U.S. Department of Health and Human Services
HRSA BPHC Bureau of Primary Health Care
Health Resources and Services Administration

PROGRAM INFORMATION NOTICE

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DOCUMENT TITLE: Federally Qualified Health Center Look-Alike Guidelines and Application

TO: Community Health Centers
Migrant Health Centers
Health Care for the Homeless Grantees
Public Housing Primary Care Grantees
Federally Qualified Health Center Look-Alikes
Primary Care Associations
Primary Care Organizations

Attached are the revised guidelines and application package for Federally Qualified Health Center (FQHC) Look-Alike designation and recertification, recently approved by the Office of Management and Budget. This document replaces Policy Information Notice (PIN) 2000-02, "Federally Qualified Health Center Look-Alike Guidelines and Application," dated October 19, 1999.

This application guidance reflects legislative, policy and technical changes since PIN 2000-02 was issued. The document contains major revisions in the program including:

- Elimination of waiver allowances under the Medicaid FQHC benefit. Organizations previously granted waivers will be given sufficient time to meet the waiver requirements.
- Applicants are asked to submit a Letter of Interest to the Bureau of Primary Health Care prior to submitting a formal application.
- A Compliance Checklist has been added.
- A checklist of required forms and documents including the affiliation checklist, detailed map, Medically Underserved Area or Medically Underserved Population designation, and not for profit status has been added.
- Reference to the Medicare, Medicaid and State Children's Health Insurance Program Benefits Improvement and Protection Act of 2000, section 702, the Medicaid Prospective Payment System for FQHCs has been added.
- Forms and data tables have changed.
- Change in Scope of Project policy and procedures have been added.

Questions regarding the FQHC Look-Alike application guide should be directed to The Division of Health Center Development.

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Attachments

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I. PURPOSE

This document provides information about the Federally Qualified Health Center (FQHC) Look-Alike Program and instructions for submitting an application for designation or recertification as a FQHC Look-Alike. The requirements described in this document are for health centers that serve a population that is medically underserved as defined in section 330 of the Public Health Service (PHS) Act.

II. LEGISLATIVE BACKGROUND FOR FEDERALLY QUALIFIED HEALTH CENTERS

The Omnibus Budget Reconciliation Acts of 1989, 1990, and 1993 amended section 1905 of the Social Security Act to create a new category of entities under Medicaid and Medicare known as FQHCs. The Social Security Act § 1905(l)(2))B) defines an FQHC for Medicaid purposes as an entity which:

> "(I) is receiving a grant under section 330 of the PHS Act, as amended;
>
> (II)(i) is receiving funding from such a grant under a contract with the recipient of such a grant, and
>
> (ii) meets the requirements to receive a grant under section 330 of such Act,
>
> (III) based on the recommendation of the Health Resources and Services Administration within the Public Health Service, is determined by the Secretary to meet the requirements for receiving such a grant including requirements of the Secretary that an entity may not be owned, controlled or operated by another entity, or
>
> (IV) was treated by the Secretary, for the purposes of part B of title XVIII, as a comprehensive Federally funded health center as of January 1, 1990,
>
> and includes an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act (Public Law (P.L.) 93-638) or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act for the provision of primary health services."

A similar definition for Medicare purposes is found at § 1861(aa)(4) of the Social Security Act.

The goal of the FQHC program is to maintain, expand and improve the availability and accessibility of essential primary and preventive health care services and related "enabling" services provided to low income, medically underserved and vulnerable populations that traditionally have limited access to affordable services and face the greatest barriers to care. As fundamental components of the health care "safety net," FQHCs provide a comprehensive system of care reflective of the community's needs and available to all persons residing in their service area(s), regardless of the person's or family's ability to pay for such services. The FQHCs further ensure access to care by establishing a schedule of discounts for persons unable to pay a full fee, including nominal or no fees for services provided to the poorest of the populations served, persons whose incomes are below 200 percent of the Federal poverty guidelines.

One of the cornerstones of the FQHC program is community involvement in both the management and governance of the health center. The FQHCs must be governed by a community-based Board of Directors, a majority of whom are users of the health center's services and who represent the health center's service area in terms of demographic factors such as race, ethnicity and gender. The Board must autonomously exercise key decision-making regarding adoption and establishment of operating and service policies, approval of the budget and grant application, strategic and operational planning, and the hiring and, if necessary, dismissal of the executive director or chief executive officer. In addition, the involvement of third parties in health center governance is specifically limited by Federal policy.

