

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 405 and 491

[CMS-1910-F]

RIN 0938-AJ17

Medicare Program; Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions; and Establishment of a Quality Assessment and Performance Improvement Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule amends Medicare certification and payment requirements for rural health clinics (RHCs) as required by the Balanced Budget Act of 1997 (BBA). It changes the definition of a qualifying rural shortage area in which a Medicare RHC must be located; establishes criteria for identifying RHCs essential to delivery of primary care services that we can continue to approve as Medicare RHCs in areas no longer designated as medically underserved; and limits waivers of certain nonphysician practitioner staffing requirements. This final rule imposes payment limits on provider-based RHCs and prohibits "commingling" (the use of the space, professional staff, equipment, and other resources) of an RHC with another entity. The rule also requires RHCs to establish a quality assessment and performance improvement program that goes beyond current regulations. Finally, this final rule addresses public comments received on the February 28, 2002 proposed rule and makes other revisions for clarity and uniformity and to improve program administration.

EFFECTIVE DATE: These regulations are effective on February 23, 2004.

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I. Background

A. General

The Rural Health Clinic Services Act of 1977 (Pub. L. 95-210, enacted December 13, 1977), amended the Social Security Act (the Act) by enacting section 1861(aa) to extend Medicare and Medicaid entitlement and payment for primary and emergency care services furnished at a rural health clinic (RHC) by physicians and certain nonphysician practitioners, and for services and supplies incidental to their services. "Nonphysician practitioners" included nurse practitioners and physician assistants. (Subsequent legislation extended the definition of covered RHC services to include the services of clinical psychologists, clinical social workers, and certified nurse midwives).

According to House Report No. 95-548(I), the purpose of Pub. L. 95-210 was to address an inadequate supply of physicians to serve Medicare and Medicaid beneficiaries in rural areas. The program addressed this problem by providing qualifying clinics located in rural, medically underserved communities with payment on a cost-related basis for outpatient physician and certain nonphysician services furnished to Medicare and Medicaid beneficiaries. (The Medicare payment provisions for rural health clinics are in sections 1833(a)(3) and 1833(f) of the Act and in our regulations beginning at 42 CFR 405.2462.)

Qualifying clinics, among other criteria, had to be located in a nonurbanized area as defined by the Census Bureau and in a health professional shortage area or medically underserved area as designated by the Health Resources and Services Administration or (since the Omnibus Budget Reconciliation Act of 1989 (OBRA '89, Pub. L. 101-239, enacted on December 19, 1989), section 6213(c)) by the chief executive officer of the State. (See section 1861(aa)(2) of the Act,

following subparagraph (K).) There are three types of shortage area designations applicable to RHC qualification: health professional shortage areas, medically underserved areas, and governor-designated shortage areas. The clinic's service area must have, in addition to being located in a nonurbanized area, one of these shortage area designations if the clinic is to qualify to receive RHC status.

Qualifying clinics also must employ a nonphysician practitioner and, to meet requirements of the OBRA '89, must have a nurse practitioner, a physician assistant, or a certified nurse midwife available to furnish patient care services at least 50 percent of the time the RHC operates.

Growth of RHCs in the Medicare Program

After a slow start, the program has recently grown at a rapid rate—from less than 1,000 Medicare-approved RHCs in 1992 to more than 3,300 in early 2001. While part of this increase has improved access to primary care services in rural areas for Medicare and Medicaid beneficiaries, there are instances in which these additional RHCs have not expanded access.

Continuing Participation

A significant factor in the growth of RHCs stems from the original (pre-BBA) RHC legislation, which included a "grandfather clause" to promote the development of RHCs. (See section 1(e) of Pub. L. 95-210, 42 U.S.C. 1395x *note*. Also see 42 CFR 491.5(b)(2).) Specifically, the third sentence of section 1861(aa)(2) of the Act stated that:

A facility that is in operation and that qualifies as a rural health clinic (under the Medicare or Medicaid program) and that subsequently fails to satisfy the requirements of clause (i) (in the second sentence of section 1861(aa)(2), pertaining to the rural and underserved location requirement), is considered as still satisfying the requirement of this clause.

This provision protected the clinic's RHC status despite any possible changes to the rural or underserved status of its service area. It allowed clinics to remain in the RHC program even though their service areas were no longer considered rural or medically underserved.

The Congress established this protection to encourage clinics to attract needed health care professionals to underserved rural areas and to retain them without being concerned about losing the shortage area designation, which would make the clinics ineligible for RHC status and its reimbursement