Health Center Program
Scope of Project Policy Manual
Draft for Comment

HRSA seeks public comment to its draft Health Center Program Scope of Project Policy Manual ("Scope Policy Manual"). We must receive your comments by February 10, 2025.

To submit comments, visit the BPHC Contact Form.

Under *Policy*, select:

1. *Comment on draft policy*
2. *Draft Scope Policy Manual*

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Introduction

In this chapter:

A. Background and Applicability

The Health Center Program is authorized by section 330 of the Public Health Service Act ("PHS Act"), 42 U.S.C. § 254b ("section 330"). Under this authority, the Health Resources and Services Administration (HRSA) provides federal award funding to entities for the purposes of delivering statutorily defined required primary health services and additional health services to medically underserved populations and provides designation as "look-alikes" to entities that HRSA determines meet the requirements of section 330 but do not receive grant funding under section 330.

The policy set forth in this Health Center Program Scope of Project Policy Manual ("Scope Policy Manual") applies to all entities that receive funds under the Health Center Program authorized by section 330 (including sections 330(e), (g), (h), and (i)). It also applies to Health Center Program look-alikes and any subrecipient of section 330 funding.[1, 2] HRSA refers to all of these entities collectively as "health centers."

Health centers are community-based and patient-directed organizations that deliver comprehensive, culturally competent, high-quality primary health care services to the nation's individuals and families living in underserved communities, including people experiencing homelessness, agricultural workers, and residents of public housing.

B. Purpose

The purpose of the Scope Policy Manual is to provide updated policy guidance as to what constitutes the Health Center Program scope of project under section 330 of the PHS Act (42 U.S.C. § 254b) ("section 330").

In this Scope Policy Manual, HRSA has updated the Health Center Program scope of project

[1] Following receipt of federal Health Center Program funding or designation, new award recipients or designees must comply with the requirements specified in the Scope Policy Manual. Notices of Funding Opportunity (NOFOs) and other applications may include specified timelines to demonstrate this compliance.

[2] A subrecipient is an organization that complies with section 330 requirements and receives a subaward from a Health Center Program award recipient. Refer to Chapter 3, Section C.2. Contracts including Subawards (Form 5A, Column II). It may be considered a "federally qualified health center," as defined in sections 1861(aa)(4)(B) and 1905(l)(2)(B)(iii) of the Social Security Act (42 U.S.C. 1395x(aa)(4)(B) and 42 U.S.C. 1396d(l)(2)(B)(iii)).

policy to:

- Consolidate scope of project-related policy into a single policy document to assist health centers in understanding scope of project;
- Align with the Health Center Program Compliance Manual;
- Integrate telehealth policy;
- Revise the descriptions of service delivery methods to better align with statutory language;
- Replace the term "target population" with the statutory terms "medically underserved population" and "special medically underserved population," as appropriate, and use the term "patient population" to refer to patients served by the health center;
- Define new criteria for health centers adding temporary service sites in response to emergency events;
- Clarify the circumstances under which health centers may provide services to patients at locations other than health center service sites within the scope of project;
- Define criteria for health centers adding service sites to their scope of project that are co-located with non-health center entities;
- Require that a health center requesting to add a contractor-operated or subrecipient-operated site must first operate 50 percent of the sites in their scope of project directly;
- Describe the circumstances under which a health center may establish a health center patient-provider relationship within its scope of project; and
- Remove scope of project process-related instructions from this policy, which will continue to remain available on HRSA's website at Scope of Project.

The Scope Policy Manual supersedes the following scope of project Policy Information Notices (PIN):

- **PIN 2007-09**: Service Area Overlap: Policy and Process
- **PIN 2008-01**: Defining Scope of Project and Policy for Requesting Changes
- **PIN 2009-02**: Specialty Services and Health Centers' Scope of Project
- **PIN 2009-05**: Policy for Special Populations-Only Grantees Requesting a Change in Scope to Add a New Target Population

In case of any conflict between provisions of the Scope Policy Manual and any previous Health Center Program policy guidance related to scope of project that remains in effect after the effective date of this policy, or any conflict between provisions of this Scope Policy Manual and any portion of a health center's application, the Scope Policy Manual controls.

Additional technical assistance resources are available on Scope of Project.

C. Health Center Responsibilities

The health center named as the Health Center Program award recipient or look-alike designee on the Notice of Award (NOA) or the Notice of Look-Alike Designation (NLD) is

responsible for ensuring that it conducts all health center activities within its HRSA-approved scope of project in accordance with Health Center Program requirements as set forth in statute and implementing regulations the terms and conditions of Health Center Program funding or designation, and in compliance with all other applicable federal laws, regulations, and policies.[3, 4] Health centers are also responsible for ensuring that services delivered by third parties within the Health Center Program scope of project, also comply with applicable requirements. Health Center Program requirements apply to all aspects of scope of project addressed in this document.

Health centers must also document and maintain an accurate scope of project on all appropriate forms in EHBs, including requesting any needed approvals from HRSA for scope of project changes.[5]

[3] For more information, refer to the Health Center Program Compliance Manual: Introduction.
[4] Health centers must abide by the HHS Office of Civil Rights Guidance that requires health centers "*to serve people most in need and to comply with federal law, services must be widely accessible. Services must not discriminate on the basis of age, disability, sex, race, color, national origin, or religion."* Therefore, health centers must ensure their sites and services accommodate individuals with disabilities including providing adequate access to these sites and services. Refer to Americans with Disabilities Act of 1990, Section 504 of the Rehabilitation Act of 1973, and Section 1557 of the Affordable Care Act.
[5] Only the health center named on the NOA or NLD can request a change in its HRSA-approved scope of project.

Chapter 1: Definition of Scope of Project and Overview

In this chapter:

A. Definition of Scope of Project

For the purposes of the Health Center Program, HRSA defines scope of project as the HRSA-approved activities carried out on behalf of a health center,[6] whether directly, by contracts (including subawards to subrecipients of section 330 funding),[7] or by cooperative arrangements. Such projects may be supported by Health Center Program award funds and other sources of revenue (non-grant funds), as documented in the health center's HRSA-approved annual project budget.[8]

A health center's scope of project consists of the following core elements:

- Medically underserved population(s) and/or special medically underserved population(s) served by the health center;
- Service area;
- Services;
- Sites; and
- Providers.

All activities within the HRSA-approved scope of project are subject to Health Center Program requirements and laws, regulations, and policies incorporated as part of the Health Center Program grant award or designation.[9]

HRSA approves a health center's initial scope of project through the health center's first approved Health Center Program application (for example, New Access Point or Look-Alike Initial Designation application). After receiving an initial Health Center Program award or

[6] Refer to Chapter 1: C. General Criteria for Including Activities within the HRSA-Approved Scope of Project.
[7] Refer to Chapter 3: Required Primary and Additional Health Services: C.2. Contracts Including Subawards (Form 5A, Column II).
[8] Scope of project also encompasses certain activities necessary to support the health center's delivery of health services within its scope of project, such as the procurement and maintenance of a health center's confidential electronic health record system and contracting for services and items to support health center operations.
[9] For more information, refer to the Health Center Program Compliance Manual.

designation establishing the scope of project, for any subsequent changes or updates, a health center must request prior approval from HRSA for a "change in the scope or the objective of the project or program (even if there is no associated budget revision requiring prior written approval)."[10] For more information on what changes to the scope of project require prior approval, refer to Chapter 10: Changes in Scope of Project.

HRSA monitors compliance and supports health centers in complying with Health Center Program requirements and in maintaining an accurate scope of project. If HRSA identifies non-compliance, HRSA may address this through legally available actions, with notice to the health center. This includes action to correct or modify a health center's HRSA-approved scope of project, requiring repayment of federal funds if resources are not used for authorized purposes or consistent with the approved scope of project, and withholding future funding. This includes cases where:

- Sites, services, or other activities are found to be inconsistent with scope of project policy;
- There is non-compliance with Health Center Program requirements or other applicable laws or requirements;
- There are patient safety concerns; or
- Immediate enforcement action by HRSA is otherwise needed.[11]

B. Governing Board Role and Authorities Related to Scope of Project

A health center's governing board required authorities[12] include determining the health center's scope of project, both for the initial application and for any changes, subject to HRSA review and approval. The governing board must approve the health center's:

- Sites;
- Hours of operation;
- Services;
- Service delivery methods;
- Decision(s) to subaward grant funds or contract to carry out a substantial portion of the health center's scope of project. This includes decisions to subaward or contract for the operation of sites and the delivery of services;
- Total budget for the scope of project; and
- Proposed changes to the scope of project (such as population served, service sites, services, service area). The governing board ensures that all changes to the scope of project are informed by and responsive to the health needs of the current patient population or of the broader medically underserved population served by the health center.

[10] 45 CFR 75.308(c)(1)(i).
[11] 45 CFR 75.371.
[12] For more information, refer to the Health Center Program Compliance Manual, Chapter 19: Board Authority.

C. General Criteria for Including Activities within the HRSA-Approved Scope of Project

A health center's HRSA-approved scope of project must be consistent with the purposes of the Health Center Program and meet all applicable Health Center Program requirements.

HRSA's approval of a health center's scope of project is dependent on a demonstration by the health center that the services delivered, sites operated, and activities conducted occur **on behalf of the health center**. Criteria for demonstrating that activities occur "on behalf of" the health center include all of the following:

a. The health center's governing board approves the site or service;
b. The health center provides services under the authority and direction of the health center's governing board and in accordance with the health center's policies and procedures;
c. The sites, services and activities benefit the health center's patient population, which must include a medically underserved population or special medically underserved population within the health center's service area;
d. Health center employees, individual contractors, and volunteers deliver in-scope services at the service site or other location at which health center services may be provided;
e. If the health center provides services to its patients through subawards, contracts or cooperative arrangements with other organizations, the health center's governing board approves such subawards, contracts, or cooperative arrangements (refer to Chapter 3, Section C.2 Contracts including Subawards (Form 5A, Column II) and Chapter 3, Section C.3 Cooperative Arrangements (Form 5A, Column III) for the requirements for services delivered via contract or cooperative arrangement);
f. The health center uses grant or non-grant funds from its Health Center Program annual budget[13] to provide services and, when applicable, the health center bills for these services and applies discounts consistent with its sliding fee discount program; and
g. The health center establishes and maintains health records for all individuals served.

Where the relevant facts as a whole (including any contracts or applicable billing and medical records) indicate that the provider, contractor or other third-party is acting on behalf of another entity or themselves and not on behalf of the health center, HRSA will not consider the service, site, or activity to be within the approved scope of project.

Situations where a health center collaborates with other community organizations to provide services that benefit populations served by the health center, including where the health center provides services for individuals who are not established health center patients, are also subject

[13] For more information, refer to the Health Center Program Compliance Manual, Chapter 17: Budget.

to the "on behalf of" criteria.[14] For example, a health center that provides immunizations to non-established patients at a community health fair would still have to demonstrate that this collaborative activity is conducted on behalf of the health center.

The Scope Policy Manual includes criteria for HRSA to approve certain changes to a health center's scope of project (for example, adding service sites and services). HRSA will specify information needed to support such change in scope requests.

