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August 5, 2013

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HEALTH FACILITIES &
SERVICES REVIEW BOARD

Mr. Mike Constantino
Illinois Health Facilities & Services Review Board
525 W. Jefferson, 2nd Fl.
Springfield, IL 62761

Re: Project # 13-036

Dear Mr. Constantino:

You requested the co-applicant Southern Illinois Healthcare Foundation's ("SIHF") provide its prior three (3) year audited financial statements, which it has done. However, as I noted, SIHF is prohibited by Federal law from using any of its grant or program income outside of its approved "Scope of Project" as a Federally Qualified Healthcare Center.

Please see the attached federal regulations and Program Information Notice ("PIN"). Please note the bottom of page 3 of the PIN. These confirm the prohibition referenced above. Also, this correspondence will serve to confirm that Touchette's operations as an acute care facility are not included in the FQHC Scope of Project of SIHF.

Thank you.

Very truly yours,

Clare Connor Ranalli

CCR/am

Encs.

cc: Courtney Avery
Larry McCulley, CEO, SIHF

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U.S. Department of Health and Human Services
HRSA
Health Resources and Services Administration

POLICY INFORMATION NOTICE

DOCUMENT NUMBER: 2008-01

DATE ISSUED: December 31, 2007
DATE REVISED: January 13, 2009

DOCUMENT NAME: Defining Scope of Project and Policy for Requesting Changes

TO: Health Center Program Grantees
Primary Care Associations
National Cooperative Agreements

The purpose of this Policy Information Notice (PIN) is to define what constitutes the scope of project for health centers funded under section 330 of the Public Health Service (PHS) Act, to specify which types of changes in scope of project require prior approval and to describe the process for health centers seeking to make changes in the approved scope of project. This PIN supersedes PINs 2000-04 and 2002-07, "Scope of Project Policy."

Scope of project defines the activities that the total approved section 330 grant-related project budget supports, the parameters for using these grant funds, the basis for Medicare and Medicaid Federally Qualified Health Center reimbursements, Federal Tort Claims Act coverage, 340B Drug Pricing eligibility and other essential benefits. Therefore, proper recording of scope of project is critical in the oversight and management of programs funded under section 330 of the PHS Act.

In this PIN, the Health Resources and Services Administration (HRSA) has updated several policies related to scope of project to clarify and improve the recording of critical information for health centers supported under the Health Center Program. Among the clarifications, HRSA has updated the definition of a service site and established site category types to assist health centers in reporting sites supported under the Health Center Program. HRSA also has included additional guidance to clarify the requirements for recording the service delivery method for required and additional services which will assist grantees to better represent the manner in which services under a health center's approved scope of project are available to the target population.

In implementing these policy clarifications, HRSA will provide all grantees with an opportunity to update their scope of project information. HRSA will work with grantees to resolve any potential issues.

This PIN also establishes expectations for the timely implementation of any request for prior approval to add or delete a service or add, delete or relocate a new service site. The effective date of an approved change in scope will be no earlier than the date of receipt of a complete application or, in cases where a grantee is not able to determine the exact date by which the

change in scope will be fully accomplished, grantees will be allowed up to 120 days following the date of the NGA indicating approval for the change in scope to implement the change (e.g., open the site or begin providing a new service). Therefore, a grantee should carefully consider its ability to accomplish the requested change within this anticipated timeframe prior to submitting a request.

HRSA will continue to utilize an electronic process, through the HRSA Electronic Handbooks (EHBs), for processing requests for prior approval of changes in scope of project. This electronic system provides for efficient processing, review and decision-making on the requested changes. However, because of the importance of the scope of project, it is crucial that grantees submit change in scope requests, to the extent practicable, 60 days in advance of the desired implementation date. It is HRSA's goal to communicate decisions on these requests within 60 days of receipt of a complete request.[1]

All grantees considering a change in scope are encouraged to carefully review this PIN prior to initiating a request. In considering a change in scope, all grantees should review the proposal with their Board of Directors and consult with their Project Officer.

If you have any questions or require further guidance on the policies detailed in this PIN, please contact the Office of Policy and Program Development on 301-594-4300. If you have any questions or require further guidance on the process for submitting requests for prior approval for changes in scope of project, please contact your Project Officer.

James Macrae
Associate Administrator

Attachment

[1] Please see PIN 2009-03 available at http://bphc.hrsa.gov/policy/pin0903.htm.

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I. PURPOSE

The purpose of this Policy Information Notice (PIN) is to describe the Health Resources and Services Administration's (HRSA) policy for an approved scope of project for health centers funded under section 330 of the Public Health Service (PHS) Act,[2] the five components of an approved scope of project, and the policy and process for health centers seeking prior approval to make changes in the approved scope of project. This PIN supersedes PINs 2000-04 and 2002-07, "Scope of Project Policy."

II. APPLICABILITY

This PIN applies to all HRSA health service delivery grants awarded under section 330 of the PHS Act, including the Community Health Center, Migrant Health Center, Health Care for the Homeless, and Public Housing Primary Care Programs collectively referred to as "grantees" or "grantee health centers." The grantee named on the Notice of Grant Award (NGA) is the entity legally accountable to HRSA for performance of the health center activities as detailed and documented in the application for section 330 funding. Please note that only the grantee of record (the organization named on the NGA) can request a change in the approved scope of project. Changes in scope involving subrecipients or subcontractors must be the submitted by the grantee of record.[3]

III. DEFINING SCOPE OF PROJECT

The scope of project defines the activities that the total approved section 330 grant-related project budget supports.[4] Specifically, the scope of project defines the approved service sites, services, providers, service area(s) and target population(s) which are supported (wholly or in part) under the total section 330 grant-related project budget. A grantee's scope of project must be consistent with applicable statutory and regulatory requirements, Health Center Program Requirements, and the mission of the health center.[5]

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[2] Organizations that are designated under the FQHC Look-Alike Program that are seeking a change to their approved scope of project should follow the process outlined in PINs for FQHC Look-Alikes on http://bphc.hrsa.gov/policy/.

[3] A subrecipient is an organization that "(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 . . ." (§1861(aa)(4) and §1905(l)(2)(B) of the Social Security Act). Subrecipients must be compliant with all of the requirements of section 330 to be eligible to receive FQHC reimbursement from both Medicare and Medicaid. The subrecipient arrangement must be documented through a formal written contract/agreement (Section 330(a)(1) of the PHS Act).

[4] Note: a "change in scope of project" under section 330 is not the same as "change in the scope of services" in Medicaid as defined in the Benefits Improvement and Protection Act (BIPA) of 2000, Section 702. The Centers for Medicare and Medicaid Services (CMS) and State Medicaid Agencies define the term "change in the scope of services" as a mechanism for adjusting the Medicaid reimbursement rate of a FQHC due to "a change in the type, intensity, duration and /or amount of services." A State approved "change in the scope of service" can result in an increase or decrease in FQHC Medicaid reimbursement. "Change in the scope of services" is defined differently in each State's Medicaid Plan. The State Medicaid Agency must be contacted directly if a change in scope of services is being requested by a health center. Please see Section VI.B. (page 27) of this PIN for additional information.

[5] For more information regarding the operation of health centers, please refer to the Health Center Program Requirements found at http://bphc.hrsa.gov/about/requirements/index.html.

A health center's scope of project is important because it:

- Stipulates the total approved section 330 grant-related project budget, specifically defining the services, sites, providers, target population, and service area for which grant funds have been approved. This total project budget includes program income and other non-section 330 funds.

- Determines the maximum potential scope of coverage (subject to certain exceptions) of the Federal Tort Claims Act (FTCA) program that provides medical malpractice coverage for deemed health centers and most individual employees (see page 26 of this PIN for more information on FTCA coverage).

- Provides the necessary site information which enables covered entities to purchase discounted drugs for their patients under the section 340B Drug Pricing Program (see page 28 of this PIN for more information on the 340B Drug Pricing Program).

