Health Center Program
Scope of Project Policy Manual

Last updated: August 11, 2026

Table of Contents

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 Manual") applies to all entities that receive funds under the Health Center Program authorized by section 330 (including subsections 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, high-quality preventive and primary health care services to individuals and families living in underserved communities across the nation.

B. Purpose

The purpose of the Scope 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 Manual, HRSA updated the Health Center Program scope of project policy to:

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

[2] A subrecipient is an organization that complies with requirements under Section 330 of the PHS Act and receives a subaward from a Health Center Program award recipient. Refer to Chapter 3, Section C.2: Contracts and Subawards (Form 5A, Column II). It may be considered 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 (42 U.S.C. 1395x(aa)(4)(A)(ii) and 42 U.S.C. 1396d(l)(2)(B)(ii)).

- Consolidate the 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;
- Provide clarifying examples (when specific examples are provided, they are not intended to be an all-inclusive list, unless otherwise noted);
- Integrate telehealth policy;
- Revise service delivery method descriptions to align with statutory language;
- Replace the term "service sites" with "sites" to include sites that do not meet the definition of a service site (for example, pharmacy sites);
- 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 HRSA-recognized 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;
- 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, such as the inclusion of information on application forms and attachments, from the scope policy. Process-related instructions remain available on HRSA's website at Scope of Project Resources.

The Scope 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

The Scope Manual controls in cases of conflict with any previous Health Center Program-disseminated non-regulatory materials related to scope of project that remains in effect after the effective date of this policy, or any conflict between provisions of this Scope Manual and any portion of a health center's application related to scope of project, the Scope Manual controls. The Scope Manual does not constitute an exhaustive listing of all guidance that may be included in terms and conditions stated in Notices of Funding Opportunities, Notices of Award, Notice of Look-Alike Designation, and other applicable laws, regulations, policies, and Executive Orders. Refer to the Health Center Program Compliance Manual, Introduction: Additional Health Center Responsibilities.

Additional technical assistance resources are available on the HRSA Scope of Project webpage.

C. Health Center Responsibilities

The health center named as the Health Center Program award recipient or look-alike designee on the Notice of Award or the Notice of Look-Alike Designation 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 under section 330 of the PHS Act and implementing regulations, the terms and conditions of Health Center Program funding or designation, and in compliance with all other applicable local, state and federal laws, regulations, and policies.[3] Health centers are also responsible for ensuring that services delivered by third parties within the Health Center Program scope of project comply with applicable requirements. Health Center Program requirements apply to all aspects of the scope of project addressed in this document.

Health centers must also document and maintain an accurate scope of project on all appropriate forms in the designated HRSA systems, including requesting any needed approvals from HRSA for scope of project changes.[4]

[3] For more information, refer to the Health Center Program Compliance Manual, Introduction.
[4] Only the health center named on the Notice of Award or Notice of Look-Alike Designation can request a change in its HRSA-approved scope of project. Subrecipients may not do so.

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, the Health Resources and Services Administration (HRSA) defines the scope of project as the HRSA-approved activities, related to the HRSA-approved Health Center Program project, carried out on behalf of a health center,[5] whether directly, by subawards, contracts,[6] or by cooperative arrangements. Such projects are 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 budget.[7] The scope of project does not include any other lines of business.

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;[8] and
- Providers.

All activities within the HRSA-approved scope of project are subject to Health Center Program requirements as set forth in statute under section 330 of the Public Health Service Act (PHS Act) and laws, regulations, and policies incorporated as part of the Health Center Program grant award or designation.[9]

[5] Refer to Chapter 1.C: General Criteria for Including Activities within the HRSA-Approved Scope of Project.
[6] Refer to Chapter 3.C.2: Contracts and Subawards (Form 5A, Column II).
[7] 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.
[8] "Sites" includes both "Service Sites" and "Other Sites." Refer to Chapter 5:Sites.
[9] For more information, refer to the Health Center Program Compliance Manual.

HRSA approves, subject to any applicable terms and conditions, the core elements of a health center's scope of project starting with the health center's first approved Health Center Program application (for example, issuing the Notice of Award for a New Access Point or the Notice of Look-Alike Initial Designation). For any subsequent changes or updates to the scope of project, 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 health centers and supports them in complying with Health Center Program requirements and in maintaining an accurate scope of project. If HRSA identifies non-compliance, HRSA may address it through legally available actions, with notice to the health center. This includes action to correct, modify, disapprove, or remove a health center's sites, services, or activities in its HRSA-approved scope of project. Actions may also include requiring repayment of federal funds, if resources are not used for authorized purposes or are not used consistent with the approved scope of project, and withholding future funding. Monitoring for compliance with the Health Center Program scope of project requirements 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;
- Any element of the scope of project, or a proposal to change the scope of project, is based on or includes inaccurate, false, or misleading information; 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—including a decision to operate a site by subrecipient or by a contract to carry out a substantial portion of the health center's scope of project;
- Hours of operation;
- Services;

[10] 2 Code of Federal Regulations (CFR) 200.308(f)(1).
[11] 2 CFR 200.339.
[12] For more information, refer to the Health Center Program Compliance Manual, Chapter 19: Board Authority.

- Service delivery methods—either directly, by contract or subaward, or by cooperative arrangement;[13]
- Total budget for the scope of project; and
- Proposed changes to the scope of project (such as population served, 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.

C. General Criteria for 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 will occur **on behalf of the health center as part of the HRSA-approved Health Center Program scope of project**. Health center services must be provided on behalf of the health center, regardless of service delivery method, and the health center governing board must have oversight over sites and services.[14, 15]

HRSA recognizes that there may be other definitions of "on behalf of." For the purposes of the Health Center Program scope of project and in this policy, this term refers specifically to services, sites, and activities that are part of the HRSA-approved Health Center Program scope of project. Other lines of business conducted by a health center entity, including the provision of health services by a health center provider under a contractual arrangement where the

[13] Board approval is only required for initial decisions to use a particular service delivery method. For example, if the Board approves a decision to provide a service through contractors, the Board does not need to approve subsequent contracts with providers for that service.

[14] Refer to the Health Center Program Compliance Manual, Chapter 4: Required and Additional Health Services, and Chapter 19: Board Authority.

[15] A change to a health center's organizational structure may impact whether health center services, site operations, and activities occur "on behalf of" the health center. If a health center's organizational structure changes during its period of performance, it must notify HRSA because this could affect the health center's entity type, eligibility for the Health Center Program, and governing board authorities. Examples of organizational changes include:

- A public agency becoming a non-profit organization,
- Revocation of non-profit corporate status,
- Merging with another organization, or
- Establishing another organization as a sole corporate member with any reserved authorities.

A health center must maintain evidence of its non-profit or public agency status on Form 1C: Documents on File. These documents must be up to date, and a health center must make those documents available for review when requested by HRSA. For information about eligible entity types and required documentation, refer to the Health Center Program Compliance Manual, Chapter 1: Health Center Program Eligibility.

health center—or a health center provider—is a contractor for a third-party entity, are not considered "on behalf of" the health center for Health Center Program scope of project purposes. Refer to Chapter 1.D. Limitations on Health Center Program Scope of Project and Other Lines of Business. A statement that a service is being provided "on behalf of" a health center for purposes of the Health Center Scope of Project does not alone create a principal-agent relationship, or any other representative relationship.

