

POLICY INFORMATION NOTICE

DOCUMENT NUMBER: 2009-02

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DOCUMENT NAME: Specialty Services
and Health Centers' Scope of Project

TO: Health Center Program Grantees.
Primary Care Associations
Primary Care Offices
National Cooperative Agreements
Federally Qualified Health Center Look-Alikes

The purpose of this Policy Information Notice (PIN) is to describe the factors that will be considered by the Health Resources and Services Administration (HRSA) when evaluating requests from Health Center Program grantees seeking to add specialty services to the scope of their Federal section 330 project. The 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 Medicaid Prospective Payment System payment and Medicare Federally Qualified Health Center reimbursements, Federal Tort Claims Act coverage, 340B Drug Pricing eligibility and other essential benefits. Therefore, proper recording of the scope of project is critical in the oversight and management of programs funded under section 330 of the Public Health Service Act.

Increasingly, Health Center Program grantees are seeking to expand their Federal scope of project to include services offered by specialists. This is in part due to difficulties faced by health center patients when they attempt to access specialty services not offered by the health center. The factors described in this PIN were developed based on HRSA's goal of supporting the extension of necessary health services to current health center patients in support of required primary health services, while ensuring that health centers continue to (1) meet the current statutory, regulatory, and policy requirements of the Health Center Program and (2) comply with Department of Health and Human Services grants regulations and policy.

Once this policy becomes effective, some health centers may determine that certain services do not meet the PIN's criteria for inclusion within the Federal scope of project. HRSA will provide all grantees with an opportunity to modify and/or update their scope information to ensure that every grantee's scope of project is consistent with the updated policies. If there are any discrepancies, HRSA will work with grantees to resolve the issues.

If you have any questions or require further guidance on the policies detailed in this PIN, please contact the Bureau of Primary Health Care, Office of Policy and Program Development at 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

Attachments

I. PURPOSE

The purpose of this Policy Information Notice (PIN) is to describe the factors that will be considered by the Health Resources and Services Administration (HRSA) when evaluating requests from health centers seeking to add specialty services to the scope of their Federal project supported under section 330¹ of the Public Health Service (PHS) Act.

II. APPLICABILITY

This PIN applies to all health centers funded under the Health Center Program authorized in section 330 of the PHS Act (42 U.S.C. 254b), as amended, specifically:

- Community Health Center (CHC) Programs, funded under section 330(e);
- Migrant Health Center (MHC) Programs, funded under section 330(g);
- Health Care for the Homeless (HCH) Programs, funded under section 330(h); and
- Public Housing Primary Care (PHPC) Programs, funded under section 330(i).

Organizations designated under the Federally Qualified Health Center (FQHC) Look-Alike Program that are seeking a change to their approved scope of project should follow the process outlined in the PINs for FQHC Look-Alikes at <http://bphc.hrsa.gov/policy>.

III. BACKGROUND

The provision of comprehensive, culturally competent, quality primary health care services to the medically underserved is a hallmark of the Health Center Program. The specific services offered by individual health centers are described in each center's "scope of project." These are the services for which Health Center Program funds and other grant-supported resources may be used.

Services supported by the Federal section 330 grant must include certain "required primary health services" listed in the Health Center Program's authorizing statute.² Health centers may also provide "additional" health services that are "necessary for the adequate support of the [required] primary health services"³ and that are "appropriate to meet the health needs of the population served by the health center."⁴ Although the Health Center Program's authorizing statute does not specifically prohibit health centers from offering particular services, Department of Health and Human Services (DHHS) grants regulations and policy require prior approval before new services may be added to a health center's federally-approved scope of project.⁵

¹ Here and throughout the PIN, "section 330" refers to section 330 of the Public Health Service Act, as amended (42 U.S.C. 254b).

² PHS Act section 330(a)(1)(A) and section 330(b)(1).

³ PHS Act section 330(a)(1)(B).

⁴ PHS Act section 330(b)(2).

⁵ See applicable section 330 program regulations, 42 CFR Part 51c.107(c), 45 CFR Parts 74.25(c)(2), and DHHS Grants Policy Statements. Requests for changes in the scope of Federal project should be submitted according to the guidelines in PIN 2008-01, "Defining Scope of Project and Policy for Requesting Changes."

Since the Health Center Program began over 40 years ago, the complexity and volume of services offered in ambulatory care settings have greatly expanded. Many technological advances now allow providers to safely perform complicated procedures on an outpatient basis, rather than in a hospital. These and other circumstances have contributed to an increasing number of requests from health centers to add specialty services to their Federal section 330 scope of project.