To ensure that there are appropriate numbers of health centers to serve the millions of uninsured and underinsured populations throughout the country, FQHC Look-Alike status was made available to those health centers that do not receive funding under section 330, but operate and provide services similar to grant-funded programs. As such, FQHC Look-Alike entities are expected to demonstrate the same commitment as grantees to serve all populations residing in their respective medically underserved communities, and to satisfy the administrative, management, governance and service-related requirements unique to section 330 funded health centers.

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), issued policy guidances to implement the BBA requirements for public and private nonprofit organizations: Policy Information Notice (PIN) 99-10, "Implementation of the Balanced Budget Act Amendment of the Definition of Federally Qualified Health Center Look-Alike Entities for Private Nonprofit Entities," issued April 20, 1999; and PIN 99-09, "Implementation of the Balanced Budget Act Amendment of the Definition of Federally Qualified Health Center Look-Alike Entities for Public Entities," issued April 20, 1999. Other relevant policy documents are PIN 97-27, "Affiliation Agreements of Community and Migrant Health Centers," issued July 22, 1997; and PIN 98-24, "Amendment to PIN 97-27 Regarding Affiliation Agreements of Community and Migrant Health Centers," issued August 17, 1998. These documents describe the statutory limits on the involvement of "another entity" in the ownership, control and/or operation of a public or private nonprofit FQHC Look-Alike entity. Potential applicants are encouraged to work closely with the HRSA Field Offices list of contacts if there are questions about the application of these policies to their particular case.

III. PAYMENT ELIGIBILITY UNDER MEDICAID AND MEDICARE

Under Medicaid, the FQHC covered core services include services provided by physicians, physician assistants, nurse practitioners, clinical nurse specialists, clinical psychologists, clinical social workers, and services and supplies incident to those services. Any other ambulatory service included in a State's Medicaid plan is considered a covered service under the FQHC benefit, if the FQHC offers such a service and meets applicable requirements for a provider of that service.

Under Medicare, FQHCs currently are eligible for payment at 100 percent of the reasonable costs for the same core services covered under the Medicaid FQHC benefit. Additionally,

Medicare FQHC includes reimbursement at 100 percent of reasonable cost for certain preventive health services that are not normally covered under Medicare.

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 new 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 new Medicaid PPS requirements in sections 1902(a)(15) and 1902(aa) of the BIPA.

The 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 PPS described in section 1902(aa) of the Act. Under BIPA, the new Medicaid PPS was effective on January 1, 2001. In the first phase of the new Medicaid PPS (January 1, 2001-September 30, 2001), States were required to pay current FQHCs either 100 percent of the average of their reasonable costs of providing Medicaid-covered services during fiscal year (FY) 1999 and FY 2000, adjusted for any increase or decrease in the scope of services furnished during FY 2001 by the FQHC (calculating the payment amount on a per visit basis), or an amount based on an alternative payment methodology mutually agreed to by and between the State agency and the FQHC (as described below). Beginning in FY 2002, and for each fiscal year thereafter, each FQHC is entitled to the payment amount (on a per visit basis) to which the center or clinic was entitled under the Act in the previous fiscal year, increased by the percentage increase in the Medicare Economic Index (MEI) for primary care services, and adjusted to take into account any increase (or decrease) in the scope of services furnished by the FQHC during that fiscal year. Newly qualified FQHCs after FY 2000 will have initial payments established either by reference to payments to other clinics in the same or adjacent areas, or in the absence of such other clinics, through cost reporting methods. After the initial year, payment shall be set using the MEI methods used for other clinics.

For the same period beginning January 1, 2001 and ending September 30, 2001, and for any fiscal year beginning with FY 2002, a State may, in reimbursing an FQHC 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.

IV. PROGRAM ELIGIBILITY

Applicants for FQHC Look-Alike designation must be operational at the time of application and meet the following requirements:

- be a public or a private nonprofit entity;
- serve, in whole or in part, a federally-designated Medically Underserved Area (MUA) or

Medically Underserved Population (MUP). (The list of MUAs and MUPs is available through the BPHC Web site: http://www.bphc.hrsa.dhhs.gov/databases/newmua/);

- meet the statutory, regulatory and program requirements for grantees supported under section 330 of the PHS Act; and
- comply with the policy implementation documents specified in Section II of this PIN for the BBA of 1997 amendment which added the requirement that an FQHC Look-Alike entity may not be owned, controlled or operated by another entity.

