Summary of Public Comments and HRSA Responses on the Draft Health Center Program Scope of Project Policy Manual

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Purpose of the Summary of Public Comments and HRSA Responses Document

On December 9, 2024, the Health Resources and Services Administration (HRSA) requested public comment for the draft Health Center Program Scope of Project Policy Manual (Scope Manual). HRSA published the notice of the draft Scope Manual in the Federal Register (89 FR 97629) and accepted comments until February 7, 2025. This document summarizes comments and provides HRSA responses to comments on the draft Scope Manual.

HRSA revised the draft policy to incorporate key suggestions and clarifications received from a range of individuals and organizations (commenters), including:

- Health centers,
- Primary Care Associations,
- National Technical Assistance Partners,
- Municipal governments, and
- Individuals.

Final Policy

HRSA's Scope Manual became effective on August 11, 2026.

Introduction

In this chapter:

A. Background and Applicability
B. Purpose
C. Health Center Responsibilities

A. Background and Applicability

Issue: Consider State or Federal Law Conflicts

Comments

Two commenters asked HRSA to consider potential conflicts with laws or other policy documents. One commenter requested that HRSA respect state nonprofit governance laws by allowing health center boards to delegate operational decisions to management and limit federal oversight to strategic decision-making, such as approving budgets and monitoring overall compliance. The commenter specifically noted possible conflicts related to pharmacy and telehealth.

One commenter suggested that HRSA should ensure that the Scope Manual is approved by President Trump's administration, particularly considering the significance of recent Executive Orders.

HRSA Response

HRSA acknowledges concerns about potential policy conflicts with state, local, and federal laws, and consistently reminds health centers in the Scope Manual to comply with such laws, where applicable. HRSA has a statutory and regulatory responsibility to monitor compliance with Health Center Program requirements, including providing oversight over each health center's scope of project. Refer to section 330(k)(3)(H) of the Public Health Service (PHS) Act (42 U.S.C. 254b) and 42 CFR Section 51c.304.

Each health center remains responsible for ensuring that they conduct all health center activities within its HRSA-approved scope of project in accordance with Health Center Program requirements as set forth in statute and implementing regulations, the terms and conditions of Health Center Program funding or designation, and in compliance with all other applicable federal laws, regulations, and policies.

The Scope Manual has been issued by the Health Resources and Services Administration, consistent with all applicable laws, regulations, and directives.

B. Purpose

Issue: Compliance Manual Versus Scope Manual

Comments

Four commenters provided feedback on the relationship between content in the Scope Manual and the Health Center Program Compliance Manual (Compliance Manual). Three commenters requested clarification on perceived discrepancies between the documents, including two commenters who requested clarification on which manual to follow and one commenter who requested a deference to the Compliance Manual for any inconsistencies related to the roles of the health center's board and its management.

HRSA Response
The Scope Manual provides clarity on how program statute applies to the Health Center Program scope of project. The Scope Manual complements the Compliance Manual. Refer to Introduction, Section B. Purpose for guidance on addressing any potential conflicts related to Health Center Program scope of project policy.

C. Health Center Responsibilities

HRSA received no comments specific to this section.

Chapter 1: Definition of Scope of Project and Overview

In this chapter:

A. Definition of Scope of Project
B. Governing Board Role and Authorities Related to Scope of Project
C. General Criteria for Including Activities within the HRSA-Approved Scope of Project
D. Limitations on Health Center Program Scope of Project and Other Lines of Business
E. Eligibility for Other Federal Programs and Associated Benefits

A. Definition of Scope of Project

Issue: Scope of Project Correction Opportunity

Comments

Seventy-three commenters requested that HRSA provide advance written notice before removing a service or site that was previously approved by HRSA. These commenters recommended modifying the draft Scope Manual to indicate that if HRSA determines a health center's scope of project requires modification or correction, HRSA will follow the process set forth in Health Center Program Compliance Manual, Chapter 2: Health Center Program Oversight, Progressive Action Overview, which describes the nature of and reason for the condition, the action needed to remove the condition, and the time allowed to take corrective action. Another commenter requested clarification of the types of issues that would lead to potential immediate enforcement scenarios. This commenter also requested examples of these potential enforcement scenarios.

HRSA Response

While the process for resolving a scope of project issue is not reflected in the Scope Manual, which focuses on policy, in response to commenters' concerns, HRSA confirms that it will provide a health center with the opportunity to respond to a notification of non-compliance with scope policy prior to any HRSA action. This will be reflected in process-specific HRSA resources.

Refer to Health Center Program Compliance Manual, Chapter 2: Health Center Program Oversight, Program Oversight. This includes actions to correct, modify, disapprove, or remove a health center's sites or services within its HRSA-approved scope of project. In some cases, immediate enforcement actions may be pursued, consistent with HHS grant regulations. This process is separate from the Progressive Action Process outlined in the Health Center Program Compliance Manual.

Issue: HRSA Approval of Changes with Providers

Comments

Two commenters requested that HRSA not require approval or formal notification via the Change in Scope (CIS) process every time there is a change with providers working at the health

center. These commenters noted there is no existing requirement to provide updates through the CIS process or implementation guidance stated in the draft Scope Manual.

HRSA Response
HRSA agrees that a health center should not be required to request formal approval from HRSA each time there is a change in providers working at the health center. Scope Manual Chapter 10: Changes in Scope of Project offers more information on what changes to the scope of project require prior approval.

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

Issue: Board Approval and Expanded Board Authority

Comments
Seventy-one commenters expressed concerns with apparent expansion of the role of the governing board for contract and cooperative arrangement management and oversight. Sixty-five commenters stated the description of board authority in the Scope Manual does not align with the Health Center Program Compliance Manual. One commenter stated this guidance would put public entities at odds with existing jurisdictional laws on contracting. One commenter noted that their organization does not often have many choices of who to contract with, as services are limited in their rural state. All seventy-one commenters included statements of undue burden on the board regarding functions typically managed by administrative staff.

Two commenters noted a lack of clarity for the health center governing board's responsibility approving service delivery methods in contracts and cooperative agreements.

Sixty-eight commenters recommended that, for consistency with a current requirement in Health Center Program Compliance Manual Chapter 19: Board Authority, that HRSA strike Scope Manual Section 1.C, criterion e and replace it with, "If the health center provides services to its patients through subawards or contracts for a substantial portion of the services, the health center's governing board approves decisions to enter into such subawards and contracts."

One commenter requested that HRSA define a list of contracts or a set dollar amount that would require board approval. The commenter stated that applying proposed requirements for all contracts is too onerous.

One commenter acknowledged their health center governing board reviews Forms 5A, 5B, and 5C annually.

One commenter wrote that if the board delegates approval and oversight responsibilities to an officer of the company, that should be sufficient to comply with stated requirements.

HRSA Response
HRSA acknowledges that the proposed language included in the draft bulleted list regarding board approval for "a substantial portion of the health center's scope of project" was unclear. HRSA revised this language to clarify limited board responsibilities for decisions to operate a site by contract or subaward. Additionally, in the bullet related to service delivery methods, HRSA added footnote 13, clarifying that board approval is only required for initial decisions to use a particular service delivery method. These revisions clarify that the board is not required to review and approve all individual contracts or contract modifications. Section 1.C, criterion e is retained and updated to align with these revisions.

HRSA declines to indicate a set dollar amount that would require board approval since this exclusion is intended to reduce the administrative burden on health centers. Dollar amounts may vary by organization, market rates, or contract requirements.

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

Issue: Collaborative Efforts in the Community

Comments
Three commenters requested additional examples and further clarification on how to demonstrate that collaborative activities in the community are "on behalf of" the health center. These commenters requested examples and guidance regarding collaborative outreach and the implications for Federal Tort Claims Act (FTCA) coverage.

HRSA Response
HRSA appreciates this feedback and encourages commenters to consider the existing examples included in the Scope Manual Section 9: Services Provided at a Location Other Than a Health Center Service Site. That section addresses how services provided at a location other than a health center service site could be included in the health center's scope of project.

HRSA cannot provide general assurance of FTCA coverage. The Department of Justice has a lead role in deciding whether or not to make the certification needed to support FTCA coverage, and courts also consider the available facts in individual cases in litigation – such decisions will depend on all of the available facts and circumstances.

Issue: "On Behalf Of"

Comments
One hundred and fourteen commenters communicated concerns about how HRSA proposed to determine that services are delivered on behalf of the health center.

Eighty-four commenters asked HRSA to exempt services delivered via cooperative agreements and contracts from the seven draft criteria. These commenters suggested it is inappropriate to

apply several criteria to services delivered through these models, particularly those requiring health center oversight and control over the operations of outside organizations.

Twenty-eight commenters highlighted examples of services that are not delivered directly to patients by the health center. These examples included services indirectly delivered through cooperative agreements, contracts, and subrecipients, and suggested that health centers have limited oversight of and ability to exert control over these scenarios. Nineteen commenters requested that services provided by cooperative agreements, contracts, and subrecipients be exempted from the proposed requirement that in-scope services be delivered by health center employees, individual contractors, or volunteers. These commenters also recommended that HRSA group and classify the seven "on behalf of" criteria according to service delivery method. One commenter requested clarification on the applicability of the "on behalf of" criteria to services provided via referrals.

One commenter noted that there is generally close coordination on subawards and cooperative arrangements. Health centers ensure compliance with programmatic requirements; however, neither the subrecipient nor the cooperative arrangement provider renders services "on behalf of" the health center, as implied by Section C.3 and 45 CFR Part 75. Consequently, HRSA's proposed "on behalf of" standard is inconsistent with 45 CFR § 75.351 and should be revised to exempt subrecipient and cooperative arrangements from HRSA's proposed "on behalf of" requirement.

HRSA Response
HRSA updated this language in the Scope Manual to reiterate that a health center is accountable for meeting all Health Center Program requirements, regardless of the service delivery method. This emphasis is added and consistent with statute and regulations, as specified in the Health Center Program Compliance Manual Chapter 12: Contracts and Subawards: "The Health Center Program award recipient must ensure that, at the time of making a subaward, each subrecipient, which is a subaward recipient of Federal funds, complies with all applicable requirements specified in the Federal award (including those found in section 330 of the Public Health Service (PHS) Act (42 U.S.C. 254b), implementing program regulations, and grants regulations in 2 CFR Part 200, formerly 45 CFR Part 75)." Additionally, Health Center Program Compliance Manual Chapter 19: Board Authority, indicates that the health center governing board has "the specific responsibility for oversight of the Health Center Program project" including "decisions to subaward or contract" for a substantial portion of services. HRSA further clarified in the final policy that the term "on behalf of" as used in the Scope Manual applies specifically to Health Center Program scope of project determinations and does not alone establish a principal-agent relationship or any other representative relationship.

A health center determines what service delivery method to use, consistent with Health Center Program Compliance Manual requirements and 2 CFR Part 200. If a health center chooses to

establish a formal written contract or a formal written referral arrangement, the health center is responsible for ensuring the contract or cooperative agreement allows it to maintain required oversight. HRSA offers each health center the flexibility to establish and manage those arrangements while maintaining compliance. This flexibility includes subrecipient arrangements.

Subrecipients are required to comply with all Health Center Program requirements. Furthermore, subrecipient oversight is required, as indicated in 2 CFR Part 200. These existing requirements are reinforced in the Health Center Program Compliance Manual. Health center oversight of subrecipients ensures subrecipients are compliant with all applicable requirements, including those indicated in the Health Center Program Compliance Manual and 2 CFR Part 200. HRSA is required by 2 CFR Part 200 to enforce these requirements on the recipient of record. The status of a subrecipient as a federally qualified health center is derived from the Social Security Act, which the Health Center Program Compliance Manual reflects, and imposes additional requirements beyond 2 CFR Part 200.

In addition, HRSA updated the list of providers that may deliver in-scope services to "health center employees, contractors, or volunteers."

