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Association**

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August 22, 2008

Kerry N. Weems  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

***RE: CMS-1910-P2, Medicare Program; Changes in Conditions of Participation Requirements and Payment Provisions for Rural Health Clinics and Federally Qualified Health Centers; Proposed Rule (Vol. 73, No. 125), June 27, 2008***

Dear Mr. Weems:

On behalf of the American Hospital Association (AHA) and our more than 5,000 member hospitals, health systems and other health care organizations, and our 38,000 individual members, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) rural health clinic (RHC) proposed rule.

The RHC program yields multiple benefits for rural hospitals, the Medicare program and people in rural areas. For rural hospitals, the RHC program allows hospitals to establish a network of services in a rural area; recruit and retain physicians; treat patients in the most appropriate setting; and ensure the financial viability of practices and hospitals serving large Medicare and Medicaid populations. For the Medicare program, RHCs reduce expenditures by providing timely access to primary health care services that can prevent trips to the emergency department and unnecessary hospitalizations. For patients, hospital-based RHCs provide a comprehensive system of care that includes primary care and hospitalization (and for many, skilled nursing care), which allows for consolidated medical records; reduced patient travel time; and a level of care that meets the standards required for hospitals. **We urge CMS to ensure that the policies it establishes through this rulemaking process maintain and strengthen these benefits.**

#### **RHC LOCATION REQUIREMENTS**

Current law requires that RHCs be located both in a non-urbanized area and in an area that has been federally designated within the previous three years as having an insufficient number of needed health care practitioners. CMS proposes to use the most recent U.S. Census Bureau list to determine if a facility is in a non-urbanized area. To determine if a facility is in an



underserved or shortage area, CMS proposes to use the most current Health Resources and Services Administration (HRSA) list of these designations. The HRSA designations that are acceptable for RHC certification purposes are:

- the geographic primary care health professional shortage areas (HPSA);
- population-group primary care HPSAs;
- medically underserved areas (MUAs) and;
- governor-designated and Secretary-certified shortage areas.

Current law also requires that every RHC must have a shortage area designation made or updated within the last three years.

While HRSA approves these designations, states are responsible for ensuring that their designations are updated on a regular basis. However, there is a disconnect between Medicare RHC policy and HRSA shortage area policy. RHC designations must be updated every three years, but HRSA requires that HPSA designations be made every four years. As a result, RHCs are in the awkward position of having to pressure their states to apply for a designation more often than they are required to under HRSA policy. The AHA is concerned that some clinics could lose their RHC status if states are unwilling to submit applications to HRSA for updated designations within the required three-year period. We have heard that some states typically wait more than three years to apply for updated designation from HRSA, and RHCs lack the leverage to compel state offices of primary care to submit applications more often than HRSA requires. **The AHA urges CMS to work closely with HRSA to educate states about the proposed RHC regulations, to encourage the states to proactively update their designations every three years and to post on their Web sites information about their applications to HRSA for designation of areas as underserved or shortage.**

#### **ESSENTIAL PROVIDER EXCEPTION**

The AHA appreciates CMS' effort to define those clinics that should continue to participate as RHCs despite their localities no longer being designated as non-urbanized areas or designated as current underserved/shortage areas. *The Balanced Budget Act of 1997* (BBA) requires that, unless clinics in such areas are "essential to the delivery of primary care services that would otherwise be unavailable in the geographic area served by the clinic," they would lose their RHC designation. This "essential provider" exception proposal set out by CMS represents a thoughtful approach to protect those clinics that are critical to maintaining access to essential health care services for persons living in rural areas. However, many rural hospitals established such clinics under the presumption that they would be protected by the grandfathering provisions contained in the law and the very survival of these clinics are dependent on the preferential treatment accorded under the RHC provisions in law.

**We urge CMS to make several clarifications and/or changes in the proposed regulations to ensure that the exceptions outlined are clear and complete.**

CMS proposes several requirements for "essential provider" status. RHCs that are located in non-urbanized areas not currently designated as an underserved/shortage area would be allowed

to apply to their CMS regional office for an “essential provider” exception if they fall into one of the following categories (as further described in the proposed rule): sole community provider; major community provider; specialty clinic (obstetrics/gynecology or pediatrics); or extremely rural community provider.

Similarly, RHCs that are located in urbanized areas with a current HRSA designation as an underserved/shortage area also would need to fall into one of the four categories noted above in order to apply for an “essential provider” exception. However, CMS would further require that these RHCs meet special location requirements. That is, they also would have to demonstrate that they are located in a level 4 or higher Rural Urban Commuting Area (RUCA) and at least 51 percent of their patients reside in an adjacent non-urban area.