Criteria for demonstrating that activities occur "on behalf of" the HRSA-approved Health Center Program scope of project 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, contractors, and volunteers deliver in-scope services or activities at a 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 the decision to provide services through such subawards, contracts, or cooperative arrangements (refer to Chapter 3, Section C.2: Contracts and 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[16] 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 when a patient-provider relationship has been established. Refer to Chapter 8, Section B: Patients and Visits.[17]

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 party or themselves and not on behalf of the health center, HRSA will not

[16] For more information, refer to the Health Center Program Compliance Manual, Chapter 17: Budget.
[17] A health center that provides services through a subrecipient or contractor does not need to establish and maintain its own record of a patient seen by the subrecipient or contractor. However, the health center must exercise subrecipient monitoring and contract oversight, including any needed access to the subrecipient's or contractor's patient health records (redacted, as needed, to remove personal identifiers). Refer to 2 CFR 200.337, 2 CFR 200.318(b), and Health Center Program Compliance Manual, Chapter 12: Contracts and Subawards. HRSA will hold the Health Center Program award recipient accountable for the subrecipient's or contractor's compliance with requirements for establishment and maintenance of health records.

consider the service, site, or activity to be within the approved scope of project.

The "on behalf of" criteria apply to situations in which a health center collaborates with other community organizations to provide certain health services that benefit populations served by the health center, including when the health center provides services to individuals who are not established health center patients.[18] For example, a health center may provide community-based health screenings to non-established patients at locations or events outside the health center, including those sponsored by a non-health center entity. However, a health center may not include within its scope of project a contract with another entity in which a health center provider is a contractor on behalf of that entity. For services to be within the scope of project, the health center would still have to demonstrate that the health screenings are performed on behalf of the health center, rather than on behalf of the other entity. Whether or not the "on behalf of" criteria are met in a specific situation depends on all of the relevant circumstances.

This Scope Manual includes criteria for HRSA to approve certain changes to a health center's scope of project (for example, adding sites and services).

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 budget (also referred to as "total 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 party (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. Other lines of business 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.

[18] For Federal Tort Claims Act (FTCA) coverage to apply to such activities, other requirements under the Federally Supported Health Centers Assistance Act (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).

A health center must exclude the costs of other lines of business from its annual budget for the health center project. However, a health center may use non-grant funds in excess of what is necessary to support the HRSA-approved project ("excess program income") to support other lines of business that further the objectives of the project by benefiting the current or proposed patient population, and where non-grant funds are not utilized for purposes that are specifically prohibited by the Health Center Program. A health center may use revenue generated from other lines of business to support the health center's scope of project.

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:

- Federally Qualified Health Center (FQHC) status, including payment rates, under Titles XVIII (Medicare) and XIX (Medicaid) of the Social Security Act;[19]
- The 340B Drug Pricing Program;[20]
- The National Health Service Corps Program; and
- The Health Center Federal Tort Claims Act (FTCA) Program[21] under the Federally Supported Health Centers Assistance Act (FSHCAA).[22]

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.

[19] 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).
[20] Refer to section 340B of the PHS Act (PDF), as amended (42 U.S.C. 256b).
[21] Refer to section 224(g)-(n) and (q) of the PHS Act (42 U.S.C. 233(g)-(n), and (q)).
[22] 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[23] or one or more of the special medically underserved population(s).[24]

B. Service Area

Health centers first propose their service area in their initial Health Center Program application. They must annually review 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, 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 boundaries of political subdivisions, school districts, and areas served by federal and state health and social service programs;

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[23] Statute requires that a health center serve a "medically underserved population," which means either:

- An urban or rural area designated by the Secretary as having a shortage of personal health services ("medically underserved area" or "MUA"),
- A population of an urban or rural area designated by the Secretary as having a shortage of personal health services or a population group designated by the Secretary as having a shortage of such services ("medically underserved population" or "MUP").

Refer to Section 330(b)(3)(A) of the Public Health Service Act (PHS Act). For the purposes of the Health Center Program scope of project, a health center receiving section 330(e) funding must serve a MUA or MUP; others must serve one or more of the statutory special medically underserved population identified in section 330.

[24] Special medically underserved populations are identified in section 330 for which funding or designation under section 330 may be made available to deliver targeted health services. Refer to sections 330(g), (h), or (i) of the PHS Act.

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; and
d. This area as documented by the ZIP Codes reported on the health center's Form 5B: Sites (Form 5B) includes, at a minimum, those ZIP Codes where at least 75 percent of current health center patients reside, based on patient origin data submitted by the health center through the Health Resources and Services Administration's (HRSA) Health Center Program Uniform Data System (UDS).[25]

A health center may also consider additional geographic or demographic characteristics when identifying its service area, such as:

- Neighborhood characteristics, including available transportation, or
- Aspects of the built environment.

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 records required primary and additional health services, subject to HRSA review and approval, on Form 5A: Services Provided (Form 5A).[26] A health center funded or designated by HRSA to provide services under section 330(e) must make all required in-scope services accessible and available 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 Public Health Service Act (PHS Act) ("special medically underserved population(s)-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 funded or designated to serve special medically underserved populations may choose to provide services to a limited number of patients (under 25 percent of total patients) who are not part of the special medically underserved 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 medically underserved population status. All services must be provided without regard to an individual's ability to pay.

[25] HRSA may include additional service area requirements in Notices of Funding Opportunities and applications.
[26] For more information on accurately completing Form 5A, refer to the HRSA Scope of Project Resources webpage, including the Form 5A Service Descriptors (PDF) and Form 5A Column Descriptors (PDF) resources.

A health center must request approval from HRSA to add a new 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).

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.[27] A health center may provide required primary and additional health services through its staff and supporting resources of the health center ("directly"), through contracts or subawards of section 330 funding, or through cooperative arrangements.[28] Collectively, the Health Resources and Services Administration (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.[29, 30]

A health center records required primary and additional health services, subject to HRSA review and approval, on Form 5A: Services Provided (Form 5A).[31] HRSA considers only those services and service delivery methods (described in Section C. Service Delivery Methods) listed on a

[27] Refer to section 330(b)(1) of the Public Health Service Act (PHS Act) (42 U.S.C. 254b(b)(1)), and 42 Code of Federal Regulations (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.
[28] Refer to section 330(a)(1) of the PHS Act (42 U.S.C. 254b(a)(1)).
[29] Health Center Program requirements are set forth in statute under section 330 of the PHS Act and laws, regulations, grant terms and conditions, and policies incorporated as part of the Health Center Program grant award or designation. Refer to the Health Center Program Compliance Manual.
[30] Quality improvement/assurance, provider credentialing and privileging, and sliding fee discount program requirements may not apply to certain services (for example, transportation). For more detail, refer to the Health Center Program Compliance Manual.
[31] For more information on accurately completing Form 5A, refer to the HRSA Scope of Project Resources webpage, including the Form 5A Service Descriptors (PDF) and Form 5A Column Descriptors (PDF) resources.

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 the organizational level and not for 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[32] offered by the health center organization, either by providing the services directly, through contracts or subawards, or through 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 applications). Health centers may request to add or delete additional services and change service delivery methods for both required and additional services 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 Public Health Service Act (PHS Act);
b. The health center provides the service, either directly, by contract or subaward, or by 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. 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 the HRSA Scope of Project webpage.