Issue: Health Records

Comments

Eighty-four commenters requested clarification of health records definitions and criteria. Commenters encouraged HRSA to distinguish between health records required for direct service provision (Form 5A: Services Provided, Column I), and for contracts, cooperative agreements, and subawards (Form 5A, Columns II and III). Commenters requested revisions reflecting that not all health center activities result in the establishment of a full health record for all individuals served. Sixty commenters encouraged specific exemptions for subrecipients, contractors, and cooperative agreements from the health record establishment and maintenance requirement.

HRSA Response

In response to this feedback, HRSA added footnote 17. HRSA clarified that health centers are required to maintain access to records, rather than directly maintain all records. This revision is consistent with 2 CFR Part 200. HRSA will continue to hold the Health Center Program award recipient accountable for subrecipient compliance. Consistent with 2 CFR Part 200 and the Health Center Program Compliance Manual, Chapters 4, 8, 10, and 18, HRSA cannot exempt a direct health center awardee that chooses to use a subrecipient, contractor, or cooperative agreement from certain applicable health record requirements, or to make corresponding content revisions to Section 1.C, criterion g, or consolidations by service agreement type.

Referrals to and follow-up from those services to Column II or III providers must be maintained in the patient's health record. HRSA recognizes that, for certain service types, a health record may not be as extensive as a health record for other services.

Issue: Organizational Contractors

Comments

Sixty-three commenters stated concerns that the proposed list of who can deliver in-scope services does not include organizational contractors. Commenters requested that HRSA add "organizational contractors" to the list in Section 1.C, criterion d for consistency with the definition of contracts in Chapter 3.

HRSA Response

HRSA concurs and removed "individual" prior to "contractors" in Section 1.C, criterion d. This revision supports the inclusion of individual and organizational contractors among those who can deliver in-scope services.

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

Issue: Excess Program Income and Non-Grant Funds

Comments

Sixty-six commenters asked HRSA to add language confirming that excess program income (EPI) may be used for other lines of business, outside of the scope of project, that further the objectives of the Health Center Program project and are not specifically prohibited by the Health Center Program statute. Commenters also requested alignment of HRSA's definition of "non-grant funds" with the statute. Two commenters requested clarification that EPI may be used to support the expenses incurred in preparing a change in scope request for a new site or services. Two commenters asked for confirmation that EPI may be used to support patients' access to care through transportation assistance or by addressing certain social determinants of health. One commenter provided examples of EPI supporting a health center owned assisted living facility and adult day care, noting both programs further the objectives of the in-scope project. Another commenter requested that HRSA further support innovative care models by allowing EPI to be used to support programs that facilitate access to healthy foods. One commenter requested that HRSA align its policies with IRS regulations. This commenter's interpretation is that IRS regulations allow unrelated business activities that remain incidental to a non-profit's overall mission, such as operating a thrift store.

HRSA Response

HRSA added language explicitly confirming that "non-grant funds in excess of what is necessary to support the HRSA-approved total budget" may be used for other lines of business that further the objectives of the project and that are not used for purposes that are specifically prohibited by the Health Center Program, aligning the Scope Manual with language from the Health Center Program Compliance Manual. HRSA confirms that activities that further the

objectives of the project and that are not prohibited by the program—such as preparing a change in scope request, providing patients transportation, and addressing other barriers to care—may use such excess non-grant funds. HRSA declines to modify this language to allow the use of program income for unrelated business activities that do not further the objectives of the project.

E. Eligibility for Other Federal Programs and Associated Benefits

Issue: Additional Associated Benefits

Comments

One commenter proposed amending the list of federal programs associated with Health Center Program funding to include: the Centers for Disease Control and Prevention (CDC) Vaccines for Children (VFC), HRSA's Health Professional Shortage Area Designation, and the Centers for Medicare & Medicaid Services (CMS) Medicare Federally Qualified Health Center (FQHC) Prospective Payment System (PPS).

HRSA Response

HRSA recognizes that some of the commenters' suggested federal programs are already reflected in other sections of the Scope Manual, and further revising the list would not be necessary. The programs listed in the Scope Manual are intended to be examples of health center-related benefits. The list is not all inclusive.

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

In this chapter:

A. Medically Underserved Populations and Special Medically Underserved Populations
B. Service Area

A. Medically Underserved Populations and Special Medically Underserved Populations

Issue: Support for Adding Medically Underserved Population (MUP) Designation

Comments

One commenter supported the requirement that a health center must serve a designated medically underserved population (MUP). The commenter suggested that to ensure better collaboration rather than competition, HRSA should require applicants applying for funding to serve Medically Underserved Populations and Special Medically Underserved Populations to obtain a letter of support from a Health Center Program award recipient currently serving that service area.

HRSA Response

Consistent with section 330(a)(1) of the Public Health Service (PHS) Act (42 U.S.C. 254b), a health center must serve either a designated MUP or a special MUP. HRSA appreciates the supportive comment. Section 6.B: Additional Factors for Adding a Site addresses the need to discuss and collaborate with other health centers when adding a site in scope. As noted in that section, collaboration must occur consistent with the Health Center Program Compliance Manual, Chapter 14: Collaborative Relationships. HRSA believes the commenter's concern is addressed by these existing elements and declines to add the specific suggested language regarding letters of support.

B. Service Area

Issue: Clarify 75 Percent Zip Code Tabulation Area (ZCTA) Requirement

Comments

Three commenters provided comments on the language related to patient origin and ZIP Code Tabulation Areas (ZCTAs). Among these, one commenter requested that HRSA better define how it completes this calculation and how a health center might ensure that it meets the requirement. Two commenters requested that HRSA consider adding more flexibility to how health centers determine which ZCTAs 75 percent of patients come from. One commenter requested confirmation that this metric includes patients seen via telehealth.

HRSA Response

For patient origin data definitions and explanations, refer to resources such as notices of funding opportunities (NOFOs), the Service Area Announcement Table (SAAT), and associated

technical assistance webpages that clarify processes. Patient origin data—including from telehealth visits—submitted by the health center through HRSA's Health Center Program Uniform Data System informs the SAAT data. The SAAT is available on the SAC Service Area Announcement Table (SAAT). HRSA updates the SAAT when additional service areas become available. The SAAT table includes the proportion of health center patients who live in that ZIP Code. Service Area Competition Frequently Asked Questions provides additional information regarding SAAT table fields and calculations. A health center is welcome to use the BPHC Contact Form for any further questions specific to its organization. Given the availability of the described resources, HRSA declines to include this information in the Scope Manual.

Please note that HRSA has updated the Scope Manual to refer to ZIP Codes instead of ZCTAs.

Issue: Clarify Annual Review of Service Area

Comments

One commenter shared support for proposed requirements regarding periodic re-evaluation of service area designations.

Additionally, two commenters recommended revising the footnote on the annual review of service area to clarify the statement that "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." Commenters asked if a health center that cannot provide services to all residents due to financial or workforce limitations would be compliant with this requirement. One commenter recommended adding "as defined by ZIP Code Tabulation Areas (ZCTAs)" in criterion after "relevant boundaries of political subdivisions, school districts, and areas served by federal and state health and social service programs" to clarify the requirement.

HRSA Response

HRSA appreciates this feedback regarding the importance of re-evaluating service area designations to support well-defined service areas. The footnote in the draft has been moved into the text of Section 2.B, criterion a, which states that the size of the catchment area must allow for health center services to be "available and accessible to the residents of the area," not that a health center must serve all residents. Additionally, HRSA declines to add "as defined by ZCTAs" to Section 2.B, criterion b, as not all political subdivisions are defined by ZIP Codes, and conforming a health center service area to political subdivisions, school districts, and areas served by federal and state health and social service programs is required in statute under section 330(k)(3)(J)(ii) of the Public Health Service (PHS) Act (42 U.S.C. 254b).

Please note that HRSA has updated the Scope Manual to refer to ZIP Codes instead of ZCTAs.

Issue: 25 Percent of Patients Outside of Service Area

Comments

Seventy-three commenters expressed support for HRSA to preserve the policy that up to 25 percent of the health center's patient population may reside outside of the service area. This policy will help health centers to serve all individuals, particularly those who are low-income and encounter significant access barriers.

HRSA Response
There is no existing HRSA policy that allows up to 25 percent of the health center's patient population to reside outside of the service area. Commenters may be referring to the Service Area Announcement Table (SAAT), which is provided as a tool to help a Service Area Competition (SAC) applicant propose a service area in their competitive application and to identify patient origin data by ZIP Code. The SAAT indicates where 75 percent of patients currently reside, so that applicants competing for the award will propose similar service areas. While the SAAT is a resource available to health centers, it does not establish HRSA policy.

The Scope Manual does state that 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. A health center must also review its service area annually and either revalidate it or request any applicable updates based on its assessment of where patients reside. Therefore, where a health center identifies significant patients residing outside its service area (for example, 10 or more patients in a ZIP Code), a health center should request an update to its Form 5B: Sites to reflect its service area accordingly.

A health center funded or designated by HRSA to provide services under section 330(e) of the Public Health Service (PHS) Act (42 U.S.C. 254b) must make services "available and accessible" to all residents of its defined service area. 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 an individual's residence. Refer to Chapter 2, Section B: Service Area.

Issue: Guidance on Serving Patients Outside of the Service Area

Comments
One commenter requested that HRSA clarify how health centers may continue serving patients outside a service area without risking compliance concerns. Many health centers serve diverse populations facing barriers to care. The commenter recommended HRSA provide clear guidance to ensure non-grant funds can support such patients while preserving flexibility in service delivery.

HRSA Response
HRSA understands that a health center may want to provide services to patients beyond its service area to address barriers to care. Scope Manual Section 8.B: Patients and Visits explains

that an individual becomes an established health center patient when a patient-provider relationship is created, which requires that an individual receive an in-scope service from a provider who is acting on behalf of the health center 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. A health center may provide in-scope services to an individual outside a service site by meeting the criteria in the Scope Manual Chapter 9: Services Provided at a Location Other Than a Health Center Service Site. For more information related to health center activities that happen outside of the scope of project, refer to Chapter 1, Section D. Limitations on Health Center Program Scope of Project and Other Lines of Business.

Issue: Relative Patient Demand

Comments

One commenter encouraged HRSA to add "relative patient demand" as a characteristic or as a new related considerations bullet. The commenter stated that raw ZIP Code Tabulation Areas (ZCTAs), emphasized in the draft policy, lack context and do not sufficiently address high patient dependence and service area penetration rates.

HRSA Response

A health center may consider relative patient demand when establishing and reviewing its service area and unmet patient need, consistent with its own policies. This decision-making discretion is consistent with the related considerations indicated in the Health Center Program Compliance Manual Chapter 3: Needs Assessment. ZIP Codes will continue to be used to reliably document the geographic distribution of limited Health Center Program resources as well as to measure and respond to unmet patient need, for example, when calculating Unmet Need Scores for applications. A health center may choose to include ZIP Codes in its service area by adding them to Form 5B: Sites locations, consistent with HRSA guidance.

Please note that HRSA has updated the Scope Manual to refer to ZIP Codes instead of ZCTAs.

Issue: Defining Service Area and Form 5B

Comments

One commenter asked for clarification as to where the annual review of updates to a service area occurs, specifically, as part of Uniform Data System report, Service Area Announcement Table (SAAT) review, or Service Area Competition report. The commenter also requested clarification on how the service area is defined in Form 5B: Sites and if health centers should annually check to ensure ZIP Codes where 75 percent of health center patients are served remain included in Form 5B.

HRSA Response

As described in the Health Center Program Compliance Manual, each health center is currently required to review its service area on an annual basis, identifying where current and proposed

populations reside by documenting those ZIP Codes in the health center's Form 5B. These ZIP Codes should include, at a minimum, those reported for 75 percent of a health center's patients in its Uniform Data System (UDS) report and should be updated as needed on an annual basis. Service area is defined in the Scope Manual Section 2.B: Service Area.