V. LETTERS OF INTEREST

The submission of a Letter of Interest (LOI) is recommended but not required in order to submit an application for FQHC Look-Alike designation. It is recommended that an applicant submit a LOI to the BPHC as soon as it begins considering applying for FQHC Look-Alike designation. A copy of the LOI should be sent to the Primary Care Association (PCA). The BPHC uses the LOI process to provide feedback to the organization to improve the quality of its application and its opportunity for designation as a FQHC Look-Alike. The BPHC will provide feedback within 30 days of receipt of the LOI and the applicant should incorporate the BPHC response prior to the application.

The LOIs should be no longer than 7 pages and address the level of need in the community for additional primary care services, provide a description of the organization that will be seeking the designation and a brief description of the proposed project.

Each LOI should include a BRIEF DESCRIPTION of each of the following:

- the name and address of the organization and sites to be designated;
- the proposed target population and service area including whether (1) it is defined as urban or rural and (2) identification of any federally-designated MUA/MUP designations to be served;
- issues creating a high need for primary health services including any significant or unique barriers to care;
- a justification of the need for FQHC Look-Alike designation by documenting the lack of sufficient health care resources in the service area to meet the primary care needs of the target population. A map of the service area with the organization and sites noted, as well as all other resources in the service area, should be included;
- the level of need in the community for additional primary care services;
- the history and mission of the organization that will be seeking the designation;
- current operational capacity of the organization, providers and services; and
- the signed compliance checklist and relevant documents. (See Form 4).

LOIs may be sent via e-mail to fqhclaloi@hrsa.gov or mailed to:

Bureau of Primary Health Care
4350 East-West Highway, 7th Floor
Bethesda, Maryland 20814
ATTN: FQHC Look-Alike LOI

A copy of the LOI should be sent to the appropriate PCA. (See attached list, Appendix B).

VI. APPLICATION PROCESS

For FQHC Look-Alike designation, an original application and two copies of the application must be submitted to the BPHC. Applications are accepted anytime throughout the year. The review and designation process is carried out by staff of the BPHC, the CMS Central Office (CO) and the CMS Regional Offices (RO)s. The role and responsibilities of each entity are as follows:

BPHC:

The BPHC is responsible for distributing application materials, providing comments on LOIs, receiving completed applications, and reviewing the application for consistency and compliance with section 330 requirements and applicable policies. While the BPHC review is usually completed within a month of receipt of the application, it may be necessary to request additional information from the applicant to clarify various aspects of or to correct minor deficiencies in the application. If the BPHC review concludes that the application meets the requirements and expectations of the FQHC Look-Alike program, the BPHC will forward a recommendation for approval to the CMS CO.

When the BPHC review determines that the application is either non-compliant with FQHC Look-Alike requirements or incomplete, the application will be returned to the applicant without further consideration. The organization may re-apply for FQHC Look-Alike designation, however, the application must demonstrate full compliance with all requirements. The applicant is encouraged to contact the PCA for assistance in addressing any deficiencies prior to re-applying.

CMS CO and RO:

As defined by Section 1905 of the Social Security Act, only the CMS has the statutory authority to designate applicants as FQHC Look-Alikes, based on the recommendation of the HRSA/BPHC. After the BPHC forwards its recommendation for designation to the CMS CO, the CMS CO forwards a memorandum to the appropriate CMS RO requesting the applicable State Medicaid Agency/Office be notified of the applicant organization's pending designation as a FQHC Look-Alike.

The State Medicaid Agency/Office has 14 days to comment on the application and submit any additional information to the CMS RO regarding the designation. If the CMS CO receives no comments, the recommendation will be accepted and the applicant organization will be designated as a FQHC Look-Alike. The CMS RO then notifies the State Medicaid Agency/Office, the CMS CO, and the BPHC of the final approval decision and the BPHC then notifies the applicant organization of the final approval decision. **Generally, the effective date of the FQHC Look-Alike designation is the date of the CMS RO letter to the State Medicaid Agency/Office regarding the final approval decision.**

In some cases, a State may request a 60 day extension to investigate any issues raised during the initial 30 day comment period. If the issues are not satisfactorily resolved within the 60 day extension, the CMS CO will notify the applicant and the BPHC that the recommendation

for FQHC Look-Alike designation will not be accepted. The BPHC will notify the applicant and the PCA. The applicant may continue to work with the State to resolve any outstanding issues and reapply for designation when the issues have been resolved.

VII. 340 DRUG PRICING PROGRAM

Organizations designated as FQHC Look-Alikes under section 330 of the PHS Act, as amended, are eligible to purchase prescription and non-prescription medications for their outpatients at reduced cost through the 340B Drug Pricing Program. FQHCs are not required to operate/own a pharmacy in order to participate in this program. Given the pharmacist shortage nationwide, FQHCs may want to consider contracting with a local pharmacy. In order to participate in this program, a health center must submit a Program Registration Form to the Office of Pharmacy Affairs, Bureau of Primary Health Care along with its Medicaid information.

