

"The purpose of this document is to provide a side-by-side comparison of organizational and programmatic options available to rural health care entities for the delivery of primary health care services."

DECEMBER 2010

INTRODUCTION

Delivering cost effective, quality primary health care in rural settings has been an ongoing challenge for rural communities across the United States for decades. The Accountable Care Act of 2010 adds an additional dimension to the complexities of appropriate health care delivery models that may be impacted by the development of Accountable Care Organizations (ACOs). Rural hospitals and health care providers must be ready for the expansion of ACO development and proactively explore health care delivery options and programs that will position them more favorably to participate directly or indirectly in these changes.

Primary care practitioners most often are those who provide initial entry into our health care delivery system. Small rural hospitals are realizing that an adequate supply of qualified primary health care providers in their communities is essential to operating a viable health care entity.

The purpose of this document is to provide a side-by-side comparison of organizational and programmatic options available to rural health care entities for the delivery of primary health care services. There is no one perfect option for all communities. In fact, a reasonable strategy for developing high quality, financially viable primary care practices may involve a series of organizational steps that begin with moving a primary care practice into one organizational model with the ultimate goal of operating under a different model.

This document provides a fairly detailed summary of the regulatory, financial and operational considerations associated with the operation of Provider-Based Physican Practices, Rural Health Clinics and Federally Qualified Health Centers. The key regulatory requirements of each status are presented, as well as the financial impact of each status, related to billing and reimbursement as well as potential grant funding opportunities specifically related to FQHC status.

Each of these programs has a specific set of regulatory guidance that should be understood before making organizational and programmatic changes.

"There is no one perfect option for all communities."

TABLE OF CONTENTS

PB Status: Requirements ... 5

Licensure ...5 Clinical Services ...5 Financial Integration...5 Public Awareness ...6 Ownership and Control ...6 Administration and Supervision ...6 Location ...7

PB Status: Benefits ... 8

Rural Health Clinics ... 8 Overhead Allocations ... 8 Physician Practices ... 9 CAH Considerations Reimbursement ... 9 CAH Considerations Location Requirements ... 10 PB RHC Clinic Exception to the CAH Location Requirement ... 11

RHC: Governance and Administrative Concerns ... 13

Location Requirement ... 13 Service Delivery Requirements ... 13 Laboratory Services ... 13 Emergency Services ... 14 X-ray Services ... 14 Hospital and Specialty Care Services ... 14 Staffing Requirements ... 14 Midlevel Practitioners ... 14 The Island Exemption ... 14 Policies and Procedures Manual and Site Surveys ... 15 Provider-Based RHCs ... 15

RHC: Benefits

Provider Recruitment ... 16

FQHC: Regulatory Considerations ... 18 FQHC Governance Requirements 18

FIGURE 1: FQHC GOVERNANCE REQUIREMENTS

FIGURE 2: REQUIRED BOARD AUTHORITIES TO BE STATED IN BYLAWS

FQHC or Look-Alike: Governance Structure Alternatives ... 23

FQHC: Regulatory Considerations .. 24

FQHC Scope of Services ... 24 Primary Care for All Life Cycles ... 24 Basic Laboratory Services ... 24 Emergency and After Hours Care ... 25 Assurance of Access to Low Cost Drugs ... 25 Preventive Health Care ... 25 Preventive Dental Care ... 26 Transportation... 26 Case Management ... 26 Inpatient Hospital and Specialty Care ... 26 Sliding Fee Scale Discounts... 26 Quality Management Program ... 26

FQHC: Options for Establishing a New FQHC .. 28

Grantee vs. Look-Alike ... 28 Look-Alike ... 28 FQHC Grantee Options ... 28 FQHC Collaboration Opportunities ... 29 Incubator Model ... 30

CONCLUSION 31

PROVIDER-BASED (PB) CLINIC CONSIDERATIONS

PB Status Requirements

Physicians' practices that are operated as integrated departments of a main provider, including a hospital or CAH, will often receive higher Medicare (and perhaps Medicaid) payments and reimbursement than the same practice operating as a freestanding physician's practice or RHC.

The PB designation requirements are very precise. The practice must conform to regulations pertaining to the following areas:

- Licensure
- Clinical services
- Financial integration
- Public awareness
- Ownership and control
- Administration and supervision
- Location

| Licensure | The PB practice must operate under the same licensure as the main provider unless a state requires a separate license, or unless state law does not permit licensure of the provider and the entity under a single license. |
|-------------------|--|
| Clinical Services | A PB entity's professional staff must have clinical privileges at the main provider, under the same monitoring and oversight policy and procedures as apply to other departments of the main provider. |
| | The medical director for the main provider must maintain a reporting relationship that is similar to that in other departments of the main provider, regarding the frequency, intensity and level of accountability of the reporting relationship. |
| | Medical staff committees or other professional committees must maintain responsibility for the quality assurance, utilization review and the coordination and integration of services between the main provider and the PB practice. |
| | Patients' medical records must be integrated into a unified retrieval system or cross- referenced with the records in the main provider. |

www.stroudwater.com

| | Patients of the PB entity, requiring further care, must be afforded access to the inpatient and outpatient services of the main provider, and are referred for such services, as appropriate. |
|--------------------------------|---|
| Financial Integration | The financial operations of the PB entity must be integrated with the financial system of the main provider. The revenue and expenses of the PB practice must be incorporated into and readily identifiable in the main provider's trial balance. The PB entity must be reported as a department on the main provider's Medicare cost report. |
| Public Awareness | The PB practice must be held out to the public and other payers as a department of the main provider. Patients must be made aware that when they enter the PB practice they are entering a department of the main provider and will be billed accordingly. |
| Ownership and Control | The PB practice must be operated under the ownership and control of the main provider as indicated as follows: |
| | The PB practice is 100% owned by the main provider The PB practice and main provider have the same governing body The PB practice and the main provider are subject to common bylaws and operating decisions and operate under the same organizational documents |
| | The main provider has the final responsibility for: Administrative decisions Approval of outside contracts Approval of personnel actions Personnel policies Medical staff appointments within the PB practice or main provider |
| Administration and Supervision | The PB practice is held to the same levels of administration and supervision as other departments of the main provider with compliance as follows: The main provider directly supervises the PB practice The main provider's facility or organizational director is responsible for daily operations in the PB practice and: Maintains the same reporting relationship and level of accountability that exists between the main provider and any of it departments Maintains the same accountability between the PB practice and the main provider's governing body as any other department |

The following services are integrated with the main provider:

- Billing services
- Records
- Human resources
- Payroll
- Employee benefit package
- Salary structure
- Purchasing services

Location A PB practice must be located within a straight-line, 35-mile radius from the main provider (not travel distance) in most situations. State or government providers, or providers appropriately related to state or local governments that also maintain a disproportionate share adjustment of 11.75% are exempt from this requirement.