Issue: Add "Access"

Comments

Seventy-two commenters requested HRSA clarify that health centers must provide access to services to all residents of its defined service area and are not required to provide services to all residents, as stated in the draft. Two commenters expressed that this statement could limit service availability if a health center cannot meet the demand of all residents. One commenter requested clarity as to how health centers can demonstrate that patients have access to all HRSA-approved, in-scope services.

HRSA Response

HRSA agrees that a health center does not need to provide services to all residents in the service area and updated the Scope Manual language to reflect that a health center must make in-scope health center services "available and accessible" for all residents.

A health center's policies and procedures should include language that both affirms all residents have access and does not restrict services to certain populations. Additionally, a health center must demonstrate access when it answers questions in a change in scope request, as well as by meeting the requirements in both the Health Center Program Compliance Manual and the Scope Manual.

Chapter 3: Required Primary and Additional Health Services

In this chapter:

A. Services Within the Scope of Project
B. Criteria Required for In-Scope Services
C. Service Delivery Methods
C.1. Direct (Form 5A, Column I)
C.2. Contracts and Subawards (Form 5A, Column II)
C.3. Cooperative Arrangements (Form 5A, Column III)
C.3.1. Provisions in Cooperative Arrangements
D. Criteria Required for Additional Health Services

A. Services Within the Scope of Project

Issue: Exempt Enabling Services

Comments

Seventy-four commenters requested that HRSA exempt services that enable individuals to use the services of the health center from certain requirements, stating that the lack of such an exemption is inconsistent with page 14 of the Site Visit Protocol. Commenters recommended adding a footnote which states, for example, "For purposes of contracts and cooperative arrangements for enabling services (for example, transportation, translation, outreach) provided via Column II or III (contracts, subawards, or cooperative arrangements), compliance is demonstrated even if the contracts or cooperative arrangements do not address all of the provisions required for clinical services (for example, general primary medical care, preventive dental)."

HRSA Response

HRSA agrees that some requirements will not be appropriate for certain services that enable individuals to use the services of the health center. HRSA added footnote 30, clarifying that the requirements for quality improvement/assurance, credentialing and privileging, and sliding fee discount may not apply to certain services, such as transportation.

Issue: Quality Improvement/Assurance (QI/A) and Contracts

Comments

Seventy-one commenters requested that HRSA clarify the relevance of QI/A requirements to contracts and cooperative arrangements from providers that may not have a QI/A program or may not want to participate in the health center's QI/A program. If HRSA determines that QI/A is a required element for contracts and cooperative arrangements, these commenters recommended that HRSA: (1) insert the term "as applicable" following the reference to QI/A, and (2) establish that compliance may be achieved through documentation other than provisions in the written contract and cooperative arrangement, such as through health center policies and procedures.

HRSA Response
HRSA updated the Scope Manual to remove the statement that contracts and cooperative arrangements must have a provision addressing QI/A. Please note that each health center is responsible for ensuring that all services—direct services, services provided through contracts, and services provided through cooperative arrangements—are provided in accordance with Health Center Program requirements. Refer to Chapter 3, Section C.2: Contracts and Subawards (Form 5A, Column II) for more information on documentation requirements.

Issue: Credentialing and Privileging Provisions in Contracts, Subaward Agreements, and Cooperative Arrangements

Comments
Seventy-four commenters stated that the second paragraph of the draft Scope Manual Section 3.A, referring to credentialing and privileging, is inconsistent with the practice for contracts, subaward agreements, and cooperative arrangements stated in the Site Visit Protocol, which provides flexibilities to demonstrate compliance that reduce administrative burden for health centers. Commenters requested HRSA clarify that, for purposes of contracts, subaward agreements, and cooperative arrangements, compliance with the provider credentialing and privileging requirement may be demonstrated through documentation other than written provisions in the underlying agreement, consistent with the Site Visit Protocol and the Health Center Program Compliance Manual. One commenter recommended clarifying that these services are required to be provided by credentialed staff or contractors.

HRSA Response
HRSA updated the Scope Manual to remove the statement from Section 3.A that contracts and cooperative arrangements must have a provision addressing credentialing and privileging. However, Sections C.2 and C.3 still require that a contract, subaward agreement, or cooperative arrangement address how provider credentialing and privileging will be accomplished. While HRSA does not expect a contract, subaward agreement, or cooperative arrangement to state that a third party follows the health center's credentialing and privileging program, HRSA expects any contract, subaward agreement, or cooperative arrangement between the health center and a third party to allow the health center to confirm that the third-party provider is either conducting credentialing and privileging or using the health center's credentialing and privileging program. HRSA updated the credentialing and privileging language in Sections C.2 and C.3 to clarify these points.

In response to these comments, HRSA also updated the language in Sections C.2 and C.3 to state that a health center may demonstrate this requirement either through a provision in the contract, subaward agreement, or cooperative arrangement, or through a separate document agreed to by both the health center and third party, outside of the contract, subaward agreement, or cooperative arrangement. This provision or document could simply state that the contractor has its own credentialing and privileging program that the health center

reviewed or has the right to review. HRSA believes this flexibility addresses concerns regarding the need to renegotiate existing contracts, subaward agreements, or cooperative arrangements. The requirement in these sections is that the health center demonstrates that it can ensure credentialing and privileging, as currently required.

Issue: Limited English Proficiency in Contracts, Subaward Agreements, and Cooperative Arrangements

Comments

Seventy-three commenters requested that access for individuals with limited English proficiency should not be explicitly addressed in contracts, subaward agreements, and cooperative arrangements, as proposed by HRSA. Sixty-nine commenters stated that these proposed requirements do not consider that contractors often access health center interpretation and translation services, and that providers who accept Medicare or Medicaid payments are already required to provide access under federal statutes and regulations. The proposed requirement would also result in an extensive administrative burden to amend most agreements. These commenters requested that compliance may be demonstrated through other documentation, consistent with the Site Visit Protocol guidance for other Health Center Program requirements.

HRSA Response

HRSA updated the Scope Manual to remove the statement from Section 3.A that contracts, subaward agreements, and cooperative arrangements must include a provision addressing access for individuals with limited English proficiency. However, Sections C.2 and C.3 still require that a health center that delivers services through contracts, subaward agreements, or cooperative arrangements must ensure that all services are made available in accordance with applicable Health Center Program statutory and regulatory requirements, including requirements associated with enabling access to health services for those with limited English proficiency. This requirement does not need to be reflected in a provision in the contract or cooperative arrangement. HRSA updated the Scope Manual to clarify that compliance may also be demonstrated through separate documentation agreed to by both the health center and the third party, outside of the contract, subaward agreement, or cooperative arrangement, reducing the need to revise existing agreements. HRSA believes this flexibility addresses concerns regarding the need to renegotiate existing contracts, subaward agreements, or cooperative arrangements. The requirement in these sections is that the health center demonstrate that it can ensure translation and interpretation, as currently required.

B. Criteria Required for In-Scope Services

Issue: Exempt Subrecipients and Cooperative Arrangements From "On Behalf Of"

Comments

Seventy-five commenters expressed concern that characterizing subrecipients and cooperative arrangements as rendering services "on behalf of" the health center is inaccurate since the board does not direct the provision of services. These commenters recommended that HRSA

indicate that the "on behalf of" requirement would not apply to subrecipient and cooperative arrangements and that the Scope Manual not characterize subrecipients as a type of contractor due to distinct legal standards. Specifically, to enhance clarity and to promote consistency with 45 CFR § 75.351 [now reflected in 2 CFR Part 200] and Health Center Program Compliance Manual Chapter 12: Contracts and Subawards, these commenters requested that the Scope Manual include a description of subrecipients that are separate from contractors.

HRSA Response
Subrecipient oversight is required, as indicated in 2 CFR Part 200. These existing requirements are reinforced in the Health Center Program Compliance Manual. HRSA therefore declines to remove the "on behalf of" requirement for the use of subrecipients and cooperative arrangements. HRSA updated the Scope Manual to reiterate that each health center is accountable for meeting Health Center Program requirements, regardless of the service delivery method. Each health center determines what service delivery method to use. If a health center chooses to establish a subaward or cooperative arrangement, the health center is responsible for ensuring the subaward or formal cooperative agreement allows the health center to maintain required oversight.

HRSA has updated the Scope Manual to clarify distinctions between contractors and subrecipients. The Scope Manual is consistent with Health Center Program Compliance Manual Chapter 12: Contracts and Subawards, which states that "The Health Center Program award recipient must ensure that, at the time of making a subaward, each subrecipient, complies with all applicable requirements specified in the Federal award (including those found in section 330 of the Public Health Service (PHS) Act (42 U.S.C. 254b)), implementing program regulations, and grants regulations in 2 CFR Part 200)." Additionally, Health Center Program Compliance Manual Chapter 19: Board Authority, indicates that the health center governing board has "the specific responsibility for oversight of the Health Center Program project" including "decisions to subaward or contract" for a substantial portion of services.

HRSA notes that in addition to meeting the requirements of 2 CFR Part 200, the status of a subrecipient as a federally-qualified health center is derived from the Social Security Act, as reflected in the Health Center Program Compliance Manual.

A health center governing board is responsible for approving the decision to provide services through a cooperative arrangement. The health center maintains responsibility for oversight of the cooperative arrangement, including the actual terms of the written agreement.

Issue: "On Behalf Of" Liability

Comments
Two commenters expressed concerns over the legal implications of using the term "on behalf of" when in-scope services are provided by contract "on behalf of the health center" by an independent entity. The commenters indicated that these entities do not have legal authority

to act on behalf of that health center and there may be unintended consequences of imposing liability on the health center for the independent entity's provision of services.

HRSA Response
HRSA acknowledges that a health center may have concerns regarding potential liability associated with choosing to use a contract or cooperative arrangement as the service delivery method for an in-scope service, as it relates to the "on behalf of" criteria. A Federal Tort Claims Act (FTCA) covered entity should consider gap or wrap-around malpractice protection for services and activities outside the Health Center Program's scope of project. A health center also has flexibility in choosing what service delivery methods it uses to provide required and additional health center services. HRSA further clarified in the final policy that the term "on behalf of" as used in the Scope Manual applies specifically to Health Center Program scope of project determinations and does not alone establish a principal-agent relationship or any other representative relationship.

C. Service Delivery Methods

Issue: Phased Implementation for Required Contracts and Collaborative Arrangements Provisions

Comments
Seventy-one commenters strongly encouraged HRSA to provide a phased implementation timeline for health centers to amend existing contracts and collaborative arrangements after publication of the Scope Manual. Commenters stated that phased implementation would reduce administrative burden and potential disruptions to patient care. These commenters expressed concern that some proposed provisions align with the Health Center Program Compliance Manual, while other proposed provisions reflect new requirements that may be inapplicable, inconsistent with existing requirements, or otherwise unnecessary to explicitly include in the body of the written arrangement.

Forty-nine commenters requested further clarification regarding the definitions or compliance requirements for required contractual provisions indicated in the Scope Manual Section 3.C.2.

One commenter stated that rigid staffing expectations may lead to inefficiencies, workforce challenges, and duplicated services in communities that could limit patient access to care.

HRSA Response
For consistency with the Health Center Program Compliance Manual and other revisions to the Scope Manual, HRSA clarified the contract provision language listed for Section 3.C.2 criteria b, c, and f, added footnotes 39, 40, 41, and 42. These new footnotes emphasize the flexibility of contract provisions to document compliance with applicable criteria. No formal phased implementation period is anticipated. A health center will have the opportunity to address any issues involving a contract or cooperative arrangement at the time the issue is identified. In

general, HRSA will typically provide a health center the opportunity to respond to a notification of non-compliance with scope policy prior to any HRSA action.