- Defines the approved service sites and services necessary for State Medicaid Agencies to calculate payment rates under the Prospective Payment System (PPS) or other State-approved alternative payment methodology (see PAL 2001-09 posted on http://www.bphc.hrsa.gov/policy/ and section 1902(bb) of the Social Security Act).[6]

- Defines the approved service sites necessary for the Centers for Medicare and Medicaid Services (CMS) to determine a health center's eligibility for Federally Qualified Health Center (FQHC) Medicare all-inclusive rate.

It is important to note that certain benefits, i.e., utilization of section 330 funds and related program income, FQHC Medicaid reimbursement, Medicare FQHC reimbursement, FTCA coverage, and 340B Drug Pricing benefits, require that activities be part of the section 330 approved scope of project and do not apply to activities that are not part of the approved scope of project. A section 330 grantee's approved scope of project may be part of a larger health care delivery system and, as such, must be distinctly defined within that context. Section 330 funded health centers may carry out other activities (i.e., other lines of business) that are not part of their scope of project and, thus, are not subject to section 330 requirements and expectations. For example, a grantee corporation may run a day care center that is not within the scope of the Federal project and does not use section 330 funds or related program income for support; therefore, it would not be eligible for the benefits that extend to activities within the grantee's scope of project such as FTCA coverage or Medicare or Medicaid reimbursement. In addition, the revenue generated from other activities (in the example above, the day care center) should be sufficient to support direct costs of the activity plus a reasonable share of overhead to ensure that section 330 funds and other grant-related income are not used inappropriately to support costs outside the approved scope of project.

[6] All Program Information Notices (PINs) and Program Assistance Letters (PALs) are available on the HRSA web site at http://www.bphc.hrsa.gov/policy/.

NOTE: While identification as a service site within a scope of project is required for participation in the FTCA, 340B Drug Pricing, and FQHC programs, it is not a guarantee that these benefits will be realized. Each of these programs has a specific application process and a comprehensive set of requirements, of which scope of project is only one. In other words, identification as a service site within a scope of project is necessary, but not sufficient, to ensure participation in the other programs. To participate, all of the requirements of the other programs must also be met. For additional information, see Section VI of this PIN.

A. Role of the Board in Scope of Project

The governing board of a health center provides leadership and guidance in support of the health center's mission and is legally responsible for ensuring that the health center is operating in accordance with applicable Federal, State and local laws and regulations. The health center governing board is responsible for establishing and approving the health center's scope of project. The annual application for section 330 funds details the scope of project supported by the grant and, per section 330(k)(3)(H) of the PHS Act (42 U.S.C. 254b), the health center governing board must approve the health center's application. It is the responsibility of the governing board to approve the overall plan and budget for the health center, the hours of operation for the health center sites, as well as the selection of the services provided by the health center. In fulfilling these responsibilities to accurately and completely delineate the health center's scope of project, the health center governing board is assuring that the health center will effectively utilize its available resources in pursuing its mission. As the board is responsible for the oversight of the health center operations, all requests for change in scope of project must be approved by the health center's governing board with approval documented in the board minutes.

B. Five Core Elements Of Scope Of Project

Five core elements constitute scope of project and address these fundamental questions:

- Where will services be provided (service sites)?
- What services will be provided (services)?
- Who will provide the services (providers)?
- What geographic area will the project serve (service area)?
- Who will the project serve (target population)?

1. Service Sites

A service site is any location where a grantee, either directly or through a sub-recipient or established arrangement,[7] provides primary health care services to a defined service area or target population (discussed respectively in Sections III.B.4. and III.B.5. of this PIN). Sites may be permanent, seasonal, mobile van, migrant voucher or intermittent as defined further below based on many factors and as

[7] Here and throughout this document "established arrangements" are intended to mean an arrangement where a service is provided through a formal written contract or cooperative arrangements (Section 330(a)(1) of the PHS Act).

appropriate for providing health care services to the target population. A service site may provide comprehensive primary care services or may provide a single service such as oral or mental health services, based on the identified needs in the community/population. Only those service sites listed on Form 5-Part B: Service Sites from the most recent approved application for Federal support or approved change in scope request are a part of a grantee's approved scope of project.

a) Definition of a Service Site

Service sites are defined as locations where all of the following conditions are met:

- health center encounters are generated by documenting in the patients' records face-to-face contacts between patients and providers;
- providers exercise independent judgment in the provision of services to the patient;
- services are provided directly by or on behalf of the grantee, whose governing board retains control and authority over the provision of the services at the location; and
- services are provided on a regularly scheduled basis (e.g., daily, weekly, first Thursday of every month).[8] However, there is no minimum number of hours per week that services must be available at an individual site.

b) Permanent Service Sites

Permanent sites meet the definition of a service site above at a fixed address specified on Form 5 – Part B: Service Sites. These sites are open year round and may be operated on a full-time or part-time basis as appropriate to meet the needs of the target population. Services at a permanent site may be offered either directly or through an established arrangement. The name and address of each permanent service site at which the grantee provides care must be listed on Form 5 – Part B: Service Sites.

c) Seasonal Service Sites

Due to the seasonality of employment, shelter, or the mobility of patients served, grantees may operate some service sites on a seasonal basis or for only part of the year. Seasonal sites meet the definition of a service site above but operate at a fixed location for less than 12 months during the year. When open, seasonal sites may be operated on a full-time or part-time basis as appropriate to meet the needs of the target population. Grantees should list the name and address of each seasonal site on Form 5 – Part B: Service Sites and indicate the approximate number of months that the site is open during the year.

[8] Note the statutory requirement in section 330(k)(3) of the PHS Act that "primary health services of the center will be available and accessible in the catchment area of the center promptly, as appropriate, and in a manner which assures continuity." In addition, note the regulatory requirement in 42 CFR 51c.303(m) that community health centers "must be operated in a manner calculated ... to maximize acceptability and effective utilization of services."

d) Special Instructions for Recording Mobile Van Sites

A fully-equipped mobile van that is staffed by health center clinicians providing direct primary care services (e.g., primary medical or oral health services) at various locations on behalf of the grantee is considered a service site. Mobile vans must meet the definition of a service site above, except that services do not need to be provided on a regularly scheduled basis, although this is encouraged to provide continuity and access to care for the target population. A grantee should separately list each mobile van (i.e., Mobile Van #1, Mobile Van #2, etc.) as a site on Form 5 – Part B: Service Sites. The specific locations where the van provides direct health care services do not need to be listed.

Vans that are not equipped or utilized for direct patient care are not service sites. These vans may be used by a grantee to transport patients or staff or to support and facilitate outreach or other enabling services. These vans should be listed on Form 5 – Part C: Other Activities (discussed in detail below), in the application for Federal support with a brief description of how the van is used.

e) Intermittent Sites

Grantees may utilize intermittent sites to provide direct primary health care services to the target population. Intermittent sites meet the definition of a service site above but operate on a regular scheduled basis for a short period of time (two months or less) at locations that change frequently as necessary to continue services to the target population. Generally, these sites are established to assure access to care for more mobile populations, such as homeless persons or migrant or seasonal farmworkers and their families, who may not be in one area for an extended period of time and, therefore, may not access services at a grantee's permanent or seasonal sites. Often, intermittent sites are established at migrant camps or homeless shelters that are open for only a short time to bring health care services directly to the target population and will be closed and re-opened at a new location as the population moves or the availability of space changes. The following are examples of potential locations for intermittent sites: 1) Shelters - Family, Adult, Homeless, Runaway Youth; 2) Day Shelters, Soup Kitchens, or Homeless Service Centers; 3) Outdoor Encampments; 4) Migrant Camps.