If a PB practice is beyond the 35-mile radius and yet can demonstrate that it serves the same patient population as the main provider over a 12-month period, it may be exempted from this requirement as well. To accomplish this, it must satisfy the 75/75 test, for **one** of the following:

- [] At least 75% of the PB practice's patients must reside in the same ZIP code areas as at least 75% of the main provider's patients in a prior 12-month period
- [] At least 75% of the PB practice's patients that require the type of care provided by the main provider received that care from the main provider in a prior 12-month period.
- [] If the PB practice was not in operation for the prior 12-month period, it must be located in the ZIP code area that is included among those ZIP code areas that during the prior 12-month period accounted for 75% of the patients served by the main provider.

The PB practice and the main provider must be located within the same state or in adjacent states when the laws regarding licensure in these states are consistent. RHCs that are PB to a main provider in a rural area with fewer than 50 available acute care beds are not subject to the 75/75 test.

PB Status Benefits

Rural Health Clinics

Medicare and Medicaid reimburse RHCs using an all-inclusive rate mechanism. This mechanism is essentially the same for PB and freestanding RHCs. As a cost containment measure, Medicare caps the all-inclusive reimbursement rate. For CY 2011, this rate is capped at \$78.07 per visit.

While this may vary somewhat from state to state, typically Medicaid reimburses RHCs based on a prospectively set, all-inclusive reimbursement rate. This rate may be based on historic 1999 and 2000 costs or based on reimbursement rates for other RHCs of similar size and in close proximity. In any case, at least initially, the Medicare and Medicaid all-inclusive rates are usually similar to one another.

The Medicaid prospective rate and the Medicare Reimbursement rate caps, once set, increase annually by the Medicare Economic Index (MEI), which has historically been between 1.5% and 3.0%, but is only 0.04% for CY 2011.

When calculating allowable costs, PB RHCs include an allocation of overhead cost from the main provider that increases the allowable cost per visit to levels that are generally greater than the allowable cost per visit for freestanding RHCs. If the main provider has fewer than 50 available acute care beds (excluding distinct units and custodial type beds) the Medicare reimbursement rate cap, described in a prior section, does not apply. Therefore, these PB RHCs will receive uncapped cost-based reimbursement from Medicare. Usually, the prospective all-inclusive reimbursement rate set by Medicaid is similar to the Medicare reimbursement rate. Once set by Medicaid, this prospective rate increases annually by the MEI percentage in exactly the same manner as a freestanding RHC subject to capped Medicare cost-based reimbursement.

OVERHEAD ALLOCATIONS - The Medicare cost reporting mechanism allocates administrative costs based on a percentage of "accumulated costs". Non-RHC Provider-Based practices must exclude physician and midlevel personnel costs from these "accumulated costs", and as a result, receive less of an administrative overhead allocation than RHCs that must include these physician and midlevel personnel costs.

The amount of overhead allocated to the RHC as compared with the other departments of the main provider is of particular interest in CAHs because it impacts the Medicare, cost-based reimbursement for the inpatient and other outpatient services. The financial impact analysis associated with converting a practice to PB RHC status in a CAH must consider the impact on the existing CAH Medicare reimbursement, as well as the change in reimbursement to the practice.

Converting a practice to PB RHC status in a non-CAH main provider moves overhead costs into the RHC without impacting the main provider's existing payments and reimbursement.

| Physician Practices | Medicare pays PB physician practices a professional fee and a facility fee (sometimes referred to as the technical component of service fee.) In a prospective payment system (PPS) hospital, the facility fee is based upon an outpatient prospective payment fee schedule. The provider also receives a professional payment that is based upon the Medicare fee schedule. Added together, the facility and professional payments are almost always greater than the individual professional fee that Medicare pays to freestanding physician practices. |
|-------------------------------------|---|
| | Because Medicare requires hospitals to split many provider-based physician practice procedure payments into separate professional and technical component bills, patients will receive two bills and the combined professional and technical co-payments for many provider-based physician services will be higher than for free-standing practices. CAHs that elect Method II billing, however, generate a single, all-inclusive bill. Even so, the Medicare co-payments are higher for CAH provider-based, Method II billing than for freestanding practice billing The two bills and higher co-payments are often reasons hospitals elect not to make physician practices provider-based. |
| CAH Considerations Reimbursement | Medicaid usually pays the provider a single payment for the combined professional and facility components of service. The fee schedules and/or reimbursement mechanism varies from state to state. |
| | PB physician practices (non-RHC) operated as departments of CAHs receive a facility and a professional payment from Medicare. These payments differ from the facility and professional payments made to PPS hospitals in the following manner: |
| | The facility component of outpatient service is reimbursed on the basis of reasonable cost, as determined in the Medicare cost report. This payment is not prospectively set and is settled at year-end, based on actual costs and charges. The CAH may elect what is referred to as Method II billing. If the CAH makes this election 30 days prior to the start of its cost reporting period, it will be paid 112% of the Medicare physician services fee schedule, using an all-inclusive bill sent to the fiscal intermediary. |
| | If the CAH does not elect the Method II billing option, it will still receive the same cost-based reimbursement for the facility component of service, but it submits a separate bill to the Part B carrier and is paid the usual payment for the professional component of |

service based upon the Medicare fee schedule.

