Supporting Statement for the Application for Certification as a Federally Qualified Health Center Look-Alike

A. JUSTIFICATION

1. Circumstances of Information Collection

This request is for an extension of OMB approval for the application guide used by organizations applying to the Secretary for designation, or recertification, as a Federally Qualified Health Center (FQHC) Look-Alike for purposes of cost-based reimbursement under the Medicaid and Medicare programs. The guide is approved under OMB No. 0915-0142 and expires October 31, 2008. No changes have been made to the application guide for this clearance request.

Background: The Omnibus Budget Reconciliation Acts of 1989, 1990 and 1993 amended section 1905 of the Social Security Act to create a new category of facility under Medicaid and Medicare known as Federally Qualified Health Centers (FQHCs). FQHCs are eligible for reasonable cost-based reimbursement for a full range of primary health care services. Congress established the new provider entity and mandated reasonable cost reimbursement in recognition of the importance of FQHCs in providing access to primary and preventive health care for underserved and vulnerable populations.

FQHCs are defined as:

a. An entity which is receiving a grant under section 330 of the Public Health Service (PHS) Act;
b. An entity which is receiving funding from such a grant under a contract with the grantee and which meets the requirements to receive a grant under section 330 of the PHS Act;
c. An entity which, based on the recommendation of the Health Resources and Services Administration (HRSA), is determined by the Secretary to meet the requirements for receiving a grant under section 330.
d. An outpatient health program or facility operated by an Indian tribe or a tribal organization under the Indian Self-Determination Act (Public Law 93-638).
e. An Urban Indian organization receiving funds under Title V of the Indian Health Care Improvement Act for the provision of primary health services.

Categories (1), (2), (4) (5) and (6) listed above automatically qualify as FQHCs; they do not need to apply for this status. The third category must apply for FQHC status as a Look-Alike by submitting an application to the Department of Health and Human Services.

The Health Centers Consolidation Act of 1996 (P.L. 104-299, Attached) consolidated, under an amended section 330 of the Public Health Service Act, four former authorities for health centers: section 329 (Migrant Health Centers), section 330 (Community Health Centers), section 340 (Health Care for the Homeless Grantees, and section 340A

(Public Housing Primary Care Centers). The Health Centers Consolidation Act also amended the Social Security Act to define FQHCs in accordance with the amended section 330. In this document, references to section 330 and to the term "health centers" refer to the amended section 330.

The Balanced Budget Act (BBA) of 1997 (P.L. 105-33) modified the definition contained in section 1905 of the Social Security Act for a FQHC Look-Alike entity by adding the requirement that an "entity may not be owned, controlled or operated by another entity". The Health Resources and Services Administration's (HRSA) Bureau of Primary Health Care (BPHC), in collaboration with the Centers for Medicare and Medicaid Services (CMS) has issued policy guidances to implement the BBA requirements for public and private nonprofit organizations currently designated, or seeking designation. The BBA of 1997 also provides for phase-out of the Federal payment share based on reasonable costs. The Medicaid prospective payment system (PPS) for FQHCs was enacted into law on December 21, 2000, under section 702 of the Medicare, Medicaid and State Children's Health Insurance Program (SCHIP) Benefits Improvement and Protection Act (BIPA) of 2000. The Medicaid PPS requirements are effective in all States, with respect to services furnished by FQHCs on or after January 1, 2001. All States, including those operating section 1115 waiver demonstration programs, are subject to the Medicaid PPS requirements in sections 1902 (a)(15) and 1902 (aa) of the BIPA.

BIPA amends section 1902(a) of the Social Security Act ("the Act") by repealing the reasonable cost-based reimbursement requirements for FQHC services previously at paragraph (13)(C) and instead requiring in paragraph (15) payment for FQHCs consistent with a new prospective payment system (PPS) described in section 1902 (aa) of the Act. Under BIPA, the new Medicaid PPS was effective on January 1, 2001. A State may, in reimbursing an FQHS for services furnished to Medicaid beneficiaries, use an alternative methodology other than the Medicaid PPS, but only if the following statutory requirements are met. First, the alternative payment methodology must be agreed to by the State and by each individual FQHC to which the State wishes to apply the methodology. Second, the methodology must result in a payment to the center or clinic that is at least equal to the amount to which it is entitled under the Medicaid PPS. Third, the methodology must be described in the approved State plan.