[32] A health center may establish a waiting list, based on its policies and operating procedures, due to high need. In such cases, the health center would be compliant with Health Center Program requirements so long as they meet all the criteria described in this Scope Manual.

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.[33] 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[34] or volunteers[35] 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 and Subawards (Form 5A, Column II)

A subrecipient or contractor relationship, for purposes of scope of project, is an agreement that is formalized by a written agreement between the health center and another entity or individual through which the health center offers one or more required primary or additional health services for its patients by subawarding or procuring the services provided from the other entity or individual.[36] Services are provided to the health center's patients by the other party pursuant to the subaward or contract and on behalf of the health center. A health center records these services provided to its patients on Form 5A, in Column II, including services delivered by:

- 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; and

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

[34] 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. For example, this may be documented by a Form W-2 that identifies the health center as the employer or by an associated employment contract with the health center.

[35] Volunteers are only eligible for Federal Tort Claims Act (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 needs 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).

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

- Another party with which the health center has a contract to provide services (for example, a laboratory services company).

Consistent with U.S. Department of Health and Human Services (HHS) grants regulations, a health center provides part of its section 330 award funding as a subaward to a subrecipient to contribute to the goals and objectives of a Health Center Program grant-supported project. In addition, in order to be certified to be a Federally Qualified Health Center (FQHC) as defined in sections 1861(aa)(4)(A)(ii) and 1905(l)(2)(B)(ii) of the Social Security Act, a subrecipient must demonstrate that it meets the requirements to receive a grant under section 330.[37]

A subrecipient that meets this description may be eligible, subject to review and approval by the HHS, to receive FQHC Medicare and Medicaid reimbursement for FQHC services provided at service sites operated by the subrecipient that are in the health center's scope of project and may also be eligible to participate in the 340B Drug Pricing Program. Also, under HRSA Federal Torts Claims Act (FTCA) regulations, a subrecipient of Health Center Program award funding that provides a full range of services on behalf of an eligible Health Center Program award recipient may be eligible to be deemed as a Public Health Service employee for purposes of FTCA coverage under the Federally Supported Health Centers Assistance Act (FSHCAA) 42 U.S.C. 233(g)-(n), but only for those services carried out under the section 330 grant-funded project.[38] Entities that are not subrecipients (and, therefore, cannot meet all other applicable eligibility requirements) are ineligible to receive such associated federal benefits.

A health center must ensure that each of its contracts or subawards for in-scope services is current,[39] executed by all parties (for example, a signed paper copy, electronically-signed documents, emails documenting acceptance), and addresses, at a minimum:

a. The specific services to be performed by the contractor or subrecipient;
b. The process for exchanging patient information between the health center and contractor or subrecipient to ensure patient access to services;
c. How the health center will access patient medical records or documentation of services provided, consistent with applicable laws—specifically, the right of the health center to access the contractor's or subrecipient's patient health records related to the services provided on behalf of the health center;
d. How provider credentialing and privileging will be accomplished;[40]

[37] A recipient-subrecipient relationship is distinct from the relationship that is formed based solely on a contract for goods or services between a health center and a contractor.
[38] 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).
[39] A contract or subaward agreement that includes a provision for automatic renewal of the agreement is considered current, unless either party gives notice of termination before the renewal date. HRSA may, at its discretion, request further information or correspondence to confirm that such a contract is current.
[40] The health center determines how to implement credentialing and privileging procedures for a contractor. For example, an individual contracted provider or a locum will participate in the health center's credentialing and privileging program. In another example, the contractor has its own credentialing and privileging program, and the health center has reviewed that program for compliance with Health Center Program requirements.

e. How the health center will pay or provide funding to the contractor or subrecipient for services the contractor or subrecipient delivers on behalf of the health center;
f. **If the contractor bills and collects for services**, the ability of the health center to review the contractor's billing and collections process and sliding fee discount schedule to ensure compliance with Health Center Program requirements;
g. The applicability of federal and state laws including those related to patient privacy, HHS grant regulations, and civil rights;[41]
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.

A health center may demonstrate that the provisions in this list are addressed if the contract or subaward agreement references the subject matter of each required provision,[42] and the health center addresses each provision:

- Within the contract or subaward agreement,
- In a separate document agreed to by both the health center and contractor or subrecipient, or
- In an appendix to the contract or subaward agreement.

Health centers that deliver services through contracts or 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.[43]

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 or individual that (1) does not involve a subaward or the purchase of services by the health center through a contract and (2) includes provisions (identified in C.3.1 Provisions in Cooperative Arrangements) that ensure the services provided by the other entity or individual to patients meet applicable Health Center Program requirements.

[41] A contract or subaward agreement provision that requires the parties to comply with all laws generally (sometimes called a "catch-all" provision) may satisfy this element. A health center should consult with its legal counsel to confirm compliance with any applicable federal and state laws.
[42] The contract or subaward agreement language can be general and reference a more comprehensive process or policy.
[43] The health center must provide services that enable individuals to access primary care services (including outreach and transportation services and, if a substantial number of the individuals in the population served by a center are of limited English-speaking ability, the services of appropriate personnel fluent in the language spoken by a predominant number of such individuals). Refer to Section 330(b)(1)(A)(iv). The health center must address patient transportation needs for any service that a portion of the health center's patient population can only access through a contract.

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 party that provides services identified in the arrangement to health center patients.

The health center maintains responsibility for oversight of the cooperative arrangement, including the actual terms of the written agreement.[44] The health center is not responsible for overseeing the delivery of the service itself. However, a health center must assist a patient in making an appointment for any service that the patient can only access through a cooperative arrangement.[45] A health center is also responsible for ensuring it receives all follow-up results and coordinates ongoing care for the patient as needed.

The health center also maintains responsibility for any follow-up care,[46] based on the care and follow-up instructions provided by the other party. 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; or
- Another party with which the health center has a cooperative arrangement to provide services).

When a health center establishes a cooperative arrangement with another party (recorded on Form 5A, Column III) ("Column III provider") to provide access to one or more required primary or additional health services for its patients, 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 "cooperative arrangement activities" (for example, assisting the patient in making the appointment, follow-up care and coordination) carried out by the health center establishing the cooperative arrangement to be in their scope of project.

In cases where another health center is acting as the Column III provider via a cooperative arrangement, that other health center may 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 health center to be an established patient of the other health center, as long as the requirements in Chapter 8, Section B: Patients and Visits are

[44] For additional oversight information, refer to C.3.1.

[45] A patient can only access a service through a cooperative arrangement when either:
(1) The health center does not offer the service through another service delivery method, or
(2) The other service delivery method is not accessible to the patient because the service is provided directly only at a service site that is a significant distance from the impacted patient.

[46] Follow-up care includes the health center's own treatment plan for the health center patient.

met.