Just as the PB RHC analysis must consider the impact of converting a freestanding practice to PB status, so is it true of the non-RHC practice. The practice will be allocated an amount of overhead costs thus changing the after allocation costs for the other departments in the CAH. Therefore, as is true for the RHC analysis, the non-RHC analysis should consider the impact of adding a PB practice on its existing CAH

CAH Considerations Location Requirements

As of September 2007, CAHs are required to comply with strict location requirement when establishing off-campus, provider-based entities. If a CAH establishes an off-campus, provider-based entity that is out of compliance with these location requirements, then the CAH will lose its CAH status.

The CAH location requirements that apply to establishing new CAHs as well as new CAH provider-based entities, are acited on the following page, as indicated in Chapter 2 of the State Operations Manual.

CAH Considerations Location

Requirements

"Pursuant to 42 CFR 485.610(b), all CAHs must be located in a rural area or area treated as rural under 42 CFR 412.232, and meet other rural requirements of 42 CFR 610(b). In addition, the regulations at 42 CFR 485.610(c) specify that one of the following 3 distances from other facilities requirements must be met:

- 35-Mile Distance: The CAH must be located more than a 35-mile drive from any hospital or other CAH; or
- 15-Mile Distance: In the case of mountainous terrain or in areas with only secondary roads available, the CAH must be located more than a 15-mile drive from any hospital or other CAH; or
- No Distance Requirement: Before January 1, 2006, the CAH was designated by the State as being a necessary provider of health care services to residents in the area."

"To be eligible for the lesser 15-mile distance standard due to mountainous terrain under §485.610(c), between the CAH and any other hospital or CAH, it must be necessary to traverse more than 15 miles of roads located in mountainous terrain identified as such on any official maps or other documents prepared for and issued to the public by the State agency responsible for highways in the State (typically a Department of Transportation or Highways), or by the U.S. Geological Survey (USGS).

A CAH would qualify for application of the mountainous terrain criterion if there is a combination of mountainous and non-mountainous terrain between it and any other hospital or CAH, so long as there is no route to any hospital or other CAH with 15 or fewer miles of roads in mountainous terrain. For example, if the route to the nearest hospital consisted of 12 miles in mountainous terrain, followed by 5 miles in non-mountainous terrain, followed by 4 miles in mountainous terrain, then the requirement for a total of more than 15 miles would be met (12 miles plus 4 miles yields 16 total miles of mountainous terrain).

To be eligible for the lesser distance standard due to the secondary road criteria under \$485.610(c) the CAH must document that there are more than 15 miles between the CAH, and any hospital or other CAH where there are no primary roads. A primary road is:

- A numbered federal highway, including interstates, intrastates, expressways or any other numbered federal highway; or
- A numbered State highway with 2 or more lanes each way; or
- A road shown on a map prepared in accordance with the U.S. Geological Survey's Federal Geographic Data Committee (FGDC) Digital Cartographic Standard for Geologic Map Symbolization as a "primary highway, divided by median strip."

A CAH may qualify for application of the "secondary roads only" criterion if there is a combination of primary and secondary roads between it and any hospital or other CAH, so long as more than 15 of the total miles from the hospital or other CAH consists of areas in which only secondary roads are available. To apply this criterion, measure the total driving distance, and subtract the portion of that distance in which primary roads are available. If the result is more than 15 miles, then the 15-mile criterion is met. "

Provider-Based Rural Health Clinic Exception to the CAH Location Requirement

Provider-based RHCs are not subject to the CAH location requirements. A CAH may develop a new provider-based RHC even if its location does not meet the CAH location requirements. RHCs must comply with the RHC location requirements, however, as explained above.

RURAL HEALTH CLINIC (RHC) CONSIDERATIONS

| RHC Governance and Administrative Concerns | The governance and administrative considerations associated with the RHC program are considerably less stringent than those considerations presented later for FQHCs. An RHC may be structured in a number of different ways running the gamut from sole practitioner to a department of another provider, such as a hospital. The RHC may be for profit or not-for-profit. Essentially, an RHC may follow virtually any possible structure available to physician practices. | |
|---|--|--|
| | There are two types of RHCs—PB and independent or freestanding. PB RHCs are clinics that are owned and operated as an "integral part" of a hospital, nursing home or home health agency. Freestanding RHCs are owned by a provider or a provider entity but do not meet the "integral part" criteria. | |
| Location Requirements | In order to be eligible for RHC status, a clinic must be located in a non-urbanized area, as defined by the U.S. Census Bureau. An RHC must also be located in a federally designated shortage area (MUA, HPSA or HPSP) that has been reviewed and approved within the prior four calendar years. | |
| - | RHCs must be located in an area that is non-urbanized and is a federally designated MUA, HPSA or HPSP that has been designated within the prior four calendar years. | |
| Service Delivery Requirements | Unlike an FQHC, an RHC has few service delivery constraints other than an RHC must be primarily in the business of providing primary care services. Family practice, general practice, internal medicine, pediatrics and obstetrics/gynecology are the services that are considered primary care for RHC services. | |
| Laboratory Services | RHCs must provide the following list of Clinical Laboratories Improvement Act waived lab services: | |
| | Chemical examination of urine by stick or tablet Examination of stool specimens for occult blood Hemoglobin or hematocrit Pregnancy tests Blood sugar Primary cultures for transmittal to a certified lab | |

