AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

March 8, 2013

Marilyn Tavenner, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue SW.
Washington, DC 20201

Re: Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden

Dear Administrator Tavenner:

On behalf of the American Academy of Family Physicians (AAFP), which represents more than 105,900 family physicians and medical students nationwide, I write in response to the Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden proposed rule released by the Centers for Medicare & Medicaid Services in the February 7, 2013 *Federal Register*.

The AAFP appreciates that CMS continues to address Medicare and Clinical Laboratory Improvement Amendments (CLIA) regulations that the agency identified as unnecessary, obsolete, or excessively burdensome for health care providers and suppliers. We continue to encourage CMS to improve the ability of family physicians to focus resources on providing patient care through the elimination and reduction of regulatory requirements that impede high-quality patient care. Our comments focus on provisions of the proposed rule relevant to family physicians.

CAH and RHC/FQHC Physician Responsibilities
Currently, Medicare requires a physician to be present in a Critical Access Hospital (CAH), Rural Health Clinic (RHC), and Federally Qualified Health Center (FQHC) at a minimum at least once in every two-week period, to provide medical direction, medical care services, consultation and supervision of other clinical staff.

In this proposed rule, CMS discusses that in extremely remote areas, some rural populations suffer from limited access to care due to a shortage of health care professionals and physicians and thus CAHs, RHCs, and FQHCs have difficulties complying with the precise biweekly schedule requirement. Accordingly, CMS proposes to eliminate the required two-week visit for CAHs, RHCs, and FQHCs. For CAHs, CMS believes that by eliminating the required two-week visit, CAHs will have greater flexibility to determine the appropriate frequency of physician visits. For CAHs, CMS proposes that a doctor of medicine or osteopathy would be present for sufficient periods of time to

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provide medical direction, consultation and supervision for the services provided in the CAH, and is available through direct radio or telephone communication for consultation, assistance with medical emergencies, or patient referral. For RHCs and FQHCs, CMS proposes that physicians would periodically review the clinic's or center's patient records, provide medical orders, and supply medical care services to the patients of the clinic or center. CMS believes that proposing language to remove these barriers will enhance patient access to care in rural and remote areas.

For the most part, the AAFP concurs with these proposals since they remove unnecessary regulatory requirements that interfere with patient access to care in rural areas. However, though we recognize that CMS is trying to offer flexibility, the AAFP has concerns over the rather vague use of the term "sufficient periods of time." In the final rule, the AAFP encourages CMS to clarify which entities are authorized to deem non-compliance with the revised proposal so that all facilities can clearly ensure full compliance with the new requirements.

Clinical Laboratory Improvement Amendments Revisions

The proposed rule also modifies CMS regulations governing proficiency testing (PT) referrals under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. CMS proposes changes that are intended to reduce confusion on the part of laboratories, lessen the risk of noncompliance, and establish policies under which certain PT referrals by laboratories would not generally be subject to revocation of a CLIA certificate, or a two-year prohibition on laboratory ownership or operation that may be applied to an owner and an operator when a CLIA certificate is revoked.

The AAFP appreciates that CMS elaborated on and clarified CLIA requirements. Likewise, the AAFP appreciates that CMS carves out an exception to the strict stance of never referring PT samples to other labs for any reason. The AAFP understands that CMS is offering a less punitive interpretation of violations. Instead of the current inflexibility, the proposed regulation would allow CMS to take into account how serious a violation might be. For example, CMS might note that the action was unintentional. The AAFP supports these proposals since they offer CMS the opportunity to show greater leniency when appropriate.

In closing, we again offer our support to CMS for adhering to Executive Order 13563 which instructs agencies to retrospectively review existing rules. We appreciate the opportunity to provide these comments and make ourselves available for any questions you might have or clarifications you might need. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org.

Sincerely,

Glen Stream, MD, MBI, FAAFP
Board Chair