Grantees should list intermittent sites as a category on Form 5 – Part B: Service Sites. The specific locations where the grantee establishes an intermittent site to provide the services do not need to be listed; however, the number of such locations should be indicated on Form 5 – Part B: Service Sites and should be updated at least annually in the grantee's application for Federal support.

f) Migrant Voucher Screening Sites

Migrant Voucher Programs are established when there is insufficient sustained demand in an area for health care services from migrant and seasonal farmworkers

to warrant establishing a permanent or seasonal service site. Often migrant voucher grantees do not provide direct health care services; rather, the grantee may establish a screening site(s) where the clinical needs of a patient are assessed and then a referral for care is made to a local provider through an established contractual arrangement. The local provider will provide the primary care services to those individuals who are referred by the voucher program. Under these arrangements, services are provided on behalf of the health center through a contractual arrangement; however, services under the contracts are generally not provided on a regular scheduled basis but instead on an as-needed basis.

Grantees should list each migrant voucher assessment/screening site as a category on Form 5 – Part B: Service Sites. As the functions of migrant voucher screening sites are predominantly administrative, where little clinical services are provided, the assessment/screening sites should be listed as administrative sites. Those voucher locations which meet the requirements of a service site should be listed as administrative/service site. The specific locations where the grantee maintains contracts for direct services do not need to be listed; however, the number of such locations should be indicated on Form 5 – Part B: Service Sites and should be updated at least annually in the grantee's application for Federal support.

g) Other Activities

Grantees often provide activities that are included in the scope of project at locations that: (1) do not meet the definition of a service site, (2) are conducted on an irregular timeframe/schedule and (3) offer a limited activity from within the full complement of health center activities included within the scope of project. These activities and locations, where clinicians and project staff go from time-to-time to seek out, engage and serve persons eligible for the project's services, are covered under the scope of the project; however, compiling an exhaustive list of such activities and locations is impractical and, therefore, should be included as general categories of activities at various locations as part of the approved scope of project.

"Other activities" may also include (1) locations for off-site activities required by the health center and documented as part of the employment agreement or contract between the health center and a provider (e.g., health center physicians providing coverage at the hospital emergency room or participating in hospital call coverage for unassigned patients in order to maintain their hospital admitting privileges) and/or (2) locations where the only services delivered do not generate encounters (i.e., filling prescriptions, taking X-rays, conducting street outreach or providing health education, etc.).

Some examples of other activities include:

- Immunizations. Providing immunizations at 15 different senior centers. Grantees should list the activity as "immunizations," the location as "senior centers" and the frequency as appropriate (e.g., four times per year).

- Admitting. Following the health center's patients to the hospital (admitting privileges). Grantees should list the activity as "admitting," the location as "hospital" and the frequency as appropriate (e.g., as required for on call arrangement, three times per week) and indicate in the description the specific hospital(s) with which the health center has such arrangements and whether health center providers see non-health center patients as part of his/her admitting privileges.

- Medical Rounds. Grantees should list the activity as "medical rounds," the location as "hospital" and the frequency as appropriate (e.g., as required for patient care, twice per week) and indicate in the description the specific hospital(s) with which the health center has such arrangements and whether the health center providers see non-health center patients as part of his/her admitting privileges.

- Home Visits. If it is the policy of the grantee that providers occasionally make home visits to health center patients, the grantee should list the activity as "home visits," the location as "patients' homes" and the frequency as appropriate (e.g., as required for patient care, five times per month).

- Health Fairs. If it is the policy of the grantee to occasionally participate in health fairs, the grantee should list the activity as "health fairs," the location as appropriate (e.g., various schools, community service centers) and the frequency as appropriate (e.g., three times per year).

- Non-Clinical Outreach. If it is the policy of the grantee that staff conduct outreach where no clinical services are offered, the grantee should list the activity as "non-clinical outreach," the location as appropriate (e.g., community neighborhoods, schools, community service centers) and the frequency as appropriate (e.g., weekly).

- Portable Clinical Care. If it is the policy of the grantee that providers conduct clinical care as part of a mobile team (for example, as part of a primary care street outreach team to serve a homeless individuals or utilizing portable dental equipment to provide oral health services at schools), the grantee should list the activity as "portable clinical care," the types of locations as appropriate (e.g., street, temporary shelters, schools, soup kitchens, labor camps) and the frequency as appropriate (e.g., weekly).

- Health Education. Grantees should list the activity as "health education," the location as appropriate (e.g., community service centers, schools) and the frequency as appropriate (e.g., six times per year).

All "other activities," their locations, estimated frequency and a brief description of the activity should be identified and briefly described on Form 5 – Part C: Other Activities in the annual application for Federal support. In addition, these activities should be described in the grant application, as they contribute to the provision of comprehensive primary care services. For items listed on Form 5-Part C, grantees should ensure that adequate and appropriate documentation has been secured to support and enable performance of these activities.

2. Services

a) Requirements and Discussion of Services

Section 330 funded health centers are required to provide, either directly or through an established arrangement, a set of primary health care services. These are defined in section 330 of the PHS Act as health services related to family medicine, internal medicine, pediatrics, obstetrics and gynecology, diagnostic laboratory and radiological services, pharmaceutical services as appropriate, and defined preventive health services. (For the complete list of required services see section 330(b)(1)(A) of the PHS Act). The specific amount and level of these services will vary by grantee based on a number of factors including, among others, the population served, demonstrated unmet need in the community, provider staffing, collaborative arrangements and/or licensing requirements.

Services provided by the grantee are defined for the organization/entity, not by individual site. Not all services must be available at every grantee service site; rather, the patients must have reasonable access to the full complement of services offered by the center as a whole, either directly or through formal established arrangements.

Because health centers provide service to diverse populations, health centers should assure services are provided in culturally and linguistically appropriate manner based on the target population(s).

Health centers may also provide "additional health services" defined in the section 330 statute as "services that are not included as required primary health services and that are appropriate to meet the needs of the population served by the health center..."[9] Grantees are reminded that once a service is included in the approved scope of project, it must be available equally to all patients regardless of ability to pay and available through a sliding fee scale.[10] Grantees, therefore, should thoroughly investigate the costs, benefits, and risks to the grantee before providing these services. In general, a grantee should demonstrate that all required primary health services are available to all patients before proposing to add additional health services.

[9] Section 330(b)(2) of the PHS Act.

[10] Section 330(k)(3)(G) of the PHS Act., 42 C.F.R. Part 51c.303(f).

Health centers often provide both clinical and non-clinical services. Generally, clinical services are those services related to the provision of direct care and include medical, dental, mental health, substance abuse, diagnostic laboratory and X-ray, and pharmacy services. Non-clinical services are those services that support and assist in the delivery of medical care and facilitate patient access to care, often described as enabling services. These include case management, outreach, transportation, translation and interpretation, health education and eligibility assistance.

The specific range of services that are available at a health center may vary based on provider qualifications and licensing requirements. Many professional, State and/or local certifying/licensing boards require and/or sanction levels or types of service based on a provider's qualifications. Similarly, State and/or local certifying bodies may require different accrediting or licensing standards for facilities. If a grantee determines that all professional, State, and local qualifications necessary for a grantee provider to provide a specific service have been met, and State and local standards/accreditation requirements of the facility have also been fully met, the procedures or levels of service sanctioned by the certifying board are included in the grantee's scope of project. For example, if the grantee employs an obstetrician who performs colposcopy, that service would be appropriate to be included in the scope of the center's project because that procedure is a normal part of the practice of obstetrics and is recognized as such under State certifying boards.

As a reminder, all providers of medical, dental, and mental health services (whether required or additional services) must be properly credentialed and privileged (i.e., appropriately trained and licensed) to perform the activities and procedures expected of them by the grantee. It is the responsibility of the grantee to ensure that all necessary credentialing of providers and licensing of the facility(ies) to provide a service, are completed before requesting that a service be included in the scope of project. (See PIN 2002-22 for additional guidance on the credentialing of providers.)

b) Delivery Method and Scope of Project

In order to ensure the availability of comprehensive services for their patients, health centers may utilize one or more of the following delivery methods to provide a service:

(1) Direct by Grantee and/or Formal Written Agreement
When a service is provided directly by the grantee (Form 5-Part A, Column I) or through a formal written contract/agreement (Form 5-Part A, Column II), the grantee is accountable for providing and/or paying/billing for the direct care. Services provided by the grantee may include, but are not limited to, those rendered by salaried employees, certain contractors, National Health Service Corps staff, and sub-recipients. In most cases, services delivered by the grantee are provided on-site at a service delivery location listed on Form 5- Part B: Service Sites. If the service is provided

by formal written agreement, the agreement must describe how the service will be documented in the patient record and if applicable, how the grantee will pay and/or bill for the service.