This PIN provides guidance to health centers seeking to add specialty services to the scope of project by describing the factors HRSA will use to evaluate these requests. HRSA believes that health centers planning to submit an application for a change in the Federal scope of project to add specialty services should be aware of the factors that will be considered when HRSA makes decisions regarding these applications. Our intention is to provide health centers with a better understanding of HRSA's evaluation criteria for requests to add specialty services to their Federal scope of project, thereby improving health centers' ability to submit requests that are eligible for approval.

IV. DEFINITIONS

A. "Scope of Project"

A health center's scope of project includes the activities that the total approved section 330 grant-related project budget supports.⁶ Specifically, the scope of project defines the approved service sites, services, providers, service area(s) and target populations(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 and the mission of the health center. A section 330-funded health center must include the provision of certain services within its scope of project, including primary health care services, referrals to providers of health-related services, patient case management services, and enabling services.⁷ Section 330-funded health centers may also provide additional health services in support of required primary health services and as appropriate for the health center population.⁸

Section 330-funded health centers may also carry out other activities (other lines of business) that are not part of their Federal scope of project and, thus, are not subject to section 330 requirements. For example, a grantee corporation may run a day care center that is not within the scope of the federally supported project and does not use section 330 funds, personnel, or related revenue for support; therefore, it would not be subject to section 330 requirements or eligible for the benefits that extend to activities within the grantee's scope of project.

⁶ For additional requirements regarding changes in the Federal scope of project, please see HRSA PIN 2008-01, "Defining Scope of Project and Policy for Requesting Changes" at www.bphc.hrsa.gov/policy/PIN0801.

⁷ PHS Act section 330(a)(1)(A) and section 330(b)(1).

⁸ PHS Act section 330(b)(2).

Eligibility for Medicaid Prospective Payment System payment,⁹ Medicare FQHC reimbursement, and Federal Tort Claims Act (FTCA) coverage for a health care service is contingent upon the inclusion of the service in the health center's approved Federal scope of project.¹⁰

B. "Provider"

The term "provider" refers to individual health care professionals (including physicians, physician assistants, nurse practitioners, and certified nurse midwives) who deliver services to health center patients on behalf of the health center. Providers 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/visit.

Grantees utilize a variety of mechanisms for provider staffing in order to maximize access to comprehensive, efficient, cost-effective, and quality health care. For instance, grantees may directly employ or contract with individual providers, may have arrangements with other organizations, or may utilize volunteers.¹¹ Grantees must ensure that for all contracted clinical staff or volunteers, there is a separate, written agreement.

C. "Service Site"

A service site is any location where a health center, either directly or through certain sub-recipients¹² or certain established arrangements,¹³ provides required primary health services and/or approved additional services to a defined service area or population. Service sites are defined as locations where all of the following conditions are met:

- health center encounters/visits are generated by documenting in the patients' record 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

⁹ To be eligible for payment at the FQHC rate, the service must also be covered as an ambulatory service in the state's Medicaid plan.

¹⁰ Inclusion in the Federal scope of project is necessary but not sufficient to qualify for these programs. For example, medical malpractice coverage under the FTCA also requires HRSA's approval of a health center's FTCA deeming application. As another example, a health center's Federal scope of project may include a service that is not covered as an "FQHC service" under the relevant State's Medicaid plan, consequently, that service would be reimbursed at a fee-for-service rate rather than a per visit rate.

¹¹ Note that volunteer providers are not covered under the FTCA for activities at the health center.

¹² For purposes of Medicaid and Medicare FQHC reimbursement, a sub-recipient is an organization that: (1) receives funding from a section 330 grant through a contract with the grantee and (2) is compliant with all of the requirements of section 330 of the PHS Act (see §1861(aa)(4) and §1905(l)(2)(B) of the Social Security Act). Requirements surrounding FTCA coverage and FQHC reimbursement rates set forth in past policy, statute, and regulations continue to apply to sub-recipients and sub-grantees.

¹³ The term "established arrangement" means an arrangement where a service is provided through a formal written contract or cooperative arrangement (see section 330(a)(1) of the PHS Act).

- services are provided on a regularly scheduled basis (e.g., daily, weekly, first Thursday of every month).¹⁴ However, there is no minimum number of hours per week that services must be available at an individual site/location.

Administrative offices or locations that do not provide direct health care services are not service sites.