The AHA has serious concerns about these proposed requirements for RHCs located in urbanized areas. A RHC has demonstrated that it is “essential” by virtue of its shortage/underserved area designation. Requiring these clinics to apply under one of the four outlined “essential provider” categories is redundant and unnecessary. **We urge CMS to change the special location requirements to allow RHCs to meet either the RUCA level 4 or higher or the 51 percent of patients residing in an adjacent nonurban area. Additionally, we recommend that RHCs in urbanized areas be able to apply for exceptions as “essential providers” without falling into one of the four categories (sole community provider, major community provider, specialty clinic or extremely rural community provider).**

**The AHA also recommends that CMS accept state designations of rural areas for RHC purposes.** That is, if a clinic is located in an urbanized area, but the area has been designated by the state via law or regulation as a rural area, CMS should accept this designation as meeting the special location requirement of being rural.

CMS states that it expects most RHCs that apply for exceptions to qualify; however, the proposed requirements for essential provider exception are so subjective in nature and described in such ambiguous language that it will be difficult to determine whether a particular clinic would qualify. Without better defined terms, RHCs seeking an “essential provider” exception will have difficulty determining how to make their case, and CMS regional offices decisions will be, by necessity, quite subjective and probably inconsistent both within and between states.

Many key elements are undefined. For instance, two of the essential provider categories use the term “participating primary care provider” but other than indicating that this would include another RHC or federally qualified health clinic, CMS does not define this term further. It is unclear whether a single physician with an internal medicine practice would qualify. It also is unclear whether a non-physician practitioner, such as a nurse practitioner or physician assistant, practicing independently would qualify. Also, two of the categories require the calculation of a “Medicare, Medicaid, low-income, and uninsured patient utilization rate.” Since the term “utilization rate” is not defined, it is unclear if this refers to the number of patients, visits, services or clinic revenues. To qualify as a “major community provider” CMS would require a RHC to demonstrate that it is accepting and treating a “major share” of Medicare, Medicaid,

low-income and uninsured patients compared to other primary care providers. However, CMS does not define “major share.” The categories also refer to “low-income” patients but that term also is not defined.

In addition, several of the requirements within these “essential provider” categories are elements about which RHCs would have no direct knowledge and/or RHCs would be required to obtain sensitive competitive information from other providers in their community. For instance, a clinic seeking designation under the “major community provider” category would have to demonstrate a threshold level of low-income patient utilization, but clinics generally do not know the income level of their patients. Also, this same category requires that the RHC applying for an exception know the share of Medicare, Medicaid, low-income and uninsured patients of all other participating primary care providers within 25 miles of the RHC. It is not clear how a RHC would obtain this very sensitive information from other primary care providers.

While we understand that CMS deliberately wrote the regulation to provide flexibility for clinics to make a case for themselves to continue to participate as RHCs, some additional clarity around the definition of terms used and some guidance or examples of what is needed to demonstrate compliance with the requirements would be helpful. **The AHA recommends that in the final rule, CMS add definitions and detail to clarify these issues. We also recommend that CMS develop a guidance document for RHCs that would clearly describe how clinics should interpret the “essential provider” requirements and the step-by-step process involved, including time frames, in applying for an exception, with examples of the type of data that would satisfy CMS requirements. CMS also should develop an application form that RHCs could use to apply for an exception and that the CMS regional offices would be required to accept.**

Finally, these ambiguities make it difficult to understand how CMS can assert that more RHCs would be able to qualify under its proposed regulations. **We recommend that CMS, together with HRSA, conduct and publish an analysis that would quantify how many RHCs currently meeting the location requirements would lose their designation under the proposed rule and how many more could qualify.**

#### **OTHER EXCEPTIONS**

The AHA believes that it would be difficult at this time to identify all circumstances under which a clinic should be legitimately deemed to be “essential to the delivery of primary care services that would otherwise be unavailable in the geographic area served by the clinic.” For instance, among the AHA’s members is a hospital that owns a RHC that serves a large Amish population. Since the Amish travel exclusively by horse and carriage, 30 minutes of travel time has an entirely different meaning for this population. Such a clinic should not lose RHC designation merely because another primary care provider is available less than 15 miles by interstate highway. RHCs that may not meet any of the proposed rule’s exceptions should have an opportunity to make their case to CMS that they be categorized as “essential providers” and potentially granted an exception. **The AHA recommends that CMS regional offices be given authority to grant such exceptions on a case-by-case basis.**