(2) Formal Written Referral Arrangement
Under a formal written referral arrangement (Form 5-Part A, Column III), the grantee maintains responsibility for the patient's treatment plan and will be providing and/or paying/billing for appropriate follow-up care based on the outcome of the referral. These referral arrangements should be formally documented in a written agreement that at a minimum describes the manner by which the referral will be made and managed and the process for referring patients back to the grantee for appropriate follow-up care.

Under these types of formal referral arrangements, if the actual service is provided and paid/billed for by another entity, then the SERVICE IS NOT included in the grantee's scope of project. However, establishment of the referral arrangement and any follow-up care provided by the grantee subsequent to the referral is considered to be part of the grantee's scope of project. For example, a grantee may have a referral arrangement for diagnostic X-ray with a hospital. As part of the referral arrangement, the hospital performs the diagnostic X-ray, bills the patient for the services and provides feedback and/or results to the grantee for appropriate follow-up care. The diagnostic X-ray service would NOT be part of the grantee's scope of project but the establishment of the referral and follow-up care provided by the grantee would be part of the grantee's scope of project.

(3) Informal Referral Arrangments or Agreements
Under informal referral arrangements or agreements (these arrangements are not captured on Form 5-Part A and are not a part of the grantee's scope of project), a grantee refers a patient to another provider who is responsible for the treatment plan and billing for the services provided and no grant funds are used to pay for the care provided. These informal arrangements/agreements are not required by HRSA to be documented in a written agreement and do not require the other provider to refer patients back to the grantee for appropriate follow-up care. For services provided by informal referral arrangements or agreements, the referral and the service and any follow-up care provided by the other entity, are considered outside of the grantee's scope of project.

Required primary health services must be provided directly by the grantee or through an established arrangement[11] such as through a formal agreement or through a formal referral arrangement. In addition, required services provided directly by the grantee or by formal agreements or formal referral arrangements must be offered on a sliding fee scale and available equally to all

[11] Section 330 (a)(1) of the PHS Act.

patients regardless of ability to pay. Therefore, informal referral arrangements are not acceptable for the provision of a required service.

Grantees should ensure that all agreements/contracts/arrangements with other providers and organizations comply with section 330 requirements and administrative regulations for the Department of Health and Human Services.[12] Grantees should also ensure that providers for any formal arrangements/agreements are properly credentialed and licensed to perform the activities and procedures expected of them by the grantee.

Note: FTCA and 340B Drug Pricing coverage does not extend to all types of contractual and referral arrangements. Health centers should refer to FTCA-related guidances, listed on page 26 of this PIN, and to Federal Register, Vol. 61, No. 207, page 55156-8, "Patient and Entity Eligibility" for clarification of the 340B Drug Pricing benefit for referrals. Remember, FTCA and 340(B) each has its own independent requirements that must be met for participation.

c) Recording Services and Delivery Method

The services provided by a grantee under the section 330 grant and the method in which they are provided must be documented on Form 5 – Part A: Services Provided. Services are reported on Form 5-Part A: Services Provided in aggregate for the grantee, not on a site-by-site basis. Since more than one delivery method may apply for a given service, more than one type of service delivery method may be indicated on the Form. Grantees must indicate at least one delivery method for each required service listed on Form 5-Part A. Only those services listed on this Form from the most recent annual application for Federal support or approved change in scope request are considered to be part of a grantee's scope of project.

Service delivery methods should be updated at least annually in the grantee's application for Federal support. If services are provided, regardless of method, at a location that meets the definition of service site, the location should be listed on Form 5 – Part B: Service Sites.

3. Providers

a) Requirements and Discussion of Providers

Providers are individual health care professionals who deliver services to health center patients on behalf of the health center. They assume primary responsibility for assessing the patient and documenting services in the patient's record. Providers include only those individuals who exercise independent judgment as to the services rendered to the patient during an encounter.

[12] 45 C.F.R. Part 74.

Grantees utilize a variety of mechanisms for provider staffing in order to maximize access to comprehensive, efficient, cost-effective, and quality health care.[13] For instance, grantees may directly employ or contract with individual providers, may have arrangements with other organizations or may utilize volunteers. Grantees are encouraged to carefully consider the benefits and risks associated with each type of staffing arrangement because of the impact it may have on management and operations. It is preferable that grantees directly employ providers; however, there can be certain situations under which it may be necessary and appropriate for grantees to engage in alternative arrangements. Grantees must ensure that for all contracted clinical staff or volunteers, there is a separate, written agreement.

As a reminder, all providers of medical, dental and mental health services must be appropriately trained and properly credentialed and licensed to perform the activities and procedures expected of them by the grantee. It is the responsibility of the health center to ensure that all necessary credentialing of providers has been completed. (See PIN 2002-22 for additional guidance on the credentialing of providers.)

b) Instructions for Recording Providers

The type and number of clinical providers including volunteers and other staff must be listed on Form 2: Staffing Profile. Providers and other staff are reported in aggregate for the grantee, not on a site-by-site basis. Providers should be updated at least annually in the grantee's application for Federal support.

c) FTCA Considerations

Please note that the definition of "provider" under the scope of project may not be consistent with the definition of provider under FTCA. Individuals covered by FTCA may include others, such as lab and radiology technicians, as described in section 224 of the PHS Act. Likewise, not all provider arrangements in the scope of project are covered by FTCA. For example, volunteer providers, physicians contracted under a professional corporation or employed by another corporation, as well as interns/residents/medical students not employed by the health center may be included as part of scope of project, but are not covered under FTCA. If providers are employees of another company, the health center would still need to have a separate written agreement with the providers.

Also of note, moonlighting, defined as engaging in professional activities outside of the provider's employment responsibilities to the primary employer (in this case the health center), is not a part of the grantee's approved scope of project. Therefore, neither the grantee nor the moonlighting provider may receive FTCA coverage for moonlighting activities.

[13] For health centers funded under section 330(e) and/or section 330(g), please see PIN 98-24, Amendment to PIN 97-27, Regarding Affiliation Agreements of Community and Migrant Health Centers, for further discussion of affiliation arrangements.

4. Service Area

a) Requirements and Discussion of Service Area

The concept of a service or "catchment" area has been part of the Health Center Program since its beginning. Although in general, the service area is the area in which the majority of the health center's patients reside, health centers may use other geographic or demographic characteristics to describe their service area. The Health Center Program's authorizing statute requires that each grantee periodically review its catchment area to:

(i) ensure that the size of such area is such that the services to be provided through the center (including any satellite) are available and accessible to the residents of the area promptly and as appropriate;[14]

(ii) ensure that the boundaries of such area conform, to the extent practicable, to relevant boundaries of political subdivisions, school districts, and Federal and State health and social service programs; and

(iii) ensure that the boundaries of such area eliminate, to the extent possible, barriers to access to the services of the center, including barriers resulting from the area's physical characteristics, its residential patterns, its economic and social grouping, and available transportation.

Public Health Service Act sec. 330(k)(3)(J)

This periodic assessment of service area should be incorporated into a grantee's annual application for Federal support. Routine patient origin studies/analyses will help to ensure that the reported service area is accurate.

The service area should, to the extent practicable, be identifiable by county and by census tracts within a county. Describing service areas by census tracts enables analysis of service area demographics. Service areas may also be described by other political or geographic subdivisions (e.g., county, township, zip codes as appropriate). Starting with calendar year (CY) 2005 Uniform Data System (UDS) data, grantees annually report information on the aggregate geographic area in which its patients reside. This enables grantees and HRSA to better identify service areas. The service area must be federally designated as a Medically Underserved Area in full or in part or contain a federally designated Medically Underserved Population (MUP).[15]

b) Recording Service Area

The service area for the grantee must be listed by census tracts and zip codes on Form 5 – Part B: Service Sites. Census tracts and zip codes for the service area are reported on a site-by-site basis. In general, those census tracts and/or zip codes

[14] Primary health services of the center must also be provided "in a manner which assures continuity." (PHS Act, section 330(k)(3)(A).)