The designation process for FQHC Look-Alikes is authorized by 42 USC 1396d (section 1905 of the Social Security Act) (Attached). The authorizing legislation provides for HRSA to recommend which non-federally funded health centers should be designated and recertified as FQHCs. Based on HRSA's recommendation, the CMS makes the final decision for FQHC designation acting on behalf of the Secretary. The application guide is used by both public and private nonprofit non-federally funded centers in applying to the Secretary to be designated, or recertified, as FQHCs.

The FQHC statute states that HRSA's recommendations for FQHC Look-Alike designation should be based on an assessment regarding how well the applicant meets the requirements for a grant under section 330 of the PHS Act. The section 330 statute,

implementing regulations and program policy documents are therefore used as the basis for the requested information in the FQHC Look-Alike application guide.

HRSA is requesting a three-year extension of OMB clearance of the current application and guidance.

2. Purpose and Use of Information

To become an FQHC Look-Alike, an entity must submit an application that includes the information and documents requested in the application guide. Applicants submit a full application in the first year only; for subsequent years the FQHC Look-Alike is asked to certify that it continues to meet the requirements for eligibility. HRSA uses the application to assess compliance with program requirements and the appropriateness of designating the entity as a FQHC Look-Alike.

FQHC Look-Alikes are designated on a site-specific basis. In the last two years approximately 52 applications were received, some of which covered multiple sites. There are currently 125 FQHC Look-Alike entities designated throughout the country covering 222 sites.

The application guide asks for specific descriptions and data in required areas. Applicants are asked to provide written documentation describing the area and population served by the organization; the health services offered by the organization; the administrative and financial management systems in place; and the organization's governance. Brief narrative descriptions are requested to support the data provided in the required tables and exhibits to enable HRSA and CMS to evaluate whether or not an organization meets the requirements of the legislation. The guide suggests that the application be limited to 25 pages, exclusive of required attachments, data exhibits and relevant supporting materials.

The procedures for reviewing applications and designating organizations and are reflected in the application guide.

3. Use of Improved Information Technology

This information collection is fully electronic. The FQHC Look-Alike application guide is available on HRSA's Bureau of Primary Health Care's (BPHC) Web Site (http://bphc.hrsa.gov/policy/) as a BPHC Policy Information Notice (PIN). It is also available through BPHC ACCESS (800-596-6405). Respondents submit the completed FQHC Look-Alike application electronically. A copy of the application guide is attached.

To improve responsiveness to the public, the BPHC's web site also allows members of the general public to submit questions to the BPHC for timely feedback to their questions and concerns.

4. Efforts to Identify Duplication

The information collected in the FQHC Look-Alike application and recertification document is not available from any other source.

The required information can only be supplied by the applicant organization. Since these organizations are not Federal grantees, HRSA has no independent knowledge of the organizations, their service areas, their health service delivery systems or governance arrangements.

5. Involvement of Small Entities

This activity does not significantly impact small entities. FQHC Look-Alike applicants represent both urban and rural areas of the country and employ from one primary care provider to more than 10. The majority of applicants are larger, urban organizations.

The initial application requests the minimal amount of information needed to assess whether an applicant meets the requirements and program expectations of section 330 of the PHS Act and the amended FQHC statute. The annual recertification application requires a subset of this information to assure continued compliance with the FQHC Look-Alike requirements. The information requested in both documents is information that successful organizations should already maintain for management purposes. This minimizes the burden on the respondent.

6. Consequences If Information Collected Less Frequently

The applicant provides the information requested for the initial designation application only one time. The information requested for the annual recertification application is needed to ensure continued compliance with program requirements.

If the information to determine continued compliance is not collected annually, both the Federal Governance and individual states are at risk of providing cost-based reimbursement to organizations that no longer meet the statutory requirements for FQHC Look-Alike designation. Since resources for on-site evaluation are limited, a minimum amount of documentation to assure continued compliance is both necessary and cost-effective.