For general information on the 340B program, please contact the Office of Pharmacy Affairs at 800-628-6297 or visit the website at http://bphc.hrsa.gov/opa.

VIII. SUPPLEMENTARY DOCUMENTS

Applicants are encouraged to thoroughly review the following reference documents prior to finalizing a decision to apply. All policy documents are posted on the BPHC web site: http://www.bphc.hrsa.gov/.

1. Health Centers Consolidation Act of 1996 (P.L. 104 – 299) (section 330 of the PHS Act, as amended)
2. PIN 98-12, "Implementation of the Section 330 Governance Requirements" (signed April 28, 1998)
3. PIN 98-23, "Health Center Program Expectations" (signed August 17, 1998)
4. PIN 98-24, "Amendment to PIN 98-27 Regarding Affiliation Agreements of Community and Migrant Health Centers" (signed August 17, 1998)
5. PIN 97-27, "Affiliation Agreements of Community and Migrant Health Centers" (signed July 22, 1997)

IX. STRUCTURE AND CONTENT OF THE APPLICATION

The requirements that must be fully addressed by the applicant are detailed in Attachment A of this PIN. The total narrative portion of the application should not exceed 25 pages, exclusive of required attachments, data exhibits and relevant supporting materials. Minor deviations from these limits are acceptable.

Applicants should submit an original and one copy of the application, with all attachments, to the BPHC and one copy to the appropriate PCA. (See Appendix B).

A. STRUCTURE OF THE APPLICATION FOR DESIGNATION (APPLICATION COMPONENTS SHOULD BE ASSEMBLED AS FOLLOWS):

- Form 1-A, Application for FQHC Designation cover page. This must be notarized.
- Table of Contents
- Form 2, Application Checklist
- Form 3, Compliance Checklist
- Project Summary
- Project Description – Narrative component
- Appendices
  - -Data Tables 1 - 5
  - -Forms 4 - 5
  - -Required Attachments
  - -Supplementary Attachments (at the discretion of the applicant)

B. CONTENT OF THE APPLICATION

1. PROJECT SUMMARY (recommend approximately 2 pages)

   The project summary is intended to be a **brief synopsis of the community/target population, the applicant organization and the scope of the proposed FQHC Look-Alike.** The applicant should summarize the need for health services in the community and the organization's response to that need. The following issues should be addressed:

   - Overview of the community/population
   - Overview of the organization
   - Project plan

2. PROJECT DESCRIPTION

   The narrative component of the application should be divided into four sections:

   Section A. Need and Community Impact;
   Section B. Health Services;
   Section C. Management and Finance; and
   Section D. Governance.

   (See Attachment A for further detail on the required elements to be addressed in each section).

3. REQUIRED ATTACHMENTS

   In addition to the data exhibits and tables, the following documents **MUST** be submitted with the application:

   - documentation of non-profit status or evidence of application for non-profit status (not required for a public entity applicant);
   - a map of the service area, with site location(s) and MUA/MUPs noted, as well as

other primary care providers including other including other FQHCs in the area (see Appendix C for sample);
- a complete copy of the applicant's most recent annual audit with auditor's opinion letter;
- a copy of the organization's schedule of discounts (see Appendix A for sample);
- signed copies of the organization's Articles of Incorporation and corporate bylaws; and
- copies of current or proposed management agreements, administrative or clinical services contracts, lines of credit, or any other type of formal affiliation relationship.

C. MULTIPLE SERVICE DELIVERY SITES

Organizations requesting designation of more than one service delivery site are not required to submit a separate application for each site. For each site being included in the designation, the following must be included: (1) a narrative description of need in the area, (2) demographics of the target population, (3) services provided, and (4) professional staffing. Tables 1-5 must be submitted for each site. The submission of information concerning user characteristics such as income and insurance status, age, sex and race on a site specific basis is preferred, but if the entity only keeps aggregated data on users, an entity-wide summary may be provided. Allowance will be made for the increased size of the application due to the submission of information on multiple sites.

X. ANNUAL RECERTIFICATION OF FQHC DESIGNATED ORGANIZATIONS

All designated FQHC Look-Alikes are required to submit an annual recertification statement to retain designation as a FQHC Look-Alike. The annual recertification statement must be notarized and submitted to the BPHC at least 2 months prior to the anniversary of the FQHC Look-Alike's designation date. The recertification statement requires updated information on users, staffing, and service delivery arrangements (for each designated site if applicable), as well as information on any administrative, management or clinical changes that have taken place during the past 12 months, including new or revised/amended contracts and affiliation agreements. All changes in scope approved during the previous year should also be addressed (see below). (See Attachment B – Requirements for Annual Recertification for FQHC Look-Alike Designated Organizations).

