexibility Act (RFA), and works with Federal agencies to ensure that their rulemakings demonstrate an analysis of the impacts that their decisions will have on small businesses.[2]

On November 1, 2001, the Centers for Medicare and Medicaid Services (CMS) filed a final rule in the *Federal Register* concerning Revisions to Payment Policies and Five-Year Review of and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 2002.[3] This comment letter is meant to inform the CMS that the final rule has the potential to significantly impact the portable x-ray and EKG provider industry.

[1] Pub. L. No. 94-305 (1976)(codified as amended at 15 U.S.C. §§ 634a-g, 637).
[2] Pub. L. No. 96-354, 94 Stat. 1164 (1981) (to be codified as amended at 5 U.S.C. §§ 601-612).
[3] 66 Fed. Reg. 552451 (November 1, 2001).

On two occasions since 1998, The Office of Advocacy has filed comments with the CMS concerning the agency's approach with respect to the determination of payment policies and adjustments to the Relative Value Units (RVU) under the Physician Fee Schedule as it directly applied to portable x-ray and EKG providers. [4] The November 1, 2001, final rule is illustrative of the fact that CMS has yet to address the specific and significant concerns raised by Advocacy in its prior comment letters. In Advocacy's opinion the CMS should immediately suspend those portions of the rule that are specifically directed at portable x-ray and EKG providers and/or consider exempting them for the following reasons:

The final rule is violative of the RFA.

The final rule does not contain a section on the RFA. Congress established the RFA because Federal agencies tend to promulgate "one-size-fits-all" regulations without considering the adverse consequences for competition, innovation, and productivity. By requiring that each agency review its regulations to ensure that small businesses are not disproportionately or unnecessarily burdened, Congress intended to increase agency awareness and understanding of the impact of regulations on small business, to require that agencies communicate and explain their findings to the public, and to provide regulatory relief to small entities where appropriate. Advocacy believes that CMS's final rule is a textbook example of the situation Congress intended to address when creating the RFA.

Whenever the RFA applies, a Federal agency must either prepare a regulatory flexibility analysis or certify (with a factual basis) that the rule will not have a "significant economic impact on a substantial number of small entities." CMS clearly violated the RFA when it failed to prepare a flexibility analysis, or certify that the rulemaking would not have a significant impact on a substantial number of small entities.

Advocacy has argued in previous comment letters on this issue that many of the affected portable x-ray and EKG providers are likely to be small entities; and that a substantial number of those businesses will be affected by CMS's decision to adjust payments under the Physician Fee Schedule. In this rule, just as CMS has done with past rulemaking regarding the Physician Fee Schedule payments to portable x-ray and EKG providers, CMS simply lumped the portable x-ray and EKG providers in with every physician practice group. This methodology is in direct conflict with the regulatory flexibility analysis requirement of the RFA as it prevents CMS from reasonably analyzing whether its actions are likely to have a significant economic impact on a substantial number of

[4] See the Chief Counsel for Advocacy's comment letters addressed to the Honorable Nancy-Ann Min DeParle, then the Administrator of the Health Care Financing Administration of the U.S. Department of Health and Human Services, dated September 10, 1998, and November 18, 1998.

portable x-ray and EKG providers. As noted by Advocacy in its September 10, 1998, comment letter,

> "'Substantial number' in the context of the instant rulemaking means the number of portable x-ray and EKG providers that will be affected by the regulation. 'Substantial number' is a relative term and does not mean the number of portable x-ray and EKG providers affected in relation to the number of physicians affected. Therefore an analysis of the impact on physicians, such as the one provided in the rule, is irrelevant. The term 'substantial number' does not even mean the number of portable x-ray and EKG providers affected in relation to portable x-ray and EKG providers not affected. 'Substantial number' refers to the proportion of portable x-ray EKG providers that currently receive a separate transportation payment and will have to comply with the new requirements."

Advocacy believes that the CMS should prepare a final regulatory flexibility analysis concerning the portable x-ray and EKG providers in connection with this rule as it will aide the CMS in understanding the true impacts that the rule will have on these industries. Further, a impact analysis will help identify alternatives to the rule that may result in lessening the impact of the rule on portable x-ray and EKG providers.

By failing to comply with the provisions of the RFA, the CMS has voluntarily decided not to address the specific and significant issues raised by Advocacy in its prior comment letters and the comments identified by industry.

A final regulatory impact analysis may reveal that the costs of the final regulation relative to portable providers outweigh the benefits. The Federal budget and Medicare potentially will suffer economic consequences if the portable industry is lost. It will ultimately cost Medicare more money to transport patients to the hospital for x-ray and EKG services. Such services a currently provided by portable x-ray and EKG providers at the patient's home, or at the health care facility. Further, the public good will be adversely impacted if elderly patients, who currently rely on the services provided by the portable industry, are required to be transported to the hospital for their studies, resulting in an increased rate of infection, and transportation injuries.

Heretofore, the CMS has failed to adequately assess the true operating costs of the portable x-ray and EKG provider industry. The CMS appears to have disregarded the pricing recommendations of the Clinical Practice Expert Panel without providing the public with a transparent way of determining the method used by the CMS in assessing industry costs. Further, the portable x-ray and EKG industry has suffered unpredictability with respect to gasoline prices that will further detrimentally affect the industry's anticipated revenue. Upon information provided by industry, Advocacy has

been told that portable companies have recently had difficulty obtaining financing based on anticipated revenue cuts caused by the provisions contained in the final rule. Lastly, regulations and requirements of skilled nursing facilities already impose cost burdens on the portable industry. Additional cost burdens imposed by the CMS in this rule amount to a regulatory "piling-on." Again, Advocacy believes that a regulatory impact analysis would allow the CMS to disclose the factual basis for its payment schedule as compared with the costs incurred by industry to provide the portable x-ray and EKG services. The regulatory impact analysis would also allow the CMS to assess any potential alternatives to the rule that would lessen the rule's impact on these small entities.

In conclusion, Advocacy believes that the CMS should stay or withdraw the provisions of the final rule that relate to portable x-ray and EKG providers until a proper analysis of the rule's impacts can be prepared. The CMS should consider reasonable alternatives to the rulemaking for portable providers including, but not limited to, exemption of the portable x-ray and EKG providers.

CMS should be aware that a violation of the RFA is judicially reviewable under section 611(a)(1) of the RFA. If CMS is sued by aggrieved or adversely affected small entities, the court may remand all or part of the rule for further analysis by the agency or impose other applicable legal remedies.

Sincerely,

Susan Walthall
Acting Chief Counsel for Advocacy

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