Issue: Non-Federal Laws in Column II Contracts

Comments

Eighty-six commenters recommended that HRSA remove the proposed language that contracts explicitly state that a health center is bound by applicable federal and state laws. The commenters note that this proposed requirement is burdensome and legally unnecessary. Additionally, they note that non-federally funded contracts are not subject to HHS grant regulations beyond what is required in the Health Center Program Compliance Manual Chapter 12: Contracts and Subawards.

HRSA Response

Consistent with section 330(k)(3)(D) of the Public Health Service (PHS) Act (42 U.S.C. 254b), 42 CFR 51c.304(d)(3)(v), and 2 CFR Sections 200.300, 200.318, 200.325, and 200.327, HRSA declines to strike the requirement, but to reduce administrative burden to health centers, HRSA has clarified in the Scope Manual that a "catch-all" provision may meet this requirement.

Issue: Directly Provided Services

Comments

Sixty-six commenters appreciated that HRSA encouraged health centers to directly provide in-scope required and additional services, but emphasized the importance of allowing flexibility through contracts, subawards, and cooperative arrangements.

HRSA Response

HRSA confirms that a health center may provide services directly or through contracts, subawards, and cooperative arrangements. HRSA removed the language in the introduction to Section 3.C that encouraged health centers to directly provide services "where feasible to reduce barriers." Please note that when a health center chooses to provide services using a contract, subaward, or cooperative arrangement, the health center must have a formal written agreement that includes the provisions discussed in Chapter 3, Sections C.2 and C.3.

Issue: Contracts, Subawards, and Cooperative Arrangements

Comments

Three commenters expressed concern over the proposed language regarding contracts, subawards, and cooperative arrangements. Two commenters requested that HRSA consider that several factors motivate health centers to use contracts, subawards, and cooperative arrangements rather than provide a service directly. One commenter requested that health centers be able to demonstrate compliance with program requirements through practical processes—such as referral tracking and access to patient records—rather than requiring the creation or revision of contracts, subawards, and cooperative arrangements.

HRSA Response
HRSA updated the Scope Manual to clarify that a health center and the provider with which it has a contract, subaward, or cooperative arrangement may satisfy these requirements with documentation that is separate from, or an appendix to, an existing written agreement.

As stated in both section 330(a)(1) of the Public Health Service (PHS) Act (42 U.S.C. 254b) and in the Scope Manual, each health center is responsible for making all in-scope services available in accordance with Health Center Program requirements, and a health center may choose to use a contract or cooperative arrangement to deliver these services. HRSA does not require a health center to select any single service delivery method.

For required services not provided directly, a contract, subaward, or cooperative arrangement must be created to provide an in-scope service. Substituting practical processes, such as referral tracking and access to patient records, in place of this requirement does not sufficiently demonstrate that a health center will consistently be able to provide required services to patients. HRSA declines to further edit these requirements, which align with statutory requirements included in section 330(a)(1) of the Public Health Service (PHS) Act (42 U.S.C. 254b).

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

Issue: Employment Agreements

Comments
Sixty-seven commenters suggested that HRSA should amend the language in the employment status footnote to reflect that many health center employees are "at-will" employees and that their employment is not governed by an employment contract.

HRSA Response
HRSA updated footnote 34 to state that a health center may generally document employment status through a W-2 "or" an employment associated contract, as well as adding "for example" to clarify this requirement.

Issue: Uniform Data System (UDS) Reporting for All In-Scope Services

Comments
One commenter stated that in-scope requirements on Health Center Program forms and annual data reporting guidance are inconsistent and should be deconflicted. For example, community health workers (CHWs) are in-scope on Form 5A: Services Provided, but it is unclear how CHWs should be reflected in annual UDS reporting. Consequently, CHW staffing is likely underreported. Additionally, HRSA's Addressing Social Risk Factors Community Health Quality Recognition (CHQR) badge recognizes absolute enabling services increases, but the full associated patient population is not reflected in the UDS Table 5. They ask that UDS reporting include patients served on Table 5, Row 27c in the cumulative total.

HRSA Response
The Scope Manual does not address UDS reporting requirements. HRSA instructions for UDS reporting are found in the UDS Manual. Because UDS reporting does not define a health center's scope of project, the topic is not addressed in the Scope Manual. However, HRSA will consider this comment with respect to the UDS process.

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

Issue: Clarify When and How FQHC Benefits Convey in Contracts

Comments
One commenter requested clarification about when certain Federally Qualified Health Center (FQHC)-related benefits, such as Federal Tort Claims Act (FTCA) coverage, are conveyed to a contracted provider. The commenter expressed concern that the lack of FTCA coverage for a contracted provider operating on behalf of the health center may create challenges for accessing certain services, especially for obstetrical and gynecological care.

HRSA Response
In response to this feedback, HRSA clarified distinctions between contractors and subrecipients, including implications for eligibility for FTCA coverage and other benefits.

HRSA cannot provide general assurance of FTCA coverage in all situations, as such determinations are fact specific.

Issue: Service Access in Contract

Comments
Fifty-two commenters recommended that HRSA not impose new requirements on how health center patients will access services (Scope Manual Section 3.C.2, criterion b) that are provided via Column II contracts or subawards. How patients access these services is typically addressed through internal protocols.

HRSA Response
HRSA updated this language to clarify that the contract should describe the process for exchanging patient information between the health center and contractor or subrecipient to ensure patient access to services. A health center must ensure that a patient presenting to a subrecipient or contracted provider is appropriately identified as a health center patient. Where a health center has internal protocols that further detail this process, the agreement between the health center and the contractor or subrecipient may simply state that the contractor or subrecipient agrees to receive patients in accordance with the health center's protocols.

Issue: Inconsistent Interpretation of Requirements

Comments

One commenter expressed concern that different site visit reviewers could inconsistently interpret the elements required in a contract or subaward under Column II, especially given the lack of a dedicated project officer assigned to the health center that the staff could work with.

HRSA Response
The Scope Manual is intended to provide general guidance on the scope of project policy and to support the consistent application of Health Center Program requirements. The Site Visit Protocol provides specific guidance on the process by which HRSA assesses compliance. HRSA also provides additional technical assistance and scope of project resources to further support the consistent application of these requirements during site visits. The Site Visit Protocol will be updated following the publication of the Scope Manual. HRSA reintroduced dedicated project officers for each health center in calendar year 2026. Health centers are encouraged to share any site visit-related concerns with HRSA by using the BPHC Contact Form.

Issue: Contracted Provider Credentialing and Privileging

Comments
Five commenters requested that HRSA revise the draft Scope Manual requirement that contractual provisions specify how contracted providers will be credentialed and privileged, to add reference to the existing flexibilities in the Site Visit Protocol. One commenter stated that their health center received resistance from outside entities when the health center requested the details of outside entities' credentialing and privileging policies.

HRSA Response
To improve clarity, HRSA added footnote 40 to the credentialing and privileging criterion (Section 3.C.2, criterion d) to acknowledge that the health center determines how to implement credentialing and privileging procedures for a contractor.

After the Scope Manual is published, HRSA will revise the Site Visit Protocol to align with the Scope Manual.

Issue: Contractor Sliding Fee Billing and Collections

Comments
Seventy-three commenters recommended that HRSA revise the Scope Manual billing and collections Section 3.C.2, criterion f, to clarify what review and approval processes apply solely to sliding fee patients. Commenters also recommended that HRSA clarify whether this criterion is applicable if the health center is not billing and collecting for the contracted services in accordance with its sliding fee discount schedule and related policies and procedures. Commenters requested that HRSA indicate that such review should be conducted consistently with the Health Center Program Compliance Manual, Chapter 9: Sliding Fee Discount Program, and Chapter 16: Billing and Collections.

Two commenters expressed concern that contract requirements, particularly those that begin with "how," are better suited to internal organizational procedures rather than explicitly stating these requirements in contracts, as such requirements could lead to inconsistent interpretations among Site Visit reviewers. Additionally, commenters expressed concern that the proposed stipulation requiring ongoing general primary care may pose challenges in certain locations where dental services are considered primary care services.

HRSA Response
HRSA revised Section 3.C.2, criterion f to specify that a contract does not require a health center to review every billing process in detail. Rather, a health center requires the "ability to review" the contractor's billing and collections process and sliding fee discount program to ensure compliance with Health Center Program requirements. HRSA agrees that criteria f only applies to situations where a contractor is billing and collecting for services. In the Scope Manual, the text "If the contractor bills and collects for services" is bolded for emphasis.

Issue: Contracted Individuals

Comments
Sixty-eight commenters urged HRSA to clarify in Section 3.C.2 that a contract is a "formal written agreement between the health center and another entity" by adding "or individual" to the definition to cover scenarios in which health centers contract with individual providers.

HRSA Response
HRSA agrees that a health center may also have formal written arrangements with individuals, not just entities, and updated the language to insert "individual" in Section 3.C.2.

Issue: Automatically Renewing Contracts or Subaward Agreements

Comments
Seventy commenters requested that HRSA specify whether an "evergreen" contract or subaward agreement provision satisfies the proposed requirement that a health center ensure that each of its contracts or subaward for in-scope services is current. Commenters noted that evergreen provisions reduce administrative burden and are commonly recognized in contract law. The commenters suggested including the following footnote in either the Scope Manual or the Site Visit Protocol: "To demonstrate that a contract is current, the contract must be in effect and unexpired. Contracts that periodically and automatically renew are consistent with such standards."

HRSA Response
HRSA agrees that an automatically renewing contract or subaward agreement provision satisfies the proposed requirement and added footnote 39 for clarification.

Issue: Contractors Versus Subrecipients

Comments

Seventy-three commenters requested that HRSA clarify language regarding subrecipients and contractors. This revised language should include a separate description of mandated provisions and definitions, drafted in alignment with 45 CFR § 75.351 [now covered by 2 CFR Part 200] and Health Center Program Compliance Manual Chapter 12: Contracts and Subawards.

HRSA Response
In response to this feedback, HRSA clarified distinctions between contractors and subrecipients, including implications for eligibility for Federal Tort Claims Act (FTCA) coverage and other benefits. HRSA notes that a description of subrecipients is included in the text of the Scope Manual Section 3.C.2. In consideration of these comments, HRSA reviewed the Health Center Program Compliance Manual Chapter 12: Contracts and Subawards and the updated HHS Grants Regulations at 2 CFR Part 200, specifically 2 CFR § 200.331 and 2 CFR § 200.332. HRSA confirms that the final language in the Scope Manual is consistent with other guidance and has determined that no additional language is needed.

HRSA recognizes that a health center may use alternate definitions of contracts and subawards for other organizational purposes. However, for the purposes of the Health Center Program scope of project, a health center should use the definitions in the Scope Manual to support accurate compliance documentation.

Issue: Alternative Contract Agreements

Comments
One commenter encouraged HRSA to offer additional flexibility for the proposed requirement that all Column II contracts be made by "purchasing the services." The commenter described alternative arrangements, such as a partnership with a residency program that is unpaid but has thus far been treated as a Column II arrangement. They suggest, instead, adding, "Contracted services including, but not limited to:" prior to listing "purchasing" as an example.

HRSA Response
HRSA changed "purchasing" to "procuring," consistent with 2 CFR Part 200, to provide additional flexibility for health centers to pursue alternative contract arrangements.

Issue: Clarify Transportation Expectations and Define Access

Comments
Three commenters expressed concern regarding proposed Column II and III (contracts, subawards, or cooperative arrangements) patient transportation requirements, citing budget and capacity constraints. One commenter stated that the proposed language conflicts with the Health Center Program Compliance Manual. All three commenters requested that HRSA further clarify stated definitions and elaborate on how the health center could demonstrate compliance.

HRSA Response
Transportation is a required service in the Health Center program. Refer to section 330(b)(1)(A)(iv) of the Public Health Service (PHS) Act (42 U.S.C. 254b). If a health center chooses to deliver services through a contract or cooperative arrangement with other parties, the health center must ensure that all services are made available in accordance with applicable Health Center Program statutory and regulatory requirements.