The BPHC will review the recertification and either contact the organization for additional information or submit a recommendation to recertify to the CMS CO. The CMS CO then notifies the appropriate CMS RO who will notify the State Medicaid Agency/Office with copies to the CMS CO and the BPHC. The BPHC will notify the FQHC Look-Alike of the continued designation.

If issues of compliance are raised during the review of the recertification, the BPHC will contact the organization for their response to the issues to assure continued compliance with the FQHC Look-Alike program. If all the issues are resolved satisfactorily within 60 days of notification, the BPHC will notify CMS CO of its recommendation to recertify. If all the issues are not satisfactorily resolved after 60 days, the organization will be notified by the BPHC that the FQHC Look-Alike designation will expire immediately.

In the event that a designated FQHC Look-Alike does not submit the documentation required for its annual recertification by the anniversary of the designation date, the BPHC will notify the FQHC Look-Alike, which, in turn, will have 30 days to submit the documentation. If the FQHC Look-Alike does not submit the documentation within the 30 day period, CMS will be notified by the BPHC and the FQHC Look-Alike designation will be terminated.

XI. CHANGE IN SCOPE OF PROEJCT

The Scope of Project defines the health center's approved project for the FQHC Look-Alike designation. An approved scope of project may be a part of a larger health care delivery system and, as such, needs to be distinctly defined within that context. FQHC Look-Alike health centers may have other activities that are not part of their approved scope of project, referred to as Other Lines of Business (OLB) and, thus, are not subject to section 330 requirements and expectations. **It is important to note that only those activities that are a part of the health center's approved scope of project are entitled to certain benefits (i.e., Medicaid PPS and FQHC payments, Medicare FQHC reimbursements, and Drug Pricing benefits).** (Note: Services that are within the approved scope of project but that are not covered as a FQHC service by Medicaid or Medicare, or not provided on an outpatient basis, are not eligible for PPS or cost-based reimbursement.)

A Scope of Project is categorized by five core elements: services, sites, providers, target population, and service area(s) and:

- Defines for the section 340B Drug Pricing Program, the necessary site information enabling covered entities to purchase discounted drugs for patients;

- Defines the approved service delivery sites and services necessary for State Medicaid Offices to calculate payment rates under the PPS or other State-approved alternative payment methodology (see Program Assistance Letter 2001-09 Department of Health and Human Services Fiscal Year 2001 Appropriations, Other Legislation, and Regulation Issuances) and subsequent information posted on www.bphc.hrsa.gov; and

- Defines the approved service delivery sites necessary for the CMS to determine a health center's eligibility for FQHC Medicare cost-based reimbursement.

All FQHC Look-Alike health centers must request prior approval from the BPHC of any changes to their approved scope of project. The requests are to be submitted to the BPHC at least 60 days before the change is anticipated to take place. All Change in Scope requests must demonstrate approval by the Board of Directors and include the Change in Scope Assurances Checklist (Form 6). If the change in scope includes additional site(s) that have a different service area and/or target population than those already being served, Board representation must be modified to represent users of the added site(s). The Change in Scope request may **not** be included as part of the recertification package but must be submitted as a separate request from the organization. The request should state whether it is to add a new site(s) or service(s), reduce services at an existing site(s), or decrease the number of previously approved sites, and must include all the required documentation (as described below).

A. REQUESTS TO ADD OR DECREASE SITE(S)

Change in Scope requests to add or decrease site(s) must include:

- a narrative description of need in the area served by each site, demographics of the target population, services provided at the site, and professional staffing, and a description of the impact of adding a or decreasing a site while ensuring the financial viability of the health center
- a map of the new site(s) service area, with site(s) location and MUA/MUPs noted, as well as other primary care providers (including other FQHCs) in the new or deleted site's service area
- any applicable referral agreements
- Tables 1-5 completed for each new or deleted site
- updated Form 5, Service Sites
- Change in Scope Assurances Checklist (Form 6)

B. REQUESTS TO ADD OR REDUCE SERVICE(S)

Change in Scope requests to add or reduce services must include:

- a narrative description of the services and the impact of adding or reducing service(s) while ensuring the financial viability of the health center.
- updated Table 1
- any applicable referral agreements
- Change in Scope Assurances Checklist (Form 6)