D. Limitations on Health Center Program Scope of Project and Other Lines of Business

A health center's HRSA-approved scope of project is limited to those services, sites, and activities that are operated or conducted on behalf of the health center, are in compliance with the requirements of the Health Center Program and are consistent with the purposes of the Health Center Program as defined in statute and regulations. Health Center Program award funds and other sources of revenue in a health center's HRSA-approved annual project budget must be used only for activities within the health center's HRSA-approved scope of project.

HRSA considers activities that are not consistent with the purposes of the Health Center Program (for example, when a health center operates a thrift store) or that a health center performs on behalf of another entity (for example, contracting to manage or staff an employer-operated health clinic or a hospital department) to be other lines of business outside of the health center's scope of project.

Other lines of business are outside the HRSA-approved scope of project and therefore are not eligible for Health Center Program funding or any Health Center Program-related federal program benefits. Refer to Section E. Eligibility for Other Federal Programs and Associated Benefits.

A health center must exclude the costs of other lines of business from its annual budget (also referred to as "total budget") for the health center project. In addition, a health center must not use Health Center Program award funds to support other lines of business or program income/non-grant funds to support other lines of business that do not further the objectives of the Health Center Program project. However, a health center may use revenue generated from other lines of business to support the health center scope of project.

[14] For FTCA coverage to apply to such activities, other requirements under FSHCAA must also be met. For additional information, refer to the Health Center FTCA Program regulations at 42 CFR part 6 and the FTCA Health Center Policy Manual (PDF).

E. Eligibility for Other Federal Programs and Associated Benefits

Health centers may be eligible for other federal programs with associated benefits that are linked to receiving Health Center Program funding or designation. These programs include but are not limited to:

- FQHC status, including payment rates, under Titles XVIII (Medicare) and XIX (Medicaid) of the Social Security Act;[15]
- The 340B Drug Pricing Program;[16]
- The National Health Service Corps Program; and
- The Health Center FTCA Program[17] under FSHCAA.[18]

These other federal programs are administered separately from the Health Center Program and have distinct statutory and regulatory eligibility, enrollment, and application requirements. These benefits are not guaranteed solely by the inclusion of services, sites, and activities in a health center's HRSA-approved Health Center Program scope of project.

[15] Refer to 42 U.S.C. 1396a(a)(15) and 42 U.S.C. 1396(a)(bb); and 42 U.S.C. 1395l(a)(1)(Z) and 42 U.S.C. 1395m(o).
[16] Refer to section 340B of the PHS Act (PDF), as amended (42 U.S.C. 256b).
[17] Refer to section 224(g)-(n) and (q) of the PHS Act (42 U.S.C. 233(g)-(n), and (q)).
[18] Please note that "scope of project" and "scope of employment" for purposes of FTCA coverage are not synonymous. For additional information, refer to the Health Center FTCA Program regulations at 42 CFR part 6. For important information relating to FTCA coverage, refer to the FTCA Health Center Policy Manual (PDF).

Chapter 2: Medically Underserved Populations, Special Medically Underserved Populations, and Service Area

In this chapter:

A. Medically Underserved Populations and Special-Medically Underserved Populations

A health center must serve a designated medically underserved population[19] or one or more of the following special medically underserved population(s):[20] migratory and seasonal agricultural workers, individuals experiencing homelessness, or residents of public housing.

B. Service Area

An initial Health Center Program application must define the boundaries of the catchment area to be served [service area] by the health center, including the identification of one or more medically underserved populations within the catchment area.[21] After initial approval, a health center may request future modifications to the service area, subject to applicable program requirements and review and approval by HRSA. A health center's service area includes, at a minimum, those ZIP Code Tabulation Areas (ZCTAs) where at least 75 percent of current health center patients reside, based on patient origin data submitted by the health center through HRSA's Health Center

[19] The term "medically underserved population" means the population of an urban or rural area designated by the Secretary as having a shortage of personal health services ("medically underserved area") or a population group designated by the Secretary as having a shortage of such services. Refer to Section 330(b)(3)(A) of the PHS Act.

[20] The following are special medically underserved populations identified in section 330 for which funding or designation under section 330 may be made available to deliver targeted health services: migratory and seasonal agricultural workers, individuals experiencing homelessness, and residents of public housing. Refer to sections 330(g), (h), or (i) of the PHS Act.

[21] The health center must define and annually review the boundaries of the catchment area to be served [service area], including the identification of the medically underserved population or populations within the catchment area to ensure that the:

a. Size of this area is such that the services to be provided through the health center (including any satellite service sites) are available and accessible to the residents of the area promptly and as appropriate;
b. Boundaries of such area conform, to the extent practicable, to relevant boundaries of political subdivisions, school districts, and areas served by federal and state health and social service programs; and
c. Boundaries of such area eliminate, to the extent possible, barriers resulting from the area's physical characteristics, its residential patterns, its economic and social groupings, and available transportation.

Program Uniform Data System.[22]

A health center must annually review and either re-validate or request any applicable updates to its service area, based on its assessment of where current or proposed patient populations reside, as documented by the ZCTAs reported on the health center's Form 5B: Sites (Form 5B).[23] A health center may also consider additional geographic or demographic characteristics when identifying its service area such as:

- Neighborhood characteristics including available transportation;
- Aspects of the built environment; or
- The residential patterns of specific underserved service area populations such as children, persons living with HIV/AIDS, or LGBTQ+ individuals.

A health center funded or designated by HRSA to provide services under section 330(e) must provide services to all residents of its defined service area. A health center must prioritize its available resources for its service area population. A health center may choose, but is not required, to extend services to individuals who reside outside its defined service area. However, a health center should address the acute needs of all individuals who present in-person at the health center for care, regardless of their residence. All services must be provided without regard to an individual's ability to pay.

A health center funded or designated only under section 330(g), (h), or (i) of the PHS Act ("special populations-only health center") must provide services to the statutorily-defined special medically underserved population(s) for which it is funded/designated within the health center's defined service area. A health center must prioritize its available resources for its special medically underserved population within the service area. A health center may choose to provide services to a limited number of patients that are not part of the defined statutory population(s) (refer to Chapter 10, Section C. Special Medically Underserved Population-Only Health Centers Adding a New Statutory Population). However, a health center should address the acute care needs of all individuals who present in-person at the health center for care, regardless of residence or special population status. All services must be provided without regard to an individual's ability to pay.

A health center must request approval from HRSA to add a new service site, regardless of whether the proposed site is within or outside the health center's current service area (refer to Chapter 5: Sites and Chapter 10: Changes in Scope of Project).

[22] HRSA may include additional service area requirements in HRSA NOFOs and applications.

[23] For more information, refer to the Health Center Program Compliance Manual, Chapter 3: Needs Assessment and 42 CFR 51c.104(b)(2).

Chapter 3: Required Primary and Additional Health Services

In this chapter:

A. Services Within the Scope of Project

A health center must provide all required primary health services and may provide additional health services that are necessary for the adequate support of required primary health services, as appropriate to meet the health needs of the population served by the health center.[24] A health center may provide required primary and additional health services through the staff and supporting resources of the health center ("directly") or through contracts (including subawards of section 330 funding) or cooperative arrangements.[25] Collectively, HRSA refers to these means of providing services as "service delivery methods" (refer to Chapter 3, Section C. Service Delivery Methods).

Health centers are responsible for making all in-scope services available in accordance with applicable Health Center Program requirements.[26] This includes ensuring that the health center has policies and procedures in place or that contracts and cooperative arrangements include provisions to address the following Health Center Program requirements:

- Quality improvement/assurance;
- Provider credentialing and privileging;
- Sliding fee discount program; and
- Access for patients with limited English proficiency.[27]

A health center records required primary and additional health services, subject to HRSA review and approval, on Form 5A: Services Provided (Form 5A).[28] HRSA considers only those services and service delivery methods (described in Section C. Service Delivery Methods) listed on a health center's Form 5A and approved by HRSA to be within the health center's scope of project. Health centers record such services on Form 5A at an organizational level and not for

[24] Refer to Section 330(b)(1) of the PHS Act (42 U.S.C. 254b(b)(1)), and 42 CFR 51c.102(h) for information on Required Primary Health Services and Section 330(b)(2) of the PHS Act (42 U.S.C. 254b(b)(2)) and 42 CFR 51c.102(j) for information on Additional (Supplemental) Services.
[25] Refer to Section 330(a)(1) of the PHS Act (42 U.S.C. 254b(a)(1)).
[26] Refer to the Health Center Program Compliance Manual.
[27] Refer to Section 330(k)(3)(K).
[28] For more information on accurately completing Form 5A, refer to Scope of Project Resources, including the Form 5A Service Descriptors (PDF) and Form 5A Column Descriptors (PDF) resources.

each individual site. A health center is not required to make all services available at every service site; rather, a health center must ensure that health center patients have access to all HRSA-approved, in-scope services offered by the health center organization, either by providing the services directly or by contracts (including subawards) or cooperative arrangements. This includes providing services that enable individuals to use the services of the health center, such as addressing relevant patient transportation needs.

Health centers must submit Form 5A as part of the initial Health Center Program application (for example, New Access Point or Look-Alike Initial Designation application). Health centers may request to add or delete services and change service delivery methods on Form 5A through HRSA's change in scope process or in response to subsequent funding opportunities, subject to HRSA review and approval.

B. Criteria Required for In-Scope Services

A health center must demonstrate that a service meets all of the following criteria to receive HRSA approval for inclusion of the service within the Health Center Program scope of project:

a. The service is a required primary health service or is an additional health service necessary for adequate support of one or more required primary health services, as appropriate to meet the health needs of the patient population, as defined by Section 330(b) of the PHS Act;
b. The health center provides the service, either directly or by contract (including a subaward) or cooperative arrangement, on behalf of the health center;
c. The health center ensures that its patient population is able to access all services offered by the health center (refer to Chapter 5, Section C. Service Sites with Limited Services); and
d. The health center's governing board has approved the service.

C. Service Delivery Methods

Health centers may use one or more of the service delivery methods described in this section to meet the Health Center Program requirement to provide required primary or additional health services for health center patients within the scope of the health center project. While health centers have flexibility to provide required primary and additional health services through different methods, HRSA encourages health centers to provide services directly where feasible to reduce barriers to accessible, patient-centered care. If a health center chooses to contract (including through a subaward) or use cooperative arrangements to provide health center services, consideration should be given to how the service delivery method increases access to care and reduces patient wait times. Health centers record the methods by which services are delivered on Form 5A. For more details about service delivery methods and Form 5A, refer to the Form 5A Column Descriptors (PDF) on Scope of Project.

Although not a service delivery method as described in this section, health centers may also have an informal arrangement to refer patients to another provider for health services. The act of referring a health center patient to another provider (the referral provider) for a service is within the scope of the Health Center Program project.[29] However, the service delivered to the patient by the referral provider is not an in-scope heath center service because the service is not delivered on behalf of the health center. Therefore, services delivered by referral providers are not documented on the health center's Form 5A.

C.1. Direct (Form 5A, Column I)

Direct services, for purposes of scope of project, are provided by health center staff who are employees[30] or volunteers[31] of the health center. Health centers record services they provide directly on Form 5A, in Column I. A health center must ensure that all employees and volunteers who provide services on behalf of the health center are credentialed and privileged to provide such services and follow the health center's policies and procedures.