[15] This requirement is not applicable to health centers requesting or receiving funding only under section 330(g), (h), and/or (i) of the PHS Act, since those centers are applying to serve populations already recognized as underserved.

listed on this Form from the most recent annual application for Federal support and/or approved change in scope request form the basis for determining service area for a grantee's scope of project. The service area for each service site should be updated at least annually in the grantee's application for Federal support.

5. Target Population

a) Requirements and Discussion of Target Population

Health centers are required to serve a "medically underserved, or special medically underserved population."[16] Each health center must define an underserved population from within the established service area to which it will direct its services. The underserved populations often face barriers in accessing health care services and disparities in their health status which are addressed through the health center operation.

This target population is usually a subset of the entire service area population, but in some cases, may include all residents of the service area if it is determined that the entire population of the service area is underserved, and lacking access to adequate comprehensive, culturally competent quality primary health care services. Although a grantee may serve diverse populations at several sites, the target population is reported in aggregate at the grantee level not on a site-by-site basis.

Section 330(e) grantees are required to make services available to all residents of the health center's service area, regardless of the individual's ability to pay.[17] Health centers may also extend services to those residing outside the service area. However, HRSA recognizes that health centers must operate in a manner consistent with sound business practices. Nonetheless, health centers should address the acute care needs of all who present for service, regardless of residence.

Some health centers receive funding to target a special population within a community. There are three such special populations: migrant and seasonal agricultural workers and their families, persons who are homeless, and/or residents of public housing. Grantees receiving special populations funding (i.e., grants under only section 330(g), (h), and/or (i) of the PHS Act) are not subject to the requirement to make services available to all residents of the service area.[18] However, these grantees are expected to address the acute care needs of anyone who presents for service. Individuals who are not members of the special population(s) served by a special populations-only grantee may then be referred to more appropriate settings for their non-acute health care needs.

[16] Section 330(a)(1) of the PHS Act.

[17] Section 330(a)(1)(B) of the PHS Act.

[18] Section 330(a)(2) of the PHS Act.

b) Recording Target Population

Information on the grantee's target population must be listed on Form 4: Community and Target Population Characteristics. Demographic, income, insurance status and other information on the service area and target population should be recorded on this Form in aggregate for the grantee as a whole, not on a site-by-site basis, and should be updated at least annually in the grantee's application for Federal support.

IV. CHANGE IN SCOPE REQUESTS

Some changes in the approved scope of project require prior approval from HRSA before being initiated; others may be implemented by the grantee without prior approval. In all cases, any changes proposed and/or implemented by a grantee must assure continued compliance with the applicable statutory, regulatory and policy requirements. In reviewing a request to change the approved scope of project, HRSA will consider whether the request furthers the mission of the health center by increasing or maintaining access, and improving or maintaining the quality of care for the target population. Requests must not result in the diminution of the grantee's total level or quality of health services currently provided to the target population. Additionally, grantees are reminded that a request to change the approved scope of project must not shift resources away from providing approved services for the target population, and must be accomplished without additional Health Center Program funding. As appropriate, changes in the approved scope of project also must assure continued service to a Medically Underserved Area (MUA) or a Medically Underserved Population (MUP). (Please note, a service site does not have to be located in an MUA in order to serve people living in the area.)

A. CHANGE IN SCOPE REQUESTS THAT REQUIRE PRIOR APPROVAL

1. Types of Change in Scope Requests that Require Prior Approval

Based on applicable section 330 program regulations, 42 CFR Part 51c.107(c), 45 CFR Parts 74 and 92, and HHS Grants Policy Statement, prior approval is required for significant changes in the approved budget or program plan including scope of project.[19] The following five types of changes are considered significant and, therefore, require prior approval from HRSA:

- **Adding a service site** not included on Form 5 – Part B: Service Sites, of the grantee's most recent application for Federal support or approved change in scope request.
- **Adding a service** not included on Form 5 – Part A: Services Provided, of the grantee's most recent application for Federal support or approved change in scope request.
- **Relocating a service site** that was included on Form 5 – Part B: Service Sites, of the grantee's most recent application for Federal support or approved change in scope request.

[19] Any activity that results in significant re-budgeting also requires prior approval. See DHHS Grants Policy Statement (HHS GPS): page II-55. ftp://ftp.hrsa.gov/grants/hhsgrantspolicystatement.pdf.

- **Deleting a service site** that was included on Form 5 – Part B: Service Sites, of the grantee's most recent application for Federal support or approved change in scope request.
- **Deleting a service** that was included on Form 5 – Part A: Services Provided, of the grantee's most recent application for Federal support or approved change in scope request.

Grantees should include in their change in scope request a detailed discussion of any potential impact on the total approved section 330 project budget, services provided, number of patients served, and number and type of providers. Any unique circumstances that are expected to impact the ability of the grantee to meet the expectations for change in scope requests must be fully explained and documented.

Note: Any request for change in scope of project must be accomplished without additional section 330 funds. Requests for change in scope of project must be approved by the Board of Directors of the grantee with approval documented in the Board minutes prior to submission to HRSA.

Because of the importance of the scope of project, it is expected that grantees will submit any change in scope request requiring prior approval **at least 60 days in advance of their desired implementation date**, to the extent practicable, following the process described in Section V of this PIN (see page 24).

2. Special Instructions for Adding a Service Site[20]

   a) Adding Sites in the Same Building, Complex or Campus

   Health centers may identify an opportunity to add a new location that meets the definition of a service delivery site (see page 5) within the same building or complex/campus where they are already have an established service delivery site providing services to the target population. In such an instance, a health center must complete a change in scope for prior approval to add the new site if the site would have a separate physical address including a different suite/office/building number. For example, a change in scope of project is required if a grantee operates a site at 345 Main Street, Suite #4 and will be adding a new site at 345 Main Street, Suite #12. If the location does not create a separate physical address, no change in scope is required.

   b) Adding Migrant Voucher Screening Sites

   If a grantee needs to add a new migrant voucher screening site, the grantee must submit a change in scope request for prior approval to add the new screening

[20] All approved change in scope requests to add a new service site must be reported to the State Medicaid Agency and the Medicare Fiscal Intermediary within 90 days of approval. See Section VI of this PIN for further information regarding notification to the State Medicaid Agencies and the Medicare Fiscal Intermediary.

location. No change in scope request is necessary to add/delete the specific locations where the grantee maintains contracts for direct services.

c) Changing from Intermittent to Permanent or Seasonal Sites

Grantees may determine that demand for primary care services from the target population at an intermittent site exceeds their expectation to provide services at that location for only a short period of time. If a grantee determines that the intermittent site should be operated for more than the expected period of time for an intermittent site (two months or less), and the site meets the definition of a service site (see page 5), the grantee must complete a change in scope request to add the location as a permanent or seasonal service site.

d) Sites Offering a Single Service

Although grantees are not required to provide all services at all service sites, patients must have reasonable access to the full complement of comprehensive services offered by the health center as a whole. The establishment of a single service or limited service site must be in a location that allows reasonable access to the full complement of services from the health center or access to the required services on a sliding fee scale basis through formal arrangements with other providers in the community.

3. Special Instructions for Adding a Service

While grantees may deliver a service by several different methods, a service will only be included in the grantee's scope of project if it is delivered directly by the grantee or through a formal written agreement such as a contract, purchase agreement, and/or written arrangement as recorded Form 5- Part A, Services, Columns I and II. **Although the arrangement with another provider under a formal referral arrangement (recorded under Column III on Form 5 – Part A) is within a grantee's scope of project, the actual service provided by the other provider under the arrangement is not included in a grantee's scope of project;** therefore, if a grantee has been providing a service only through a formal or informal referral arrangement and wishes to begin providing this service directly or through formal agreement as part of their scope of project (e.g., the service is **ONLY** recorded in Column III and is being moved to Columns I and/or II on Form 5- Part A), the grantee MUST submit a change in scope request to add the service to the scope of project and begin providing this service.