D. Primary Health Care Services

Health services related to family medicine, internal medicine, pediatrics, obstetrics and gynecology, preventive dental care, and mental health/substance abuse treatment are considered by HRSA to be “primary health care services” and are included among the health services that health centers are required to provide directly or through contracts or established arrangements under section 330. Services provided by primary health care clinicians as part of their ordinary scope of practice are *not* considered “specialty services.” This PIN addresses change in scope requests to add services other than services generally provided under these primary health care categories.

E. “Specialty Services”

HRSA considers specialty services to be within the broad category of “additional” health services, defined in section 330 as services that are not included as required primary health care services and that are (1) necessary for the adequate support of primary health services and (2) appropriate to meet the health needs of the population served by the health center.¹⁵ In most cases, HRSA will consider diagnostic/screening procedures, as well as some treatment procedures, to be within the scope of the health center’s section 330 project as “additional” health services. For example, where the health center serves a population with a high prevalence of diabetes, endocrinology, podiatry, and optometry/ophthalmology services could be considered both “supportive” of primary health services for the diabetic health center patients as well as appropriate to meet the health center population’s needs. (See additional discussion below, in section VI.A and VI. B. of this PIN.)

F. “Specialists”

For purposes of this PIN, a specialist is considered to be an appropriately licensed and credentialed health care provider (see section VI.E. of this PIN) who has been granted appropriate specialty-specific privileges by the health center. The full range of services within a specialist’s area of expertise may or may not be within the Federal scope of project.

¹⁴ 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 health centers “must be operated in a manner calculated ... to maximize acceptability and effective utilization of services.”

¹⁵ PHS Act section 330(a)(1)(B) and section 330(b)(2).

V. GENERAL REQUIREMENTS FOR REQUESTING A CHANGE IN SCOPE OF PROJECT

Health centers must obtain prior approval for significant changes in the approved Federal scope of project.¹⁶ Adding a service not currently included in Form 5 – Part A (“Services Provided”) is considered a significant change and, therefore, requires prior approval.¹⁷ Prior approval is also required if a grantee is providing a service via an informal referral arrangement and wants to provide the service directly or by formal agreement.

Once a service is included in the approved Federal scope of project, it must be offered on a sliding fee scale and be available equally to all patients regardless of ability to pay. Health centers, therefore, must thoroughly investigate the costs, benefits, and risks (e.g., financial risks) of adding any new service (including specialty services) to the scope of project. Additional costs may include, for example, salaries, bad debt, equipment and training-related costs. In general, a health center must demonstrate that it is equipped in terms of technology, finances, and personnel to provide the additional services and continue to demonstrate that all required primary health services will remain available to all patients before proposing to add additional health services.

VI. FACTORS THAT WILL BE CONSIDERED WHEN EVALUATING A REQUEST TO ADD SPECIALTY SERVICES TO THE SCOPE OF PROJECT

As stated above, services provided by primary care clinicians as part of their ordinary scope of practice are not considered specialty services; thus, this PIN is not directly applicable to requests to add such services to the Federal section 330 scope of project.

Although prior approval is still necessary, in general, the addition of services listed as examples of “additional health services” in section 330(b)(2) of the PHS Act will be considered appropriate for inclusion within the health center’s Federal scope of project. These services include: behavioral and mental health and substance abuse services;¹⁸ recuperative care services; environmental health services; and occupation-related health services for migratory and seasonal agricultural workers.

When reviewing a request to add specialty services to the Federal scope of project, HRSA will evaluate the request using the factors listed below. These factors were developed taking into consideration HRSA’s goal of supporting the extension of necessary health services to current health center patients in support of required primary health services while ensuring that health centers continue to (1) meet the current statutory, regulatory, and policy requirements of the Health Center Program and (2) comply with DIIHS grants regulations and policy.

¹⁶ See section 330 program regulations, 42 CFR Part 51c.107(c), and 45 CFR Part 74.25.

¹⁷ For additional requirements regarding changes in the Federal scope of project, please see Attachment A of this PIN, which lists the approval criteria for prior approval of a Federal change in scope request, as well as HRSA PIN 2008-01, “Defining Scope of Project and Policy for Requesting Changes.”

¹⁸ Section 330(h) Health Care for the Homeless grantees are required to provide substance abuse services. (Section 330(h)(2) of the PHS Act.)