RHC

| Emergency Services | An RHC must provide medical emergency procedures as a first response to common life threatening injuries and acute illnesses, similar to those services commonly provided in a physician's office. |
|--|---|
| X-ray Services | An RHC is required to provide X-ray services either directly or through arrangement with another entity. |
| Hospital and Specialty Care Services | An RHC must have arrangements with other Medicare/Medicaid health care providers to furnish services for hospital and specialty care. |
| Staffing Requirements | An RHC must demonstrate that it has adequate staffing to provide those services essential to the operation of the practice. |
| Midlevel Practitioners | Generally, RHCs are required to employ a physician assistant, nurse practitioner or nurse midwife for at least 50% of the time that the practice is open to see patients. For example, if the RHC is open to see patients 24 hours per week, a midlevel needs to be available to see patients at least 12 hours per week. If an RHC is open to see patients 60 hours per week, the RHC must employ a midlevel practitioner at least 30 hours per week. |
| - | RHCs must employ a midlevel provider (physician assistant, nurse practitioner or nurse midwife) for at least 50% of the time that the practice is open to see patients. |
| The Island Exemption | The Omnibus Budget Reconciliation Act of 1989 included a provision that exempted an RHC located on an island, regardless of the presence of a bridge or causeway, from the 50% midlevel practitioner requirement. Legislation 42 USC 1395x reads: |
| Human Services s (2) of the Social S be certified as suc | CERTAIN FACILITIES AS RURAL HEALTH CLINICS - The Secretary of Health and hall not deny certification of a facility as a rural health clinic under section 1861 (aa) ecurity Act if the facility is located on an island and would otherwise be qualified to h a facility but for the requirement that the services of a physician assistant or nurse wided in the facility." |

RHC

It is important that this provision not be confused with the elimination of waivers that occurred in the mid 1990's. This is an exemption, not a waiver, of the 50% midlevel practitioner requirement.

Policies and Procedures Manual and Site Surveys

RHCs are subject to routine site surveys provided by the state offices of licensure and certification on behalf of CMS. Every practice that applies for RHC status will be surveyed to ensure compliance with the RHC conditions of participation. Existing RHCs should assume that they will receive unannounced site surveys no more than annually, although the frequency of these surveys varies from state to state and year to year.

The RHC will be required to maintain an extensive policies and procedures manual. This manual must be constantly updated and revised to reflect current operations of the RHC. This manual will be subject to intense scrutiny by the surveyors and is key to passing the site survey.

PB RHCs PB RHCs must satisfy all of the RHC requirements discussed previously, as well as requirements for PB facilities. The PB designation requirements are very precise. The practice must conform to regulations pertaining to the following areas:

- Licensure
- Clinical services
- Financial integration
- Public awareness
- Ownership and control
- Administration and supervision
- Location

Participants in the RHC program are eligible for several benefits, including enhanced Medicare and Medicaid reimbursement and eligibility for an automatic facility HPSA designation.

RHC Benefits

See note p. 8 on overhead allocations

The primary benefit of RHC status is enhanced reimbursement from Medicare and Medicaid. Medicare and Medicaid reimburse RHCs using an all-inclusive rate mechanism. This mechanism is essentially the same for PB and freestanding RHCs. As a cost containment measure, Medicare caps the all-inclusive reimbursement rate. For CY 2011, this rate is capped at \$78.07 per visit.

Medicaid reimburses RHCs based on a prospectively set, all-inclusive reimbursement rate. This rate may be based on historic 1999 and 2000 costs or based on reimbursement rates for other RHCs of similar size and in close proximity. In any case, at least initially, the Medicare and Medicaid all-inclusive rates are usually similar to one another.

The Medicaid prospective rate and the Medicare Reimbursement rate caps, once set, increase annually by the Medicare Economic Index (MEI), which is usually between 1.5% and 3.0% but in 2011 is only 0.04%.

When calculating allowable costs, PB RHCs include an allocation of overhead cost from the main provider that increases the allowable cost per visit to levels that are generally greater than the allowable cost per visit for freestanding RHCs. If the main provider has fewer than 50 available beds (excluding distinct units and custodial type beds) the Medicare reimbursement rate cap, described previously, does not apply. Therefore, these PB RHCs will receive uncapped cost-based reimbursement from Medicare. Usually, the prospective all-inclusive reimbursement rate set by Medicaid is similar to the Medicare reimbursement rate. Once set by Medicaid, this prospective rate increases annually by the MEI percentage in exactly the same manner as a freestanding RHC subject to capped Medicare cost-based reimbursement.

Provider Recruitment

HPSA is a Health Professional Shortage Area

HPSP is a Health Professional Special Population RHCs are also eligible for automatic facility HPSA status. The Safety Net Amendments of 2002 contained a provision to automatically certify certain types of safety net providers, including CHCs, FQHC Look-Alikes, and RHCs as facility HPSAs. Automatic facility HPSA status enables RHCs that are not currently located in an HPSA or HPSP to recruit primary care physicians and midlevel providers (physician assistants, nurse practitioners, and certified nurse midwives) from the National Health Service Corps and primary care physicians through the J-1 Visa Waiver program. In order to be eligible for facility HPSA designation, an RHC must agree to provide services to all individuals, regardless of ability to pay, and provide a formal sliding fee discount scale for services.

RHC

FEDERALLY QUALIFIED HEALTH CENTER (FQHC) CONSIDERATIONS

FQHCs, also known as Community Health Centers are community-based and patientdirected organizations that serve populations with limited access to health care, typically including low income populations, the uninsured, those with limited English proficiency, migrant and seasonal farmworkers, individuals and families experiencing homelessness, and those living in public housing.

The Community Health Center program has been in existence for over 40 years and is supported by the Health Resources and Services Administration. Grant-supported FQHCs must meet specific criteria that are delineated in Sections 1861(aa)(4) and 1905(1)(2)(B) of the Social Security Act. The grant program is operated under the Health Center Program (Section 330 of the Public Health Service Act).

FQHCs may be:

- Community Health Centers
- Migrant Health Centers
- Healthcare for the Homeless Programs
- Public Housing Primary Care Programs

In addition to grant funded FQHCs, the program supports non-grant funded FQHCs that are called FQHC Look-Alikes. The FQHC Look-Alike must meet the definition of a health center under Section 330 of the Social Security Act, however the Look-Alike does not receive federal grant funding under Section 330.

