



Main Office
7200 Wisconsin Ave.
Suite 210
Bethesda, MD 20814
301.347.0400 Tel
301.347.0459 Fax

**Division of Federal, State
and Public Affairs**
1400 Eye Street, NW
Suite 330
Washington, DC 20005
202.296.3800 Tel
202.296.3526 FAX

Office of Information and Regulatory Affairs
Records Management Center
Office of Management and Budget
Attention: Mabel Echols
NEOB
725 17th Street NW, Room 10102
Washington, D.C. 20503

**RE: Request for Comment – “Federal Regulatory Review,” 74 *Fed. Reg.* 8819
(February 26, 2009)**

To Whom It May Concern:

The National Association of Community Health Centers (NACHC) is pleased to respond to the above-cited request for comment from the Office of Management and Budget (OMB). NACHC is the national membership organization for federally-supported and federally recognized health centers (hereinafter interchangeably referred to as “health centers” or FQHCs) throughout the country, and is an Internal Revenue Code Section 501(c)(3) organization. NACHC also serves as a source of information, analysis, research, education, training, and advocacy regarding medically underserved people and communities.

BACKGROUND

There are, at present, approximately 1,200 health center entities nationwide, which serve as the health care homes to more than eighteen (18) million persons at more than 7,000 sites located in all fifty (50) states, Puerto Rico, the District of Columbia, the U.S. Virgin Islands and the Pacific Islands. Most of these health centers receive federal grants under Section 330 of the Public Health Service Act (42 U.S.C. §254b) from the Bureau of Primary Health Care (BPHC), within the Health Resources and Services Administration (HRSA).¹ Under this authority, health centers fall into four general categories: (1) those centers serving medically underserved areas and/or populations (invariably poor communities), (2) those serving homeless populations within a particular community or geographic area, (3) those serving migrant or seasonal farm worker populations within similar community or geographic areas, and (4) those serving residents of public housing. Although there are some slight differences in the grant requirements for each of these four program types, for all intents and purposes, the ways in which these health centers operate are identical.

¹ In addition to those health centers receiving grant funds pursuant to one or more of the Section 330 funding programs, there are certain entities that are designated by the Centers for Medicare and Medicaid Services (CMS) as FQHCs, by virtue of the fact that they meet all of the requirements to receive a Section 330 grant, but do not receive funding from HRSA. For purposes of this comment, unless otherwise noted, we do not distinguish between grantees and FQHC look-alike entities, collectively referring to both types of organizations as “FQHCs” or “health centers.”

To qualify as a Section 330 grantee, a health center must (among other requirements) be located in or serve a federally-designated Medically Underserved Area (MUA) or Medically Underserved Population (MUP). Additionally, a substantial number of health centers are located in or serve an area, population or facility that has been designated as a Health Professional Shortage Area (HPSA). A health center's board of directors must be composed of at least fifty-one percent (51%) active patients of the health center, and the health center must offer a comprehensive continuum of care to all persons in its service area, regardless of their ability to pay or insurance status.

The Section 330 grants are intended to provide funds to assist health centers with the costs of providing comprehensive preventive and primary care (including medical, dental, behavioral health, and pharmaceutical) and enabling services to uninsured and underinsured low-income patients, as well as to maintain the health center's infrastructure. Patients from eligible communities who are not low-income or who have insurance (whether public or private) are expected to pay for the services rendered. Approximately 35.4% of the patients served by health centers are Medicaid/SCHIP recipients, approximately 7.6% are Medicare beneficiaries, and approximately 38.9% are uninsured.

COMMENT ON REVISING THE REGULATORY REVIEW PROCESS

NACHC is pleased that OMB is inviting public comment on how to improve the regulatory review process. As federal grantees, FQHCs are subject to a myriad of regulations governing, among other things: the type, level and range of services provided; the persons to whom and the manner by which such services are furnished; the governance and operation of the health center organization; the health center's financial and clinical administration; the expenditure of funds; and the relationships between the health center and other providers, suppliers, vendors, and other third parties. Unnecessary delays in rulemaking inevitably impact the ability of health centers to operate effectively, often resulting in untimely and inappropriate action (or reaction) and ultimately impacting not only the health center but also its medically underserved patients. Similarly, the recent enhancement of the role of "political" considerations as a component of the review process while lessening the interests of the public serves only to the detriment of the individuals who should benefit most from rulemaking – persons in need of government assistance to protect their interests, such as the low-income, vulnerable populations served by health centers.