C.2. Contracts including Subawards (Form 5A, Column II)

A contract,[32] for purposes of scope of project, is a formal written agreement between the health center and another entity through which the health center offers one or more required primary or additional health services for its patients by purchasing the services provided from the other entity.[33] Contracted services are provided to the health center's patients by the other entity pursuant to the contract and on behalf of the health center. A health center records these services provided to its patients on Form 5A, in Column II. Contracted services include services delivered by:

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[29] Refer to Section 330(b)(1)(A)(ii) of the PHS Act (42 U.S.C. 254b(b)(1)(A)(ii)).

[30] For Form 5A: Column I, to demonstrate employee status, the individual will, in most circumstances, receive a salary (with applicable taxes and benefits deducted) from the health center on a regular basis. This is generally documented by a Form W-2 that identifies the health center as the employer and an associated employment contract with the health center.

[31] Volunteers are only eligible for FTCA coverage through the Health Center Volunteer Health Professionals (VHP) Program, which requires that a deemed health center apply for protections for each individual licensed or certified volunteer health professional through a VHP deeming sponsorship application. A health center that uses volunteers who are not eligible to be deemed through the VHP Program or that provides health services that are not eligible for liability protections through the VHP Program need to obtain private malpractice liability insurance applicable to those actions. More information on the requirements for the Health Center VHP Program, including the current VHP Deeming Sponsorship Application Instructions, are available on Federal Tort Claims Act (FTCA).

[32] HRSA recognizes that there may be other definitions of contracts and subawards; however, for the purposes of the Health Center Program scope of project, health centers would use the definitions in this Manual for accurate documentation. The HHS grants regulations in 45 CFR Part 75 define a contract as a legal instrument by which a non-Federal entity purchases property or services needed to carry out the project or program under a Federal award. When a health center purchases required primary and additional health services to carry out its scope of project, the health center would record this in Form 5A: Column II.

[33] Refer to the Health Center Program Compliance Manual, Chapter 12: Contracts and Subawards for more information on procurement requirements.

- an individual provider with whom the health center has a contract;
- a group practice with which the health center has a contract;
- a locum tenens or staffing agency with which the health center has a contract;
- another entity with which the health center has a contract to provide services (for example, a laboratory services company).

For the purposes of the Scope Policy Manual, a "subrecipient" receives section 330 award funding under a subaward contract from a Health Center Program award recipient and demonstrates compliance with all of the requirements of section 330—including providing all required primary health services—in accordance with Sections 1861(aa)(4)(A)(ii) and 1905(l)(2)(B)(ii) of the Social Security Act.

A recipient-subrecipient relationship is distinct from the relationship that is formed based on a contract between a health center and a contractor, as described above. A subrecipient that meets this description may be eligible, subject to review and approval by the Department of Health and Human Services (HHS), to receive FQHC Medicare and Medicaid reimbursement for FQHC services provided at service sites operated by the subrecipient and may also be eligible to participate in the 340B Drug Pricing Program. A subrecipient of Health Center Program award funding that provides a full range of health care services on behalf of an eligible Health Center Program award recipient also may be eligible to be deemed as a Public Health Service employee for purposes of FTCA coverage under FSCHAA, but only for those services carried out under the section 330 grant-funded project.[34] A contractor that is not a subrecipient that complies with section 330 requirements is generally ineligible to receive such associated federal benefits.

Therefore, while a health center may provide services within its scope of project by contract with another entity, providing in-scope services through such a third-party contract does not automatically make the third-party entity a "health center" within the meaning of the Scope Policy Manual.

A health center must ensure that each of its contracts (including subawards) for in-scope services is current, executed by all parties (for example, a signed paper copy, electronically-signed documents, emails documenting acceptance), and addresses and includes, at a minimum:

a. The specific services to be performed by the contractor;
b. How health center patients will access services provided by the contractor;
c. How patient medical records or documentation of services provided will be maintained; and shared, consistent with applicable laws with the health center—specifically, the process for the contractor to provide information related to the services provided by the contractor, such as follow-up instructions or laboratory, radiology, or other results;

[34] For more information regarding the availability of liability protections, including FTCA coverage, under FSHCAA, refer to 42 U.S.C. 233(g)-(n), 42 CFR 6.3(b), and the FTCA Health Center Policy Manual (PDF).

d. How provider credentialing and privileging will be accomplished;
e. How the health center will pay or provide funding to the contractor for services the contractor delivers on behalf of the health center;
f. If the contractor bills and collects for services, the billing and collections process, including the requirement that the health center review and approve the contractor's compliant sliding fee discount schedule;
g. The applicability of federal and state laws including those related to patient privacy, HHS grant regulations, and civil rights;
h. Compliance with any other applicable requirements of the health center's federal award; and
i. Any additional applicable requirements, including those identified in Chapter 12: Contracts and Subawards of the Health Center Program Compliance Manual.

Health centers that deliver services through contracts, including subawards, must ensure that all services are made available in accordance with applicable Health Center Program statutory and regulatory requirements, including the application of sliding fee discounts and additional requirements associated with enabling access to health services for those with limited English proficiency and addressing patient transportation needs.

C.3. Cooperative Arrangements (Form 5A, Column III)

A cooperative arrangement, for purposes of scope of project, is a formal written arrangement between a health center and another entity that (1) does not involve the purchase of services by the health center through a contract or subaward and that (2) includes provisions (identified in C.3.1 Provisions in Cooperative Arrangements) that ensure that the services provided by the other entity to patients meet applicable Health Center Program requirements.

While HRSA prefers health centers provide services directly, HRSA recognizes that in limited situations, health centers may choose to use cooperative arrangements to provide services. These situations may include when a health center is unable to meet the demand for services itself or when a cooperative arrangement with a community-based provider is a more efficient and effective means of delivering a service. In cooperative arrangements, the health center collaborates with another entity that provides services identified in the arrangement to health center patients.

The health center maintains responsibility for oversight of the cooperative arrangement. The health center also maintains responsibility for the patient's treatment plan and any follow-up care, based on the care and follow-up instructions provided by the other entity. A health center records services provided through a cooperative arrangement on Form 5A, in Column III. Services provided through cooperative arrangements include services delivered by:

- an individual provider with whom the health center has a cooperative arrangement;
- a group practice with which the health center has a cooperative arrangement;

- another entity with which the health center has a cooperative arrangement to provide services).

When a health center establishes a cooperative arrangement with another entity to provide access to one or more required primary or additional health services for its patients (recorded on Form 5A, Column III), HRSA does not consider the required primary or additional health services provided through the cooperative arrangement to be in the scope of project of the health center establishing the cooperative arrangement. HRSA only considers the activities carried out by the health center establishing the cooperative arrangement to be in their scope of project. For example, a health center might use a cooperative arrangement to provide access to laboratory services. In this arrangement, the health center would assist the patient in making an appointment for the laboratory service and would ensure that it receives all follow up results and coordinates ongoing care for the patient as needed.

In cases where the other entity in a cooperative arrangement is itself also a health center, that other entity may appropriately record services provided under the cooperative arrangement on its own Form 5A, in Column I. In these instances, HRSA would consider an individual receiving services from the other entity to be an established patient of the other entity, as long as the requirements in Chapter 8, Section B. Patients and Visits are met.

C.3.1. Provisions in Cooperative Arrangements

A health center must ensure that each of its cooperative arrangements for services is current, executed by all parties (for example, a signed paper copy, electronically-signed documents, emails documenting acceptance, or a memorandum of agreement signed by both parties), and address, at a minimum, the following provisions:

a. The specific activity(ies) or services to be performed by the other entity;
b. How the other entity will apply a sliding fee discount to its schedule of charges for services the other entity provides to health center patients;[35]
c. How patients will access services provided by the other entity;
d. How patient medical records or documentation of services provided will be maintained and shared, consistent with applicable laws, with the health center-specifically, the process for the other entity to provide information related to the services provided by the other entity, such as follow-up instructions or laboratory, radiology, or other results; and
e. Any provisions required by federal and state laws, including those related to patient privacy, HHS grant regulations, and civil rights.

Health centers that deliver services through cooperative arrangements with other entities must ensure that all services are made available in accordance with applicable Health Center Program statutory and regulatory requirements, including ensuring appropriate provider

[35] Refer to the Health Center Program Compliance Manual, Chapter 9: Sliding Fee Discount Program.

credentialing and privileging, enabling access to services for those with limited English proficiency and addressing patient transportation needs.

Health centers should note that eligibility to be deemed as a PHS employee for purposes of FTCA coverage, to participate in the 340B Drug Pricing Program, or to receive Medicare/Medicaid FQHC reimbursement does not convey to another entity that provides services under a cooperative arrangement with the health center.

An informal relationship that only facilitates access of the health center patient to care from another entity, without the health center providing oversight of the arrangement to ensure that the services provided comply with all applicable Health Center Program requirements and without additional collaboration between the health center and the other entity, is not considered a cooperative arrangement.

D. Criteria Required for Additional Health Services

A health center may propose to provide additional health services that are necessary for the adequate support of one or more required primary health services and that are appropriate to meet the health needs of the population served by the health center. A health center must demonstrate that an additional health service meets all of the following criteria to receive HRSA approval for inclusion of the service within the Health Center Program scope of project:

a. The additional health service meets all the criteria outlined in Chapter 1: Definition of Scope of Project and Overview and Chapter 3, Section B. Criteria Required for In-Scope Services;
b. The additional health service supports one or more required primary health services that the health center currently provides, either directly or via contract; and
c. There is a demonstrated need for the additional health service within the population served by the health center.[36]

[36] Health centers that are funded or designated to provide services under section 330 (except those health centers receiving funding or designation only under sections 330(g), (h), or (i)) must provide health services to all residents of the area served by the health center (the "catchment area" or “service area”), regardless of an individual’s ability to pay.

Chapter 4: Services Provided via Telehealth

In this chapter:

A health center must make required primary and additional health services provided at its service sites available to all residents of its service area and ensure that services are accessible promptly and in a manner which assures continuity of service to the residents of the service area. A health center may use telehealth (also referred to as telemedicine) as a means to complement in-person services provided at its service sites and deliver required primary and additional health services to health center patients where it is necessary or helpful in ensuring access to care. [37, 38] The use of telehealth does not substitute for the delivery of in-person services at health center service sites because not all required primary health services can be delivered via telehealth and not all health center patients have access to or prefer to use telehealth technology. Health centers should endeavor to make services available in-person whenever possible.

A. Considerations for Delivering Services via Telehealth

Within the context of the Health Center Program scope of project, telehealth is not a service or a service delivery method requiring specific HRSA approval; rather, telehealth is a mechanism or means for delivering a health service to health center patients using telecommunications technology or equipment.

A health center should consider the needs of the population served and seek patient input in deciding whether and when to provide services by telehealth. Because not all services can be provided via telehealth, and patients may not want to receive services via telehealth, health centers should not broadly substitute telehealth services for in-person services.