FQHC Regulatory Considerations

FQHC Governance Requirements

Reminder: FQHCs are also known as CHCs, Community Health Centers The FQHC / CHC governance requirements as stated in PHS Section 330(e) CHC are very strict and are the most frequent reasons organizations forego the enhanced reimbursement available through FQHC status. FQHC Look-Alikes are also required to meet these stringent requirements.

The autonomy of the FQHC is strictly enforced. That autonomy relates to the basic premise of the program that FQHCs are operated under the authority of the consumer controlled board. That autonomy is clarified in Policy Information Notice (PIN) 92-27:

"To be in compliance requires that the FQHC / CHC or FQHC Look-Alike maintain full autonomy over health care, personnel, financial and quality assurance policy direction.

The Bureau of Primary Health Care (BPHC) is concerned that through some affiliation agreements, centers will be out of compliance with §330 requirements. That is, they will diminish their substantive §330 role in carrying out health center activities, merely serve as a conduit to another party for a grant award and/or other benefits (e.g., those of FQHC, Federal Tort Claims Act (FTCA), and the 340B Low Cost Drug Pricing Program), and/or vest in another party the ultimate authority to oversee and approve key aspects of health center activities.

All FQHCs must comply with section 1905(l)(2)(B) of the Social Security Act which states that an FQHC Look-Alike entity may not be owned, controlled, or operated by another entity. While the legislation specifies FQHC Look-Alikes, this policy has been implemented for FQHC grantees as well."

In order to evaluate FQHC governance issues, the FQHC governance requirements are detailed in Figure 1 and the associated activities and authorities of the governing body are presented in Figure 2.

| Figure | I:FQHC | Governance | Requirements |
|--------|--------|------------|--------------|
| | | | |

| Requirement | Typical Changes Needed to Comply with FQHC Requirements | Additional Information on Requirement |
|---|---|--|
| | Corporate Status | |
| Corporate Status: Must be a 501(c)(3) corporation or a public entity | A new 501(c)(3) corporation may need to be established | Often, large organizations have corporations that are not being used, and may be restructured to comply for the FQHC |
| Corporate Membership: No outside organization can be in controlling position | A new board may need to be developed with appropriate bylaws, committees, etc. | An outside organization can be represented on an FQHC board as long as it is less than 50% of a quorum |
| Health center's mission must be addressed | Include Mission Statement in bylaws | |
| | Board Membership | |
| Board of Directors must have between nine and 25 members | Articles of Incorporation may need to be developed Bylaws must reflect 9-25 directors | Samples of these documents are available, and it is advised they be used to assure inclusion of all FQHC required elements |
| A majority of board members must be users of the FQHC | Include in bylaws | Parent or guardian of child user may be counted as user |
| Less than 50% of non-user members may derive >10% of income from the healthcare industry | Include in bylaws | |
| The FQHC board must be representative of the user population (income, race, ethnicity, age) | Include in bylaws | |
| Board members must live and/or work in the service area | Include in bylaws | |
| Board representation of the target population must be addressed in bylaws | Include in bylaws | |
| Board of Directors must be empowered with certain responsibilities | Bylaws must include all required responsibilities | See separate list of required responsibilities |
| Terms and limits of board membership must be defined | Bylaws must define term limits for board members | |
| Selection/Removal Process: The Board of Directors must be self-perpetuating | Bylaws must reflect a self-perpetuating board | |

| Requirement | Typical Changes Needed to Comply with FQHC Requirements | Additional Information on Requirement |
|---|--|---|
| | Board Officers | |
| The responsibilities of officers of the board must be specified | Officers of the board need to be selected from the board membership | The board chair should not be filled by a designated member from an affiliated organization |
| Must provide for periodic change in leadership (term limits) | Bylaws must define term limits for board officers | |
| The board member selection/removal process must be specified | Bylaws need to specify how potential board members are identified, selected and under what terms they can be dismissed | |
| The board officer selection/removal process must be specified | The removal process needs to be delineated in bylaws | |
| | Board Committees | |
| Must have Executive, should have Finance, Personnel, Planning and Quality Management—others as needed | Include required committees and identify any special needs for resident physicians, etc. | Only Executive Committee may be authorized to act for full board |
| Membership must be specified | All committee membership needs to be defined | Committees may include membership from outside the board |
| Responsibilities must be defined | Each committee's responsibilities need to be defined | |
| | Board Meetings | |
| Must meet at least monthly | Specify monthly meetings in bylaws | |
| Must specify what constitutes a quorum | Define quorum in bylaws | An outside organization represented of an FQHC board must be less than 50% of a quorum |
| Acceptable venues must be addressed | Venues for monthly board meetings need to be specified in bylaws | |
| Specify recording, distribution and storage of minutes, with minutes approved at the subsequent meeting | Include in bylaws | |
| Must specify a tracking mechanism for policies, decisions | Include in bylaws | |
| Must specify policies for avoidance of conflict of interest | Include in bylaws | |
| No board member may be an employee or immediate family of an employee | Include in bylaws | |
| Must include provisions for going into Executive Session | Include in bylaws | |

| Requirement | Typical Changes Needed to Comply with FQHC Requirements | Additional Information on Requirement | |
|--|---|---|--|
| Board Dissolution | | | |
| Must specify terms of dissolution | Include in bylaws | Include reversionary rights if applicable | |
| Applicable Only in Situations Where the Board Positions Can be Filled by Another Organization | | | |
| Representatives of outside organizations cannot be majority of quorum It is recommended that members representing outside organizations not be officers | Must be addressed if organizations will be allowed to nominate board members Assure officers (at least board chair) are not representing outside organizations | | |
| Organizations that have been allocated board positions can make nominations to the Nominating Committee but those individuals must be approved by the board, not an outside organization | Must be addressed if organizations will be allowed to nominate board members | | |