Cases where a grantee moves a service(s) from one site to another site in the approved scope of project do not require prior approval. However, in doing so, grantees should assure that the population accessing the service at the original site will continue to have reasonable access to the service once it is relocated.

4. Special Instructions for Relocation of a Site

Health centers may engage in different types of relocations to maximize access to services for the target population. In some cases, this may involve complete relocation, and in others, only partial relocation.

Grantees moving **all** clinical services from an approved permanent or seasonal service site to a new location must submit a request for prior approval to relocate the service site. Requests for relocation will be examined to assure continued access for the populations served by the service site to be relocated. Such requests should demonstrate that the relocation furthers the mission of the health center by increasing or maintaining access and improving or maintaining the quality of care for the target population currently served by the grantee. Requests for relocation must not result in the diminution of the grantee's total level or quality of health services currently provided to the target population.

Cases where a grantee is moving only a portion of its current clinical services from an approved permanent or seasonal service site to a new location that is not a part of the approved scope of project, are not considered a relocation of the service site but rather, the addition of a new service site. In this situation, the grantee must submit a change in scope request to add a service site for the new location as the existing site will continue to operate as a service site, meeting the definition described above in III.B.1. (see page 5).

Changes in locations for intermittent sites (when operated for two months or less) are not considered relocations and, therefore, do not require prior approval. However, if an intermittent site becomes a permanent or seasonal site (i.e., will be operated for more than two months), the grantee must submit a change in scope request to add the site as a permanent or seasonal site.

5. Special Instructions for Deleting a Site or Service

There may be circumstances that require grantees to cease operation of a site or the provision of a particular service. Because of the potential implication on access to care for the target population, any request to delete a service or service site from a grantee's scope of project will not be approved without a full examination of the issues surrounding the perceived need to delete the site or service. Grantees are reminded that the deletion of a site or a service must not result in elimination or reduction in access to required services under section 330 of the PHS Act for populations currently served by the health center. Grantees must demonstrate that the requested deletion will not reduce access to services or the ability of current patients to receive the same level of care. As a reminder, grantees must provide all required services directly or through an established arrangement (i.e., a formal written contract/agreement or a formal written referral arrangement); therefore, a grantee may not request to delete a required service.

6. Special Considerations for Changes in Scope of Project

a) Future Federal Funding to Support a Change in Scope Request

A key requirement for every change in scope request is that the grantee must document that the requested change can be fully accomplished with no additional Federal support. In other words, in a request to add a site or service a grantee must demonstrate that adequate revenue will be generated to cover all expenses as well as an appropriate share of overhead costs incurred by the health center in administering the new site or service. If additional Federal funds will be necessary to fully implement the proposed change in scope, it will not be approved. Grantees that require additional Federal grant support to implement the proposed change should consider competitive funding opportunities. Specific eligibility for additional Federal support will be included in each announced funding opportunity.

Grantees considering submitting a change in scope to add a service delivery site that will be the basis for later submission of a competitive grant application (i.e., for Expanded Medical Capacity) should proceed with care. As stated previously, a change in scope request must include only the level of services that can be maintained without additional Federal support. Grantees are strongly advised against establishing a new service or site that is dependent on new future grant support, since such support is not guaranteed.

b) Financial Impact

While many grantees have undertaken changes to their scope of project to improve their financial viability, changes in scope of project that are not carefully planned may pose high risks. A complete financial analysis of the impact of a change in scope is imperative to ensure long-term viability of the health center. In particular, grantees should examine the overall costs of the activity and the potential for reimbursement as part of this analysis. **Approval of a change in scope request is contingent on submission of a budget demonstrating break-even (worst case scenario) or the potential for generating additional revenue.** Grantees are strongly encouraged to thoroughly review any change in scope request that could result in a significant increase or decrease in the total budget of the health center. Because unforeseen events may occur making original projections inaccurate, grantees should continually monitor the progress of their requested change in scope and be prepared to take action should revenues fail to meet or exceed expenses. Additional revenue obtained through the addition of a new service or site must be invested in activities that further the objectives of the approved health center project, consistent with and not specifically prohibited by section 330(e)(5)(D)(3).

c) Impact on Neighboring Health Centers

Health centers should coordinate and collaborate with other section 330 grantees, FQHC Look-Alikes, State and local health services delivery projects, and programs in the same or adjacent service areas serving underserved populations to create a

community-wide service delivery system. Section 330 of the PHS Act specifically requires that applicants for health center funding have made "and will continue to make every reasonable effort to establish and maintain collaborative relationships with other health care providers in the catchment area of the center."[21] The goal of collaboration is to utilize the strengths of all involved organizations to best meet the overall health care needs of the area's underserved population. In addition, continued collaboration among providers will help to ensure that organizations are aware of and, where possible, maximize the benefits of, all organizations.

When a change in scope of project (e.g., the addition or relocation of a service site) is proposed, it is essential that a grantee consider the population(s) served by other existing providers of care, including other section 330 funded health centers, and the impact of the proposed change in scope on the viability of these neighboring health centers. Meeting the health care needs of the community and target population, ensuring that limited Federal grant dollars are used efficiently and effectively to provide access to as many underserved people as possible and the potential impact of a change in scope request on a neighboring health center(s) are key in decisions related to service area overlap.

The potential for service area overlap through a change in scope request will prompt further review, analysis and resolution before HRSA will be able to make a final decision on a health center's request. When a proposed change in scope has the potential to create a service area overlap, documentation of support, and/or cooperation from a neighboring health center(s) in the form of a Board of Directors-endorsed letter is desirable. If the health center is not able to document the support of other local providers for its request, it should provide an explanation for the lack of such documentation. In cases where there may be a service area overlap, additional information such as patient origin studies/analyses or an onsite visit may be necessary prior to a final HRSA decision. (See Service Area Overlap PIN, 2007-09 dated March 12, 2007 available at http://www.bphc.hrsa.gov/policy/pin0709.htm.)

7. Criteria for Prior Approval of a Change in Scope Request

All requests for change in scope of project requiring prior approval (see in Section IV.A. of this PIN on page 16), will be reviewed to determine if the request:

1) will not require any additional section 330 funding to be accomplished;
2) does not shift resources away from providing services for the current target population;

3) furthers the mission of the health center by increasing or maintaining access and improving or maintaining quality of care for the target population;

[21] Section 330(k)(3)(B) of the PHS Act.

4) is fully consistent with section 330 of the PHS Act and Health Center Program Expectations including appropriate governing board representation for changes in service sites and populations served;

5) provides for appropriate credentialing and privileging of providers;

6) does not eliminate or reduce access to a required service;

7) does not result in the diminution of the grantee's total level or quality of health services currently provided to the target population;

8) continues to serve a Medically Underserved Area (MUA) in whole or in part, or Medically Underserved Population (MUP)[22] [Please note that a service site does not have to be located in an MUA to serve it];

9) demonstrates approval from the health center's Board of Directors, with approval documented in the Board minutes; and

10) does not significantly affect the current operation of another health center located in the same or adjacent service area, preferably, but not necessarily, by documenting support to the extent possible from any neighboring health centers.

B. OTHER CHANGE IN SCOPE REQUESTS

The following changes are not considered significant[23] and, therefore, do not require prior approval. Each grantee is expected to discuss any such changes and/or updates in the next application for Federal support.

- **Adding a service to a site where both the service and site are already within the approved scope of project.** If a grantee currently provides a service within the scope of project, no prior approval is necessary to add the service to a service site already in the approved scope of project. For example, a grantee provides mental health services at one service site and chooses to add that service to another service site already within the approved scope of project; no request for prior approval of the change is necessary. The service and service site must be previously documented on Form 5 – Part A: Services Provided and Form 5 – Part B: Service Sites, respectively, of the grantee's most recent application for Federal support or approved change in scope request.