HRSA recognizes the need for additional clarity on requiring transportation for a service provided via either Column II or III. HRSA updated the Scope Manual language to explicitly state that a health center must address patient transportation needs for any service that certain health center patients can only access through a contract or cooperative arrangement. This situation might occur either because the health center does not offer the service through another service delivery method or because the other service delivery method is not accessible to some patients in the service area without transportation (for example, the service is provided directly only at a service site that is a significant distance from the impacted patients).

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

Issue: Change "Oversight" to "Coordination" for Cooperative Arrangements

Comments
Sixty-nine commenters requested a revision to indicate the health center is responsible for "coordination," not "oversight" of cooperative arrangements. Commenters suggested other specific revisions for consistency with Health Center Program Compliance Manual Chapter 4: Required and Additional Health Services, and in consideration of arrangement obligations and liability risks.

HRSA Response
HRSA declines to change "oversight" to "coordination." A health center is responsible for ensuring that all services—direct services, services provided through contracts, and services provided through cooperative arrangements—are provided in accordance with Health Center Program requirements. Refer to section 330(a)(1) of the Public Health Service (PHS) Act (42 U.S.C. 254b). When a health center chooses to offer a service through a cooperative arrangement, the health center must oversee the arrangement to ensure that services provided on behalf of the health center are delivered according to the terms of the arrangement.

Issue: Flexibility for Column III Patient Appointment Assistance

Comments
Sixty-six commenters expressed concern that health centers must assist patients in making appointments to receive services via cooperative arrangements, and that health centers must receive follow-up results from cooperative arrangement providers. The commenters recommended using the word "may" instead of "would" to reflect that the language does not denote a requirement.

HRSA Response
HRSA clarified the language in Scope Manual Section 3.C.3 to reflect the requirement for assisting patients in making appointments consistent with making all required services under Sections 330(a)(1) and 330(b)(1)(A)(iv) of the Public Health Service Act available and accessible to all residents of the service area. HRSA recognizes that it may not be appropriate in all situations to require a health center to assist patients in making appointments to receive services via a cooperative arrangement. For example, where a patient can access the same service either through a cooperative arrangement or directly from the health center at a nearby site, then the appointment assistance requirement would not apply.

HRSA emphasizes that providing services via a cooperative arrangement is more than just a referral. When a health center chooses to include a service in its scope of project that a portion of the health center's patient population can only access through a cooperative arrangement, meaning that there is no other option for those patients to receive that health service, the health center must ensure the patient receives the in-scope service by providing appointment assistance. This situation might occur either because the health center does not offer the service through another service delivery method, or because the other service delivery method is not accessible to a patient, or because the service is provided directly only at a service site that is a significant distance from the impacted patient. Refer to the final language in Section 3.C.3.

Issue: Automatically Renewing Cooperative Arrangements

Comments
Seventy commenters requested that HRSA clarify whether an "evergreen" provision in a cooperative arrangement satisfies the proposed requirement for a current cooperative arrangement, stating that evergreen provisions reduce administrative burden and are commonly recognized in contract law. The commenters suggested including the following footnote in either the Scope Manual or the Site Visit Protocol: "To demonstrate that a cooperative arrangement is current, the cooperative arrangement must be in effect and unexpired. Cooperative arrangements that periodically and automatically renew are consistent with such standard."

HRSA Response
HRSA agrees that an automatically renewing provision may satisfy the requirement for a current cooperative arrangement. Footnote 47 was added to the Scope Manual for clarification.

Issue: Clarity on Meaning of Treatment Plan

Comments
Sixty-seven commenters expressed concern regarding the requirement that health centers are responsible for a patient's treatment plan and any follow-up care, based on the care and follow-up instructions provided by the cooperative arrangement partner. Commenters requested that HRSA remove reference to a "treatment plan" and maintain that health centers

are responsible for "appropriate" follow-up care. One commenter requested further clarity on a health center's responsibility for a patient's treatment plan and any follow-up care for specialty services not within a health center's expertise, such as knee surgery.

HRSA Response
To improve clarity, HRSA removed the reference to "treatment plan" in the body of the text and added footnote 46 to specify that the health center's oversight of a patient's follow-up care at the health center includes the health center's own treatment plan for the patient.

To reduce redundancy, HRSA declines to add "appropriate" before follow-up care in this section, as "any" is already included.

Issue: Add "Or Individuals" to Cooperative Arrangements Definition

Comments
Sixty-three commenters requested a minor revision to the cooperative arrangements definition in Section 3.C to reflect that cooperative arrangements may be entered into with individuals.

HRSA Response
HRSA agrees that cooperative arrangements may be entered into with individuals. The Scope Manual language now includes "individuals."

Issue: Services Provided Via Cooperative Arrangement by Other Federally Qualified Health Centers (FQHCs)

Comments
Two commenters requested that HRSA specify that a health center may enter into a cooperative arrangement with another health center. One commenter requested that HRSA add a fourth bullet to Section 3.C.3 that indicates a health center may enter a cooperative arrangement with another health center to provide required and additional health services. They also requested that, if a cooperative arrangement is with another health center, the provisions detailed in the Scope Manual should not be required in the written document because the partnering health center is already required to comply with HRSA standards.

One commenter requested that HRSA insert the following language to highlight the purpose and intent of this section: "In cases where the other entity in a cooperative arrangement is itself also a health center, that other entity may appropriately record services provided under the cooperative arrangement on its own Form 5A: Services Provided, in Column I. In these instances, HRSA would consider an individual receiving services from the other entity to be an established patient of the other entity, as long as the requirements in Chapter 8, Section B: Patients and Visits are met."

One commenter recommended HRSA instead remove this paragraph in Section 3.C.3 related to a health center acting as a Column III cooperative arrangement provider to ensure that patients

receiving services through cooperative arrangements are recognized as established patients of both the health center and cooperative arrangement provider that is another health center.

HRSA Response
To further support collaboration between health centers, HRSA added a clarifying reference to cooperative arrangements where another health center is the Column III provider in Chapter 3, Section C.3, and a new sentence expressing HRSA's support for collaboration between health centers in Chapter 6, Section A. HRSA is choosing to add this clarification rather than deleting the paragraph related to this topic.

Chapter 3, Section C.3 of the Scope Manual and Form 5A, Column III both reference parties that a health center may enter into an agreement with, which includes other health centers. A health center providing an in-scope service via Column III must have a formal written arrangement, even if that arrangement is with another health center. This requirement supports accountability, compliance, and comprehensive service delivery.

C.3.1. Provisions in Cooperative Arrangements

Issue: Non-Federal Laws in Column III Cooperative Arrangements

Comments
Forty-eight commenters recommended that HRSA strike Section 3.C.3.1, criterion e in its entirety, stating that it is burdensome and with no substantive legal effect. Commenters indicate that while it is preferable for cooperative arrangements to include the stated provision, the absence of such terms does not exempt either party from legal obligations under applicable law. Additionally, commenters note that HHS grant regulations apply solely in cases where funds are expended and would not apply to cooperative arrangements as stated.

HRSA Response
HRSA agrees that HHS grant regulations do not apply to cooperative arrangements. In response, that language is removed. HRSA concurs that a health center must comply with applicable federal, state, and local laws. HRSA will not require a health center to include the specific language in Section 3.C.3.1, criterion e within the cooperative arrangement so long as the element is addressed as described in the Scope Manual. Refer to footnote 48. HRSA also added language clarifying that a "catch-all" provision may satisfy this requirement.

Issue: Remove Required Provisions in Cooperative Arrangements

Comments
Seventy-four commenters recommended that HRSA delete the proposed requirement that a health center include the required provisions stated in this section in the cooperative arrangement itself. Commenters requested that HRSA also acknowledge that an internal procedure, in lieu of a provision in the cooperative arrangement, is sufficient to demonstrate compliance. Fifty-five commenters requested additional clarification of the provisions related to discounts, patient access, and applicability of federal and state laws.

One commenter requested that, rather than providing a formal arrangement as proposed by the Scope Manual, a health center be allowed to demonstrate a compliant Column III cooperative arrangement through simpler, more practical means, such as documenting referrals, proof of service receipts, or receipt of provider records.

HRSA Response
Whether a health center chooses to deliver a service(s) through a contract, subaward, or cooperative arrangement, the health center must ensure that the service it provides to patients meets all Health Center Program requirements. HRSA agrees that compliance may be demonstrated without the inclusion of related provisions in a cooperative arrangement and may instead be documented elsewhere. The Scope Manual now includes amended language and additional footnotes, including footnotes 47 through 51, to provide greater flexibility. A health center and cooperative arrangement provider may now satisfy these requirements with documentation that is separate from, or an appendix to, an existing written agreement.

Issue: Use of Other Documentation to Demonstrate Compliance

Comments
Forty-five commenters asked HRSA to revise the proposed requirements to permit the use of "other documentation" to demonstrate compliance, for consistency with other key programmatic guidance. This revision would closely align with Health Center Program Compliance Manual Chapter 9: Sliding Fee Discount Program and the Site Visit Protocol. The latter permits a health center to provide "other documentation" to demonstrate the application of a sliding fee discount under a cooperative arrangement, such as the other entity's charity care policy, in lieu of a written agreement.

HRSA Response
HRSA added footnotes 47 through 51 to Section 3.C.3.1, providing greater flexibility to demonstrate compliance. HRSA will not require a health center to include the specific language in Section 3.C.3.1, criterion e, within the cooperative arrangement so long as the element is addressed consistent with footnote 48 in the Scope Manual. HRSA also added language in footnote 51 clarifying that a "catch-all" provision may satisfy this requirement.

D. Criteria Required for Additional Health Services

Issue: Oppose "Support" Standard for Specialty Services

Comments
Sixty-seven commenters urged HRSA to revise Section D by adding examples of additional and specialty services, along with clear criteria for including them in scope. Commenters expressed concern about whether specific services currently offered by health centers meet HRSA's "support" standard, questioned the exclusion of key 42 CFR Part 51c references, and noted inconsistencies with PIN 2009-02: Specialty Services and Health Centers' Scope of Project. PIN 2009-02 states that such services should logically extend or complement required primary care.

All commenters recommended, at a minimum, adding a footnote clarifying that the new criteria do not exclude advanced or specialty services. Also, commenters recommended cross-referencing to "supplemental services," as defined in 42 CFR § 51c.102(j), and adding additional examples of allowable specialty services from PIN 2009-02.

Eight commenters asked HRSA to clarify the definition of a specialty service. One of these commenters requested a process for HRSA to answer questions about specialty services. Commenters recommend that HRSA include an abbreviated version of the general criteria in PIN 2009-02 for including additional and specialty services, or, at a minimum, a footnote indicating that "the new criteria are not intended to preclude the inclusion of advanced additional services and specialty services necessary for the health and well-being of health centers' patient populations."

HRSA Response
Section 330(b)(2) of the Public Health Service (PHS) Act (42 U.S.C. 254b(b)(2)) discusses "additional health services" and does not specifically reference "specialty services."

The language in this section of the Scope Manual is consistent with PIN 2009-02, which also states that additional health services are "necessary for the support of primary health services." Aligning with section 330(a) and (b) of the Public Health Service (PHS) Act (42 U.S.C. 254b (a) and (b)), HRSA declines to add a footnote related to specialty services. HRSA also declines to include examples of additional services, as each health center may consider a broad range of services that meet these criteria.

Issue: Revise Footnote to Provide Services to All Residents

Comments
One commenter requested that the footnote in this section be revised to state that health centers make services "available" to all residents of the service area, rather than that a health center must "provide health services to all residents."

HRSA Response
HRSA concurs and updated footnote 52.