Figure 2: Required Board Authorities to be Stated in Bylaws

| FQHC Board Activity/Authority | Notes |
|---|---|
| Select/dismiss/evaluate Executive Director | Chief Executive Officer (CEO) position needs to be specifically |
| | included |
| Set scope of services | Include required services plus those that address local |
| | conditions |
| Set hours of operation | Assure access by including non-traditional hours |
| Decide service delivery location(s) | Add to bylaws |
| Set general financial policies | Add to bylaws |
| Set personnel policies/maintain payroll | Add to bylaws |
| Establish sliding fee plan | Bylaws should show that CFHC board approves sliding fee |
| | discount program for all patients < 200% of the FPL |
| Establish service fees | Add to bylaws |
| Participate in development of budget | Add to bylaws |
| Approve budget | Add to bylaws |
| Approve grant applications | Add to bylaws |
| Long-range and strategic planning for all components | Add to bylaws |
| Strategic planning for FQHC | Add to bylaws |
| Establish priorities | Add to bylaws |
| Establish quality management plan and audit procedures | Must cover patient satisfaction, clinical, work force and |
| | environment, cost, productivity and health outcomes |
| Provide for independent A-133 audit | Add to bylaws |
| Provide for board training and development | Add to bylaws |
| Evaluate board activities | Add to bylaws |
| Establish health care policies | Add to bylaws |
| Establish collaborative relationships with area providers | Add to bylaws |
| Assure compliance with applicable laws and regulations | Add to bylaws |

FQHC or Look-Alike Governance Structure Alternatives The Bureau of Primary Health Care (BPHC) encourages FQHCs to affiliate with other entities to strengthen their ability to achieve their mission. However, BPHC is concerned that some affiliation agreements may compromise the FQHCs compliance with program requirements. As stated earlier, an FQHC may not be owned, controlled, or operated by another entity. Furthermore, applications with any current or past affiliation with another organization are likely to be subject to a higher level of scrutiny in comparison to applications by organizations without these connections.

Spinning off or giving up control of the FQHC or Look-Alike applicant can be a matter of great anxiety for the corporate parent. A freestanding FQHC may prove to not be a collaborative partner supportive of the former parent's mission or a competitive relationship could actually develop. It is also very possible that the FQHC would still require some form of subsidization from the former parent corporation. In fact, BPHC expects that historical levels of support be continued for some period of time after FQHC approval, as grant funds may not supplant existing funding sources. Without the corporate linkage, providing a subsidy is manageable, yet more complicated from a legal and BPHC perspective. If the former parent is comfortable with its new relationship to its former operation, the benefits of FQHC or Look-Alike status, and the level of subsidization required to support the delivery of primary care in its service area, a harmonious relationship can exist.

The required timing of a spin-off, or modification of bylaws, would differ between an FQHC and a Look-Alike application. FQHC designation is obtained as a result of attaining CHC funding. A CHC new start application is reviewed based upon what the applicant entity "plans to be" as opposed to how it exists as of the date of application and new start guidelines allow an approved applicant 120 days from the notice of grant award to enact any changes necessary to be fully compliant. Therefore, proposed, compliant bylaws could be developed and included in a grant application with implementation contingent upon funding approval.

Contrary to the new start CHC applicant, an FQHC Look-Alike applicant is required to be fully compliant as of the date of application submission. This would require setting up a new corporation, complete with bylaws and a history of at least a few meetings for the CFHC prior to submission of its Look-Alike application. A "leap of faith" is required, as the restructuring will take place prior to approval for the designation. However, one of the differences between submitting a CHC grant application and an FQHC Look-Alike application is that the funding of the grant is an "if", and the approval of Look-Alike status is a "when". Look-Alike status is not competitive, and once the application is submitted, it is just a matter of waiting on approval and/or negotiating any details with BPHC.

One of the issues that needs to be considered in anticipation of the possibility of setting up a new 501(c)(3) corporation is the time required for the establishment of this corporation. In some states, this process can require several months.

An FQHC or Look-Alike must provide the following basic services :

- [] Primary care for all life cycles
- Basic laboratory services []
- Emergency and after-hours care F 1
- ss to low cost drugs
- care
- care
- and specialty care
- liscounts
- ent program
- otocols

l services are very basic, an understanding of the Following is a brief description of each requirement.

Pri at the FQHC must provide services to infants through C must provide the services directly and may not satisfy this reement with an outside entity, although, to some extent a ervices may be provided under agreement.

> rements about the type of laboratory services required of an ment is met through either the provision of services directly ith another provider, such as a hospital or laboratory service. ostic radiology services. Provisions should be made to assure that uninsured patients have access to needed diagnostic testing, but there is no specific requirement for the FQHC to underwrite a sliding fee discount for these services if they are provided at a location other than the FQHC. Hospital charity care policies are typically adequate to fulfill this requirement.

FQHC Regulatory Considerations

FQHC Scope of Services

| | Emergency and aft |
|--------------------------------|---|
| | [] Assurance of acces |
| | [] Preventive health c |
| | [] Preventive dental c |
| | [] Transportation |
| | [] Case management |
| | [] Inpatient hospital a |
| | [] Sliding fee scale di |
| | [] Quality manageme |
| | [] Written clinical pro |
| | While some of the required requirements is important. I |
| imary Care for All Life Cycles | This requirement means that elderly patients. The FQHC requirement through an agree minimal number of these se |
| Basic Laboratory Services | There are no specific requir FQHC on-site. The requirer or through arrangements wi The same is true for diagno |
| | |

Emergency and After Hours Care

Provisions must be made for appropriate handling of emergency cases presenting at the FQHC. However, there is no requirement for these provisions to be more than what is normally available in a non-FQHC practice. Patients must have access to a provider during non-traditional hours. There should be at least one clinic session that is outside normal working hours. Emergency coverage may be met with an after-hours call schedule specific to each practice, including other providers in the community. The basic requirement is that patients must be able to talk with medical personnel. The only unacceptable arrangement would be an answering machine instructing patients to go to the local emergency room. After-hours calls may be forwarded to the hospital where personnel speak with the caller.