### **PROCESS FOR ESSENTIAL PROVIDER STATUS AND TIMETABLE**

The AHA seeks clarification regarding whether there is an appeals process for clinics whose application for an “essential provider” exception has been denied by the regional office. **If there is an appeals process, we request that CMS explain the process in the final rule and clarify what happens to the designation during the appeal.**

### **PAYMENT METHODOLOGY FOR RHCs**

In the proposed rule, CMS implements section 1833(a)(3) of the *Social Security Act*, which requires that beneficiary coinsurance and deductible amounts be subtracted from reasonable costs to determine the Medicare payment amount, and which limits the Medicare payment amount to no more than 80 percent of “costs which are reasonable and related to the cost of furnishing such services...” Although this provision has been a part of the statute for more than 30 years – as long as the RHC provider designation has been in existence – CMS has not implemented or enforced it and has instead been paying RHCs at 80 percent of the facility’s all-inclusive rate per visit subject to a payment limit, without regard to the deductible and coinsurance amounts billed to Medicare beneficiaries.

CMS’ interpretation of this statutory provision will have serious negative implications for the financial viability of RHCs, which will experience substantial reductions in Medicare payments. In combination with the requirement that RHCs implement a mandatory quality assessment and performance improvement (QAPI), which will increase the cost of being an RHC, this payment reduction on top of already inadequate payment levels will threaten continued participation in the program for many RHCs.

We question CMS’ motivation in implementing this new interpretation of statute after 30 years. RHC program is not one whose rate of growth has elicited concern from federal advisory committees, federal oversight agencies or Congress. In fact, if CMS has been incorrectly interpreting the RHC statute for such a significant period of time, why hasn’t Congress clarified its intent in the intervening years or changed the law? **We urge CMS not to implement this payment policy change and instead continue to pay for RHC services in the current manner. However, if CMS must implement this change, we recommend that it define “costs that are reasonable,” in the context of 1833(a)(3)(A), to mean that the clinic’s reasonable costs as derived from the hospital’s (for provider-based RHCs) or independent RHC’s Medicare cost report, and not to use the *Social Security Act* 1833(f) limit on payment as the cap.**

### **EXCEPTION TO THE PER VISIT PAYMENT LIMIT**

The BBA added an exception to the per-visit payment cap for RHCs based in small rural hospitals with less than 50 beds and allows these clinics to be reimbursed using a reasonable cost methodology. CMS has established two alternatives for determining whether a hospital may be exempted from the per-visit payment limit. One approach is for RHCs that are a part of a hospital with fewer than 50 available beds. This approach has not changed from current CMS policy. The second approach would provide the exception to RHCs that are a part of a hospital that has 50 or more available beds, is a sole community hospital located in a level 9 or 10 RUCA

and has a hospital average daily census of 40 or less. The policy in the second approach differs from current CMS policy. Instead of using Urban Influence Codes to identify hospitals located in sparsely populated rural areas, the proposed rule would use RUCAs, which CMS believes is a better assessment of the local area's degree of rurality.

The AHA appreciates CMS' development of the alternative definition and the agency's recognition of the fragility of these small hospitals' clinics and their dependency on cost reimbursement for continued survival. This alternate definition will allow some small, financially strapped hospitals to obtain an exception to the payment cap. **The AHA recommends that for the purpose of defining this second alternative, CMS increase the allowed limit on the average daily census to "less than 50."** This would comport more closely with the 50 available bed used in the first approach.

In addition, we are concerned that the regulatory language describing these two options for an exception to the per-visit payment limit is confusing and can be easily misinterpreted to imply that under both alternatives, the hospital would need to have fewer than 50 available beds. In fact, we believe that CMS staff drafting the impact analysis in the rule may have misinterpreted the regulation in this way. On page 36,713 of the June 27 *Federal Register* it states, "There are currently 909 provider-based RHCs whose parent hospital has fewer than 50 beds. *Of these* [emphasis added], 354 are in UICs 9-12 and are therefore eligible for the exception to the per visit payment limit."

To ensure that this exception is clear and properly interpreted, and incorporating our recommended change in the average daily census limit, **we recommend that CMS revise the regulatory language to read:**

**If an RHC is an integral and subordinate part of a hospital, it can receive an exception to the per visit payment limit if:**

- (i) the hospital has fewer than 50 beds as determined at Sec. 412.105(b) of this chapter; or**
- (ii) the hospital's average daily patient census count of those beds described in Sec. 412.105(b) of this chapter does not exceed 50 and the hospital meets both of the following conditions:**
  - (A) It is a sole community hospital as determined in accordance with Sec. 412.92 or essential access community hospital as determined in accordance with Sec. 412.109(a) of this chapter; and,**
  - (B) It is located in a level 9 or 10 Rural-Urban Commuting Area (RUCA).**

#### **COMMINGLING**

The AHA appreciates CMS' clarification in the proposed rule that a RHC that is part of a multipurpose clinic may house other entities (such as private medical practices, X-ray and lab clinics, dental clinics, emergency room) in the non-RHC space which may bill the assigned Medicare administrative contractor, fiscal intermediary or carrier as long as accounting methods appropriately allocate costs between entities. This flexibility will allow Medicare beneficiaries

and others in these vulnerable and often remote communities easier access to a comprehensive set of health care services at the same location.