A health center is responsible for maintaining its operations, including developing and implementing its own policies or operating procedures for delivering services via telehealth, in compliance with all Health Center Program requirements and all other applicable federal, state, and local laws and regulations.[39] Among other considerations, a health center using telehealth to deliver in-scope services to health center patients is responsible for all of the following:

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[37] For purposes of the Health Center Program, telehealth is defined as the use of electronic information and telecommunication technologies to support long-distance clinical health care, patient and professional health-related education, health administration, and public health.
[38] Telehealth resources are available at Telehealth.HHS.gov.
[39] 42 CFR § 51c.304(d)(3)(v).

a. Ensuring that patients receiving services via telehealth have access to all of the health center's HRSA-approved in-scope services;
b. Creating health center policies or operating procedures that delineate health center staff roles and responsibilities (for example, how informed consent of patients to receive care by telehealth is obtained, including patients' ability to opt out of receiving services by telehealth);
c. Billing for the services provided via telehealth, including providing applicable sliding fee discounts for patients in alignment with Health Center Program requirements;
d. Adhering to all standards of care/practice and maintaining compliance with all applicable federal, state, and local requirements regarding provider licensure and scope of practice, including those that apply to staff, with particular consideration for requirements and limitations applicable to the use of telehealth to provide services across state lines; and
e. Complying with all federal, state, and local laws and requirements applicable to the delivery of health services via telehealth.

Review PAL 2020-01: Telehealth and Health Center Scope of Project (PDF) for further considerations.

B. Criteria for Delivering Services via Telehealth

Section 330 authorizes a health center to provide health services to residents of a geographic catchment area. The catchment area includes, at a minimum, the ZCTAs where at least 75 percent of current health center patients reside based on patient origin data submitted by the health center through HRSA's Health Center Program Uniform Data System. Within this context, a health center can provide services via telehealth to new or established patients who are physically located within a health center's service area or within areas adjacent[40] to the health center's service area.

Subject to compliance with the considerations in Section A. Considerations for Delivering Services via Telehealth, a health center may deliver in-scope services via telehealth if all of the following criteria are met:

a. The health center documents and follows an intake process used for all individuals who will access health center services via telehealth. For example, the intake process could include procedures for gathering patient information, assessing eligibility for sliding fee discounts,[41] and informing patients of other services offered by the health center;

[40] Areas adjacent to a health center's service area are the ZCTAs that border the ZCTAs identified by the health center on its Form 5B: Sites.
[41] A health center is required to make services available to all residents of the health center's service area, regardless of an individual's ability to pay (Section (k)(3)(G) of the PHS Act).

b. The health center takes appropriate steps to determine and record the location of patients accessing services via telehealth and to assure that services are provided to each patient in a manner consistent with applicable federal, state, and local laws.
c. Individuals receive an in-scope required primary or additional health service (as documented on the health center's HRSA-approved Form 5A: Services Provided);
d. New or established patients receiving services via telehealth reside within the health center's service area or within areas adjacent to the health center's service area.[42] If an established patient no longer resides within the health center's service area or within an area adjacent to the service area, the health center may continue to provide services via telehealth to the patient for a limited period of time (for example, up to 1 year), for the purposes of continuity of care while the patient finds a new medical home. These telehealth visits are subject to any applicable laws or restrictions, including those for licensure and medical practice, that pertain to the provision of health care through telehealth;[43]
e. The provider delivers the in-scope service on behalf of the health center and may be physically located at a health center service site or at another location (for example, at the provider's home or at a non-health center community facility); and
f. For each individual patient visit, the health center establishes and maintains a patient health record for the services delivered via telehealth, including documenting the services provided and the patient's location, in a health center medical record, consistent with applicable standards of practice.

[42] Refer to footnote 40.
[43] Health Center Program policy does not preempt federal or state law or regulation. Health centers considering providing services across state lines using telehealth should consult private legal counsel about potential legal issues related to applicable state and federal laws.

Chapter 5: Sites

In this chapter:

A. Service Sites Within the Scope of Project

A service site is a location, approved by HRSA, where health centers provide required primary or additional health services on behalf of the health center and that meets the criteria in Section B. Criteria Required for Service Sites.

A service site may be operated by a:

- Health center, or
- Contractor (which may be a subrecipient of section 330 grant funds)[44] that provides services on behalf of the health center.

Health centers may also document "other sites" within their scope of project that do not meet the criteria in Section B. Criteria Required for Service Sites but where health centers carry out activities that support the Health Center Program scope of project. Other sites (refer to Section E. Requirements for Documenting Other Sites) require approval by HRSA and are defined as sites where the health center conducts administrative functions, provides enabling services that do not generate patient visits, or provides pharmaceutical services.

Health centers record service sites and other sites, subject to HRSA review and approval, on Form 5B: Sites. All sites must be listed on a health center's Form 5B and approved by HRSA to be part of the health center's scope of project.[45]

Health centers must submit Form 5B as part of the initial Health Center Program application (for example, New Access Point or Look-Alike Initial Designation application). Health centers

[44] Organizations that receive federal award funding from a health center and demonstrate compliance with all of the requirements of section 330 ("subrecipients") may meet the definition of "federally qualified health center" under sections 1861(aa)(4)(A)(ii) and 1905(l)(2)(B)(ii) of the Social Security Act and, may be eligible, subject to review and approval by HHS, to receive FQHC Medicare and Medicaid reimbursement for services provided at service sites operated by the subrecipient and may also be eligible to participate in the 340B Drug Pricing Program. Subrecipients of section 330 funding that provide a full range of health care services on behalf of an eligible award recipient also may be eligible for FTCA coverage under FSCHAA, but only for those services carried out under the grant-funded project.

[45] Refer to Scope of Project Resources for additional details and instructions for accurately recording service sites within the scope of project.

may request to add or delete sites on Form 5B through HRSA's change in scope process or in response to subsequent funding opportunities, subject to HRSA review and approval.[46]

Service sites are further categorized by location type (including permanent, seasonal, or mobile unit), as described in Section D. Service Site Types.

Health centers may also provide in-scope services at locations that are not sites (recorded on Form 5B) under certain limited circumstances (refer to Chapter 9: Services Provided at a Location Other Than a Health Center Service Site).

B. Criteria Required for Service Sites

A health center must demonstrate that a location meets all of the following criteria to receive HRSA approval for inclusion as a service site within the Health Center Program scope of project:

a. Services are provided at the service site on behalf of the health center to patients of the health center;
b. Providers at the service site deliver in-scope required primary or additional health services on behalf of the health center directly (as documented on Form 5A, Column I) or through a contract (as documented on Form 5A, Column II);
c. Patients receiving services at the service site have access to all in-scope services, including any services that are not offered at the service site, which includes an assessment of patient need for and access to transportation;
d. The health center governing board:
    i. has approved the addition of the service site, the hours of operation, and services to be provided at the service site, and
    ii. retains control and authority over the provision of all services provided by the health center at the service site;[47]
e. Health center visits are generated at the service site through the delivery of required primary or additional health services to health center patients and are documented in patient health records maintained by or accessible to the health center;[48, 49] and

[46] For health centers proposing sites that will serve residents of public housing under Section 330(i), refer to Chapter 6, Section B. Additional Factors for Adding a Service Site.
[47] For more information, refer to the Health Center Program Compliance Manual, Chapter 19: Board Authority.
[48] A location where health center patients are not seen in-person and where providers are delivering services only via telehealth does not meet the definition of a service site.
[49] A location where the only services provided are through Cooperative Arrangements (Form 5A, Column III) does not meet the definition of a service site.

f. Services are provided to health center patients at the service site on a regularly-scheduled basis (for example, daily, weekly, first Thursday of every month).[50, 51]

C. Service Sites with Limited Services

A health center is required to provide all required primary health services to its patient population. The health center may also provide additional health services approved by HRSA. However, a health center is not required to provide all services in its scope of project at each of its service sites. For example, to best meet patient needs, a health center may provide only oral or mental health services at a specific service site. If a health center provides only a subset of services or a single service at a service site, the health center must ensure patients receiving services at the limited-service site have access to all other health center in-scope services, including an assessment of patient need for and access to transportation.

D. Service Site Types

Health center sites that meet the criteria for a service site as described in Section B. Criteria Required for Service Sites are further categorized on Form 5B according to the following definitions:[52]

D.1. Permanent Service Sites

HRSA defines a permanent service site as a service site that operates at a fixed physical address for 12 months of the year. Health centers record permanent service sites on Form 5B for HRSA review and approval.

D.2. Seasonal Service Sites

HRSA defines a seasonal service site as a service site that operates at a fixed physical address for fewer than 12 months of the year. Health centers record seasonal service sites

[50] Section 330(k)(3) of the PHS Act states, "(P)rimary 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." For more information, refer to the Health Center Program Compliance Manual, Chapter 6: Accessible Locations and Hours of Operation. In addition, note 42 CFR 51c.303(m) (community health centers "must be operated in a manner calculated […] to maximize acceptability and effective utilization of services."). An individual site may be operated on a full-time or part-time basis.

[51] Unlike permanent or seasonal service sites, a mobile service site does not need to provide services on a regularly-scheduled basis.

[52] Migrant voucher screening sites are screening sites 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. An existing migrant voucher screening site that meets the service site definition may continue to be documented as a "Migrant Voucher Screening Site" location type on Form 5B.

on Form 5B for HRSA review and approval.

D.3. Mobile Service Sites

HRSA defines a mobile service site, also known as a "mobile facility" or "mobile unit," as a mobile home, trailer, or other large vehicle that is equipped and licensed to render in-scope services on behalf of the health center. These vehicles travel to various locations throughout the service area to treat patients inside the mobile service site. Unlike permanent or seasonal sites, a mobile service site does not need to provide services on a regularly-scheduled basis.

Health centers record mobile service sites on Form 5B for HRSA review and approval. Health centers must receive HRSA approval for each mobile service site. The physical address of a mobile service site recorded on Form 5B is the primary address where the mobile service site is parked when not in use.

Mobile service sites do not include vehicles that are used only to transport patients, health center staff, or medical equipment.

E. Requirements for Documenting Other Sites

A health center is required to document on Form 5B, locations operated on behalf of the health center that do not meet the Service Site Definition in Section B. Criteria Required for Service Sites, but where the health center provides one or more of the following in-scope health activities:

a. Administrative work for the health center project (for example, billing and accounting, information technology, human resources).
b. Services that do not generate a patient visit (for example, insurance enrollment, eligibility assistance, receiving services under the Women, Infants and Children (WIC) Program). If the enabling or other service does generate a patient visit and all other site criteria are met, the location is categorized as a service site.
c. Pharmaceutical services at a stand-alone pharmacy site that do not generate a patient visit.

Administrative, enabling, pharmaceutical or other activities that are provided at an existing, in-scope service site (already documented on Form 5B) do not need to be documented in a separate "Other Sites" entry on Form 5B.

Chapter 6: Additional Considerations When Adding a Service Site to Scope of Project

In this chapter:

A. Service Area Overlap Considerations

HRSA has a responsibility to ensure that limited federal award funds and resources are used efficiently and effectively to provide access to as many underserved people as possible. This includes determining the extent to which the location of health center sites will provide for an appropriate distribution of resources throughout the country.[53]

HRSA recognizes there are communities with underserved populations with significant or specific needs, where it may be appropriate and beneficial to both the community and any health centers in the area for service areas to overlap. However, under other circumstances, allowing for service area overlap may not be an efficient and effective use of Health Center Program funds and resources. Therefore, HRSA will consider all the following factors when assessing a request to add a service site that could result in service area overlap:[54]

a. The extent to which the proposed service site will serve an area where unmet need exceeds the capacity of the existing health center service site(s) or other safety net providers, and
b. The degree to which the addition of the proposed site will complement and not duplicate existing services in the overlapping service area.