Assurance of Access to Low Cost Drugs

This requirement has become more of a priority due to the increase in barriers to obtaining prescribed medications. FQHCs must have provisions to assure that patients obtain needed medications. This requirement can be met through the provision of samples, assistance with the enrollment of patients in pharmaceutical company indigent care programs and formal arrangements with local pharmacies for the provision of discounts to low-income patients. Once FQHC status is obtained, this requirement can be met through participation in the Federal 340B Discount Pharmacy Program, either through an on-site pharmacy, or through an arrangement with a local pharmacy.

Preventive Health Care

There are no specific requirements for the type of preventive health services to be provided. The range of preventive services may mimic or exceed traditional private practices. BPHC does provide a list of suggested preventive services :

- [] Immunizations for children
- [] Cancer screening
- [] Lead screening
- [] HIV/STD assessment and management
- [] Oral health education
- [] Individual patient education during a visit
- [] Screening clinics/health fairs
- [] On-demand pregnancy testing
- [] Case management

- [] Immunizations for adults
- [] TB testing for high-risk patients
- [] Domestic violence screening and referral
- [] Pediatric vision/hearing screening
- [] Family planning and counseling
- [] Patient education classes
- [] Pregnancy outreach
- [] Immediate pregnancy test result availability

| Preventive Dental Care | Due to the increase in barriers to obtaining services, particularly for Medicaid and uninsured patients, this requirement has also become more of a priority. Basic preventive care may be provided during the course of a primary care exam. However, the FQHC is expected to exceed this basic screening and either provide dental services directly or have arrangements with a local dental provider to assure access. This requirement does not go so far as to require that the FQHC subsidize a dental sliding fee scale with a private dentist; however, such an arrangement would definitely be viewed favorably in an application. If the FQHC provides dental services through its sites, the FQHC is expected to offer its sliding fee discounts to dental patients. |
|--|--|
| Transportation | An FQHC is required to provide transportation services, as necessary, for appropriate patient care either directly or through arrangement. This requirement may be met through the maintenance of a list of volunteers available to provide transportation, an arrangement with another organization that provides transportation for vulnerable people or through the provision of bus tokens or taxi vouchers. |
| Case Management | An FQHC is required to provide case management. This requirement is usually met through coordination of referrals within the practice as well as with other health care providers. FQHCs must provide assistance to patients in scheduling referred or arranged services and must follow-up to ensure that referrals are followed through and that necessary information makes its way into the primary care medical record. |
| Inpatient Hospital and Specialty Care | It is required that an FQHC provide inpatient and specialty services either directly or through arrangements. There is no specific requirement for an FQHC to underwrite sliding fee discounts for specialty services although increasingly BPHC is requiring FQHCs to show evidence that specialists will provide care to their low-income and uninsured population. |
| Sliding Fee Scale Discounts | An FQHC must utilize a sliding fee scale with varying discounts available based on patient family size and income in accordance with federal poverty guidelines. The discount must be available for patients with incomes less than 200% of the Federal Poverty Level (FPL) for services provided directly by the FQHC. There is no specific requirement for these discounts to be funded for non-FQHC providers, or for hospital- based care; however, such arrangements would be viewed favorably in review of an application. If the FQHC provides non-essential services (such as cosmetic services) these may be excluded from the sliding fee discount. The FQHC has flexibility in the |

| | determination of the amount of discount. For example, the requirement states that those |
|----------------------------|---|
| | individuals at or below 100% of the FPL may be charged a nominal fee. This nominal |
| | fee has been defined by individual FQHCs to be anywhere within a range of 5 to 50% |
| | of customary charges. Increasingly, BPHC is requesting that FQHCs provide needed |
| | services free of charge to their populations under 100% of the FPL. |
| | |
| Quality Management Program | An FQHC is required to have an ongoing quality management program that identifies |
| | problems and takes the necessary actions to correct those problems. |
| | |
| Written Clinical Protocols | It is required that an FQHC have written clinical protocols in place. FQHCs must attest |
| | to maintenance of non-physician protocols, health maintenance protocols by age group |
| | and other clinical protocols, as determined appropriate by the site. |
| - | |
| | It is important to note that, while mental health and substance abuse counseling have not |
| | traditionally been mandated services, BPHC has elevated its expectation for new CHCs |
| | and Look-Alikes to take responsibility for assuring access to these services for its target |
| | population. Such access can be in the form of referrals to community mental health |
| | providers although potential CHCs that provide mental health and substance abuse |
| _ | counseling on site are more competitive for grant approval. |

Options for Establishing a New FQHC

Grantee vs. Look-Alike

As previously indicated, it is possible to establish a grant funded FQHC or a non-grant funded FQHC Look-Alike. FQHC grants are highly competitive and funding is far from a certainty. Grant applications may only be submitted once HRSA announces new start funding opportunities. These opportunities may not be made available each year and in the past have not occurred for two years or more. 2010 was the first year of a 5-year funding window that will see around \$11 billion in new grant monies being awarded to new and existing FQHCs. As a result, at least one new start or new access point funding opportunity is anticipated each year through 2014.

Look-Alike FQHC Look-Alike applications may be submitted at any time. The Look-Alike application process is not competitive and if an applicant is compliant with FQHC Program Expectations (similar to the conditions of participation regulations for hospitals and Rural Health Clinics), the Look-Alike application will be approved.

Typically Look-Alike applications are submitted by non-FQHC entities that are interested in getting into the FQHC program. There are relatively few FQHC Look-Alikes in the country, about 75 were reported in the spring of 2010, because many Look-Alikes submit successful FQHC grant applications and move from Look Alike status to grantee status.

FQHC Grontee Options New Start Grantee Status

There are three opportunities for establishing a new FQHC access point. The most difficult is to prepare and submit a new start FQHC application for the purpose of establishing a new FQHC entity in an area that is not currently served by an FQHC.