Chapter 4: Services Provided via Telehealth

In this chapter:

A. Considerations for Delivering Services via Telehealth
B. Criteria for Delivering Services via Telehealth

A. Considerations for Delivering Services via Telehealth

Issue: Telehealth Flexibilities

Comments

Seventy-three commenters expressed support for the stated importance of telehealth flexibilities. Seventy commenters expressed appreciation that services provided via telehealth do not require HRSA approval and that, through HRSA's proposed policy, individuals can become new patients through a telehealth visit. Four commenters reiterated the importance of maximum flexibility to serve all patients.

HRSA Response

HRSA concurs with commenters regarding the importance of telehealth flexibility for health centers and appreciates commenters' support for this policy.

Issue: Patient Preference for Telehealth

Comments

One commenter expressed concern regarding accessibility to services via telehealth. The commenter stated that some patients prefer telehealth visits and that some services, such as psychiatry, are only available via telehealth in their state. The commenter requested that HRSA revise the proposed sentence "Health centers should endeavor to make services available in-person whenever possible" to read as "Health centers should endeavor to make services available via the mode preferred by the patient for that service at that time."

HRSA Response

HRSA recognizes that not all services can be offered via telehealth. Additionally, HRSA recognizes that not all health center patients have access to or prefer to use telehealth technology. HRSA declines to change this language because a health center must provide residents with access to all in-scope services under section 330(a)(1) and (b) of the Public Health Service (PHS) Act (42 U.S.C. 254b(a)(1) and (b)). HRSA recognizes that a health center will have multiple considerations for whether and when to provide services via telehealth, including but not limited to patient preference, and therefore declines to include the suggested language.

Issue: Language Regarding Telehealth Consent

Comments

Seventy-three commenters requested a revision to the proposed Section 4.A, criterion b requirement that the health center must maintain policies and operating procedures that address "patients' ability to opt out of receiving services by telehealth." Considering varying state telehealth laws governing informed consent, commenters recommended striking "including patients' ability to opt out of receiving services by telehealth." The commenters noted that a health center may not be subject to informed consent laws and that HRSA policy regarding telehealth should not extend to legal matters otherwise dictated by state law. These commenters recommend that HRSA clarify that the examples are not required.

HRSA Response
HRSA removed the clause related to a patient's ability to opt-out of services by telehealth.

Issue: No Telehealth from Provider's Home

Comments
Two commenters expressed concerns over providers conducting telehealth visits from their homes. One commenter requested that telehealth not be conducted from a provider's home due to the health center's inability to monitor confidentiality, personal interruptions, and disruptive background noises. One commenter stated a provider's home does not meet the definition of a service site. This commenter requested clarification on whether providers are no longer required to be located at an in-scope health center site for Federal Tort Claims Act (FTCA) coverage.

HRSA Response
Telehealth visits from a provider's home support Health Center Program in-scope services. HRSA encourages health centers to use established telehealth flexibilities to expand access to care. As of calendar year 2026, a provider may receive CMS reimbursement for services provided from a provider's home, provided the service is covered by the payer, telehealth is a permitted modality of care within the referring provider's scope of practice, and the provider is enrolled as a participating provider. Each health center has the discretion to set requirements for a provider's workspace, consistent with applicable laws and regulations, including privacy laws.

A health center should refer case-specific FTCA questions to HRSA using the BPHC Contact Form. Responding to specific questions or factual scenarios is beyond the scope of these comments.

Issue: Audio-Only Telehealth

Comments
One commenter suggested HRSA state that some patients may benefit from audio-only services provided by telehealth.

HRSA Response

HRSA emphasizes that each health center has the discretion to determine whether and how it chooses to provide services via telehealth, consistent with applicable laws.

Issue: Supersede Telehealth Program Assistance Letter (PAL)

Comments

Seventy commenters expressed concern that Program Assistance Letter (PAL) 2020-01: Telehealth and Health Center Scope of Project (PDF) covers regulations already set forth by PIN 2008-01 or the proposed Scope Manual. Commenters recommended that HRSA either consolidate PAL 2020-01 into the draft Scope Manual or modify PAL 2020-01 so that the PAL exclusively addresses telehealth considerations not addressed in Chapter 4, notably the chart on page 5 of PAL 2020-01. One commenter requested that the Scope Manual supersede PAL 2020-01. The commenter notes that the definition of a service site in PAL 2020-01 is inconsistent with the Scope Manual.

HRSA Response

PAL 2020-01 highlights key implementation, utilization, and considerations for the telehealth information included in the Scope Manual. Implementation tools, including PALs, are updated as necessary following the issuance of any new Health Center Program policy guidance.

B. Criteria for Delivering Services via Telehealth

Issue: General Concern Regarding Geographic Restriction

Comments

One hundred and ten commenters urged HRSA to remove or amend the proposed geographic telehealth restriction. They expressed concern that there would be unintended negative consequences for the quality of care, access to services, and health outcomes for the most vulnerable and underserved patients. They stated that these patients may not reside in the service area or an adjacent area at the time of their visit and could not access in-scope services under the proposed policy.

Eighty-seven commenters requested that HRSA adjust the draft policy to permit that up to 25 percent of in-scope telehealth visits may fall outside the proposed geographic limitation. They offered examples of periodic exceptions to patient care in the proposed policy. Commenters maintained that the adjusted flexibility they propose could enhance in-scope service access and reduce the risk of activities falling outside the compliance requirements of section 330 of the Public Health Service (PHS) Act (42 U.S.C. 254b) and Federal Tort Claims Act (FTCA) protections.

Fifty-six commenters expressed concern that the proposed policy requiring the patient's physical presence within the service area or adjacent area at the time of the telehealth visit will create unnecessary access barriers, administrative burden, such as building a new eligibility determination system, and compliance risk. They encouraged HRSA not to limit telehealth access that would be permitted under applicable state telehealth laws.

Fifteen commenters recommended using both residency and physical location to determine eligibility for in-scope services provided by telehealth. Commenters noted that if one location category is prioritized, HRSA should use the residency standard, aligned with section 330 of the Public Health Service (PHS) Act (42 U.S.C. 254b).

Nine commenters stated that the narrow restriction of telehealth services to the service area and the adjacent service area limits the health center's ability to provide care. They noted that the draft policy makes an arbitrary distinction for patients who reside outside of the service area, with services required if in-person, but prohibited if the patient is remote.

Two commenters expressed concern that the proposed geographic limitations on telehealth will restrict patients' access, especially in rural areas, to providers who accept Medicaid and 340B discounted prescription drugs, because of the 340B program's eligibility requirements. One commenter noted that the proposed limitations will negatively impact health centers' bottom lines, especially given pharmaceutical manufacturers' contract lock-out policies and decreased reimbursement from pharmacy benefit managers.

Two commenters expressed concerns about workforce shortages and stated that restricting telehealth based on patient location could present operational barriers. One commenter highlighted that due to workforce shortages, individuals may seek care outside a health center's service area.

One commenter suggested that any geographic restrictions would adversely impact patients with mobility challenges and would violate the Americans with Disabilities Act (ADA).

One commenter voiced concern that the proposed service area boundaries and telehealth provision limit patients' choice in their care and stated that these constraints are arbitrary. They voiced concern that this provision is a departure from HRSA's culture of patients having choice in their care and how they are served.

HRSA Response
HRSA appreciates commenters' feedback on restrictions to a health center's use of telehealth and carefully reviewed these concerns. However, the Health Center Program's authorizing statute under section 330(a)(1) of the Public Health Service (PHS) Act (42 U.S.C. 254b (a)(1)) ties the services provided by a health center to a geographic service area, or "catchment area" and the geographic restrictions included in the Scope Manual are aligned with statute and remain in the final policy.

HRSA updated the Scope Manual to refer to either the patient's physical location or residency for telehealth purposes, as the applicable criteria. Whether a patient may receive a service via telehealth as an in-scope service depends on the patient's physical location or residency at the

time of the service. Additionally, HRSA updated the definition of the term "adjacent to" to align with existing Health Center Program policy documents.

Regarding concerns about FTCA coverage, coverage depends only in part upon whether a service is within the health center's scope of project. A health center should refer case-specific FTCA questions to HRSA using the BPHC Contact Form.

HRSA believes that the geographic restrictions on telehealth balance section 330 requirements for providing services in the catchment area with the need to ensure access to care for all individuals, including those with disabilities.

Issue: Special Medically Underserved Population (MUP) Exemption

Comments

Fifty-seven commenters recommended that patients who fall within one of the statutorily defined special medically underserved populations (homeless individuals, migratory and seasonal agricultural workers, and residents of public housing) should be exempt from the telehealth geographic restriction. Twenty commenters suggested exempting migratory and seasonal agricultural workers and homeless individuals from the residency requirement for in-scope services provided by telehealth, due to their lack of a permanent address.

HRSA Response

HRSA declines the requested exemption because the Health Center Program's authorizing statute under section 330(a)(1) and (g)(A) and (B) of the Public Health Service (PHS) Act (42 U.S.C. 254b(a)(1) and (g)(A) and (B)) ties the services provided by a health center to "all residents of" the catchment area, for the community, homeless population and public housing residents and, for migratory and seasonal agricultural workers, to individuals who are "within a designated catchment area." To provide more clarity and flexibility, HRSA changed "residency" to "either physical location or residency" in the Scope Manual.

Issue: Patients in Nursing Homes and Telehealth

Comments

One commenter requested clarification on whether patients in nursing homes may be established via telehealth, or whether patients must first be established at a permanent service site identified on Form 5B: Sites.

HRSA Response

As stated in Section 4.B, "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 to the health center's service area." Therefore, a patient who receives a service provided via telehealth at their residence—regardless of the type of residence—may be established as a health center patient, so long as the residence is in the service area or within areas adjacent to the health center's service area and meets all other

requirements in the Scope Manual. Note, however, that providing telehealth services to established patients in a nursing home (or long-term care facility) does **not** make that location part of the health center's scope of project.

Issue: Remove Form 5A Documentation Requirement

Comments

One commenter requested that the criterion indicated in Section 4.B, criterion c, be removed because they perceive the reference to be duplicative of Form 5A documentation requirements, specifically regarding the language: "Individuals receive an in-scope required primary or additional health service (as documented on the health center's HRSA-approved Form 5A: Services Provided)."

HRSA Response

HRSA believes that Section 4.B, criterion c, which clarifies that the service is documented on Form 5A, is not duplicative. Therefore, HRSA declines to remove this criterion.

Issue: General Federal Tort Claims Act (FTCA) Concern Regarding Geographic Flexibility

Comments

Seven commenters requested that HRSA clarify the requirements outlined in Sections 4.A and 4.B, citing Federal Tort Claims Act (FTCA) coverage concerns. Specifically, concerns regarding proposed requirements that patients be physically located in the health center service area or an adjacent service area, at the time of a telehealth visit, and concerns over providing in-scope services via telehealth when a health center patient is physically located outside the service area or adjacent area.

HRSA Response

HRSA acknowledges that only services provided within a health center's scope of project may be covered by FTCA. A health center should therefore consider that services that are not considered within a health center's scope of project in accordance with this policy may not be eligible for FTCA coverage. HRSA cannot provide general assurance of FTCA coverage. The Department of Justice has a lead role in deciding whether or not to make the certification needed to support FTCA coverage, and courts also consider the available facts in individual cases in litigation – such decisions will depend on all of the available facts and circumstances.

Issue: Reconsider Time Limits

Comments

Three commenters requested that HRSA reconsider imposing a one-year time restriction on how long health centers may serve patients via telehealth once patients are no longer physically located in the health center's service area.

HRSA Response

HRSA declines to change the language in the Scope Manual related to the time restriction on providing telehealth services to patients who are no longer either physically located within or a resident of the health center's service area or areas adjacent to the health center's service area. Refer to section 330(a)(1) of the Public Health Service (PHS) Act (42 U.S.C. 254b), which ties the health center's scope of project to a service area. The language in the Scope Manual is consistent with the geographic service areas specified in the Health Center Program statute.