It is this last point that NACHC wishes to address in its comment. NACHC believes that encouraging a greater level of public participation in the agency regulatory processes would serve the interests of both the particular agency as well as the general population. In this respect, NACHC encourages an increased use of the Negotiated Rule Making (NRM) process.² In enacting the NRM Act, Congress found that: "[N]egotiated rulemaking, in which the parties who will be significantly affected by a rule participate in the development of the rule, can provide significant advantages over adversarial rulemaking ... Negotiated rulemaking can increase the acceptability and improve the substance of rules, making it less likely that the affected parties will resist enforcement or challenge such rules in court. It may also shorten the amount of time needed to issue final rules."³

² See the Negotiated Rulemaking Act of 1990 (Pub. Law 101-648, as amended by Pub. Law 102-354 and Pub. Law 104-320; 5 U.S.C. §§ 561 – 570).

³ Pub. Law 101-648, Section 2.

A National Performance Review Report published in 1993 by the White House Office of Communications explicitly recognized the NRM process as a means for more efficient rulemaking, stating that “[W]e believe negotiated rulemaking ... is a process every rulemaking agency should use more frequently,” and specifically calling upon federal agencies to make greater use of the NRM process.⁴ In the words of the Report, “[T]he negotiating process allows informal give and take that can never happen in court or in a public hearing.”

Engaging in a NRM process affords the agency and relevant stakeholders the opportunity to discuss and resolve issues from the outset, without undue delay and false starts. In particular, because the NRM process permits relevant stakeholders to “sit at the table” with the agency to work out issues “face-to-face,” the impact and policy implications of a proposed rule may be more keenly understood, thus avoiding potential controversies (and further delay) after publication.

Last year, HRSA published a second proposed rulemaking to revise and consolidate the methodology and process for designating MUA/Ps and HPSAs – ten years after the first proposed rulemaking. As noted above, FQHC eligibility requires the health center to be located in or serve an MUA/P. Further, HPSA designation is critical to attain eligibility for funding and other resources through a wide variety of federal programs beneficial to preserving and enhancing the health care safety net. Given the growing number of medically underserved communities and populations combined with the decreasing availability of federal and state financial resources to support services to the underserved, securing and maintaining HPSA designation (and thus being able to access related benefits) is crucial to the continued operation of health centers.

While certain features of the second proposed rule represented a marked improvement over HRSA’s first attempt, various stakeholders, including NACHC, had numerous grave concerns regarding the specific elements and requirements of the proposed rule. The proposed rule was rescinded, sending HRSA “back to the drawing board” for a second time. Overall, a rulemaking crucial to the operation (and in some cases survival) of health centers is now entering its second decade with no timeline in sight for a third proposed (or final) rule.

NACHC believes that the HRSA rulemaking described above would benefit greatly from an increased use of the NRM process. Given the numerous concerns raised in response to the second proposed rulemaking, holding a NRM would have been a sound approach for developing a regulation in which complex technical considerations must be weighed, an intricate series of formulas must be developed and applied, and the policy implications of these considerations and formula applications must be translated into fair and transparent government standards regarding program eligibility and resource allocation. Further, because the HPSA/MUA designations are so foundational to such a wide swath of U.S. health policy, revision to the designation formula would seem to compel a process that aims for inclusiveness, transparency, and careful attention to both technical and policy matters.

⁴ See *National Performance Review Report: Chapter 4*, 1993 WL 366414 (White House), September 7, 1993.

Thank you for the opportunity to comment on the revision to the regulatory review process. If you have any questions about the contents of this document, please call or email me at 202-296-0158; rschwartz@nachc.com .

Sincerely,

A handwritten signature in cursive script, appearing to read "R. Schwartz".

Roger Schwartz
Associate Vice President of Executive Branch Liaison