As applicable, HRSA will examine applications for funding or look-alike initial designation and change in scope requests for potential service area overlap. HRSA may request additional information prior to making a final funding, designation, or change in scope decision. Refer to Section B. Additional Factors for Adding a Service Site for additional information on the impact of service area overlap on change in scope decisions.

[53] Refer to 42 CFR 51c.305.

[54] A health center award recipient or look-alike may add service sites and expand its service area through the change in scope process, and a health center award recipient may also add service sites and expand its service area through new or supplemental funding applications.

B. Additional Factors for Adding a Service Site

In addition to the criteria in Chapter 5: Sites, HRSA may request more information about a proposed service site or disapprove a request to add a proposed service site based on any of the following factors:[55, 56]

a. The proposed service site is at a location where there is a lack of significant unmet need as determined by HRSA. HRSA may base a determination of unmet need in the service area of the proposed site on some or all of the following:
    i. HRSA's Service Area Needs Assessment Methodology;
    ii. The number of patients proposed to be served by the new service site (for example, if the proposed number of patients to be served exceeds the total number of low-income patients unserved by existing Health Center Program award recipients and designees in the new service site's service area); or
    iii. Analysis showing a high rate of Health Center Program award recipient and designee penetration of the low-income population (for example, a penetration rate greater than the 75th percentile of service areas based on HRSA's data).
b. The proposed service site is **outside** the health center's existing service area, and there is significant unmet need **inside** the existing service area as determined by HRSA. Significant remaining unmet need in an existing service area may be based on some or all of the following:
    i. HRSA's Service Area Needs Assessment Methodology, or
    ii. Analysis showing a low rate of Health Center Program penetration of the low-income population in the health center's existing service area (for example, 25 percent or lower based on HRSA's data);
c. The proposed service site is located within the same building or is close (for example, within 1 mile in an urban area or within 5 miles in a rural area) to a service site operated by another health center;
d. The location of the proposed service site is significantly distant from the health center's nearest service site (for example, greater than 15 miles in an urban area or greater than 30 miles in a rural area);
e. The proposed service site would alter the health center's service area such that the service area would not conform to relevant boundaries of political subdivisions, school districts, and federal and state health and social service programs;
f. If the proposed site is located in a new service area, the degree to which meaningful community input from the new service area informed the proposed service site addition,

[55] The Scope Policy Manual does not constitute an exhaustive listing of all policy guidance that may be included in terms and conditions stated in NOFOs, NOAs, and other applicable laws, regulations, and policies. Refer to the Health Center Program Compliance Manual, Introduction: Additional Health Center Responsibilities.

[56] In addition to the factors included in this subsection, HRSA may also conduct this analysis based on a relevant subset of Health Center Program service areas (for example, health centers within a specific geographic area such as a state or health centers serving a similar demographic population such as a rural population or a statutory designated special population).

specifically at least one of the following:

i. A statement from a patient board member living in the proposed new service area that describes that board member's consultation with other residents of the target community, such as through one or more focus groups or community meetings;
ii. A petition signed by a significant number of residents of the proposed new service area;[57]
iii. Results of a statistically significant survey of residents in the proposed new service area;[58] or
iv. Another similar mechanism designed to gather representative input from residents of the proposed new service area.

g. The degree to which the health center has demonstrated coordination and collaboration with other Health Center Program award recipients and designees serving the service area of the proposed service site, consistent with the Health Center Program Compliance Manual.[59]
h. For a proposed service site that will serve residents of public housing[60] under Section 330(i), whether:
    i. The proposed service site is located in public housing or is otherwise immediately accessible[61] to public housing; or
    ii. The health center identifies and documents which patients seen at the service site live in public housing or areas immediately accessible[62] to such public housing, and documents the specific public housing units.
i. Whether HRSA has previously disapproved the request to add a service site at the same location.
j. The proposal includes inaccurate, false, or misleading information.
k. For a proposed service site that will not provide all of the health center's in-scope services through in-person visits, a demonstration of how patients at the proposed site will have access to all in-scope services.

C. Service Sites Co-located with Other Organizations

A health center may request to add a service site operated by the health center at a location where another organization provides health or other services (referred to as a "co-located" service site). The health center must demonstrate to HRSA that the health center is providing services at

[57] For example, either 2 percent or 200 of the adult residents of the proposed service area, whichever is less.
[58] For example, a random sample of at least 100 adult residents with a confidence level of at least 90 percent.
[59] Refer to the Health Center Program Compliance Manual, Chapter 14: Collaborative Relationships.
[60] Public housing includes public housing agency-developed, owned or assisted low-income housing, including mixed finance projects, but excludes housing units with no public housing agency support other than Section 8 housing vouchers. (Section 330(i) of the PHS Act)
[61] For the purposes of service sites, the term "Immediately accessible" means that the service site is within or adjacent to the public housing and that no physical barriers (for example, a highway or river) exist that prevent this medically underserved population from accessing the service site.
[62] For the purposes of individuals who are eligible to receive services under 330 (i), "immediately accessible" means that the individuals live in areas that are adjacent to the public housing and that no physical barriers exist between the areas where the individuals live and the public housing.

the service site on its own behalf, the services it provides are within the scope of its Health Center Program project, and the site meets all service site criteria in the Service Site Definition (refer to Chapter 5, Section B. Criteria Required for Service Sites). For example, a health center may request approval for a co-located service site in a room or suite of rooms leased in a building(s) on a hospital campus, on a school campus, in a behavioral health organization facility, or in a library.[63]

For services that health centers provide at such locations, the health center must demonstrate that its operations are separate from the operations of the other organization and that the service site is operated independently from the other entity and on behalf of the health center.

In addition, a health center proposing a co-located service site must demonstrate that the proposed site meets all of the following criteria to receive HRSA approval for inclusion of the site within the Health Center Program scope of project:

a. The health center's governing board maintains full authority and control over the delivery of health services at the location and operates the service site in compliance with all Health Center Program requirements;
b. The health center demonstrates on an ongoing basis that the services delivered at the co-located service site meet all of the criteria outlined in Chapter 1: Definition of Scope of Project and Overview, including that services are delivered on behalf of the health center and the proposed site meets all service site criteria in the Service Site Definition (refer to Chapter 5, Section B. Criteria Required for Service Sites);
c. The health center's contracts, memoranda of understanding, or memoranda of agreement with applicable parties and other relevant documents ensure that the health center:
    i. Independently provides services or conducts activities at the co-located service site on behalf of the health center;
    ii. Maintains separate clinical and fiscal operations;
    iii. Maintains a retrievable patient health record for each patient receiving services at the service site;
    iv. Maintains financial, billing, and audit records for its services performed at the service site; and
d. The health center informs patients that they are being seen by a provider working on behalf of the health center, including by posting signage at the co-located service site, providing information on the health center's website, and directly informing the patient verbally or with documentation they are in a health center location and that they can access services regardless of ability to pay.

A health center may provide services as part of the scope of project to health center patients as part of the continuum of health center care ("continuity of care") at locations that are not service sites, so long as they provide such services on behalf of the health center (and not as a contract service on behalf of another entity) and in accordance with

[63] For service sites located in buildings or campuses that are owned or operated by another entity, refer to Instructions for Form 5B: Service Sites for guidance on accurately recording the physical addresses of such sites.

Health Center Program requirements. For example, a health center may provide labor and delivery services to an established health center patient at a hospital. A health center may also provide other services to established health center patients in community-based settings, such as a rehabilitation facility or nursing home. However, HRSA does not consider the provision of continuity of care at a hospital, nursing home, or other community-based location on its own to meet the criteria of a service site because the health center's governing board does not have full authority and control over the delivery of services at the location and the service site criteria above are not met. For information on the criteria for providing in-scope services at a location other than a health center service site, refer to Chapter 9: Services Provided at a Location Other Than a Health Center Service Site.

Providing health services on behalf of another entity or operating or managing a facility or the delivery of health care on behalf of another entity (including a hospital or nursing home) is not an activity within the scope of the Health Center Program. In addition, a health center that operates a facility on behalf of another entity, would do so as another line of business outside the scope of the project because the operation and management of these facilities and the provision of services on behalf of another entity, is not consistent with the purpose of the Health Center Program.

D. Service Sites Operated by Contractors including Subrecipients

A health center requesting to add a service site operated entirely by a contractor, including a subrecipient, must demonstrate that the contractor will operate the site on behalf of the health center within the scope of the Health Center Program project, and in compliance with all applicable Health Center Program requirements for operating the site.

A health center may propose to add a service site that will be operated by a:

- Contractor organization that does not meet all Health Center Program requirements ("contractor") but is party to a contract that ensures the requirements of section 330 apply to the delivery of health care on behalf of the health center at the service site;[64] or
- Subrecipient contract organization that receives section 330 award funding (subaward) from a health center award recipient and demonstrates compliance with all of the requirements of section 330 ("subrecipient").[65]

[64] Because it does not meet section 330 requirements, such an entity would *not* be eligible to be a "federally qualified health center" as defined in Sections 1861(aa)(4)(A)(ii) and 1905(l)(2)(B)(ii) of the Social Security Act (SSA). Such an entity is not eligible for FTCA liability protections under FSHCAA, which only convey from a deemed health center to a subrecipient organization that provides a full range of services on behalf of the health center. For additional information, refer to Federal Tort Claims Act (FTCA).

[65] ***For subrecipient-operated sites:*** The health center must demonstrate that the subrecipient operating the proposed site meets all Health Center Program requirements and the terms and conditions of the federal award. A

While health centers have flexibility to operate sites through contracts (including subawards to subrecipients), HRSA encourages health centers to directly operate their service sites where feasible in order to reduce barriers to accessible, patient-centered care. If a health center chooses to operate one or more sites through a contract (including through a subaward), consideration should be given to how this model increases access to care and reduces patient wait times.

Therefore, HRSA will not approve requests[66] for contractor or subrecipient-operated sites unless the health center currently and will continue to:

- Deliver General Primary Medical Care, at a minimum, directly through its own employees and volunteers (as documented on General Primary Medical Care via Form 5A: Column I).
- Directly operate at least 50 percent[67] of service sites.

Any health center proposing a contractor-operated or subrecipient-operated service site must demonstrate in its change in scope request or in new or supplemental funding applications, and must continue to demonstrate on an ongoing basis, that the proposed service site meets all of the following criteria to receive HRSA approval to include the site within the Health Center Program scope of project:

a. The service site meets all of the criteria outlined in Chapter 1: Definition of Scope of Project and Overview and Chapter 5, Section B: Criteria Required for Service Sites;
b. The services that the contractor or subrecipient will provide at the service site meet all criteria for Form 5A, Column II: Contracted Services (refer to Chapter 3, Section C.2: Contracts including Subawards (Form 5A, Column II));
c. The health center assesses and addresses patient transportation needs to ensure access for all services offered by the health center (for example, the contractor will provide transportation to other health center service sites);
d. The health center provides good cause justification for operating the service site through a contractor or subrecipient as opposed to the health center operating the service site directly;
e. The health center's good cause justification supports the selection of a specific, contractor or subrecipient and demonstrates that the contractor or subrecipient has the capabilities, resources, and experience with the health center patient population necessary to operate the service site on behalf of the health center;

"subrecipient" receives section 330 award funding under a contract (a "subaward") from a health center award recipient to operate a service site and meets all section 330 requirements. Such an entity may be eligible, subject to review and approval by HHS, to be a "federally qualified health center" (FQHC) and thereby receive FQHC Medicare and Medicaid reimbursement in accordance with Sections 1861(aa)(4)(A)(ii) and 1905(l)(2)(B)(ii) of the Social Security Act (SSA). For more information on contracts and subawards, refer to the Health Center Program Compliance Manual, Chapter 12: Contracts and Subawards as well as the Glossary.