A. Necessary for the Adequate Support of Primary Care

Section 330 authorizes the provision of “additional” health services “as may be appropriate for particular centers” when those services are “necessary for the adequate support of the [required] primary health services.”¹⁹ Therefore, when requesting a change in scope to add a specialty service to the Federal scope of project, a health center must demonstrate how the new service will support the provision of the required primary care services provided by the health center. In other words, the health center must show that the proposed services function as a logical extension of the required primary care services already provided by the health center and/or that the proposed services complement the required primary health care services. Examples of services that may be a complementary extension of primary health care include:

- pulmonary consultations, and/or examinations, where the health center serves a substantial number of patients with asthma, COPD, Black Lung, or tuberculosis;
- cardiology screenings and diagnoses, where the health center serves a substantial number of patients at risk for heart disease or high blood pressure;
- minor podiatry outpatient procedures or examinations, where the health center serves a population with a high prevalence of diabetes;
- psychiatric consultations, examinations and differential diagnoses, where the health center serves a substantial number of patients with mental health and/or substance abuse diagnoses;
- periodontic services, where the health center serves a significant population of children with poor oral health;
- colonoscopies; and
- appropriate oncological care of health center patients with cancer.

B. Demonstrated Need for the Proposed Specialty Service

Section 330 authorizes the provision of non-required “additional” health services when appropriate to meet the needs of the target population. Therefore, when requesting a change in scope to add a specialty service to the Federal scope of project, a health center must demonstrate and document the target population’s need for the proposed service. Unmet need should be described both in narrative format and with data.

In addition, when proposing the addition of a specialty service, the health center must demonstrate its ability to maintain the level and quality of the required primary health services currently provided to the target population (see section V above).

C. Funding/Budget/Financial Risk

Any requested change in the Federal scope of project must be fully accomplished with no additional section 330 grant support. In assessing the financial impact of adding a service, a health center should consider whether the service will be considered a “FQHC service” and, therefore, be eligible for enhanced FQHC Medicaid/Medicare reimbursement. In general, the site or service to be added must be able to generate

¹⁹ PHS Act Section 330(a)(1)(B).

adequate revenue to cover all expenses, including overhead costs incurred by the health center in managing the site or service. If additional Federal funds will be necessary to fully implement the change in Federal scope, the grantee should apply for competitive funding as appropriate, with the awareness that Federal grant dollars are limited. And, as stated above, the provision of any additional service must not compromise the provision of required primary health care services. In summary, when requesting a change in Federal scope to add a specialty service to the scope of project, a health center must demonstrate that adding the new service (1) will not jeopardize the health center's overall financial stability and (2) will be accomplished with no additional section 330 grant funds.

D. Location of the Service

In order to ensure that the proposed new service will be accessible to health center patients, and that the health center will be able to maintain appropriate control over service delivery, the service must be provided at an approved site (see definition above) within the Federal scope of project, at a new site that will be proximate to available FQHC services,²⁰ or at a location where in-scope services are provided but that does not meet the definition of a service site. Therefore, when requesting a change in the Federal scope of project to add a specialty service, a health center must (1) describe the specific location of the proposed service and (2) demonstrate that the service will be provided at an approved health center site, a proposed new site proximate to available FQHC services or at a location where in-scope services are provided but that does not meet the definition of a service site. In all cases, health centers must ensure that adequate and appropriate documentation has been secured to support and enable performance of the specialty services (e.g., translation and transportation services as needed).

If a specialty service is provided at a location that does not meet the definition of a service site, the health center must document the manner by which the referral will be made and managed and the process for facilitating appropriate follow-up care at the health center. Additionally, health centers must ensure services are provided in culturally and linguistically appropriate manner based on the target population(s). And finally, 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 according to 42 C.F.R. 51c.303(f). Specifically, the discounted fee schedule must provide a full discount to individuals and families with annual incomes at or below the poverty guidelines (only nominal fees that do not impede access to care may be charged) and for those with incomes between 100 percent and 200 percent of poverty, fees must be charged in accordance with a sliding discount policy based on family size and income. No discounts may be provided to patients with incomes over 200 percent of the Federal poverty level.²¹

²⁰ In the latter case, both the service and the site would need to be added to the scope of project.

²¹ Section 330(k)(3)(G) of the PHS Act and 42 CFR Part 51c.303(f).