C.3.1. Provisions in Cooperative Arrangements

A health center must ensure that each of its cooperative arrangements for services is current,[47] 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 addresses, at a minimum, the following provisions:[48]

a. The specific activity(ies) or services to be performed by the other party;
b. How the other party will apply a discount to its schedule of charges[49] for services the other party provides to health center patients;[50]
c. The process for exchanging patient information between the health center and the other party to ensure patient access to services;
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 party to provide information related to the services provided by the other party, 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 and civil rights.[51]

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

[47] To demonstrate to HRSA the currentness of the agreement, a cooperative arrangement that includes a provision for automatic renewal of the arrangement is considered current by HRSA, unless either party gives notice of termination before the renewal date. HRSA may, at its discretion, request further information or correspondence to confirm that such a cooperative arrangement is current.

[48] The provisions in this list will be considered addressed if the cooperative arrangement:
(1) References the subject matter of the required provision, and
(2) Either addresses the provision:
(a) Within the contract, or
(b) In a separate document agreed to by both the health center and the other party, or in an appendix to the cooperative arrangement.
Criteria b. is an exception; refer to the next footnote for additional information.

[49] The other party's schedule of charges may differ from a health center's schedule of charges.

[50] Discounts will be applied to any charges for the Column III services based on income and family size. Where the other party does not agree to a discount program that meets Health Center Program requirements for all patients seen through the cooperative arrangement, a health center must document that it ensures by other means that fees for such services are discounted as required under the Health Center Program. This would include documentation of an agreement by the other party to inform the health center of any fees charged to health center patients. Refer to the Health Center Program Compliance Manual, Chapter 9: Sliding Fee Discount Program.

[51] A cooperative arrangement provision that requires the parties to comply with all laws generally (sometimes called a "catch-all" provision) may satisfy this element. A health center should consult with its legal counsel to confirm compliance with any applicable federal and state laws.

credentialing and privileging, enabling access to services for those with limited English proficiency. (Section 330(b)(1)(A)(iv)). The health center must address patient transportation needs for any service that a portion of the health center's patient population can only access through a cooperative arrangement.

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 from a health center to another party, including a party 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 party, 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 party, 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.[52]

[52] 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 make required and additional health services within their scope of project available and accessible 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 to deliver required primary and additional health services to health center patients when necessary or helpful to ensure access to care. [53, 54] 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 Health Resources and Services Administration (HRSA) approval; rather, telehealth is a mechanism or means for delivering health services to health center patients using telecommunications technology or equipment.

A health center should consider the needs of the population served and seek patient input when 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.[55] 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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[53] 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.
[54] Telehealth resources are available at Telehealth.HHS.gov.
[55] 42 Code of Federal Regulations (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;
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 ZIP Codes 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 either physically located within or a resident of a health center's service area or areas adjacent[56] to the health center's service area.

Subject to 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,[57] and informing patients of other services offered by the health center;

[56] For the purposes of this policy, areas adjacent to a health center's service area are: 1) The local jurisdiction (county, township, borough, parish, city, or equivalent type of minor civil division) adjacent to the area covered in whole or in part by the ZIP Codes, for each approved service site, as identified by the health center on its Form 5B: Sites (Form 5B), and 2) Any ZIP Codes not identified on Form 5B, but that are within such local jurisdictions covered in part by the service area ZIP Codes.
[57] 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 330(k)(3)(G) of the Public Health Service Act).

b. The health center takes appropriate steps to determine and record the location of patients accessing services via telehealth and to ensure that services are provided to each patient in a manner consistent with applicable federal, state, and local laws, including licensure;
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 are either physically located within or a resident of the health center's service area or areas adjacent to the health center's service area.[58] If an established patient is no longer either a resident of or physically located within the health center's service area or areas adjacent to the health center's 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). 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;[59]
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.

[58] For the purposes of this policy, areas adjacent to a health center's service area are: 1) The local jurisdiction (county, township, borough, parish, city, or equivalent type of minor civil division) adjacent to the area covered in whole or in part by the ZIP Codes, for each approved service site, as identified by the health center on its Form 5B, and 2) Any ZIP Codes not identified on Form 5B, but that are within such local jurisdictions covered in part by the service area ZIP Codes.

[59] 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. Sites Within the Scope of Project

Health centers record service sites and other sites, subject to the Health Resources and Services Administration (HRSA) review and approval, on Form 5B: Sites (Form 5B).[60] 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.[61]

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 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.[62]

A service site is a location, approved by HRSA, where a health center provides 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 or subrecipient of section 330 grant funds[63] that provides services on behalf of the health center.

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[60] In addition, a health center will record on Form 5B locations where the health center provides services consistent with Policy Information Notice (PIN) 2024-05 (PDF). Refer to the HRSA Scope of Project Resources webpage for additional guidance on documenting sites in scope.

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

[62] For health centers proposing sites that will serve residents of public housing under section 330(i), refer to Chapter 6, Section B: Factors for Adding a Service Site.

[63] Organizations that receive federal award funding from a health center and demonstrate compliance with all requirements of section 330 ("subrecipients") may meet the definition of "federally qualified health center" (FQHC) under sections 1861(aa)(4)(A)(ii) and 1905(l)(2)(B)(ii) of the Social Security Act. A subrecipient may be

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 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 patient support services that do not generate patient visits, provides only pharmaceutical services, or provides transitional care in a carceral setting ("TCCS").[64]

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 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;[65]
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: Services Provided (Form 5A), Column I) or through a contract or subaward (as documented on Form 5A, Column II);[66]
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. Approved the addition of the service site, the hours of operation, and services to be provided at the service site, and

eligible, subject to review and approval by the U.S Department of Health and Human Services, 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 Health Center Program award recipient also may be eligible for Federal Tort Claims Act (FTCA) coverage under the Federally Supported Health Centers Assistance Act (FSHCAA), but only for those services carried out under the grant-funded project.

[64] Refer to Policy Information Notice (PIN) 2024-05 (PDF).

[65] 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.

[66] A location where the only services provided are through cooperative arrangements (Form 5A, Column III) does not meet the definition of a service site.

ii. Retains control and authority over the provision of all services provided by the health center at the service site;[67]

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[68] 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).[69] Unlike permanent or seasonal service sites, a mobile service site or temporary emergency site does not need to provide services on a regularly scheduled basis.[70]

C. Service Sites with Limited Services

A health center is required to make all required primary health services and all HRSA-approved additional services available and accessible to its patient population. 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.[71]

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:[72]

[67] For more information, refer to the Health Center Program Compliance Manual, Chapter 19: Board Authority.
[68] For this criterion, "accessible" means that the health center must have the right to access these records, but the health center does not need to be the record custodian. For example, the record custodian could be a subrecipient or contractor who operates the service site.
[69] Section 330(k)(3) of the Public Health Service 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 Code of Federal Regulations (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.
[70] Refer to Chapter 7: Temporary Service Sites Added in Response to Emergency Events.
[71] When deciding to add a limited-service site, a health center should consider whether such a site will be eligible for federally qualified health center (FQHC) reimbursement rates under Medicare and Medicaid, as there may be requirements for FQHC reimbursement rates related to a site providing comprehensive services.
[72] 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. HRSA will work with a health center that has existing migrant voucher screening sites to determine whether the site meets the service site definition.