[66] This excludes public agency awardees whose co-applicant provides services and health centers that only receive section 330(g) award funding.

[67] When a health center proposes to operate more than 50 percent of sites through contractors or subrecipients, HRSA will evaluate such situations on a case-by-case basis to determine whether the circumstances justify an exception to this requirement.

f. The contract to operate the service site is made according to the health center's written procurement procedures that comply with all federal requirements, including, as applicable, those set forth in 45 CFR Part 75; and
g. The contract to operate the service site includes provisions for all of the following:
    i. The health center's governing board retains its authority to approve the hours of operation and services provided at the contracted site, evaluate the performance of the contractor or subrecipient in operating the service site (for example, based on quality assurance/quality improvement assessments), and take appropriate follow-up actions.
    ii. The contractor or subrecipient will maintain proper financial records and make the records accessible to the health center;
    iii. The contractor or subrecipient will provide data necessary to meet the health center's applicable federal financial and programmatic reporting requirements; and
    iv. The contractor or subrecipient will follow HHS grants requirements for record retention and access, audit, and property management.[68]

In order to receive HRSA approval for inclusion of the service site within the Health Center Program scope of project, a health center must meet additional criteria, depending on whether the site will be contractor-operated or subrecipient-operated, in D.1 Requirements for Service Sites Operated by Subrecipients or in D.2. Requirements for Service Sites Operated by Contractors that Do Not Meet All Health Center Program Requirements.

D.1. Requirements for Service Sites Operated by Subrecipients

For subrecipient-operated sites, the health center must document at the time the contract (also called a "subaward") is executed, and must ensure on an ongoing basis, that the subrecipient that will operate the service site will:

a. Receive section 330 award funds under a contract (subaward) to operate the service site; and
b. Meet all Health Center Program requirements, including terms and conditions applicable to the award recipient's Health Center Program federal award.[69] For example, a health center receiving funding under section 330(e) must ensure that the subrecipient meets all Health Center Program requirements applicable to a section 330(e) award recipient, including being a private nonprofit or public entity, being governed by a patient-majority governing board, providing all required primary health services and billing for health services on a sliding fee scale.

Health centers are responsible for ensuring on an ongoing basis that subrecipients comply with Health Center Program requirements, the terms and conditions of Health Center Program funding, and all other applicable federal laws, regulations, and policies.

[68] For further guidance on these requirements, refer to the HHS Grants Policy Statement (PDF).
[69] Refer to the Health Center Program Compliance Manual, Chapter 12: Contracts and Subawards.

During Health Center Program site visits or application reviews, HRSA requires the Health Center Program award recipient to provide documentation of its subrecipient's compliance with applicable Health Center Program requirements. This includes, but is not limited to, documentation demonstrating compliance with requirements found in Section 330 of the PHS Act (42 U.S.C. § 254b), 42 CFR part 51c, and 42 CFR part 56. All subrecipients must also comply with applicable grants requirements, particularly those set forth in 45 CFR 75.351-353. HRSA reserves the right to disapprove or remove service sites operated by awardees or look-alikes, subrecipients, or contractors, if compliance with applicable Health Center Program requirements is not demonstrated or if the site, service, or activity is inconsistent with scope of project policy.

In addition, to be eligible for liability protections under FSHCAA/FTCA, the Health Center Program award recipient must document at the time the subaward contract is executed, and ensure on an ongoing basis, that the subrecipient provides the full range of services on behalf of the health center funding recipient.[70]

D.2. Requirements for Service Sites Operated by Contractors that Do Not Meet All Health Center Program Requirements

A contractor that, as an organization, does not meet Health Center Program requirements may operate a service site on behalf of a health center if the contractor otherwise operates the service site in compliance with all applicable Health Center Program requirements, as further described in this section and as specified in the contract between the health center and the contractor organization. A health center might propose a site operated by this type of contractor if it is unable to meet the demand for services themselves to operate the site directly or when the contractor is a more efficient and effective means by which to operate its site.

Operating a service site through such a third-party contract does not automatically make the third-party entity a "health center" within the meaning of the Scope Policy Manual.[71] Entities operating service sites that do not comply with Health Center Program requirements (for example, the contractor organization does not have a patient majority governing board) do not meet the definition of an FQHC. In addition, they are not eligible for liability protections under FSHCAA because they do not, as organizations, meet the applicable requirements to be deemed as a Public Health Service employee for this purpose.

The contract between the health center and the contractor that will operate the service site must address the implementation of applicable Health Center Program requirements at the service site. Specifically, the health center must ensure that the contract addresses:

[70] Refer to 42 CFR 6.3(b) and the FTCA Health Center Policy Manual (PDF).
[71] Refer to Chapter 3, Section C.2. Contracts including Subawards (Form 5A, Column II).

a. How the health center's sliding fee discount program will be used for eligible patients and that no patient will be denied services due to inability to pay, in accordance with the health center's policies;
b. How patients will be screened for sliding fee discount program eligibility (for example, the health center will directly screen its patients for eligibility prior to the patients accessing services at the contractor-operated service site);
c. How the contractor ensures that its providers are licensed, certified, or registered as verified through a credentialing process, and in accordance with applicable federal, state, and local laws;
d. How the contractor ensures that its providers are competent and fit to perform the contracted services, as assessed through a privileging process;
e. How the contractor ensures confidentiality of patient medical and billing records;
f. How the contractor ensures and assesses the quality of patient care through its quality assurance programs;
g. How the language access needs of health center patients will be addressed (for example, the health center will provide the contractor with access to the health center's language interpretation line); and
h. How the contractor ensures that at least one person trained and certified in basic life support is present at the site during regularly-scheduled hours of operation.

Chapter 7: Temporary Service Sites Added in Response to Emergency Events

In this chapter:

A. Adding Temporary Service Sites in Response to Emergency Events

A health center may request a change in scope of project to temporarily add a service site to provide in-scope services in response to an emergency event(s) by using a streamlined HRSA notification and approval process. For the purposes of the Scope Policy Manual and other related policy issuances, unless otherwise specified, an "emergency" is an event that:

a. Affects the patient population, other residents of the service area, or the community at large, and
b. Precipitates declaration of a state of emergency or a major disaster at a local, state, regional, or national level by a public official legally authorized to declare a state of emergency, for example a governor, the Secretary of the United States Department of Health and Human Services, or the President of the United States.

Examples of events that may precipitate an emergency declaration may include the following: hurricanes, floods, earthquakes, tornadoes, wide-spread fires, and other natural/environmental disasters; civil disturbances; terrorist attacks; collapses of significant structures within the community (for example, buildings, bridges); infectious disease outbreaks; and other public health threats.

When an emergency has not been declared by a legally authorized public official, HRSA will evaluate the situation on a case-by-case basis to determine whether the circumstances and emergency-related needs justify the approval of a temporary service site.

HRSA may approve a temporary service site for up to 90 days.[72]

[72] HRSA will consider requests for extensions of such approvals if the health center sufficiently justifies continued emergency-related needs for the temporary service site. HRSA may determine not to extend approval for a temporary site beyond 1 year.

B. Criteria for Adding Temporary Service Sites in Response to Declared Emergencies

A health center that requests approval from HRSA to add a temporary service site to its scope of project due to an emergency as described in Section A: Adding Temporary Service Sites in Response to Emergency Events must, in addition to meeting the criteria in Chapter 5, Section B. Criteria Required for Service Sites, demonstrate that the proposed temporary service site meets all of the following criteria:

a. The purpose of the temporary service site is to provide in-scope services to the patient population, other residents of the service area, or the community at large impacted by the emergency. This is limited to serving communities within the health center's service area or adjacent areas[73, 74]
b. The health center staff provides services at the proposed temporary service site on a temporary basis;
c. The health center staff provides only in-scope services at the proposed temporary service site;[75, 76, 77]
d. The activities the health center proposes to conduct at the proposed temporary service site are on behalf of the health center;
e. The health center must maintain, to the extent possible, the existing level of services at its current sites; and
f. The health center demonstrates it is coordinating its emergency response efforts with federal, state, or local emergency response efforts, including with other health centers in the geographic area.

A health center proposing to add a temporary service site that meets these criteria can request approval through a streamlined process detailed in PAL 2020-05: Requesting a Change in Scope to Add Temporary Service Sites in Response to Emergency Events (PDF).

[73] Areas adjacent to a health center's service area are the ZCTAs adjacent to the ZCTAs identified by the health center on its Form 5B: Sites, as the "Service Area ZIP Codes" for each approved site in the health center's scope of project.
[74] In situations where the purpose of the temporary service site is to serve communities outside either the health center's service area or adjacent areas, HRSA will evaluate such situations on a case-by-case basis to determine whether the circumstances and emergency-related needs justify the approval of temporary service sites.
[75] All applicable state licensure requirements apply in all instances. For more information on requirements related to credentialing and privileging of providers, refer to the Health Center Program Compliance Manual, Chapter 5: Clinical Staffing and PAL 2024-01 Temporary Privileging of Clinical Providers by Deemed Public Health Service Employee Health Centers Impacted by Certain Declared Emergencies or Other Emergency Situations (PDF).
[76] For information on FTCA coverage and related topics for FTCA-deemed Health Center Program award recipients, refer to the FTCA Health Center Policy Manual (PDF) and Health Center Volunteer Health Professionals (VHPs) Application.
[77] HRSA considers only those services and service delivery methods approved and included on a health center's Form 5A to be within the health center's HRSA-approved scope of project. Refer to Chapter 3, Section B. Criteria Required for In-Scope Services.

Chapter 8: Providers, Patients, and Visits

In this chapter:

A. Providers

Health Center providers[78] are clinical staff who deliver required primary or additional health services to patients on behalf of the health center. Clinical staff include licensed independent practitioners (for example, physician, dentist, physician assistant, nurse practitioner), other licensed or certified practitioners (for example, registered nurse, licensed practical nurse, registered dietitian, certified medical assistant), and other clinical staff providing services on behalf of the health center (for example, medical assistants or community health workers in states, territories or jurisdictions that do not require licensure or certification).[79]

Health centers may use a variety of mechanisms for provider staffing, including directly employing or contracting with individual providers, contracting with other organizations, and engaging volunteers.

