

April 28, 2000

Hon. Nancy-Ann Min DeParle
Health Care Financing Administration
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Proposed Rule on the Medicare Program and Rural Health Clinics:
Amendments to Participation Requirements and payment Provisions,
and Establishment of a Quality Assessment and Performance
Improvement Program; 65 Fed. Reg. 10,450 (February 28, 2000)

Dear Administrator DeParle:

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. Among other things, the Chief Counsel of Advocacy is required by section 612(a) of the Regulatory Flexibility Act (RFA)(1) to monitor agency compliance with the RFA. The Chief Counsel of Advocacy is also authorized to appear as *amicus curiae* in any action brought in court to review a rule, 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) The Chief Counsel appreciates the opportunity to comment on the above-referenced regulation relative to the potential impact on small businesses.

The proposal seeks to amend the regulations of the Health Care Financing Administration (HCFA) to revise certification and payment requirements for Rural Health Clinics (RHCs) pursuant to the Balanced Budget Act of 1997 (BBA). It would include a new definition of what constitutes a qualifying rural shortage area in which a Medicare RHC must be located; establish criteria for identifying RHCs essential to delivery of primary care services that can continue to be approved as Medicare RHCs in areas no longer designated as medically underserved; and limit waivers of certain non-physician practitioner staffing requirements. It also would impose payment limits on provider-based RHCs and prohibit "commingling" the use of the space, equipment and other resources of an RHC with another entity. Finally, the rule would require RHCs to establish a quality assessment and performance improvement program that goes beyond current regulations.

In spite of these sweeping proposed changes, HCFA has certified, pursuant to section 605(b) of the RFA, that the regulation will not have a significant economic impact on a substantial number of small entities.(3) This conclusion is not consistent with HCFA's statements in the regulation. HCFA states that, "the provisions could be controversial," "not all of the potential effects of these provisions can definitely be anticipated," and "it is impossible to quantify meaningfully a projection of the future effect of all of these

provisions on RHC's operating costs or on the frequency of substantial noncompliance and termination procedures.”(4) HCFA also states that, for RFA purposes, all RHCs are considered to be small entities.(5) Based on this “analysis”, HCFA concludes that there will be no significant impact on a substantial number of small entities.

There definitely seems to be a disconnect in HCFA's rationale. Although the term “substantial number” is not defined in the RFA, certainly “all small businesses” constitutes a substantial number. Moreover, even though HCFA states more than once that it cannot determine the impact, it is still somehow possible for the agency to conclude that there will be no significant impact. Agencies must provide a factual basis for their certifications pursuant to section 605(b) of the RFA. This particular section of the RFA was enhanced/beefed-up in 1996 when it was amended by the Small Business Regulatory Enforcement Fairness Act.(6) Prior to the amendments, the section had only required that agencies provide a “succinct statement” to justify a certification. The subsequent change to the “factual basis” requirement is significant because agencies must now thoroughly explain the justification that underlies the certification. The instant RHC regulation clearly lacks a factual basis for its certification.

With regard to the impact of the regulation, HCFA should have been able to reasonably foresee that there would be a significant impact on at least some small entities—particularly the subset of small entities with the fewest resources that exist in frontier regions. In one instance, if an RHC falls outside of the newly designated shortage area, then that RHC can no longer maintain its RHC designation. HCFA states that less than 5% of all participating RHCs could lose their designation status, and that those affected would simply continue to participate under Medicare and Medicaid and receive payment on a fee-for-service basis. There is no mention of the costs involved in transition to a fee-for-service contract. Moreover, in some cases, because of state regulations, providers may not have the flexibility of working in a non-RHC setting.

HCFA intends to provide a 90-day period in which to complete and submit an exception request or be denied further participation as a certified RHC. In those situations where the RHC withdraws from the program because their application for exception was rejected, the 90-day period is not a sufficient amount of time to close its remaining claims, receive reimbursement, apply for new provider numbers, retool its financial operations and billing procedures, etc. The period of time suggested by HCFA may not even be sufficient to alert beneficiaries and locate new providers. In addition, the loss of continuity of care imposes a social cost, even if it is not calculable. Any or all of these changes could take months to complete.

The proposal establishes new prohibitions against the commingling of RHC operations with non-RHC operations—presumably to prevent Medicare reimbursements from being fraudulently double billed. The exact parameters of this particular requirement are unclear; but, on its face, the proposal does not seem to take into account the fact that there are legitimate reasons to share office space. In the case of some very rural clinics, it may not be possible for a practitioner to afford separate space and staff to meet the proposed standards. Also, the industry reports that many provider-based and independent

RHCs secure the services of medical specialists on a part-time basis—perhaps a obstetrician who comes in occasionally to provide services that might not be available otherwise. The specialist may wish to retain the ability to bill Medicare Part B directly. There ought to be some sort of waiver provision to accommodate situations like this. Otherwise, beneficiary access to specialized care may be unnecessarily barred.

Finally, the proposal contains a set of exceptions that RHCs may use to maintain their RHC designation in spite of the fact that their community may no longer meet any of the definitions of “underserved.” However, the exceptions would not be available to RHCs located in areas no longer designated as “non-urbanized” by the Bureau of the Census. The focus of RHC designation has always been, and should always be, based on access to and delivery of care. The fact that an area is no longer “non-urbanized” has little to do with access and delivery issues; and may unnecessarily eliminate clinics that offer valuable services to their respective communities.

These are just a few of the impact-generating provisions contained in the proposed rule. This cursory review at least demonstrates that the impact of this regulation could be very significant for a number of small businesses. Advocacy believes that HCFA should not have certified the regulation. Instead, the agency should have prepared an initial regulatory flexibility analysis pursuant to section 603 of the RFA to determine, with greater accuracy, the impact of the regulation. A more careful analysis may have revealed less burdensome alternatives that would still allow HCFA to meet its objectives.

Thank you for your consideration of these comments. Please do not hesitate to contact our office if you have any questions, 202-205-6533.

Sincerely,

Jere W. Glover
Chief Counsel for Advocacy

Shawne Carter McGibbon
Asst. Chief Counsel for Advocacy

ENDNOTES

1. 5 U.S.C. § 601 et seq.
2. *Id.*
3. 65 Fed. Reg. at 10,461.
4. *Id.* at 10,460-61.
5. *Id.* at 10,460.
6. Pub. L. No. 104-121, 110 Stat. 857.