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 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, if applicable under state law, licensed to render in-scope services on behalf of the health center. These vehicles travel to various locations throughout the health center's service area to treat patients inside the mobile service site.[73] 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.[74]

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, directly-operated locations 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 center activities:

[73] Mobile service sites may be used to provide services to a health center's service area based on the ZIP Codes identified on Form 5B for the permanent service sites and seasonal service sites, as well as areas adjacent to those ZIP Codes. Refer to Sections D.1 and D.2; refer to Section 4.B: Criteria for Delivering Services via Telehealth for the definition of "adjacent." A health center may not add additional ZIP Codes to its service area that are only served by the mobile service site and not identified on Form 5B for a permanent or seasonal service site.
[74] Additional guidance on documenting a mobile site location will be included in the Instructions for Form 5B: Sites.

a. Administrative work for the health center project (for example, billing and accounting, information technology, and 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 patient support or other service generates 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.
d. Transitional Care in a Carceral Setting location where the health center provides services consistent with Policy Information Notice (PIN) 2024-05 (PDF).

Administrative, patient support, 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: Considerations When Adding a Service Site to Scope of Project

In this chapter:

A. Service Area Overlap Considerations

The Health Resources and Services Administration (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 responsibility includes determining the extent to which the location of health center sites will provide for an appropriate distribution of resources throughout the country and support collaboration between health centers.[75]

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:[76]

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: Factors for Adding a Service Site for additional information on the impact of service area overlap on change in scope decisions.

[75] Refer to 42 Code of Federal Regulations (CFR) 51c.305.
[76] A Health Center Program award recipient or look-alike may add service sites and expand its service area through the change in scope process, and a Health Center Program award recipient may also add service sites and expand its service area through new or supplemental funding applications.

B. 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:[77]

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 Unmet Need Score;
    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);
    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); or
    iv. Data from other relevant parties—including health centers serving the proposed service area—related to current capacity, utilization rate, unmet need, and existing or proposed partnerships or expansion plans.
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 Unmet Need Score, 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 service area (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 existing boundaries of political subdivisions, school districts, and relevant boundaries of federal and state health and social service programs.[78]

[77] In addition to the factors included in this subsection, HRSA may also conduct an 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 medically underserved population).

[78] HRSA recognizes that a health center may have a service area that crosses political boundaries (for example, a

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, 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;[79]
    iii. Results of a statistically significant survey of residents in the proposed new service area;[80] 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 demonstrates coordination and collaboration with each Health Center Program award recipient and designee serving the service area of the proposed service site, consistent with the Health Center Program Compliance Manual.[81]
h. For a proposed service site that will serve residents of public housing[82] under section 330(i), whether:
    i. The proposed service site is located in public housing or is otherwise immediately accessible[83] to public housing; or
    ii. The health center identifies and documents which individuals seen at the service site live in public housing or areas immediately accessible[84] 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. 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.
k. The proposal includes inaccurate, false, or misleading information.

As part of its change in scope request to add a new site, a health center may submit additional information or documentation for HRSA consideration, including letters of support from

health center near a state border may serve patients in multiple states; that health center may include ZIP Codes along both state's border in its service area).

[79] For example, either 2 percent or 200 of the adult residents of the proposed service area, whichever is less.

[80] For example, a random sample of at least 100 adult residents with a confidence level of at least 90 percent.

[81] Refer to the Health Center Program Compliance Manual, Chapter 14: Collaborative Relationships.

[82] 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 Public Health Service Act (PHS Act).

[83] 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.

[84] For the purposes of section 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.

community partners[85]

C. Service Sites Co-located with Other Organizations or Other Lines of Business

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). A health center may also request to add a service site at a location where the health center or a health center parent, affiliate, or subsidiary operates an other line of business. The health center must demonstrate to HRSA that the health center is providing services at 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 service site, operated and controlled by the health center, that is co-located in a room or suite of rooms leased in a building(s) such as:

- A hospital campus;
- A school campus;
- A behavioral health organization facility;
- A library; or
- At another location where the health center operates an other line of business, such as a soup kitchen.[86]

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 or other line of business and that the service site is operated independently from the other entity or other line of business and on behalf of the health center.[87]

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:[88]

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 as set forth in statute under section 330 of the Public Health

[85] For example, a health center that is proposing a site within one mile of another health center's existing site may choose to provide a letter from the other health center that supports the specific proposed site.
[86] For service sites located in buildings or campuses that are owned or operated by another entity, refer to Instructions for Form 5B: Sites for guidance on accurately recording the physical addresses of such sites.
[87] Refer to Chapter 1.C: General Criteria for Including Activities within the HRSA-Approved Scope of Project.
[88] A health center must comply with all federal, state, or local legal requirements applicable to the particular co-location model, including requirements for operating within a school location, provided that such other requirements do not conflict with Health Center Program requirements.

Service Act (PHS Act) and laws, regulations, and policies incorporated as part of the Health Center Program grant award or designation;

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 service site meets all service site criteria (refer to Chapter 5, Section B: Criteria Required for Service Sites);
c. The health center maintains an agreement with the other party (through a contract, memoranda of understanding, memoranda of agreement, or other relevant document) to 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 that they are in a health center location and that they can access services regardless of ability to pay.

A health center may—as part of its scope of project and as part of the continuum of health center care ("continuity of care")—provide services to established health center patients at locations that are not service sites, such as labor and delivery services at a hospital or follow-up care at a rehabilitation facility or nursing home so long as such services are provided on behalf of the health center and are in accordance with Health Center Program requirements. HRSA does not consider the provision of continuity of care at these locations 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 party or operating or managing a facility or the delivery of health care on behalf of another party (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 party, would do so as an "other 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 party is not consistent with the purpose of the Health Center Program.

D. Service Sites Operated by Contractors or Subrecipients

A health center requesting to add a service site operated entirely by a contractor, or a subrecipient, must demonstrate that the entity 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 service site.

A site is "contractor-operated" or "subrecipient-operated" when the contractor or subrecipient has functional control and responsibility over the service site's day-to-day operations. A directly-operated site (not contractor- or subrecipient-operated) is one where on-site staff directly employed by the health center have functional control and responsibility over the service site's day-to-day operations.

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

- Contractor organization that is paid with 330 award funds but does not meet all Health Center Program requirements ("contractor"). The health center ensures the delivery of health care on behalf of the health center at the service site meets the requirements of section 330 by including the required provisions in the contract;[89] or
- Subrecipient organization that receives section 330 award funding ("subaward") from a Health Center Program award recipient and demonstrates compliance with all of the requirements of section 330 ("subrecipient").[90]

While health centers have flexibility to operate service sites through agreements with subrecipients or contractors, the purpose of the Health Center Program is best achieved when the awarded health center directly operates the in-scope sites, and the health center governing board has direct oversight over the operations of the site. 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, per statute and regulations.[91]

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[89] ***For contractor-operated sites:*** A contractor-operated site is not a subrecipient and does not meet the definition of "federally qualified health center" (FQHC) under sections 1861(aa)(4)(A)(ii) and 1905(l)(2)(B)(ii) of the Social Security Act (SSA). A contractor is not eligible for Health Center Program-related benefits, including Federal Tort Claims Act (FTCA) liability protections under the Federally Supported Health Centers Assistance Act (FSHCAA) and FTCA Program regulations at 6 CFR part 6, FQHC reimbursement rate under Medicare and Medicaid, and 340B Drug Pricing Program.

