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Centers for Medicare & Medicaid Services
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CMS ISSUES PROPOSED CHANGES IN CONDITIONS OF PARTICIPATION REQUIREMENTS AND PAYMENT PROVISIONS FOR RURAL HEALTH CLINICS AND FEDERALLY QUALIFIED HEALTH CENTERS

OVERVIEW

The Centers for Medicare & Medicaid Services (CMS) today issued a proposed rule to update certification and participation regulations and payment provisions for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs). The rule would establish location requirements and exception criteria for RHCs; revise the RHC and FQHC payment methodology; require RHCs to establish a quality assessment and performance improvement (QAPI) program; allow RHCs to contract with RHC non-physician providers under certain circumstances; and propose other changes to update the regulations to clarify existing requirements, provide the opportunity to make program improvements, and comply with statutory requirements.

BACKGROUND

On February 28, 2000, CMS published a proposed rule, “Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions; and Establishment of a Quality Assessment and Performance Improvement Program.” This proposed rule revised certification and payment requirements for RHCs and FQHCs as required by the Balanced Budget Act of 1997 (BBA). The final rule was issued on December 24, 2003.

On December 8, 2003, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) became law. Section 902 of the MMA established timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation and stated that, in most situations, there cannot be more than three years between the publication of a proposed and final rule.

To comply with the MMA requirement that a final rule not be published more than three years after the proposed rule, CMS published a notice on September 22, 2006, that

suspended the December 24, 2003, final rule. The Code of Federal Regulations currently reflects the regulations that were in effect before December 2003.

The rule proposes additional updates to, and clarifications of, the provisions published in the previous rule, and provides the public with the opportunity to comment on these proposed changes.

PROPOSED CHANGES TO THE RHC/FOHC PROGRAM

Location Requirements

The proposed rule would:

- Require that currently participating RHCs and clinics that enter the RHC program be located in a non-urbanized area, as defined by the U.S. Census Bureau;
- Require that currently participating RHCs and clinics that enter the RHC program be located in an area that has been designated or certified by the Secretary within the previous three years as having an insufficient number of needed health care practitioners. The following designations would meet this requirement: Health Professional Shortage Areas (HPSAs) that are Primary Care Geographic HPSAs or Primary Care Population-based HPSAs; Medically Underserved Areas (MUA); and Governor-Designated and Secretary-Certified Shortage Areas. By law, these are the only types of designations accepted for RHC certification;
- Provide a process and clear timeframes under which an existing RHC could request an exception to the location requirements as an “essential provider.” An RHC could receive an exception to the location requirements if it met the criteria as either a (a) sole community provider, (b) major community provider, (c) specialty clinic, or (d) extremely rural community provider;
- Require that an RHC that does not meet the location requirements must also demonstrate that at least 51 percent of its clients resided in adjacent non-urbanized areas, and that the RHC is located in a level 4 or higher Rural Urban Commuting Area (RUCA);
- Protect RHCs from decertification if the Health Resources and Services Administration (HRSA) had received an application to update the area’s designation before the end of the three-year period. If an application had not been submitted to HRSA before the end of the three-year period, the RHC would be required to submit an application for a location requirement exception within 90 days after the three-year period to its CMS regional office to continue to operate as an RHC;
- Require that a clinic be decertified as an RHC 180 days after the date that the RHC no longer met the location requirements if (a) an application to update the

designation had not been submitted to HRSA on time; (b) an application for a location requirement exception has not been submitted to its CMS regional office on time, (c) an application to designate or update the area's designation was submitted on time but ultimately did not qualify; or (d) an application for an exception to the location requirements was submitted to its CMS regional office on time but ultimately did not qualify. Decertification would occur on the last day of the month in which the 180-day limit was met. A clinic that is decertified as a RHC could apply to become another type of Medicare provider that would then bill Medicare using the Part B fee-for-service system;

- Provide an additional 120-day extension of RHC status to provider-based RHCs that did not meet the location requirements and did not qualify for an exception if they have submitted an application to CMS to be another type of Medicare provider that required a state survey for certification; and
- Solicit comments on the appropriateness of having a mental health specialty clinic as an exception to the location criteria, considering the statutory limitations of the provision of mental health services in an RHC.

Staffing Requirements

The proposed rule would:

- Eliminate the restrictions on RHC contracting with non-physician providers. RHC would still be required to employ a Nurse Practitioner (NP) or Physician Assistant (PA), but as long as this requirement was met the clinic could enter into contracts with physician or non-physician providers; and
- Create a one-year waiver of the requirement that an RHC have an NP, PA, or Certified Nurse Midwife (CNM) providing services at least 50 percent of the time that the clinic operates if the RHC demonstrated that, despite reasonable efforts, it was unable to hire or contract for the services of an NP, PA, or CNM in the previous 90-day period. The statute requires a minimum of six months between the granting of these waivers. Only existing RHCs could apply for such a waiver, and an RHC that has submitted a waiver request could not be de-certified while its request was under review, for a period not to exceed six months.

Payment Requirements

The proposed rule would:

- Revise the payment methodology to be consistent with statutory requirements that set Medicare payment at 80 percent of reasonable costs (after application of deductibles). Beneficiary deductibles and coinsurance charges would be deducted from approved reasonable costs, and RHCs and FQHCs would be paid the

balance, up to the payment limit. Total payment to RHCs and FQHCs for Medicare services could not exceed the approved reasonable cost amount;

- Provide an exception to the payment limit for provider-based RHCs that were part of a hospital with fewer than 50 beds when the RHC was located in a level 9 or 10 RUCA;
- Clarify the circumstances under which an RHC and a Medicare Part B physician practice, or a Medicaid fee-for-service practice, could operate simultaneously;
- Hold hospital-based RHCs to the same payment system and limits that apply to independent RHCs, except for clinics based in small hospitals (fewer than 50 beds); and
- Remove RHC and FQHC services from the skilled nursing facility consolidated billing provisions.

The proposed rule also solicits comments on payment for high cost drugs in an RHC. Because drugs are included in the all-inclusive rate per visit, RHCs may face a dilemma in deciding whether to provide certain high-cost drugs in the RHC that would benefit their patients but also may put the clinic at risk financially. CMS is soliciting comments on potential solutions that can be addressed through regulation or program guidance. Any possible solution would need to take into account the agency's legislative authority, which does not generally allow reimbursement to RHCs for drugs, CMS' policy on commingling, and the need for administrative accountability.

Health, Safety, and Quality

The proposed rule would

- Require RHCs to establish a QAPI program. The statute requires RHCs to have a QAPI program and appropriate procedures for review of utilization of clinic services, as specified by the Secretary of Health and Human Services. CMS developed the requirement to reflect the industry standards that are directed at improving outcomes of care and patient satisfaction. The QAPI program would enable the organization to systematically review its operating systems and processes of care to identify and implement opportunities for improvement. The QAPI program would replace the longstanding annual program evaluation requirement;
- Require RHCs and FQHCs to maintain and document their infection control process;
- Require RHCs and FQHCs to post their hours of operation; and

- Update the physical plant and environment requirement to include compliance with infection control standards of practice; and update the patient health records requirement to reflect advancements in technology and treatment. These changes would incorporate into regulation CMS' existing programmatic instructions.

The proposed rule may be viewed at http://federalregister.gov/OFRUpload/OFRData/2008-13280_PI.pdf. Comments must be submitted by 5:00 p.m. Eastern time August 27, 2008.

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