In addition, we are pleased with CMS' clarification that a hospital-based RHC may share its health care practitioners with the hospital emergency department (ED) in an emergency and that RHC physicians are permitted to provide on-call services for the ED as long as conditions for certification and salary allocation requirements are met. This clarification will benefit many hospitals struggling to meet their obligations under the Medicare provider agreement to maintain a list of on-call physicians available to provide call services for patients with emergency medical conditions and should ultimately help to support local access to specialist services in emergencies.

#### **PAYMENT FOR SERVICES TO SKILLED NURSING FACILITY PATIENTS IN HOSPITALS**

The proposed rule states that RHCs cannot bill for services furnished to inpatient hospital or critical access hospital (CAH) patients. This statement overlooks the skilled nursing patients who receive post-hospital skilled nursing care in hospital and CAH swing beds. To address potential confusion regarding this oversight, the AHA requests that CMS clarify that eligible RHC practitioners providing care to hospital swing-bed patients who are skilled nursing patients covered under Part A are exempt from skilled nursing facility consolidated billing and may directly bill Medicare under the patient's RHC benefit.

#### **QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT PROGRAM**

The AHA supports the development of QAPI programs in RHCs to improve patient safety, quality of care and patient satisfaction. We are pleased that the proposed regulation emphasizes CMS' commitment to making the QAPI requirements reflective of the complexity of the RHC's organization and services and flexible enough to allow clinics to develop creative programs meeting the needs of the RHC and the scope of its services.

While it is true that effective QAPI programs will need to be flexible and scalable to the size and staff limitations at the clinics, it also is true that by their very nature, RHCs are facilities that are stretched to the limit in terms of both staff time and financial resources. **Therefore, the AHA recommends that CMS grant RHCs a grace period of at least six months after the final regulation is published to develop and implement their QAPI programs. We also suggest that CMS continue to provide technical assistance to RHCs in complying with the QAPI requirements.**

Many hospitals have developed strong hospital-wide QAPI programs as part of their accreditation requirements. In most case, hospital-based RHCs are fully integrated into the quality activities of such programs. **The AHA believes that when such hospital-wide QAPI programs are in place, the RHC should be considered as meeting the QAPI condition of participation for RHCs.**

#### **EMERGENCY SERVICES AND TRAINING**

The AHA supports CMS' proposal to update its RHC emergency services regulation to reflect current industry standards and procedures, and to eliminate the prescriptive list of drugs and biologicals that RHCs are currently required to have available and replace it with a more general standard. We also agree that RHCs should have available commonly used equipment and supplies for emergency first response procedures.

**The AHA also would support a new requirement for RHCs to have automated external defibrillators (AEDs) available in their facilities** These life-saving devices are already commonly available in hospital-based RHCs. Because RHCs are often located in remote areas where advanced emergency care might not otherwise be easily accessed, requiring AEDs is the right policy to adopt.

#### **AUTHENTICATION OF PATIENT HEALTH RECORDS**

CMS proposes to update its patient health record requirements to require that all entries in the medical record, whether electronic or manual, must be legible, complete, dated, timed and authenticated promptly in written or electronic form by the person responsible for ordering, providing or evaluating the service furnished. All entries in the patient health record would be required to be authenticated within 48 hours unless state law designates a different time frame.

The AHA is concerned that requiring authentication within 48 hours in all instances is unrealistic and burdensome. There are many circumstances in which 48 hours would not be an adequate time frame to obtain physician authentication. For instance, if care were provided on a Friday, it would be difficult to obtain a physician's signature over the weekend. Also, if the RHC's transcription service staff were short due to illness or a death or if there were some other loss of transcription services, a period longer than 48 hours would be needed. **The AHA recommends that CMS change the general standard to 72 hours for authentication of entries onto the patient's health record and allow a longer time frame in extenuating circumstances.** This flexibility will not adversely affect patient safety or quality of care.

Thank you again for the opportunity to comment. If you have any questions, please feel free to contact me or Roslyne Schulman, senior associate director for policy, at (202) 626-2273 or [rschulman@aha.org](mailto:rschulman@aha.org).

Sincerely,

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