

essential provider under this section, CMS will:

(i) Grant an exception to one or more RHCs in a given service area if CMS determines the clinics each meet the criteria set forth in paragraphs (b)(2)(ii) or (b)(2)(iii) of this section.

(ii) Use the following criteria in determining distances corresponding to 30 minutes travel time:

(A) Under normal conditions with primary roads available within 20 miles.

(B) In areas with only secondary roads available within 15 miles.

(C) In flat terrain or in areas connected by interstate highways within 25 miles.

(2) *Conditions for exception.* To receive an exception, the RHC must meet one of the following conditions:

(i) *Sole community provider.* The RHC is the only participating primary care provider within 30 minutes travel time.

For purposes of this exception, a participating primary care provider means an RHC, an FQHC, or a physician practicing in either general practice, family practice, or general internal medicine that is actively accepting and treating Medicare beneficiaries and low-income patients (Medicaid beneficiaries and the uninsured, regardless of their ability to pay).

(ii) *Major community provider.* The RHC has Medicare and low-income patient (Medicaid and uninsured) utilization rates equal to or above 51 percent or low-income patient utilization rates equal to or above 31 percent. The RHC is also actively accepting and treating a major share of Medicare, Medicaid, and uninsured patients (regardless of their ability to pay) compared to other participating RHCs that are within 30 minutes travel time; or, if the clinic is the only participating RHC within 30 minutes travel, the RHC is actively accepting and treating a major share of Medicare, Medicaid, and uninsured patients (regardless of their ability to pay) compared to other participating primary care providers.

(iii) *Specialty clinic.* The RHC (located within 30 minutes travel time) is the sole or major source of pediatric or OB/GYN services for Medicare (where applicable), Medicaid, and uninsured patients (regardless of their ability to pay) and is actively accepting and treating these patients. Only clinics that exclusively provide pediatric or OB/GYN services can receive an exception under this test. A specialty clinic is also an RHC that is the sole source of mental health services, as defined in § 405.2450. For purposes of meeting this test, mental health services must be furnished onsite to clinic

patients. Clinics applying as a major source of pediatric or OB/GYN services must have low-income patient (Medicaid and uninsured) utilization rates equal to or above 31 percent.

(iv) *Extremely rural community provider.* The RHC is actively accepting and treating Medicare, Medicaid, and uninsured patients (regardless of their ability to pay) and is located in a frontier county (less than six persons per square mile) or in a level 8 or level 9 nonmetropolitan county using urban influence codes as defined by the U.S. Department of Agriculture.

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■ 5. In § 491.8, revise paragraph (a)(6) and add a new paragraph (d) to read as follows:

§ 491.8 Staffing and staff responsibilities.

(a) * * *

(6) A physician, nurse practitioner, physician assistant, nurse-midwife, clinical social worker, or clinical psychologist is available to furnish patient care services at all times the clinic or center operates. In addition, for RHCs, a nurse practitioner, physician assistant, or certified nurse midwife is available to furnish patient care services at least 50 percent of the time the RHC operates.

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(d) *Temporary staffing waiver.* (1) CMS may grant a temporary waiver of the RHC staffing requirements in paragraphs (a)(1) and (a)(6) of this section 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 nurse midwife, nurse practitioner, or physician assistant to furnish services at least 50 percent of the time the RHC operates.

(2) CMS terminates the RHC from participation in the Medicare program, if the RHC is not in compliance with the provisions waived under paragraphs (a)(1) and (a)(6) of this section at the expiration of the waiver.

(3) The RHC may submit its request for an additional waiver of staffing requirements under this paragraph no earlier than 6 months after the expiration of the previous waiver.

■ 6. Revise § 491.11 to read as follows:

§ 491.11 Quality assessment and performance improvement.

The RHC must develop, implement, evaluate, and maintain an effective, ongoing, data-driven quality assessment and performance improvement (QAPI) program. The self-assessment and performance improvement program

must be appropriate for the complexity of the RHC's organization and services and focus on maximizing outcomes by improving patient safety, quality of care, and patient satisfaction.

(a) *Standard: Components of a QAPI program.* The RHC's QAPI program must include, but not be limited to, the use of objective measures to evaluate the following:

(1) Organizational processes, functions, and services.

(2) Utilization of clinic services, including at least the number of patients served and the volume of services.

(b) *Standard: Program activities.* (1) For each of the areas listed in paragraph (a)(1) of this section, the RHC must do the following:

(i) Adopt or develop performance measures that reflect processes of care and RHC operation and is shown to be predictive of desired patient outcomes or be the outcomes themselves.

(ii) Use the measures to analyze and track its performance.

(2) The RHC must set priorities for performance improvement, considering either high-volume, high-risk services, the care of acute and chronic conditions, patient safety, coordination of care, convenience and timeliness of available services, or grievances and complaints.

(3) The RHC must conduct distinct improvement projects; the number and frequency of distinct improvement projects conducted by the RHC must reflect the scope and complexity of the clinic's services and available resources.

(4) The RHC must maintain records on its QAPI program and quality improvement projects.

(5) An RHC may undertake a program to develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This activity will be considered to fulfill the requirement for a project under this section.

(c) *Standard: Program responsibilities.* The RHC's professional staff, administrative officials, and governing body (if applicable) are responsible for the following:

(1) Ensuring that quality assessment and performance improvement efforts effectively address identified priorities.

(2) Identifying or approving those priorities and for the development, implementation, and evaluation of improvement actions.