[90] ***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 "subrecipient" receives section 330 award funding (a "subaward") from a Health Center Program award recipient to operate a service site and meets all requirements under section 330 of the PHS Act. Such an entity may be eligible, subject to review and approval by the U.S. Department of Health and Human Services (HHS), to be a "federally qualified health center" 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 SSA. Refer to Chapter 3.C.2 Contracts and Subawards (Form 5A, Column II). 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.

[91] Refer to 42 CFR 51c.305(d)-(f), (l) and section 330(k)(2) of the PHS Act.

Therefore, HRSA will not approve new requests[92] for contractor or subrecipient-operated service 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: Services Provided (Form 5A), Column I); and
- Directly operate at least one[93] service site on its Form 5B: Sites.

Any health center proposing a contractor- or subrecipient-operated service site must demonstrate that the service site meets all of the following criteria:[94]

a. The service site meets all of the criteria outlined in Chapter 1, Section A: Definition of Scope of Project 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 and 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);[95]
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;
    i. A good cause justification is documentation that 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;
e. The contract or subaward to operate the service site is made according to the health center's written procurement and other procedures that comply with all federal requirements, including, as applicable, those set forth in 2 Code of Federal Regulations (CFR) Part 200; and
f. All of the following provisions are included in either the contract to operate the service site or another document agreed to by both the health center and contractor or subrecipient:
    i. The health center's governing board retains its authority to approve the hours of operation and services provided at the contracted service site, evaluate the

[92] This excludes public agency awardees whose co-applicant provides services and health centers that only receive section 330(g) award funding.
[93] When a health center that does not directly operate at least one service site proposes to operate a new service site through a contractor or subrecipient, HRSA may, at its discretion, evaluate such situations on a case-by-case basis to determine whether the circumstances justify an exception to this requirement. A health center that does not directly operate at least one of its service sites at the time of publication of this policy is not out of compliance with this policy, and this policy does not require a health center to close any existing service sites based on its current number of contractor- and subrecipient-operated sites. However, a health center that does not directly operate at least one of its service sites may not add more contractor- or subrecipient-operated sites until it has added at least one directly operated service site.
[94] A health center must demonstrate its contractor- or subrecipient-operated site meets the criteria in this chapter in its change in scope request or in new or supplemental funding applications, and on an ongoing basis.
[95] Refer to section 330(b)(1)(A)(iv).

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.[96]

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 service sites, the health center must document at the time the subaward agreement is executed, and must ensure on an ongoing basis for the length of the agreement, that the subrecipient operating the service site will:

a. Receive section 330 award funds under a 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.[97] For example, a health center receiving funding only under section 330(e) (in other words, not receiving funding under a special medically underserved population funding stream) 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. A subrecipient is not eligible for any governance waivers if the Health Center Program award recipient is not eligible for that waiver.

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.

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

[96] For further guidance on these requirements, refer to the HHS Grants Policy Statement at HHS Grants Policies & Regulations.
[97] Refer to the Health Center Program Compliance Manual, Chapter 12: Contracts and Subawards.

(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 2 CFR 200.331-333.

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

A health center might propose a contractor-operated service site if the health center is unable to operate the service site directly or when the contractor is a more efficient and effective means by which to operate the service site. A health center is responsible for ensuring that a service site operated by a contractor is in compliance with all applicable Health Center Program requirements, as further described in this section. Refer to Chapter 3.C.2 Contracts and Subawards (Form 5A, Column II) for a list of necessary provisions in the contract between a health center and a contractor organization.

Operating a service site through such a third-party contract does not make the third-party entity a "health center" within the meaning of the Scope Manual.[98] Entities operating service sites that do not comply with Health Center Program requirements (for example, the third-party organization does not have a governing board that meets the same requirements as the Health Center Program award recipient) do not meet the definition of an Federally Qualified Health Center (FQHC) under the Social Security Act.[99] In addition, contractor entities that operate health center service sites are not eligible for liability protections under Federally Supported Health Centers Assistance Act (FSHCAA).

HRSA, through its oversight of the health center, will ensure that the health center can demonstrate that it is meeting all Health Center Program requirements at contractor operated sites. 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 or another document agreed to by both the health center and contractor addresses:

a. How the health center's sliding fee discount program will be applied to 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 based on income and family size (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;[100]

[98] Refer to Chapter 3, Section C.2: Contracts and Subawards (Form 5A, Column II).
[99] Refer to sections 1861(aa)(4)(B) and 1905(l)(2)(B)(ii) of the Social Security Act (42 U.S.C. 1395x(aa)(4)(B) and 42 U.S.C. 1396d(l)(2)(B)(ii)).
[100] The contract language can be general and reference a more comprehensive process or policy. The health center

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 contractor will ensure that health center patients with Limited English Proficiency are able to access services (for example, the health center will provide the contractor with access to the health center's interpretation assistance services);[101]
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; and
i. How the contractor demonstrates that it maintains professional and medical malpractice liability insurance for its personnel who provide services to the health center.

determines how to implement credentialing and privileging procedures for a contractor-operated site. For example, the contractor has its own credentialing and privileging program, and the health center has reviewed that program for compliance.

[101] Refer to section 330(b)(1)(A)(iv).

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 Health Resources and Services Administration (HRSA) notification and approval process. For the purposes of the Scope Manual and other related program guidance, unless otherwise specified, an "emergency" is an event that:

a. Affects the health center's patient population, other residents of the service area, or the community at large,
b. And either:
    - Precipitates a declaration of a state of emergency or a major disaster at a local, state, tribal, territorial, 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; or
    - When an emergency has not been declared, HRSA determines, on a case-by-case basis, that the circumstances and emergency-related needs justify the approval of a temporary service site.

Examples of events that may precipitate an emergency declaration 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 urgent public health threats.

HRSA may approve a temporary service site for up to 90 days.[102]

[102] HRSA may consider requests for extensions of up to 90 days, for such approvals, if the health center sufficiently justifies continued emergency-related needs for the temporary service site. HRSA will not extend approval for a temporary site in response to an emergency event beyond one year from the original approval.

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,[103] 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;[104, 105]
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;[106, 107, 108]
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, tribal, territorial, or local emergency response efforts, including with other health centers in the geographic area.

[103] Temporary service sites do not need to have regularly scheduled hours to meet the requirements in Chapter 5. Refer to Chapter 5.B: Criteria Required for Service Sites.
[104] For the purposes of this policy, areas adjacent to a health center's service area are: 1) The local jurisdiction (county, township, borough, parish, city, or equivalent type of minor civil division) adjacent to the area covered in whole or in part by the ZIP Codes, for each approved service site, as identified by the health center on its Form 5B: Sites (Form 5B), and 2) Any ZIP Codes not identified on Form 5B, but that are within such local jurisdictions covered in part by the service area ZIP Codes.
[105] 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.
[106] 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).
[107] For information on Federal Tort Claims Act (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.
[108] HRSA considers only those services and service delivery methods approved and included on a health center's Form 5A: Services Provided to be within the health center's HRSA-approved scope of project. Refer to Chapter 3, Section B: Criteria Required for In-Scope Services.

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). For discussion of eligibility for Federal Torts Claims Act (FTCA) coverage under emergencies, refer to 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).

