AMERICAN ACADEMY OF FAMILY PHYSICIANS

STRONG MEDICINE FOR AMERICA

August 22, 2008

Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1910-P2
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Mr. Weems:

I am writing on behalf of the American Academy of Family Physicians (AAFP), which represents over 93,000 physicians and medical students nationwide. Specifically, I am writing to offer our comments on the proposed rule regarding changes in conditions of participation requirements and payment provisions for rural health clinics (RHCs) and federally qualified health centers (FQHCs). The Centers for Medicare and Medicaid Services (CMS) published the proposed rule in the *Federal Register* on June 27, 2008. Since nearly 21% of family physicians practice in rural areas and many family physicians work with RHCs and FQHCs, this proposed rule is of interest to us.

RHC Location Requirements and Exceptions

In the proposed rule, CMS proposes changes to the RHC location requirements in such a way that CMS estimates 500 of the current 3,700 RHCs would no longer meet the location requirements. Unless they qualified for one of the exceptions proposed by CMS, these RHCs would lose their RHC status and related cost-based reimbursement, potentially causing them to reduce services or discontinue serving Medicare beneficiaries.

Unfortunately, CMS does not estimate the number of beneficiaries who may lose services as a consequence. The elimination of 500 RHCs could leave many rural and frontier communities without adequate health care resources. The impetus for CMS to make such potentially significant changes is not clear, especially since, as CMS states, "The estimated Medicare savings associated with the decertification of certain RHCs from the Medicare program are not considered significant."

Some of the exception criteria also appear to be problematic, and it is not apparent that an RHC can even collect or show the information that CMS is proposing to require in the exception process. For instance, one of the exceptions open to RHCs that no longer otherwise meet the location requirements for RHCs is the "Major Community Provider" exception. According to

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proposed 42 CFR 491.5(c)(2), an RHC must meet the following conditions to be considered a major community provider:

(i) Has a Medicare, Medicaid, low income and uninsured patient utilization rate greater than or equal to 51 percent or a low-income patient utilization rate greater than or equal to 31 percent.
(ii) Is actively accepting and treating a major share of the Medicare, Medicaid, low-income, and uninsured patients (regardless of their ability to pay) compared to other participating primary care providers that are within 25 miles of the RHC.

The proposed rule does not define what constitutes “a major share.” It also offers no suggestions as to how an RHC can determine its share of the Medicare, Medicaid, low-income, and uninsured patients compared to other participating primary care providers when the patient mix of other primary care providers is not public information and, in fact, may be considered proprietary information by those providers.

The AAFP believes that the possibility of a large impact on safety net providers combined with the lack of an impact analysis related to the number of beneficiaries affected necessitates a delay in finalizing the proposal until further impact analysis is done. We urge CMS to do such analysis and share its findings before finalizing its proposals related to the location requirements.

Staffing Requirements

We also wish to take issue with the proposed amendment to 42 CFR 491(8)(a)(6), which requires RHCs to have a nurse practitioner, physician assistant, or certified nurse midwife available to furnish patient care services at least 50% of the time that the RHC operates. We recognize that this proposed amendment is intended to align the regulations with the statute, which includes a similar provision.

While the law originally was intended to increase rural residents' access to health care services, the requirement now limits staffing flexibility for family physicians that operate rural health clinics. An informal survey of AAFP members indicated that it is frequently easier to recruit and employ a physician than it is to find a mid-level practitioner. Ironically, under the current provision, AAFP members have been threatened with decertification, even though all care was being delivered by physicians.

Part of the challenge may stem from shifting practice patterns for nonphysician practitioners. Trends indicate that mid-level providers are moving toward subspecialization and urban/suburban settings. For instance, a 2004 report from the American Academy of Nurse Practitioners indicates that 1.6 percent of its members -- down from 2.4 percent in 1989 -- practiced in communities of fewer than 1,000 people and 18.7 percent of its members -- down from 22.7 percent in 1989 -- practiced in communities of 1,000 to 24,999 people.