- **Change in the number of intermittent sites**, previously documented on Form 5 – Part B: Service Sites, of the grantee's most recent application for Federal support

[22] Required for health centers funded under section 330(e).

[23] Based on applicable section 330 program regulations, 42 CFR Part 51c.107(c), 45 CFR Parts 74 and 92, and HHS Grants Policy Statement.

or approved change in scope request. The number of such sites should be updated at least annually in the application for Federal support.

- **Change to providers** listed on Form 2: Staffing Profile of the grantee's most recent application for Federal support or approved change in scope request. Only those requests affecting providers that are linked with changes in sites or services require prior approval. No change in scope request is required in cases where a grantee changes the type of provider used to provide a service under the approved scope of project. For example, if the grantee has been providing mental health services using a social worker and decides to add a psychologist, and there is no change in the services provided (i.e., mental health), the grantee does not need to request prior approval to make this change.

- **Change to the hours of operation of a service site** previously approved on Form 5 – Part B: Service Sites, of the grantee's most recent application for Federal support or approved change in scope request. The hours for each site should be updated at least annually in the application for Federal support.

Note that any change in scope of project must be accomplished without additional section 330 funds.

C. CHANGE IN SCOPE DURING EMERGENCIES FOR HEALTH CENTERS

During an emergency, health centers are likely to play an important role in delivering critical services and assisting in the local community response. **Health centers deemed under FTCA should refer to PIN 2007-16, "Federal Tort Claims Act (FTCA) Coverage for Consolidated Health Center Program Grantees Responding to Emergencies." (See http://www.bphc/policy/pin0716/.)**

For the purposes of this section, an "emergency" or "disaster" is defined as an event affecting the overall target population and/or the community at large, which precipitates the declaration of a state of emergency at a local, State, regional, or national level by an authorized public official such as a governor, the Secretary of the U.S. Department of Health and Human Services, or the President of the United States. Examples include, but are not limited to: hurricanes, floods, earthquakes, tornadoes, wide-spread fires, and other natural/environmental disasters; civil disturbances; terrorist attacks; collapses of significant structures within the community (e.g., buildings, bridges); and infectious disease outbreaks and other public health threats.

In situations where an emergency has not been officially declared, but the health center is unable to operate, HRSA will evaluate on a case-by-case basis whether extraordinary circumstances justify a determination that the situation faced by the health center constitutes an "emergency."

HRSA recognizes that during an emergency, health centers are likely to participate in an organized State or local response and provide primary care services at temporary

locations. Temporary locations include any place that provides shelter to evacuees and victims of an emergency. It also includes those locations where mass immunizations or medical care is provided as part of a coordinated effort to provide temporary medical infrastructure where is it most needed. These temporary locations will be considered part of a health center's scope of project if all of the following conditions are met:

1. Services provided are on a temporary basis;

2. Temporary locations are within the health center's service area or neighboring counties, parishes, or other political subdivisions adjacent to the health center's service area;

3. Services provided by health center staff are within the approved scope of project; and

4. All activities of health center staff are conducted on behalf of the health center.

To assure that the emergency response at temporary locations is considered part of the center's scope of project, the health center must provide the following information to its HRSA Project Officer by phone, e-mail, or fax: (1) health center name; (2) the name of a health center representative and this person's contact information; and (3) a brief description of the emergency response activities. Health centers must submit this information as soon as practicable but no later than 15 calendar days after initiating emergency response activities. HRSA will determine on a case by case basis whether extraordinary circumstances justify an exception to this 15-day requirement. If the HRSA Project Officer is not available, the health center should contact the BPHC's main phone line at 301-594-4110.

If a health center needs to continue operating at a temporary location beyond 90 days from the onset of the emergency, the health center must submit a formal change in scope request to add the site. Health centers are expected to submit the formal request with sufficient time for HRSA processing.

V. PROCESS FOR CHANGE IN SCOPE OF PROJECT REQUESTS

All grantees considering a change in scope are encouraged to carefully review this PIN prior to initiating a request. In considering a change in scope, all grantees should review the proposal with their Board of Directors and consult with their Project Officer.

A. MECHANISM TO SUBMIT REQUESTS FOR PRIOR APPROVAL

An electronic process through HRSA's Electronic Handbook (EHB) has been developed for obtaining prior approval for the five types of change in scope of project requests requiring prior approval (see page 16 of this PIN). The EHB is designed to streamline the grants administration process and enable grantees to communicate with HRSA and conduct activities electronically. The EHB can be accessed from anywhere on the Internet using a standard web browser https://grants.hrsa.gov/webexternal/. When a grantee initiates a change in scope request, the EHB will assign a tracking number.

Grantees may create and submit a change in scope request in one session, or create and save part of a request, using the assigned tracking number to return as many times as necessary to complete the request before submitting it for HRSA review.

B. CHANGE IN SCOPE DETERMINATIONS AND TIMELINE

Because of the importance of scope of project, it is expected that grantees will request prior approval at least 60 days in advance of their desired implementation date for changes in scope for service delivery sites and services provided. There may be circumstances where submitting a change in scope request early may not be possible; however, the goal is to minimize these occurrences through careful planning. Timely submission of a change in scope request is important to ensure Medicaid and Medicare FQHC reimbursement, FTCA coverage, and 340B Drug Pricing benefits for the specific site/service, as appropriate.

If additional information or clarification is needed, the Project Officer will notify the grantee of the deficiencies of the request through the EHB, and the grantee will be given 60 days to provide the additional information. If the requested information is not provided by the grantee by the end of 60 days, the change in scope request will be denied and the grantee will be notified of this decision through the EHB. If a request is denied, the grantee will have to submit a new request for prior approval in order to implement the change in scope.

Due to the varying complexity of requests, in some cases it may be necessary to extend the HRSA review period if additional analysis, such as an on-site consultation, is warranted. In those cases, the grantee will be notified through the EHB within the initial 60 day review period of the potential delays in processing the request.

HRSA will indicate the final decision within 60[24] days of a complete change in scope request in one of the following two ways:

1) Notice of Grant Award (NGA) indicating approval; or
2) an email through EHB indicating disapproval.

C. EFFECTIVE DATE OF APPROVAL

The effective date of an approved change in scope will be no earlier than the date of receipt of a complete request for prior approval. In cases where a grantee is not able to determine the exact date by which a change in scope (i.e., adding a site or service) will be fully accomplished, grantees will be allowed up to 120 days following the date of the NGA indicating approval for the change in scope to implement the change (e.g., open the site or begin providing a new service). Therefore, grantees should carefully consider their ability to accomplish the requested change within this anticipated timeframe prior to submitting a request. If a grantee does not or is unable to implement the requested change in scope within 120 days of approval, the grantee must immediately notify the Project Officer in

[24] Please see PIN 2009-03 available at http://bphc.hrsa.gov/policy/pin0903.htm on the revision made to PIN 2008-01.

writing with an appropriate justification for the unanticipated delay and a detailed plan for completing the requested scope change. The BPHC will consider, on a case by case basis, exceptions to the 120 implementation requirement only if the grantee provides sufficient and compelling justification of the unique and unavoidable circumstances that will prevent the grantee from meeting this expectation.

As a reminder, all grantees should ensure that any application for Federal support documents the total scope of project and all activities added through an approved change in scope of project during the preceding budget period.