Issue: Part-Time Residency or Temporary Absence

Comments

Eighty-three commenters requested edits addressing part-time residency or temporary absence of a patient from the service area. Seventy commenters requested that HRSA consider part-time residency in a service area sufficient to qualify them to receive in-scope services via telehealth. Twenty-three commenters asked HRSA to allow residents who are temporarily absent from, or part-time residents of, the service area to receive health center services via telehealth.

HRSA Response

HRSA agrees that part-time residents and residents temporarily absent from the service area may qualify to receive in-scope services through telehealth for a limited period. HRSA updated the language in Section B to clarify that, for the purposes of providing telehealth to patients, the "physical location" or "residence" of the patient determines eligibility for services. This change in language eliminates the need to define part-time residency or temporary absence. As noted in the policy, a health center may continue to provide services via telehealth to an established health center patient who is no longer a resident of or physically located in the service area or an area adjacent to the service area for a limited period (for example, up to 1 year).

Issue: "Adjacent" Definition

Comments

Sixty-one commenters recommended that HRSA align its use of the term "adjacent" in the Scope Manual with what is in other recent policy (specifically, PIN 2024-05). One commenter suggested HRSA add an additional section of the definition that includes "sincere and immediate State borders, representing patient population travel patterns capturing common work, housing, education, and social service access to the Health Center."

HRSA Response

HRSA agrees that the Scope Manual definition of "adjacent" should align with the language used in PIN 2024-05. HRSA updated the language in Section B. Given that HRSA has clarified the definition of "adjacent" in a manner consistent with existing policy, HRSA declines to add an additional section to the definition.

Chapter 5: Sites

In this chapter:

A. Service Sites Within the Scope of Project
B. Criteria Required for Service Sites
C. Service Sites with Limited Services
D. Service Site Types
  D.1. Permanent Service Sites
  D.2. Seasonal Service Sites
  D.3. Mobile Service Sites
E. Requirements for Documenting Other Sites

A. Service Sites Within the Scope of Project

Issue: Registering Mobile Units in HRSA Systems

Comments

Twenty-five commenters urged HRSA to allow mobile vans to be registered in HRSA systems using a unique suite number at the street address where they are generally parked overnight. Commenters stated that requiring a mobile unit to use the identical address as the permanent site creates significant billing issues, as the Centers for Medicare & Medicaid Services (CMS) will not recognize more than one National Provider Identifier (NPI) per address.

HRSA Response

Additional guidance on documenting a mobile service site location will be included in the Instructions for Form 5B: Sites. HRSA notes that if the street address of the mobile service site is located outside of the service area, documenting that address on Form 5B does not expand the health center's service area. Refer also to Section 5.D.3, footnote 73.

Issue: Additional Documentation Examples Regarding Hospital-Based Activities

Comments

One commenter requested more information on how to document hospital-based activities and asked HRSA to provide examples of allowable hospital-based activities.

HRSA Response

All in-scope services, including any services provided at a hospital, such as labor and delivery, should be documented on Form 5A: Services Provided. Only locations that meet the service site criteria discussed in Section 5.B may be added as a service site on Form 5B: Sites.

Issue: Clarifications Related to the Change in Scope (CIS) Request Process

Comments

Two commenters noted that the draft Scope Manual does not address the effective date of Change in Scope (CIS) requests. Based on language in PIN 2008-01,[1] HRSA previously advised health centers that the effective date would be the date on which a health center submitted the CIS. Based on a recent CIS submission, the effective CIS date submitted differed from the CIS date reflected by HRSA in HRSA systems. Due to the conflicting dates, the commenters recommend HRSA expressly address the process for determining the effective dates of CIS requests in the draft Scope Manual.

One commenter requested a clearer process for health centers to seek guidance on scope of project and to document HRSA's answers to questions throughout the CIS process. The commenter stated that the current process is challenging since the original question is often not included when BPHC replies, making it difficult for health centers to understand the change.

HRSA Response
The Scope Manual provides updated policy guidance on a health center's scope of project and does not discuss the process for CIS requests. HRSA will consider these comments when making future edits to the Instructions for Form 5B: Sites and when HRSA updates applicable CIS resources.

B. Criteria Required for Service Sites

Issue: Individual Site Approval/Control

Comments
Seventy-one commenters expressed concern that requiring the board to approve services on an individual site basis would create inefficiencies and impose a significant burden. Commenters request that HRSA revise Section 5.B, criterion d.i to state that the board "has approved the addition of the service site and its hours of operation, as well as the health center's overall scope of services."

HRSA Response
Services are approved at the organizational level, not at the site level. The Scope Manual language requiring board approval of "the health center's overall scope of services" is consistent with existing Health Center Program policy, including Health Center Program Compliance Manual Chapter 19: Board Authority, Demonstrating Compliance, and thus, HRSA declines to edit language in this section.

Issue: Feasibility

Comments

[1] PIN 2008-01, "The effective date of an approved change in scope will be no earlier than the date of receipt of a complete application or, in cases where a grantee is not able to determine the exact date by which the change in scope will be fully accomplished, grantees will be allowed up to 120 days following the date of the Notice of Grant Award indicating approval for the change in scope to implement the change (e.g., open the site or begin providing a new service)."

Three commenters expressed concern that the proposed "Section B. Criteria Required for Service Sites and C. Service Sites with Limited Services" requirements are not feasible due to resource limitations that could prevent a health center from offering a new service to all or some of its established patients. If implemented, the proposed requirements may place some health centers out of compliance or force some not to implement new services. All three commenters provided examples of dental or behavioral health services to reinforce this concern, noting that they may have the resources to hire only one dentist, even if there is a much higher patient need beyond what one provider can support.

Additionally, one commenter sought clarification on how health centers could affirm that patients receiving services at a limited-service site have access to all other health center in-scope services, including a needs assessment and transportation access. One commenter asked, "If a CHC can't meet all the needs, are they allowed to meet some of the needs?" One commenter asked for greater clarity on how HRSA will evaluate whether patients have access to all health center services and whether health centers meet their patients' transportation needs. The commenter also asked whether, when addressing these needs, a health center may pilot a new service to a small group of patients before making it available to the patients throughout the service area.

HRSA Response
Consistent with established policy, HRSA clarified throughout the Scope Manual that a health center is only required to ensure its patient population can "access" all services offered by the health center and is not required to "provide" in-scope services to all patients. Refer to Chapter 3: Required Primary and Additional Health Services. HRSA recognizes that a health center may have capacity limitations for providing certain services. HRSA added footnote 32 to Section 3.C, clarifying that when a health center provides a service and needs to establish a waiting list due to high need, the health center would be compliant with requirements provided it meets all applicable criteria described in the Scope Manual.

Regarding the comment on piloting a new service to a small group of patients before making the service available to all patients, whether this proposed service meets applicable Scope Manual criteria depends on the specifics of the Change in Scope (CIS) request, which should be submitted through the designated HRSA systems.

Under section 330(b)(1)(A)(iv) of the Public Health Service (PHS) Act (42 U.S.C. 254b), transportation is a required service. HRSA evaluates whether a health center is compliant with making required services available and accessible to all residents using the Health Center Program Compliance Manual. The Health Center Program Compliance Manual Chapter 4: Required and Additional Services states that each health center determines the level or intensity of required and additional services, as well as the method for delivering these services, based on factors such as the needs of the population served, demonstrated unmet

need in the community, provider staffing, and collaborative arrangements. Additional information can also be found on Scope of Project Resources.

Issue: Revise Footnote Regarding Locations Where Patients Are Not Seen in Person

Comments

Two commenters requested that HRSA clarify footnote 65 in Section 5.B, which states that a location where patients are not seen in person and providers are only delivering care via telehealth does not meet the definition of a service site. Both commenters expressed concerns about the restriction, and one expanded on the impact on the rural community.

HRSA Response

HRSA acknowledges commenters' concerns over this footnote. However, HRSA declines to revise this footnote as more information on providing services via telehealth is available in Chapter 4: Services Provided via Telehealth. In response to the question about services provided via telehealth at a non-health center site, a health center may provide services via telehealth, even if the location of the provider is not a service site. Please refer to Chapter 4 for more information.

Issue: Patient Records

Comments

Sixty-nine commenters agreed that patient records should be maintained and accessible to health centers for patients accessing services at the health center or through contracts. However, commenters recommended that Section 5.B, criterion e be edited to read, "Health center visits are generated at the service site through the delivery of required primary or additional health services to health center patients and, for services provided at sites operated directly by the health center or by a contractor on behalf of the health center, are documented in patient health records maintained by or accessible to the health center." All 69 commenters also recommended replacing the term "accessible" with "retrievable" for consistency with the Health Center Program Compliance Manual, specifying that "retrievable" means the health center must have reasonable access to these records, but it does not need to be the custodian.

HRSA Response

HRSA appreciates the feedback. A health center must be able to access patient health records for any service site documented as part of the health center's scope of project on Form 5B: Sites. To align with this requirement, HRSA declines to update Section 5.B, criterion e.

HRSA added footnote 68 to criterion e to clarify that "accessible" means "the health center must have the right to access these records, but the health center does not need to be the record custodian."

C. Service Sites with Limited Services

Issue: Change "Provide" to "Make Available"

Comments

One commenter asked that HRSA change "provide" to "make available" in Section 5.C, "A health center is required to provide all required primary health services to its patient population."

HRSA Response

HRSA appreciates this suggestion and updated "provide" to "ensure access to."

D. Service Site Types

Issue: Delete Section D: Service Site Types

Comments

One commenter asked that HRSA delete Section 5.D: Service Site Types.

HRSA Response

HRSA declines to remove this section.

D.1. Permanent Service Sites

HRSA received no comments specific to this subsection.

D.2. Seasonal Service Sites

HRSA received no comments specific to this subsection.

D.3. Mobile Service Sites

Issue: Mobile Sites

Comments

Fifty-seven commenters recommended that HRSA insert the term "as applicable" following the statement that a mobile service site must be "licensed to render in-scope services on behalf of the health center," as licensing is a matter of state law.

HRSA Response

HRSA appreciates the feedback and added the language "if applicable under state law."

E. Requirements for Documenting Other Sites

Issue: Contracted Administrative Work Reflected on Form 5B

Comments

Two commenters noted that it would be administratively burdensome for health centers to document on Form 5B: Sites (Form 5B), the sites where administrative functions (e.g., billing) are operated under a contract. One commenter also noted that it would be administratively burdensome to require health centers to document the locations where they participate in

community events on Form 5B and asked whether this type of activity would require formal Board approval to be included on Form 5B.

HRSA Response
HRSA acknowledges the concerns about administrative burden. HRSA updated the Scope Manual to clarify that only directly-operated locations that do not meet the Service Site Definition in Section B: Criteria Required for Service Sites should be documented on Form 5B as an Other Site, consistent with criteria in Section 5.E.

Issue: Documenting Locations That Do Not Meet Service Site Criteria

Comments
Six commenters requested clarification on how to document locations that do not meet the service site criteria. Two inquired as to how the new process will affect Federal Tort Claims Act (FTCA) coverage. One requested clarification as to whether HRSA's policy for seasonal sites operating less than twelve months per year has changed, given that its organization could not enter shorter seasonal durations for school-based sites in HRSA systems.

HRSA Response
HRSA acknowledges the concerns about documenting locations that do not meet the service site criteria. Activities that do not meet the service site criteria or requirements for documenting other sites should follow the guidance provided in Chapter 9: Services Provided at a Location Other Than a Health Center Service Site. These activities do not need to be recorded on Form 5B: Sites. HRSA recommends that health centers refer case-specific FTCA questions or case-specific systems-related questions to HRSA using the BPHC Contact Form.

Issue: "Other" Non-Service Sites

Comments
Sixty-seven commenters requested that HRSA explicitly confirm that it will continue to use the current scope adjustment process or a similar streamlined process when approving the addition and deletion of Other Sites under Section 5.E. All of these commenters cited increased administrative burden if the current process or a similar streamlined one is not kept in place.