Chapter 8: Providers, Patients, and Visits

In this chapter:

A. Providers

Health Center providers 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[109] (for example, depending on state law, physician, dentist, physician assistant, nurse practitioner, clinical psychologist, pharmacist),
- Other licensed or certified practitioners (for example, depending on state law, registered nurse, licensed practical nurse, registered dietitian, clinical social worker, 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).[110]

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 an **established health center patient** when the health center patient-provider relationship is established.[111] The health center **patient-provider relationship** is established when **all** the following criteria are met:

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[109] A licensed independent practitioner (LIP) is a physician, dentist, nurse practitioner, nurse midwife, or any other individual permitted by law and the organization to provide care and services without direction or supervision, within the scope of the individual practitioner's license and consistent with individually granted clinical privileges. Refer to Policy Information Notice (PIN) 2011-02: Free Clinics Federal Tort Claims Act (FTCA) Program Policy Guide (PDF).

[110] For more information, refer to the Health Center Program Compliance Manual, Chapter 5: Clinical Staffing.

[111] Health center "patient" (also called "established 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 Health Resources and Services Administration (HRSA)-approved Health Center Program scope of project.

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 either physically located within or a resident of the health center's service area or 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.[112, 113]

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.[114, 115]

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).

[112] For more information, refer to the Health Center Program Compliance Manual, Chapter 10: Quality Improvement/Assurance.
[113] 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 the Federally Supported Health Centers Assistance Act (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."
[114] A group visit may establish a patient-provider relationship so long as the visit meets all other applicable Health Center Program compliance requirements.
[115] 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

Health center services (as documented on Form 5A: Services Provided (Form 5A)) that are provided on behalf of a health center at a Health Resources and Services Administration (HRSA)-approved service site (as documented on Form 5B: Sites (Form 5B)) 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 patien**t, as part of continuity of care, 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:

1. The health center provider is delivering the service to an established health center patient on behalf of the health center, as further described in this policy, 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);
2. The service provided is an in-scope service; and
3. The health center documents the encounter in the established patient's health center records.

A health center may also provide in-scope services on behalf of the health center to individuals who are **not established** patients of the health center at a location that is not a HRSA-approved service site if all the following criteria are met: [116, 117]

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. If the service generates a patient visit (refer to Chapter 8, Section B: Patients and Visits), 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
d. The in-scope service provided falls within one or more of the following categories:

[116] The Federally Supported Health Centers Assistance Act (FSHCAA) defines the availability of liability protections, including Federal Tort Claims Act (FTCA) coverage, and specifically limits coverage for services provided to individuals who are not health center patients.
[117] In-scope services provided via telehealth are subject to the criteria in Chapter 4: Services Provided via Telehealth and are not subject to the criteria in this chapter. An individual may become an established health center patient via telehealth consistent with both Chapters 4 and 8.

i. **Portable Care and Outreach:** Health center staff may provide in-scope required primary or additional health services to individuals at various community locations that are not service sites (refer to Chapter 5, Section B: Criteria Required for Service Sites), at locations accessible to or frequented by underserved populations, to meet the needs of those populations. Such **locations must be within the health center's service area,** and services must be provided on an ad-hoc basis rather than on a regularly-scheduled basis. This includes providing care at locations that do not meet the definition of a service site. Examples include residence camps, farm fields or canneries, shelters, or soup kitchens. Portable care may include health center staff conducting health education, outreach, screening, immunizations, or other clinical or non-clinical services at health fairs or other community-based settings.[118]

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.[119, 120]

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.[121]

iv. **Emergency Response Activities:** Health center staff may provide in-scope required primary or additional health services during declared emergencies to individuals at various locations that do not meet the temporary service site definition described in Chapter 7, Section A: Adding Temporary Service Sites in Response to Emergency Events. 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 geographically as described in Chapter 7, Section B: Criteria for Adding Temporary Service Sites in Response to Declared Emergencies.[122] 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

[118] Refer to 42 Code of Federal Regulations (CFR) 6.6(e)(4)(i).
[119] Refer to 42 CFR 6.6(e)(4)(ii).
[120] Scheduled surgeries for individuals that are not established health center patients are not considered in scope.
[121] Refer to 42 CFR 6.6(e)(4)(iii).
[122] In situations where the purpose of the activity is to serve communities outside the geographic areas described in Chapter 7, 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.

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. 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.[123]

[123] 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 the Health Resources and Services Administration (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)."[124, 125] A health center proposing to make a change to its scope of project[126] 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. Will be accomplished without additional Health Center Program federal award funding (for Health Center Program award recipients only);
c. Will not shift resources away from carrying out the current HRSA-approved scope of project; and
d. Will either:
    i. Deliver services, operate sites, and conduct activities **on behalf of** the health center; and address unmet need, maintain, or increase access to care for the patient population; *or*
    ii. Remove a site or service without reducing or limiting the accessibility of services available to the patient population (for example, the health center documents that closing a service site will not reduce the ability of established patients to access health center services).

For any change in scope request, HRSA may request more information, as needed, to make an approval or disapproval decision. A requested change in the scope of project is reflected in

[124] Refer to 2 Code of Federal Regulations (CFR) 200.308(f)(1).
[125] HRSA may take administrative action to correct a health center's Form 5A: Services Provided (Form 5A) or Form 5B: Sites (Form 5B), with notice to the health center, so that the health center's scope of project is consistent with scope of project policy. Refer to Chapter 1.A: Definition of Scope of Project.
[126] 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 Federally Qualified Health Center (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.

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.

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

To make a change to its scope of project, the health center must submit a request through the designated HRSA system, which allows HRSA to review and approve the change. There are two kinds of change in scope (CIS) requests:

- Formal: A formal change in scope request is required to make any of the following changes to a health center's scope of project:
  - Adding or deleting a service or service delivery method;[127] or
  - Adding or deleting a site, including moving a site from one physical address to another.

- Scope adjustment: A scope adjustment is required for other changes. Examples where scope adjustments may be used are updates to:
  - A required service where a newly-funded or newly-designated health center failed to verify the service was implemented within 120 days of the initial funding or designation notice,
  - An existing service where the requested change is adding either a Column I or Column II service delivery method on Form 5A, or
  - Information about a site (such as hours of operation, months of operation, ZIP Codes).

Refer to the HRSA Scope of Project webpage for additional information on the process and timelines for making changes to a health center's scope.

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 Public Health Service Act (PHS Act) ("special medically underserved population-only health center") must provide services to the statutorily-defined special medically underserved population(s) for

[127] If a health center has a service in both Columns I and III of Form 5A and the requested change is to only delete the Column III service delivery method, a formal change in scope is not required.

which it is funded/designated within the health center's defined service area. A special medically underserved population-only health center may provide services to patients who are not within its funded/designated population.

However, if the number of such patients becomes more than 25 percent of the health center's total patient population, a special medically underserved population-only health center must request prior approval from HRSA to reallocate its funding. Reallocating funding will allow a health center to continue providing services within the scope of the health center's project to the patients not previously within its funded/designated population.

For example, a health center that is only funded to serve homeless individuals (a section 330(h) recipient) now has a patient population that includes 30 percent or more general medically underserved patients. This health center must submit a request to reallocate its funding to include section 330(e) funding. HRSA approval of the reallocation also adds the general medically underserved patient population to the health center's scope of project, and the health center must demonstrate that it meets both 330(h) and 330(e) requirements.