VI. ADDITIONAL SCOPE OF PROJECT POLICY ISSUES

A. SCOPE OF PROJECT AND FTCA COVERAGE

FTCA coverage is limited to staff and services that are documented as being within the approved scope of project and included in provider employment agreements or contracts. **The requirements and other information regarding FTCA coverage and the deeming process can be found in the following PINs and PALs**:

- PIN 1999-08, "Health Centers and The Federal Tort Claims Act"
- PIN 2001-11, "Clarification of Policy for Health Centers Deemed Covered Under the Federal Tort Claims Act for Medical Malpractice"
- PIN 2001-16, "Credentialing and Privileging of Health Center Practitioners"
- PIN 2002-22, "Clarification of Bureau of Primary Care Credentialing and Privileging Policy Outlined in Policy Information Notice 2001-16"
- PIN 2002-23, "New Requirements for Deeming under the Federally Supported Health Centers Assistance Act"
- Program Assistance Letter (PAL) 99-15, "Questions and Answers on the Federal Tort Claims Act Coverage for Section 330, Deemed Grantees"
- PAL 2005-01, "Federal Tort Claims Act Policy Clarification on Coverage of Corporations under Contract with Health Centers"
- PAL 2001-25, "Procedures for General Inquiries on Federal Tort Claims Act Coverage"
- PIN 2005-19, "Federal Tort Claims Act Coverage for Deemed Consolidated Health Center Program Grantees Responding to Hurricane Katrina."
- PIN 2007-16, "Federal Tort Claims Act (FTCA) Coverage for Health Center Program Grantees Responding to Emergencies"

These PINs and PALs can be found online at http://bphc.hrsa.gov/policy/.

Questions concerning FTCA should be directed to:

FTCA Program
DHHS/HRSA/BPHC
5600 Fishers Lane, Room 15C-26
Rockville, MD 20857
Phone: 301-594-2469
Fax: 301-594-5224

Email: HealthCenterFTCA@hrsa.gov

B. SCOPE OF PROJECT AND FQHC MEDICAID PPS OR ALTERNATIVE METHODOLOGY REIMBURSEMENT

After a change in scope of project that may generate a FQHC Medicaid reimbursement (e.g., PPS or APM) adjustment is approved, it is the responsibility of the grantee to notify its State Medicaid Agency of the change(s) within 90 days following HRSA approval.

Most State Medicaid Agencies require a HRSA approved change in scope project to process requests for changes in Medicaid PPS or APM (e.g., rate for new starts or rate increase/decrease). **Please note that the change in scope of project for grantees discussed under this PIN is not the same as a change in the scope of services for increased/decreased reimbursement (PPS or APM) through Medicaid.** The CMS and State Medicaid Agencies define the term "change in the scope of services" to refer to a mechanism for adjusting the reimbursement rate of a FQHC due to "a change in the type, intensity, duration, and/or amount of services." The HRSA approved change in scope modifies the services or sites in the grantee's scope of project for the section 330 grant. It does not approve a "change in the scope of services" for State Medicaid reimbursement purposes. Grantees should contact their State Medicaid Agency for further information about their "change in the scope of services" policy and procedures.

C. SCOPE OF PROJECT AND MEDICARE FQHC COST-BASED REIMBURSEMENT

After a change in scope of project is approved, it is the responsibility of each grantee to notify its Medicare Fiscal Intermediary in a timely manner following the HRSA approval for the purposes of receiving the Medicare FQHC reimbursement rate.

In order for any new service delivery site(s) to be recognized by Medicare as a FQHC and be reimbursed the FQHC all-inclusive rate, a complete CMS 855A Form must be filed with the appropriate Medicare Fiscal Intermediary. (A copy of the CMS 855A Form is available at http://www.cms.hhs.gov/cmsforms/downloads/cms855a.pdf.) For each new site added to the approved scope of project, a health center must submit the CMS 855A Form, a copy of the HRSA Notice of Grant award that includes the address for applicable site(s) being enrolled, along with the necessary accompanying documents (see page 41 of CMS-855A) to the appropriate Fiscal Intermediary. In addition, the Medicare Fiscal Intermediary should be notified within 30 days of all site address changes and changes in ownership. All other changes to enrollment should be reported within 90 days.

A unique National Provider Identifier (NPI) number is necessary for each site when completing the CMS 855A Form. The NPI is a standard unique health identifier for health care providers and is assigned by the National Plan and Provider Enumeration System (NPPES). The NPI is necessary for HIPAA standard transactions under Medicare. Those transactions include the electronic claim, eligibility inquiry and response, claim status inquiry and response, payment and remittance advice, prior authorization/referral, and coordination of benefits transactions. **Grantees are required to obtain a NPI for each service site in order to bill Medicare, Medicaid and other payers.**

Complete instructions for completing the NPI application process is available at http://www.cms.hhs.gov/NationalProvdentStand/03_apply.asp#TopOfPage. Grantees can obtain a NPI number(s) in two ways: 1) by going to the CMS website at https://nppes.cms.hhs.gov to fill out an application on-line; or 2) by completing a paper application form (CMS-10114) available from http://www.cms.hhs.gov/forms or by calling the NPI Enumerator at 1-800-465-3203 to request a copy.

D. Scope of Project and The Section 340B Drug Pricing Program

Health centers qualify as covered entities under the section 340B Drug Pricing Program. Please note, however, that while identification as a service site within a scope of project is necessary for participation in 340B, the program has its own requirements that must be met. For information on participating in the 340B Program, please call the Office of Pharmacy Affairs at 1-800-628-6297 or 301-594-4353, or visit the following website http://www.hrsa.gov/opa.

E. Scope of Project and Accreditation

Grantees accredited by an external accrediting body, e.g., the Joint Commission, are responsible for notifying the accrediting body of organizational changes if required by the accrediting body, as these may result in a requirement for an extension survey. Please refer to the accrediting body's policies and procedures for further guidance.

VII. CONTACT INFORMATION

If you have any questions or require further guidance on the scope of project policy detailed in this PIN, please contact the Office of Policy and Program Development at 301-594-4300. If you have questions or require additional assistance regarding the process for requesting prior approval of changes in scope, please contact your Project Officer.

ELECTRONIC CODE OF FEDERAL REGULATIONS

e-CFR Data is current as of July 30, 2013

Title 42: Public Health
PART 51c—GRANTS FOR COMMUNITY HEALTH SERVICES
Subpart A—General Provisions

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§ 51c.107 Use of project funds.

(a) Any funds granted pursuant to this part, as well as other funds to be used in performance of the approved project, may be expended solely for carrying out the approved project in accordance with section 330 of the Act, the applicable regulations of this part, the terms and conditions of the award, and the applicable cost principles prescribed in subpart Q of 45 CFR part 74.

(b) Project funds awarded under this part may be used for, but need not be limited to, the following:

(1) The costs of acquiring and modernizing existing buildings (including the costs of amortizing the principal of, and paying interest on, loans), but only in accordance with subpart E of this part and as approved in the grant award;

(2) The costs of obtaining technical assistance to develop and improve the management capability of the project, but only as approved by the Secretary;

(3) The reimbursement of members of the grantee's governing board, if any, for reasonable expenses actually incurred by reason of their participation in board activities;

(4) The reimbursement of governing board members for wages lost by reason of participation in the activities of such board if the member is from a family with an annual family income below $10,000 or if the member is a single person with an annual income below $7,000;

(5) The cost of delivering health services, including services rendered on a prepaid capitation basis, to residents of the project's catchment area within the following limitations: grant funds may be used to pay the full cost of project services to individuals and families with annual incomes at or below those set forth in the most recent "CSA Income Poverty Guidelines" (45 CFR 1060.2) issued by the Community Services Administration; and to pay the portion of the cost of services provided in accordance with the schedule of discounts which, under such schedule, is uncompensated; *Provided,* That (i) charges will be made to such individuals and families in accordance with § 51c.303(f) of subpart C; (ii) reasonable effort shall be made to collect such charges under a billing and collections system; and (iii) the charge to grant funds shall exclude any amounts collected pursuant to paragraph (b)(5)(ii) of this section;

(6) The cost of insurance for medical emergency and out-of-area coverage;

(7) The cost of providing to the staff of the project training related to the provision of health services provided or to be provided by the project, and, to the staff and governing board, if any, training related to the management of an ambulatory care facility, consistent with the applicable requirements of 45 CFR part 74; and

(8) The cost of developing and maintaining a reserve fund where required by State law for prepaid

health care plans.

(c) Prior approval by the Secretary of revisions of the budget and project plan is required whenever there is to be a significant change in the scope or nature of project activities.

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