E. Additional Considerations

1. State Licensing: Providers must be properly licensed, according to their State or territory's laws, to be included within the health center's Federal scope of project. Approval of a request to add providers of new services to the Federal scope of project is contingent upon the health center's demonstration that all providers associated with the new service meet the professional, State, and local qualifications necessary to provide that service.
2. Credentialing and Privileging: All providers must be properly credentialed and privileged to perform the activities and procedures expected of them by the health center. "Credentialing" is the process of assessing and confirming the qualifications of a licensed or certified health care practitioner. "Privileging" is the process of authorizing a licensed or certified health care practitioner's specific scope of patient care services. Privileging is performed in conjunction with an evaluation of an individual's clinical qualifications and/or performance. It is the responsibility of the health center to ensure that all credentialing and privileging of providers have been completed before including a service in the Federal scope of project. Therefore, a health center requesting the addition of a specialty service to the Federal scope of project must demonstrate that the credentialing and privileging requirements have been met.²²
3. Potential Staffing Arrangements/Corporate Structure: Health centers utilize a variety of mechanisms for provider staffing. For instance, health centers may directly employ or contract with providers and/or have arrangements with other organizations for clinical staffing of the health center. Health centers are encouraged to carefully consider the benefits and risks associated with various staffing arrangements because each impacts health center costs and operations differently. When evaluating change in Federal scope requests, HRSA will examine the proposed staffing arrangement as part of a review of the impact of the proposed change on the total organization (e.g., whether the arrangement necessitates an affiliation agreement). Therefore, health centers requesting the addition of a specialty service to the Federal section 330 scope of project must provide a clear and comprehensive description of the relevant staffing arrangements and describe any potential impact on the overall organization.

VII. FTCA COVERAGE

To ensure continuity of FTCA coverage, any specialty service added to the Federal scope of project must be described in the health center's next funding application (Service Area Competition or Budget Period Renewal). However, inclusion of a service within the Federal scope of project is, in and of itself, not enough to guarantee FTCA coverage. FTCA deeming requirements must also be met. For more information on policies and procedures related to FTCA deeming, please consult PAL 2008-05, "New Requirements for Deeming under the

²² See PIN 2002-22 (<http://bphe.hrsa.gov/policy/pin0222.htm>) for additional guidance on the credentialing and privileging of providers.

Federally Supported Health Centers Assistance Act for Calendar Year 2009” (<http://www.bphc.hrsa.gov/policy/pal0805.htm>) and the HRSA web site (<http://www.bphc.hrsa.gov/ftca>).

Also note that the definition of “provider” under the Federal scope of project may not be consistent with the definition of provider under the relevant statutory FTCA provisions. Individuals covered by the FTCA may include others, such as certain lab and radiology technicians, as described in section 224 of the PHS Act. Likewise, not all provider arrangements in the Federal scope of project are covered by the FTCA. For example, volunteer providers, physicians contracted under a professional corporation or employed by other corporations, and interns/residents/medical students not employed by the health center may be included as part of the Federal scope of project, but are not covered under the FTCA. **In circumstances where the provider arrangement does not meet the criteria for FTCA coverage, health centers should ensure that the provider has sufficient alternative malpractice insurance.**

VIII. EFFECTIVE DATE

Once this policy becomes effective, some health centers may determine that certain services do not meet the PIN’s criteria for inclusion within the Federal scope of project. HRSA will provide all grantees with an opportunity to modify and/or update their scope of project information to ensure that every grantee’s scope of project is consistent with the updated policies. If there are any discrepancies, HRSA will work with grantees to resolve the issues.

IX. CONTACTS

If you have any questions or require further guidance on the policies detailed in this PIN, please contact the Bureau of Primary Health Care, Office of Policy and Program Development at 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.

ATTACHMENT A**Overview -- Criteria for Prior Approval of a Change in Federal Scope Request**

All requests for change in Federal scope of project requiring prior approval will be reviewed by HRSA to determine if the request complies with the following criteria:

- 1) meets the "no additional section 330 funding" requirement;
- 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 current target population;
- 4) is fully consistent with section 330 of the PHS Act, applicable regulations and policies, 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) or Medically Underserved Population (MUP). Please note that the 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 regarding the change of scope and documentation of this approval 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, as demonstrated by a Board of Directors-endorsed letter of support from neighboring health centers or an explanation why such a letter(s) cannot be obtained.

Requests for a change in Federal scope of project to add specialty services must meet all of the following additional requirements:

- 1) demonstrates, in narrative format and with data, that there is current unmet need in the target population for the proposed new service;
- 2) demonstrates that the proposed new service is necessary for the adequate support of primary health care to the target population (i.e., demonstrates that the proposed services function as a logical extension of the required primary health care services already provided by the health center and/or that the proposed services complement the required primary health care services);
- 3) demonstrates that adding the new service will not jeopardize the health center's overall financial stability and will be accomplished with no additional grant funds; and
- 4) describes the location of the proposed new service, and demonstrates that the services will be provided at an approved site within the scope of project, a proposed new site proximate to available FQHC services, or at a location where in-scope services are provided but that does not meet the definition of a service site.