A special medically underserved population-only health center proposing to add a new medically underserved population or special medically underserved population to its scope of project via a HRSA prior approval must document that the requested change will:

a. Maintain, to the extent possible, the existing level of services for the special 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 special medically underserved population(s).[128]

If HRSA approves a health center's request to add a new special 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 special medically underserved population.

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

[128] Health Center Program requirements are set forth in statute under section 330 of the PHS Act and laws, regulations, and policies incorporated as part of the Health Center Program grant award or designation. Refer to the Health Center Program Compliance Manual for program requirements.

D. Additional Scope of Project Information and Resources

The HRSA Scope of Project Resources webpage 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 special medically underserved 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.

Glossary

All terms in this glossary are defined for the purposes of the Health Resources and Services Administration Health Center Program scope of project policy.

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 Health Resources and Services Administration-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 the Health Resources and Services Administration, 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 the Health Resources and Services Administration when a health center proposes to make changes to its scope of project, even if there is no associated budget revision. Refer to Chapter 10: Changes in Scope of Project and the HRSA Scope of Project webpage.

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 between the health center and another entity or individual 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 or individual. (Section 330(a)(1) and 2 Code of Federal Regulations 200.1). Such contracts, when entered into by a funding recipient, are subject to requirements for contracts under the grants regulation.

Contractor: An entity or individual, 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 or individual.

Contractor-Operated Site: A service site is "contractor-operated" when the health center maintains oversight and the contractor has functional control and responsibility over the site's day-to-day operations, as further described in this manual.

Cooperative Arrangement: A formal written arrangement between a health center and another entity or individual that (1) does not involve the purchase of services by the health center through a contract or a 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 or individual meet applicable Health Center Program requirements as set forth in statute under section 330 of the Public Health Service Act and laws, regulations, and policies incorporated as part of the Health Center Program grant award or designation.

Directly-Operated Site: A directly-operated service site (not contractor-operated) is one where on-site staff directly employed by the health center have functional control and responsibility over the service site's day-to-day operations.

Emergency: An event that:

a. Affects the health center's patient population, other residents of the service area, or the community at large; and
b. Precipitates declaration of a state of emergency 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): An organization, as defined in the Social Security Act, that qualifies for specific reimbursement systems under Medicare and Medicaid. Eligible organizations include organizations receiving grants under section 330 of the Public Health Service Act, subrecipients that meet the requirements of section 330, look-alikes, and certain tribal organizations. (Section 1861(aa)(4)(B) and section 1905(l)(2)(B) of the Social Security Act).

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

Form 5B: Sites: Official documentation of service sites and other sites included in a health center's Health Resources and Services Administration (HRSA)-approved scope of project. This form is contained in the health center's folder in the designated HRSA systems. Refer to the HRSA Scope of Project webpage for additional information.

Medically Underserved Area (MUA): An urban or rural area designated by the Secretary as having a shortage of personal health services. Refer to section 330(b)(3)(A) of the Public Health Service Act and the Health Resources and Services Administration Shortage Designation for definitions and more information about MUAs.

Medically Underserved Population (MUP): The population of an urban or rural area designated by the Secretary as having a shortage of personal health services or a population group

designated by the Secretary as having a shortage of such services. Refer to section 330(b)(3)(A) of the Public Health Service Act (42 U.S.C. 254b(b)(3)(A)) and the Health Resources and Services Administration Shortage Designation for definitions and more information about MUPs.

On Behalf Of: An activity is provided "on behalf of a health center as part of the Health Resources and Services Administration (HRSA)-approved Health Center Program scope of project" when the activity meets the criteria in Chapter 1, Section C: General Criteria for Including Activities within the HRSA-Approved Scope of Project. Criteria for demonstrating that activities occur "on behalf of" the HRSA-approved Health Center Program scope of project 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, contractors, and volunteers deliver in-scope services or activities at a 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 the decision to provide services through such subawards, contracts, or cooperative arrangements (refer to Chapter 3, Section C.2: Contracts and 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 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.

HRSA recognizes that there may be other definitions of "on behalf of." For the purposes of the Health Center Program scope of project and in this policy, this term refers specifically to services, sites, and activities that are part of the HRSA-approved, Health Center Program scope of project. Other lines of business conducted by a health center entity, including the provision of health services by a health center provider under a contractual arrangement where the health center—or a health center provider—is a contractor for a third-party entity, are not considered "on behalf of" the health center for Health Center Program scope of project purposes. Refer to Chapter 1.D. Limitations on Health Center Program Scope of Project and Other Lines of Business. A statement that a service is being provided "on behalf of" a health center for purposes of the Health Center Scope of Project does not alone create a principal-agent relationship, or any other representative relationship.

Other Lines of Business: Activities conducted by a health center that are outside the health center's Health Resources and Services Administration-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 Program).
c. Pharmaceutical services at a stand-alone pharmacy site that do not generate a patient visit.
d. Transitional Care in a Carceral Setting location where the health center provides services consistent with Policy Information Notice (PIN) 2024-05 (PDF).

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

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 either physically located within or a resident of the health center's service area or 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.
d. A group visit may establish a patient-provider relationship so long as the visit meets all other applicable Health Center Program compliance requirements.

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 under Section 330(a)(1)(A) of the Public Health Service Act (PHS Act), as defined in section 330(b)(1) of the PHS Act. (Refer to the HRSA Scope of Project Resources webpage for more information.)

Scope of Project: The Health Resources and Services Administration (HRSA)-approved activities carried out on behalf of a health center, whether directly, by contractor, 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 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 Act (42 U.S.C. 254b): The authorizing legislation for the Health Center Program, including, for example, subsections 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 applications 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 Codes 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 contractors, subawards or cooperative arrangements. (Refer to Chapter 3, Section C: Service Delivery Methods).

Service Site: A service site is a location, approved by the Health Resources and Services Administration (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: Services Provided, Column I) or through a contract or subaward (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. 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). Unlike permanent or seasonal service sites, a mobile service site or temporary emergency site does not need to provide services on a regularly-scheduled basis.

(Refer to Chapter 5.B Criteria Required for Services Sites, 5.C Service Sites with Limited Services, and 5.D Service Site Types)

Special Medically Underserved Population: A specific population group designated by the Secretary as having a shortage of health services. Refer to sections 330(b)(3)(A) and 330(g), (h), or (i) of the Public Health Service Act.

Subaward: Part of a section 330 award provided by a Health Center Program award recipient to a subrecipient to contribute to the goals and objectives of a Health Center Program grant-supported project. In addition, in order to be certified 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, a subrecipient must demonstrate that it meets the requirements to receive a grant under section 330. A subaward may be provided through any form of legal agreement, including an agreement that the Health Center Program award recipient considers a contract. (2 Code of Federal Regulations 200.1).

Subrecipient: An entity that receives part of or all of a section 330 award funding under a subaward from a Health Center Program award recipient to contribute to the goals and objectives of a Health Center Program grant-supported project. (2 Code of Federal Regulations 200.1). In addition, in order to be certified 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, a subrecipient must demonstrate that it meets the requirements to receive a grant under section 330.

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 Service 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. A group visit is considered a visit so long as it meets all other applicable Health Center Program compliance requirements. Refer to definition of "Patient-Provider Relationship."