B. Patients and Visits

For purposes of scope of project, an individual becomes a health center patient when the health center patient-provider relationship is established.[80] The health center **patient-provider relationship** is established when **all** the following criteria are met:

a. An individual receives an in-scope required primary or additional health service from a provider (employee, contractor, or volunteer) who is providing the service on behalf of the health center;
b. An individual receives an in-scope service either in-person or via telehealth where the individual is physically located within the health center's service area or within an area

[78] Health centers should consult the FTCA Health Center Policy Manual (PDF) for information about the applicability of FTCA coverage for specific providers including employees, individual contractors, and volunteer health professionals.
[79] For more information, refer to the Health Center Program Compliance Manual, Chapter 5: Clinical Staffing.
[80] Health center "patient" and "visit" are defined in this document solely for purposes of Health Center Program scope of project policy. These definitions do not extend to any services, activities, or programs outside the Health Center Program scope of project (refer to Chapter 1, Section D. Limitations on Health Center Program Scope of Project and Other Lines of Business). Health Center Program award recipients and look-alikes may be eligible for other federal benefits. These benefits are administered separately from the Health Center Program and have distinct eligibility and enrollment requirements, including separate requirements for the establishment of the patient-provider relationship, and such benefits are not guaranteed solely by inclusion of services, sites, and activities in a health center's HRSA-approved Health Center Program scope of project.

adjacent to the health center's service area (refer to Chapter 4: Services Provided via Telehealth); and

c. The health center establishes a health record for the individual that documents the visit and will be maintained by the health center.[81, 82]

For the purposes of scope of project, a **health center visit** occurs when a provider delivers an in-scope required primary or additional health service on behalf of the health center to a health center patient and the service is documented in the patient's health center record.[83] As a reminder, a health center must ensure that an individual who becomes a health center patient has access to all health center in-scope services (refer to Chapter 3: Required Primary and Additional Health Services).

[81] For more information, refer to the Health Center Program Compliance Manual, Chapter 10: Quality Improvement/Assurance.

[82] Triage activities that pre-date the initial patient-provider visit, such as handling calls from individuals not yet registered as patients, may establish a patient-provider relationship only for the purposes of FTCA coverage under FSHCAA. However, the triage activity, while potentially an in-scope activity, is not considered a "service" for the purposes of Health Center Program scope of project policy. Refer to the FTCA Health Center Policy Manual (PDF), "C.3. Provision of Services to Health Center Patients."

[83] Moonlighting, which is defined as engaging in professional activities outside of a health center employee's responsibility under the Health Center Program project, is not within the HRSA-approved scope of project, and in these circumstances, a health center visit would not occur.

Chapter 9: Services Provided at a Location Other Than a Health Center Service Site

In this chapter:

A. Health Center Services Provided to an Established Health Center Patient

Health center services (as documented on Form 5A: Services Provided) that are provided on behalf of a health center at a HRSA-approved service site (as documented on Form 5B: Sites) and which meet the criteria within this Scope Manual, are within the Health Center Program scope of project.

Health center services provided to an **established health center patient** at a location that is not a HRSA-approved service site (for example, the health center provider conducts home visits for primary care or the provider rounds on hospitalized health center patients after labor and delivery) are within the scope of the health center project when all of the following criteria are met:

a. The health center provider is delivering the service to an established health center patient on behalf of the health center while either employed by the health center (Form 5A, Column I) or while providing services on behalf of the health center as part of the Health Center Program project under a contract (Form 5A, Column II);
b. The service provided is an in-scope service;
c. The health center documents the service and visit in the established patient's health center records.

B. Health Center Services Provided to Individuals Who Are Not Established Health Center Patients

Subject to the criteria in Chapter 8, Section B. Patients and Visits, individuals who receive an in-scope service at a location other than a health center service site may become newly-established health center patients. A health center may provide in-scope services on behalf of the health center to individuals who are **not established** patients of the health center[84] at a

[84] FSHCAA limits the availability of liability protections, including FTCA coverage, for services provided to individuals who are not health center patients.

location that is not a HRSA-approved service site if all the following criteria are met:

a. The health center provider is delivering the service on behalf of the health center, while either employed by the health center (Form 5A, Column I) or while providing services as part of the Health Center Program project under a contract (Form 5A, Column II);
b. The service provided is an in-scope service;
c. The service is provided within the health center's service area, with the exception of hospital and coverage related activities, after-hours cross-coverage activities, and emergency response activities as described in criteria e.;
d. If the service generates a patient visit, the health center documents the visit in a record that identifies the provider, the individual served, the service(s) provided, and the date of service; and
e. The in-scope service provided falls within one or more of the following categories:
    i. **Portable Care and Outreach:** Health center staff may provide in-scope required primary or additional health services to individuals who are not established health center patients at various community locations that are not service sites (refer to Chapter 5, Section B. Criteria Required for Service Sites). Portable clinical care is when health center staff travel to and deliver in-scope services at locations accessible to or frequented by underserved populations to meet the needs of those populations. **Locations where portable clinical care is delivered must be within the health center's service area.** These services are provided on an ad-hoc basis rather than on a regularly-scheduled basis. This includes providing outreach and care at locations such as agricultural worker residence camps, farm fields or canneries, outdoor encampments, a street corner (for example, providing street medicine), shelters, or soup kitchens. Such portable care may include health center staff conducting health education, outreach, screening, vaccinations, or other clinical or non-clinical services at health fairs or other community-based settings.[85]
    ii. **Hospital-Related Activities:** Where periodic hospital call or hospital emergency room coverage is required by the hospital as a condition for obtaining admitting privileges, and where there is documentation for the particular health care provider that this coverage is a condition of employment at the health center, health center staff may provide in-scope required primary or additional health services at a hospital.[86]
    iii. **Coverage-Related Activities:** As part of a health center's arrangement with local community providers for after-hours coverage of its patients, and where the health center's providers are required by their employment contract to provide periodic or occasional cross-coverage for patients of these providers, health center staff may provide in-scope required primary or additional health services through documented coverage arrangements.[87]

[85] Refer to 42 CFR 6.6(e)(4)(i).
[86] Refer to 42 CFR 6.6(e)(4)(ii).
[87] Refer to 42 CFR 6.6(e)(4)(iii).

iv. **Emergency Response Activities:** Health center staff may provide in-scope required primary or additional health services during declared emergencies to individuals who are not established health center patients at various locations that do not meet the service site definition (refer to Chapter 7, Section A. Adding Temporary Service Sites in Response to Emergency Events for the definition of a declared emergency). The purpose of these temporary emergency response activities is to provide in-scope services to the patient population, residents of the service area, or the community at large impacted by the emergency. These activities are limited to locations within the health center's service area or adjacent areas.[88, 89] The health center may provide services at specific locations on an ad-hoc basis rather than on a regularly-scheduled basis. The health center coordinates these emergency response activities with state or local emergency response efforts, including coordinating with other health centers in the geographic area.

v. **Certain Individual Emergencies:** Health center staff may provide in-scope required primary or additional health services—at or near a health center site or while performing in-scope services at a location that is not a health center site—when the provider temporarily treats or assists in treating an individual who is not a health center patient. The health center must have documentation (such as employee manual provisions or an employee contract) that the provision of individual emergency treatment is a condition of employment at the health center when the practitioner is already providing in-scope services.[90]

[88] Areas adjacent to a health center's service area are the ZCTAs adjacent to the ZCTAs identified by the health center on its Form 5B: Sites, as the "Service Area ZIP Codes" for each approved site in the health center's scope of project.

[89] In situations where the purpose of the activity is to serve communities outside either the health center's service area or adjacent areas, the health center must request prior approval from HRSA and HRSA will evaluate such situations on a case-by-case basis to determine whether the circumstances and emergency-related needs justify the approval of such activities.

[90] Refer to 42 CFR 6.6(e)(4)(iv) for specific coverage for health centers deemed under the FTCA.

Chapter 10: Changes in Scope of Project

In this chapter:

A. Overview

Health centers must request prior approval from HRSA for a "change in the scope or the objective of the project or program (even if there is no associated budget revision requiring prior written approval)."[91, 92] A health center proposing to make a change to its scope of project[93] via HRSA's change in scope process must document that the requested change:

a. Is consistent with the purposes of the Health Center Program and meets all applicable program requirements;
b. Is undertaken to:
    i. Deliver services, operate sites, and conduct activities **on behalf of** the health center; and
    ii. Address unmet need or maintain or increase access to care for the patient population;
c. Will be accomplished without additional Health Center Program federal award funding (for award recipients only); and
d. Will not shift resources away from carrying out the current HRSA-approved scope of project.

For any change in scope request, HRSA may request more information as needed to make an approval or disapproval decision.[94]

For related requirements and guidance on the role of health center governing boards in proposed changes to a health center's scope of project, refer to the Health Center Program

[91] Refer to 45 CFR 75.308(c)(1)(i).
[92] HRSA may take administrative action to correct a health center's Form 5A: Services Provided or Form 5B: Sites, with notice to the health center so that the health center's scope of project is consistent with scope of project policy.
[93] A "change in scope of project" under the Health Center Program is not the same as a state-approved change in the scope of services which may result in an increase or decrease in FQHC Medicaid reimbursement and which is defined within each state's Medicaid Plan. The State Medicaid Agency must be contacted directly if a health center is requesting a change in scope of services for the purposes of FQHC Medicaid reimbursement.
[94] A requested change in the scope of project is reflected in the health center's scope of project only after the change is approved by HRSA and verified as implemented and operational by the health center.

Compliance Manual, Chapter 19: Board Authority. The health center is responsible for ensuring all activities within the approved scope of project comply with all federal, state, and local laws and requirements applicable to the delivery of health services.

B. Changes to Services or Sites

A health center must request prior approval by HRSA to make any of the following changes to its scope of project:

- Adding or deleting a service or service delivery method; or
- Adding or deleting a site.

In addition, a health center must request prior approval by HRSA for other changes (for example, updating hours or months of operation for a service site) to its scope of project through the Scope Adjustment[95] request process.

C. Special Medically Underserved Population-Only Health Centers Adding a New Statutory Population

A health center funded or designated only under section 330(g), (h), or (i) of the PHS Act ("special population-only health center") must provide services to the statutorily-defined special medically underserved population(s) for which it is funded/designated to provide services within the health center's defined service area. A special population-only health center may provide services to patients who are not within its funded/designated population. However, a special population-only health center must request prior approval from HRSA to add a new medically underserved population if the number of such patients becomes more than 25 percent of the health center's total patient population, in order to continue providing services to these patients within the health center's scope of project. For example, if a health center that is only funded to serve individuals experiencing homelessness (section 330(h)) now has a patient population that includes 30 percent or more general medically underserved patients (section 330(e)), the health center must submit a request to add the section 330(e) population to its scope of project and the health center must demonstrate that it meets both 330(h) and 330(e) requirements.

A special population-only health center proposing to add a new medically underserved

[95] If a health center needs to make a change to its scope of project, the health center must submit a CIS request through the HRSA Electronic Handbooks (EHBs). This allows HRSA to review and approve the change. There are two kinds of CIS requests:

- *Formal*: a formal CIS is for a significant change.
- *Scope Adjustment*: a scope adjustment is for a smaller change.

Examples where Scope Adjustments may be used are to update a required service, update an additional service, or update information about a site (such as hours of operation, months of operation, ZIP Codes). Refer to Scope of Project for additional information on the process and timelines for making changes to a health center's scope.

population to its scope of project via HRSA's change in scope process must document that the requested change will:

a. Maintain, to the extent possible, the existing level of services for the medically underserved population for which section 330(g), (h) or (i) funding is awarded; and
b. Meet all Health Center Program requirements that apply to the current and proposed new medically underserved populations.[96]

If HRSA approves a health center's request to add a new medically underserved population to the health center's scope of project, HRSA will not provide additional federal support to serve this population. Instead, HRSA will reallocate a portion of the health center's existing Health Center Program award to support services for the new medically underserved population.

