

the size and scope of the clinics and how complex the QAPI program will be for each clinic. In developing the requirement, we wanted to assure flexibility for RHCs so that both large and small clinics can develop a program that reflects the resources and complexity of each clinic's organization and services. We estimate it will take a clinic approximately 40 hours to develop a QAPI program from a variety of assumptions. First, the hospital QAPI condition of participation estimates 80

hours for a hospital to develop the program. We expect that at the level-of-effort for a RHC would be less than that for a hospital QAPI program as hospitals provide more services than RHCs. For hospital provider-based clinics, we expect that they would already have experience with the QAPI process. Therefore, their level-of-effort would be reduced. The 40-hour time estimate also recognizes that the time will vary based on the simplicity or complexity of the program that a clinic develops. We also

estimate that the RHC will spend an additional 4 hours a year collecting and analyzing data. In addition, we estimate that clinics will spend 3 hours a year training and or updating staff on their QAPI program. Since the QAPI program will replace the current annual evaluation requirement, the administrative burden and annual review of policies and procedures are currently covered by 0938–0334.

Requirement	Annual burden hours	One-time burden hours
Program Development	40 hrs × 3,300 = 132,000
Data Collection and Analysis	13,200	
Training	3 hrs × 3,300 = 9,000
Total	13,200	141,000

These are preliminary projections that may change slightly as we update the PRA submission.

To maintain the data required by § 491.11, we estimate it will take each clinic 1 hour per year to meet this requirement. Since there are an estimated 3,341 facilities, the total burden associated with this requirement is 3,341 annual hours.

We have submitted a copy of this final rule to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Information Services, Information Technology Investment Management Group, Attn.: Dawn Willingham (Attn: CMS–1910–F), Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, CMS Desk Officer.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 491

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural areas.

■ For the reasons set forth in the preamble, The Centers for Medicare & Medicaid services amends 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart X—Rural Health Clinic and Federally Qualified Health Center Services

■ 1. The authority citation for part 405 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. In § 405.2401(b), revise the definition of “rural health clinic” to read as follows:

§ 405.2401 Scope and definitions.

* * * * *

(b) Definitions.

* * * * *

Rural health clinic (RHC) means an entity that:

(1) Meets the requirements of section 1861(aa)(2) of the Act and part 491 of this chapter concerning RHC services and conditions for approval.

(2) Has filed an agreement with CMS that meets the basic requirements described in § 405.2402 to provide RHC services under Medicare.

(3) Does not share space, staff, supplies, records, and other resources during RHC hours of operation with a private Medicare or Medicaid practice

operated by the same physicians and nonphysician practitioners working for the RHC. Operation of a multipurpose clinic with other types of health providers or suppliers is permissible subject to the provisions in paragraph (4) of this definition.

(4) Appropriately allocates and excludes from the RHC cost report the net non-RHC costs if it operates at a multipurpose location that involves the sharing of common space, medical support staff, or other physical resources with other health care providers or suppliers.

* * * * *

■ 3. Revise § 405.2410 to read as follows:

§ 405.2410 Application of Part B deductible and coinsurance.

(a) *Application of deductible.* (1) Medicare payment for RHC services begins only after the beneficiary has incurred the deductible. Medicare applies the Medicare Part B deductible as follows:

(i) If the deductible is fully met by the beneficiary before the RHC visit, Medicare pays 80 percent of the all-inclusive rate.

(ii) If the deductible is not fully met by the beneficiary before the visit and the amount of the RHC's reasonable customary charge for the service that is applied to the deductible is—

(A) Less than the all-inclusive rate, the amount applied to the deductible is subtracted from the all-inclusive rate and 80 percent of the remainder, if any, is paid to the RHC; or

(B) Equal to or exceeds the all-inclusive rate, no payment is made to the RHC.

(2) Medicare payment for FQHC services is not subject to the usual Part B deductible.