7. Consistency With the Guidelines in 5 CFR 1320.5(d)(2)

This data collection fully complies with the guidelines in 5 CFR 1320.5(d)(2).

8. Consultation Outside the Agency

The notice required in 5 CFR 1320.8(d) was published in Volume 73, No. 141, pages 42579-42580 of the Federal Register on July 22, 2008. There were no comments from the public.

The following three FQHC Look-Alikes were asked for feedback on the clarity of information in the application, burden estimates, and ways in which the burden might be reduced:

Nasemma Shafi, Compliance Analyst
Whitman-Walker Clinic, Inc.
1407 South Street Northwest
Washington, DC 20009-3819
202-797-4410

Robin A. Pierce, Executive Director
Smith House Health Care Center
39 Farrell Road
Willsboro, NY 12996-8862
518-963-4275

Gilda Zárate-Gonzalez, Administrative Specialist
Tulare County Health and Human Services Agency
5957 S. Mooney Blvd.
Visalia, CA 93277-9394
559-737-4660

The respondents thought the instructions in the application guide were clear, and the requested information was reasonable and available within any effectively operated health care organization.

In addition, the following organizations were consulted regarding the FQHC Look-Alike application guide. HRSA works closely with CMS throughout the FQHC Look-Alike designation and recertification process and to update policy as needed. HRSA consults with staff of the National Association of Community Health Centers and its membership on FQHC policy issues to gain feedback from the field. HRSA also works with the State Primary Care Organizations (PCOs) and Primary Care Associations (PCAs) via the PCA/PCO Workgroup to gain feedback on emerging policy issues from a State perspective.

Mel Schmerler
CMSO/FCHPG/DBEMC
S2-01-16
7500 Security Blvd
Baltimore, MD 21244-1850
410-786-3414

Kim Sibilisky, Executive Director
Michigan Primary Care Association
2525 Jolly Road, Suite 280

Okemos, MI 48864
517-381-8000

Freda Mitchum
National Association of Community Health Centers, Inc.
7200 Wisconsin Ave., Suite 210
Bethesda, MD 20814
301-347-0400

9. Remuneration of Respondents

Respondents will not be remunerated.

10. Assurance of Confidentiality

No personally identifiable information is requested.

11. Questions of a Sensitive Nature

There are no questions of a sensitive nature.

12. Estimates of Annualized Hour Burden

Form Name	Number of Respondents	Responses per Respondent	Hours per Respondent	Total Hour Burden	Wage Rate	Total Hour Cost
Application	40	1	100	4,000	$30	$ 120,000
Recertification	100	1	15	1,500	$30	$ 45,000
Total Burden	140	1		5,500		$165,000

Basis for Burden Estimates:

Application: Based on previous experience, our annual estimate for the next three years is an average of 40 new applications per year for a total burden of 4,000 hours for new applications.

Recertification: Approximately 100 sites are estimated to request recertification annually for a total burden of 1,500 hours for recertification.

The estimated burden hour cost to respondents is $165,000, assuming an average salary of $30 per hour (5,500 x $30/hour).

13. Estimates of Annualized Cost Burden to Respondents

There are no costs to the respondents for capital and startup.

14. Estimates of Annualized Cost to the Government

An estimated 7 FTEs at a GS 13 level are needed to review and process the applications and recertifications in the CMS Regional Offices and at CMS and HRSA Headquarter Offices. The total annual cost to the Federal Government is about $625,000 per year. This level of effort has proved adequate for reviewing the applications and recertification documents.

15. Changes in Burden

The current approved burden estimate for this project is 4,000 respondent hours annually. This request is for a total annual burden hour of 5,500, an increase of 1,500 hours. This is a program adjustment resulting from an increase in the annual estimated number of respondents.

16. Time Schedule, Publication and Analysis Plans

There are no plans to analyze or publish this information.

17. Exemption for Display of Expiration Date

No exemption is requested and the expiration date will be displayed.

18. Certifications

This information collection fully complies with the guidelines in 5 CFR 1320.9. The certifications are included in the package.

ATTACHMENTS

Legislative Authority

42 USC 1396d (section 1905 of the Social Security Act)

Application Guide