A health center funded or designated under section 330(e) is not required to request prior approval to add a new target population because it is already required to provide services to all residents of the health center's service area, including any statutorily-defined special populations that reside within the service area.

D. Additional Scope of Project Information and Resources

Scope of Project contains information about the process and timelines for making changes to a health center's scope of project, including changes to services, service sites, or medically underserved special population(s) served by the health center. It also provides information on which changes to a health center's scope of project require HRSA prior approval, what information must be submitted to HRSA to support requests for different changes in scope, and additional resources for understanding how to document scope of project.

[96] Refer to the Health Center Program Compliance Manual for program requirements.

Glossary

All terms in this glossary are defined for the purposes of HRSA Health Center Program scope of project policy.

330(g) Migratory and Seasonal Agricultural Workers (MSAW):

- Migratory agricultural workers who are individuals whose principal employment is in agriculture, and who have been so employed within the last 24 months, and who establish for the purposes of such employment a temporary abode;
- Seasonal agricultural workers who are individuals whose principal employment is in agriculture on a seasonal basis and who do not meet the definition of a migratory agricultural worker;
- Individuals who are no longer employed in migratory or seasonal agriculture because of age or disability who are within such catchment area; and/or
- Family members of the individuals described above.

Agriculture refers to farming in all its branches, as defined by the North American Industry Classification System under codes 111, 112, 1151, and 1152.
(Section 330(g) of the PHS Act)

330(h) Homeless Population: Individuals:

- Who lack housing (without regard to whether the individual is a member of a family);
- Whose primary residence during the night is a supervised public or private facility that provides temporary living accommodations;
- Who reside in transitional housing; and/or
- Who reside in permanent supportive housing or other housing programs that are targeted to homeless populations.

Under section 330(h) a health center may continue to provide services for up to 12 months to formerly homeless individuals whom the health center has previously served but are no longer homeless as a result of becoming a resident in permanent housing and may also serve children and youth at risk of homelessness, homeless veterans, and veterans at risk of homelessness. (Section 330(h) of the PHS Act)

330(i) Residents of Public Housing: Residents of public housing and individuals living in areas immediately accessible to public housing. Public housing includes public housing agency-developed, owned or assisted low-income housing, including mixed finance projects, but excludes housing units with no public housing agency support other than Section 8 housing vouchers. (Section 330(i) of the PHS Act)

Annual Budget (Also referred to as "Total Budget"): The budget for the Health Center Program project which includes the Health Center Program Federal award funds and all other sources of revenue that support the health center scope of project and includes costs for sites, services, activities and staffing within the HRSA-approved scope of project.

Additional Health Services: Services that are not included as required primary health services and that may be offered as appropriate, after approval by HRSA, to meet the health needs of the population served by the health center and as necessary for the adequate support of required primary health services. (Section 330(b)(2) of the Public Health Service Act)

Change in Scope: A prior approval request submitted to HRSA when a health center proposes to make changes to its scope of project, even if there is no associated budget revision requiring prior approval. Refer to Chapter 10: Changes in Scope of Project and Scope of Project.

Co-Located Site: A service site operated by the health center on its own behalf that is at a location where another organization also provides health or other services.

Contract: A formal written agreement (which may include a subaward) between the health center and another entity through which the health center offers one or more required primary or additional health services or provides for the operation of a service site for its patients by purchasing the services provided by the other entity.

Contractor: An entity, which may include a subrecipient with which a health center has a formal written agreement to offer one or more required primary or additional health services for its patients or to operate a service site whereby the health center purchases the services provided by the entity.

Cooperative Arrangement: A formal written arrangement between a health center and another entity that (1) does not involve the purchase of services by the health center through a contract or subaward and that (2) includes provisions (refer to C.3.1 Provisions in Cooperative Arrangements) that ensure that the services provided by the other entity meet applicable Health Center Program requirements.

Emergency: An event that:

a. Affects the patient population, other residents of the service area, or the community at large, and
b. Precipitates declaration of a state of emergency or a major disaster at a local, state, regional, or national level by a public official legally authorized to declare a state of emergency, for example a governor, the Secretary of the United States Department of Health and Human Services, or the President of the United States.

Federally Qualified Health Center (FQHC): Organizations that qualify for specific reimbursement systems under Medicare and Medicaid. Eligible organizations include organizations receiving grants under section 330 of the PHS Act, look-alikes, and certain tribal organizations. (Section 1861(aa)(4)(B) and section 1905(l)(2)(B) of the SSA).

Form 5A: Services Provided: Official documentation of the required primary and additional health services included in a health center's HRSA-approved scope of project and their corresponding methods of service delivery. This form is contained in the health center's folder in EHBs. Refer to Scope of Project for additional information.

Form 5B: Sites: Official documentation of sites included in a health center's HRSA-approved scope of project. This form is contained in the health center's folder in EHBs. Refer to Scope of Project for additional information.

Medically Underserved Population: The population of an urban or rural area designated by the Secretary as having a shortage of personal health services ("medically underserved area") or a population group designated by the Secretary as having a shortage of such services. Refer to Section 330(b)(3)(A) of the PHS Act and HRSA Shortage Designation for definitions and more information about MUAs and MUPs.

Other Lines of Business: Activities conducted by a health center that are outside the health center's HRSA-approved scope of project and are not eligible for Health Center Program funding or any Health Center program-related federal program benefits. Refer to Chapter 1, Section D: Limitations on Health Center Program Scope of Project and Other Lines of Business for additional information.

Other Sites: Locations operated on behalf of the health center that do not meet Criteria Required for Service Sites, but where the health center provides one or more of the following in-scope activities:

a. Administrative work for the health center project (for example, billing and accounting, information technology, human resources).
b. Services that do not generate a patient visit (for example, insurance enrollment, eligibility assistance, services under the Women, Infants and Children (WIC) Program).
c. Pharmaceutical services at a stand-alone pharmacy site that do not generate a patient visit.

Patient: An individual who has established a patient-provider relationship with the health center.

Patient-Provider Relationship: The relationship established when:

a. An individual receives an in-scope required primary or additional health service from a provider (employee, contractor, or volunteer) who is providing the service on behalf of the health center;
b. An individual receives an in-scope service either in-person or via telehealth where the individual is physically located within the health center's service area or within an area adjacent to the health center's service area (refer to Chapter 4: Services Provided via Telehealth); and

c. The health center establishes a health record for the individual that documents the visit and will be maintained by the health center.

Providers: Clinical staff (employees, contractors, or volunteers) who deliver required primary or additional health services to patients on behalf of the health center. Clinical staff include licensed independent practitioners (for example, physician, dentist, physician assistant, nurse practitioner), other licensed or certified practitioners (for example, registered nurse, licensed practical nurse, registered dietitian, certified medical assistant), and other clinical staff providing services on behalf of the health center (for example, medical assistants or community health workers in states, territories or jurisdictions that do not require licensure or certification).

Required Primary Health Services: Those services that a health center must provide, as defined in Section 330(b)(1) of the Public Health Service Act. (Section 330(a)(1) of the Public Health Service Act). (Refer to Scope of Project Resources for more information.)

Scope of Project: The HRSA-approved activities carried out on behalf of a health center, whether directly, by contracts (including subawards), or by cooperative arrangements. Scope of project activities may be supported by Health Center Program award funds and other sources of revenue (non-grant funds), as documented in the health center's HRSA-approved annual project budget. A health center's scope of project consists of the following core elements:

- Medically underserved population(s) and/or special medically underserved population(s) served by the health center;
- Service area;
- Services;
- Sites; and
- Providers.

Section 330 of the Public Health Service (PHS) Act (42 U.S.C. 254b): The authorizing legislation for the Health Center Program, as amended including sections 330(e), (g), (h), and (i)).

Service Area (also referred to as "catchment area"): The physical boundaries of the area to be served by the health center as defined in the health center's initial application and inclusive of one or more medically underserved populations within the defined area. A health center's service area includes, at a minimum, those ZIP Code Tabulation Areas (ZCTAs) where at least 75 percent of current health center patients reside, based on patient origin data submitted by the health center through HRSA's Health Center Program Uniform Data System.

Service Delivery Methods: The allowable methods by which a health center may provide required primary and additional health services. Services may be delivered through the staff and supporting resources of the health center ("directly") or through contracts (including subawards) or cooperative arrangements. (Refer to Chapter 3, Section C. Service Delivery Methods).

Service Site: A service site is a location, approved by HRSA, where health centers provide required primary or additional health services on behalf of the health center. Service sites meet all the following criteria:

a. Services are provided at the service site on behalf of the health center to patients of the health center;
b. Providers at the service site deliver in-scope required primary or additional health services on behalf of the health center directly (as documented on Form 5A, Column I) or through a contract (as documented on Form 5A, Column II);
c. Patients receiving services at the service site have access to all in-scope services, including any services that are not offered at the service site, which includes an assessment of patient need for and access to transportation;
d. The health center governing board:
    i. has approved the addition of the service site, the hours of operation, and services to be provided at the service site, and
    ii. retains control and authority over the provision of all services provided by the health center at the service site;
e. Health center visits are generated at the service site through the delivery of required primary or additional health services to health center patients and are documented in patient health records maintained by or accessible to the health center; and
f. Services are provided to health center patients at the service site on a regularly-scheduled basis (for example, daily, weekly, first Thursday of every month).

Special Population [Special Medically Underserved Population]: A specific population group designated by the Secretary as having a shortage of health services. The following special medically underserved populations are identified in section 330 for which funding or designation may be made available to deliver targeted health services: migratory and seasonal agricultural workers, individuals experiencing homelessness, and residents of public housing. Refer to sections 330(b)(3)(A) and 330(g), (h), or (i) of the PHS Act.

Subaward: A specific kind of contract that provides section 330 award funding from a health center award recipient to a contractor that demonstrates compliance with all of the requirements of section 330, including providing all required primary health services in accordance with Sections 1861(aa)(4)(A)(ii) and 1905(l)(2)(B)(ii) of the Social Security Act.

Subrecipient: A specific kind of contractor that receives section 330 award funding under a contract (a "subaward") from a health center award recipient and demonstrates compliance with all of the requirements of section 330, including providing all required primary health services, and generally, operating one or more service sites, in accordance with Sections 1861(aa)(4)(A)(ii) and 1905(l)(2)(B)(ii) of the Social Security Act. A subrecipient organization that complies with section 330 requirements may be considered a "federally qualified health center," as defined in sections 1861(aa)(4)(B) and 1905(l)(2)(B)(iii) of the Social Security Act (42 U.S.C. 1395x(aa)(4)(B) and 42 U.S.C. 1396d(l)(2)(B)(iii)).

Telehealth: The use of electronic information and telecommunication technologies to support long-distance clinical health care, patient and professional health-related education, health administration, and public health.

Temporary Site: A site that meets the Service Site definition and which is added to scope for a limited time period in response to an emergency event.

Visit: When a provider delivers an in-scope required primary or additional health service on behalf of the health center to a health center patient and the service is documented in the patient's health center record.

ZIP Code Tabulation Area (ZCTA): ZCTAs are generalized area representations of United States Postal Service ZIP Code service areas. ZCTAs were created to differentiate between areal service areas and mail delivery.