Join an Existing FQHC Grantee

Another way to establish a new FQHC access point is to work with an existing FQHC. There are a few advantages to doing this. First, the FQHC understands the FQHC Program Expectations and is a compliant organization. Second, there may be more funding opportunities for existing FQHCs to establish new access points for service delivery. Third, it is not necessary for a new access point to provide all of the required FQHC services as long as the services are accessible within the FQHC network of service locations.

FQHC Collaboration Opportunities

The Affordable Care Act, enacted in 2010, provides a requirement that Community Health Centers (FQHCs) demonstrate that they have made, and will continue to make, reasonable efforts to maintain collaborative relationships with other health care providers in their catchment areas. Specifically, the legislation lists Rural Health Clinics, low-volume hospitals, Critical Access Hospitals, Sole Community Hospitals, and Medicare Dependent Hospitals as the entities with which a Community Health Center should demonstrate a collaborative relationship.

The primary purpose of this requirement is to reduce competition and service duplication between Community Health Centers and these other entities; Community Health Centers are encouraged to contract with these other entities in order to provide required Community Health Center services to the health center's service area population.

New Access Point grant applications and Service Expansion grants will be judged and scored, in part, on the extent to which they demonstrate the collaboration and coordination of the delivery of health care services with other health care providers in their service area.

Participating in collaborative efforts with a Community Health Center does carry a number of factors that must be considered by the Community Health Center and the collaborating entity. The following is excerpted from the Program Assistance Letter 2011-02, dated November 23, 2010:

- Health centers are responsible for maintaining oversight over all sites and services within their federally approved scope of project, including assuring that patients have access to the health center's full range of services;
- Health centers must assure that all services included under their federally approved scope of project, including those performed under contract, are available to patients regardless of their ability to pay;
- Health Center Program grantees must comply with section 330 of the PHS Act and the HHS grant regulations, including those specific to the provision of required services (and payment for those services to the extent that they are not provided directly by the health center) and to procurement of goods and services, as outlined in 45 CFR § 74.40 through 74.48 or 45 CFR § 92.36(b) through (i), as applicable; and,
- Benefits that are afforded to health centers from programs other than under Section 330 (i.e., Federal Tort Claims Act coverage, 340B pricing, reimbursement as a FQHC under Medicare/Medicaid/CHIP) are determined by the applicable laws and rules of the respective programs. Therefore, the terms of the contractual agreement should be constructed accordingly.

Understanding these factors associated with such a collaborative initiative is key to maintaining a productive and mutually beneficial relationship. This collaboration initiative may provide support for the provision of health care services in a Community Health Center's service area, without the need to develop duplicative service delivery mechanisms in the Community Health Center's service area and may provide a mechanism for using grant dollars to support the delivery of FQHC services by health care entities that otherwise would not qualify for Section 330 funding.

Incubator Model

There is one additional way to establish a new FQHC that is a compromise between establishing a new FQHC entity and establishing a new access point through a parent FQHC entity. This is referred to as the "incubator model". The incubator model establishes a new FQHC access point that is initially operated as a site of an existing FQHC. The new access point site is operated as part of the existing FQHC for a predetermined number of years, typically one or two. After the predetermined time period, that new FQHC access point splits off from the existing and becomes its own, independent FQHC entity. When it splits off, the newly independent FQHC entity usually takes with it a portion, not all, of the original grant award that was made to the existing FQHC when the new access point was established. For example if the original new access point grant award was for \$600,000 a year, the incubator FQHC site might take \$400,000 of the grant when it splits from the existing FQHC.

HRSA is in favor of this model because it involves creating a new access point by an existing FQHC that is in compliance with FQHC program expectations and understands the goals and mission of the Community Health Center program. Key to making this work is for the involved parties to work out the details for the spin off of the new FQHC prior to submitting a new access point application. The two entities then understand how long they will be operating as one, when they plan to split and how much of the grant will be retained by the existing FQHC and how much of the grant will go with the newly independent FQHC. As one might imagine, working through all of these details before a grant is awarded is crucial to a smooth transition.

Conclusion

There are four general options for configuring the delivery of primary care in a community. The option that provides the most flexibility with the least financial advantage is the freestanding physician practice. The remaining three options are more financially advantageous, but are less flexible in structure and services delivery.

The provider-based physician practice generates significantly higher Medicare payments as compared with a freestanding physician practice, but the provider-based practice must be fully integrated into a hospital and operated as a department of the hospital. In recent years hospitals have been acquiring physician practices in order to stabilize their market and retain physician services in their service area.

The Rural Health Clinic program provides enhanced Medicare and Medicaid reimbursement for services provided in the RHC office, long-term care facilities or the patient's home. An RHC may be either freestanding or provider-based. An RHC that is operated as a department of a hospital with fewer than 50 available acute care inpatient beds receives uncapped cost reimbursement for services provided to Medicare patients and Medicaid pays these practice all-inclusive payments that are usually similar to the Medicare reimbursement. All other freestanding and provider-based RHCs that are operated as departments of larger hospitals receive capped Medicare reimbursement that is \$78.07 per visit for CY 2011 and is similar for Medicaid.

The RHC program is restricted to rural areas with federal shortage area designations. RHCs must comply with the RHC conditions of participation that are less flexible than the provider-based regulations.

The third programmatic option for providing primary care services in a community or service area is through the FQHC program. The financial advantages of participating in the FQHC grantee program are significant; however, this is the most restrictive of all the options, as evidenced by the discussions above.

Each of these programs has its own advantages and disadvantages and the requirements of each program must be understood before proceeding to develop a new practice or convert an existing practice to a new status. It is also possible that a practice is converted to one status as a different status is being pursued. For example, a practice may be converted to provider-based status while an RHC certification application is in process. In fact the final goal might be to submit a successful FQHC grant application, but in the mean time the practice is operated as a provider-based practice or a freestanding FQHC Look Alike. There are a variety of options and a strategy to obtain the desired status may require a number of steps before being attained. Understanding all of the options is key to achieving desired goals.

ROBERT ELLIS, M.B.A.

(V) 207-692-0777
(C) 207-592-0863
(F) 207-692-2338

STROUDWATER ASSOCIATES