The statutory and proposed regulatory requirement that an RHC have a nurse practitioner, physician assistant, or certified nurse midwife available to furnish patient care services at least

50% of the time that the RHC operates leads to another problematic statutory and proposed regulatory provision. Specifically, CMS proposes to amend 42 CFR 491.8(d) to conform to section 1861(aa)(7) of the Social Security Act and specify that CMS may grant a temporary waiver of the RHC staffing requirements noted above for a 1-year period to a qualified RHC, if the RHC requests a waiver and demonstrates that it has been unable, despite reasonable efforts in the previous 90-day period, to hire a certified nurse-midwife, nurse practitioner, or physician assistant to furnish services at least 50 percent of the time the RHC provides clinical services, or to hire a PA or NP as a direct employee. CMS terminates the RHC from participation in the Medicare program, if the RHC is not in compliance with the waived staffing provisions at the expiration of the waiver, and the RHC may submit its request for an additional waiver of staffing requirements no earlier than 6 months after the expiration of the previous waiver.

We appreciate CMS implementing the waiver but question whether the proposal allows enough flexibility for an RHC that seeks a waiver, recruits a non-physician during the year and then loses that provider before the waiver expires and the six-month waiting period to submit another waiver request passes. As noted above, trends indicate that mid-level providers are moving toward subspecialization and urban/suburban settings, which will make it difficult to recruit and retain them in RHCs within the timeframes afforded by the law and proposed amendment to the regulations.

The AAFP has urged Congress to change the law to allow for the employment of nonphysician practitioners or physicians, depending on who was available and could provide the highest quality of care. Until Congress acts on this issue, we urge CMS not to further hamstring RHCs staffed by physicians by amending the regulations as proposed.

Quality Assessment and Performance Improvement (QAPI) Program

In the proposed rule, CMS proposes to revise 42 CFR 491.11 to set forth explicit requirements for a mandatory QAPI program. CMS estimates it will take each RHC approximately 40 hours of physician and staff time, at an approximate cost of $1,100 per RHC, to develop its QAPI program and an additional seven hours of staff time annually, at an approximate cost of $196 per year, for each RHC to implement its QAPI program.

The AAFP is a supporter of quality improvement in health care. However, we have concerns with the proposed QAPI program mandate. First, we note that CMS has offered no corresponding incentive or reward to go along with its mandate. Whereas CMS provides other Medicare providers with incentives or rewards for quality improvement (e.g., the Physician Quality Reporting Initiative), it gives RHCs an unfunded mandate to adopt a QAPI program.

Second, CMS seems to have underestimated the paperwork requirements of these programs. For instance, the seven hours per year includes only four hours for data collection and analysis. Over the course of a year and thousands of encounters, this hardly seems realistic for a QAPI program that would require the RHC to evaluate organizational processes, functions and services and the use of clinic services, including at least the number of patients served and the volume of services, as well as adopt or develop performance measures that reflected processes of care and

RHC operation and were shown to be predictive of desired patient outcomes or were the outcomes themselves. The RHC would have to use the measures to analyze and track its performance. Also, the RHC would have to conduct distinct improvement projects and maintain records on its QAPI program for each of the areas listed under the standard in § 491.11(a) (i.e., organizational processes, functions and services and the use of clinic services). What CMS is proposing with respect to its proposed QAPI program would seem to involve significant and substantial amounts of effort on the part of a RHC, effort which is not reflected in CMS's estimate of the impact on RHCs.

Given these concerns, we would encourage CMS to reconsider its proposed QAPI program mandate. Specifically, we would encourage CMS to restructure its proposal to provide RHCs a positive incentive to engage in quality improvement and to recognize more accurately the financial and staff resources the quality improvement will require of RHCs.

Thank you for your time and consideration of these comments. We appreciate the opportunity to share our concerns on behalf of our rural members, especially those who work with RHCs and FQHCs.

Sincerely,

Rick Kellerman MD

Rick Kellerman, M.D.
Board Chair

RK:kjm