One commenter requested that HRSA clarify how to demonstrate compliance with the new Form 5B: Sites (Form 5B) requirements for enabling and outreach services in the community, citing that requiring approval and detailed documentation could create a significant burden and limit access.

One commenter recommended that stand-alone pharmacy sites, including 340B contract pharmacies, should not be included on Form 5B. Instead, the commenter suggested that tracking health center pharmacies should be managed through the HRSA Office of Pharmacy Affairs, following currently established protocols, stating that the requirement to include these

pharmacy sites on Form 5B creates a significant burden for Health Center Program award recipients and HRSA.

HRSA Response
The Scope Manual does not address the process of scope adjustment. HRSA intends that, for the addition of other non-service sites, a health center will be able to complete the change-in-scope with minimal administrative burden, similar to the current addition of an administrative-only site.

Only health center-operated pharmacies should be included on Form 5B. HRSA declines to edit the Scope Manual to exclude health center-operated pharmacies from Form 5B, because the health center provides the in-scope health center activity of pharmaceutical services at that site. A 340B contract pharmacy should not be included in the health center's scope of project.

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

In this chapter:

A. Service Area Overlap Considerations
B. Additional Factors for Adding a Service Site
C. Service Sites Co-Located with Other Organizations or Other Lines of Business
D. Service Sites Operated by Contractors Including Subrecipients
D.1. Requirements for Service Sites Operated by Subrecipients
D.2. Requirements for Service Sites Operated by Contractors That Do Not Meet All Health Center Program Requirements

A. Service Area Overlap Considerations

Issue: Consolidate Chapters 5, 6, and 10

Comments

One commenter suggested that, in the name of readability, the content of Chapters 5, 6, and 10 is similar and should be consolidated.

HRSA Response

HRSA appreciates the commenter's suggestion. HRSA uses chapters to divide the content of the Scope Manual with the intent of improving readability; HRSA declines to consolidate these sections.

Issue: Expand Supportive Collaborative Arrangements Language

Comments

One commenter requested that HRSA add language to support collaborative arrangements between health centers to expand access.

HRSA Response

HRSA supports the collaboration between health centers to expand access for patients. Chapter 3, Section C.3 discusses the ability of health centers to work together using a collaborative arrangement. Additionally, in Chapter 6, Section B, factor g and the accompanying footnote 81, HRSA indicates that when determining whether to approve a proposed new site, HRSA will consider the degree to which a health center demonstrated coordination and collaboration with other health centers serving the service area of the proposed service site, consistent with the Health Center Program Compliance Manual. For clarity, HRSA added a sentence supporting collaboration between health centers in the first paragraph of Scope Manual Section 6.A.

Issue: Include Specific Service Area Overlap (SAO) Assessment Process

Comments

Seventy-two commenters expressed concern that Section A does not provide a clear and concise process with well-defined factors that HRSA will use to assess service area overlap. Related concerns include the extent to which HRSA considers whether the unmet need in the proposed area exceeds the capacity of the proposed site to complement and not duplicate existing area services. These commenters suggested that, at a minimum, HRSA should cross-reference Section B, factors a, b, and g, which address unmet need assessment and resource coordination.

One commenter also wanted HRSA to encourage more collaboration between health centers and better focus on need when assessing Look-Alike Health Centers or Hospital-Owned Health Centers that want to expand into areas served by funded health centers.

One commenter expressed concern with the service area overlap analysis and approval process impacting rural communities that benefit from a network of overlapping services.

HRSA Response
HRSA acknowledges the concerns of service area overlap evaluation factors, which the Scope Manual clarifies for the first time. HRSA will consider the factors outlined in Section B when determining whether to approve a proposed site. The Scope Manual balances health centers' flexibility to propose new sites with HRSA's statutory and regulatory responsibility to ensure appropriate distribution of resources across the country. HRSA will apply the guidance in this chapter to all health centers. The final sentence of Section A cross-references to Section B. HRSA declines to explicitly cross-reference only some of the factors, as all the factors in Section B are applicable.

Issue: Antitrust Violations

Comments
One commenter expressed concern that restricting service area overlap may stifle competition and violate the Sherman Antitrust Act. The commenter requested that HRSA remove proposed service area overlap restrictions to prioritize patient access, encourage collaboration among health centers, and simplify rural expansion documentation by focusing on the demonstration of community need.

HRSA Response
HRSA acknowledges the commenter's concern about restricting service area overlap. However, HRSA declines to remove or update the language in Section B because HRSA is responsible for ensuring that limited federal award funds and resources are used efficiently and effectively to provide access to primary care services.

B. Additional Factors for Adding a Service Site

Issue: Support Demonstration of Unmet Need

Comments

One commenter expressed support for requiring a more detailed justification for new site approvals, including demonstrating unmet need rather than assuming service gaps.

HRSA Response
HRSA appreciates the feedback. The following resources offer HRSA's methodology for quantifying unmet need and may be used by a health center when providing justification for a new service site: Service Area Needs Assessment Methodology Unmet Need Score (UNS) User Guide (PDF) and Data Sources Used in the Unmet Needs Score (UNS) (PDF) are available on the Unmet Need Score Map Tool.

Issue: Sites Outside of the Service Area

Comments
Sixty-seven commenters expressed concern that factor 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") could hinder health center expansion. The commenters request that HRSA add the following at the end of the first sentence: "absent justification for proposing a site outside of the health center's existing service area."

HRSA Response
In order to provide clear and well-defined criteria, HRSA declines to add the proposed additional language. HRSA clarified in this section that a health center may include any additional documentation or information in its request to add a new site that it considers important for HRSA's review.

Issue: Relocation CIS Consideration

Comments
One commenter requested that HRSA provide language under factor c, related to a site proposed within 1 mile in an urban area and 5 miles in a rural area from a different health center's existing site, not be applied to proposals where the health center is replacing a site currently in the health center's scope of project with a new site in the health center's existing service area that will serve the same portion of the service area.

HRSA Response
HRSA declines to exempt site relocation from Section B, factor c. HRSA will review all change in scope requests to add a new site, including relocated sites, to a health center's scope of project.

Issue: Community Input

Comments
Sixty-seven commenters expressed concern regarding the methodology for gathering community input when proposing a new service site. Commenters recommend that HRSA allow greater flexibility in how a health center demonstrates community input by revising this factor to state: "[I]f 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, through a methodology that may include but is not limited to: (i) …; (ii) …; and/or (iii) …," in lieu of the current language that requires the health center to use at least one of the examples provided by HRSA.

HRSA Response
In Section 6.B, factor f, element iv states, "Another similar mechanism designed to gather representative input from residents of the proposed new service area." Since this language already provides a health center with the flexibility requested by the commenters, HRSA declines to add the suggested language.

Issue: Support Documented Engagement with Existing Providers

Comments
One commenter requested clarification that the Scope Manual will require letters of support for service area expansion, particularly from the dominant health center in the service area.

HRSA Response
HRSA appreciates the request for clarification on letters of support. While the Scope Manual does not discuss letters of support, it clarifies that HRSA will consider the degree to which a health center demonstrated coordination and collaboration with each Health Center Program award recipient and designee serving the service area of the proposed service site.

Issue: No Automatic Disapproval Based on Additional Factors

Comments
Sixty-five commenters asked HRSA to expressly indicate in Section B that examples are provided solely for explanatory purposes, that examples are neither exhaustive nor dispositive, and will not lead to an automatic disapproval for site additions or findings on compliance reviews.

HRSA Response
HRSA added language to the Introduction, Section B. "Purpose," explaining that the stated examples within each factor are not intended to be an all-inclusive list and serve a clarifying purpose. HRSA will review all Change in Scope (CIS) requests to add a new site and may consider the factors indicated in Section 6.B, as stated in the Scope Manual. Because all CIS requests are reviewed individually, no disapproval will occur automatically.

Issue: Expand Section 6.B Locality-Based Considerations

Comments
Four commenters expressed concern that the list of criteria in Section 6.B will limit access to care. Commenters recommended broadening the list of criteria to incorporate locality-based determinations of need.

One commenter expressed concern regarding the limitations of Health Center Program penetration data and the considerable variation of the data across and within states. All five commenters recommended that HRSA not rely on this measure until there is a way to consider the impact of non-health center providers.

HRSA Response
The Scope Manual states that HRSA may base a determination of unmet need on some or all of the listed measurements. While there may be limitations to some of the measurements, a health center may provide additional data, such as a needs assessment based on local data, that it would like HRSA to consider when submitting a change in scope request to add a new site. HRSA added language at the end of Section B to clarify that a health center may submit any additional information or documentation for HRSA's consideration.

Issue: Reference Distance in Time and Miles

Comments
One commenter encouraged HRSA to include time, in addition to miles, as the standard of distance. In rural and rugged areas, such as West Virginia, distance is referenced in terms of time instead of miles.

HRSA Response
HRSA added language to the Introduction, Section 6.B. "Purpose" clarifying that the examples provided within stated factors are illustrative examples. The examples are not all inclusive. HRSA added language at the end of Section 6.B to clarify that a health center may submit additional information or documentation for HRSA's consideration, such as travel time.

Issue: Clarify Factor e for Disapproval

Comments
Two commenters asked HRSA for greater clarity on how HRSA may use Section 6.B, factor e, related to altering a service area's political subdivisions, to evaluate whether to approve a request to add a proposed service site. One commenter noted that factor e. seems to contradict the use of ZIP Code Tabulation Areas (ZCTAs) to describe service areas, in addition to being repetitive of section 330 of the Public Health Service (PHS) Act (42 U.S.C. 254b). One commenter asked for clarification on how a health center operating near state lines would be impacted by this factor.

HRSA Response
As with all the factors in Section 6.B, HRSA may request more information about a proposed service site or disapprove a request to add a proposed service site based on the outlined factors. In the case of Section 6.B, factor e, HRSA may consider whether a proposed new site conforms to the relevant boundaries of the health center's existing service area. HRSA recognizes that service areas may cross political boundaries and added footnote 78 to factor e, clarifying that service areas crossing political boundaries are permissible.

Please note that HRSA has updated the Scope Manual to refer to ZIP Codes instead of ZCTAs.

Issue: Patient Projections for Change in Scope (CIS) Requests

Comments

One commenter expressed concern over the section, indicating that HRSA may base a determination of unmet need on the number of patients proposed to be served by the new service site. The commenter indicated that once the change in scope is approved, the provider could increase the number of patients, potentially taking patients away from other health centers in the service area.

HRSA Response

In response to this comment, HRSA has updated Section 6.B, factor a to allow consideration of 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.

As noted in factor a of this section, HRSA may base a determination of unmet need in the service area on all or some of the data types listed, of which the proposed number of patients to be served is one type.

Issue: Previous HRSA Disapproval of Site

Comments

Sixty-four commenters expressed concern over Section 6.B, factor i, which considers disapproval of an initial add service site request in a subsequent submission decision. The commenters requested to remove the factor entirely or alter it to add specific stipulations.

HRSA Response

While HRSA acknowledges these concerns, HRSA declines to remove or edit Section 6.B, factor i. Previous disapproval of a request is one of many factors that HRSA may consider when reviewing a site addition request. Each factor is not necessarily a determining factor, and HRSA will review each request on a case-by-case basis.

Issue: Site Near Another Health Center

Comments

Sixty-seven commenters highlighted scenarios where a proposed service site may be or needs to be located within the same building or near another health center (Section 6.B, factor c) and requested that HRSA allow health centers to justify proposing to add such a site. Commenters shared an example of adding a site near a limited service site. One commenter requested that HRSA consider whether new health centers could bring better care to shared service areas when existing health centers within the service area are not providing quality care.

Four commenters expressed support for HRSA's proposal to ensure a minimum distance between health centers when approving the addition of new sites. One commenter asked HRSA to consider that allowing new access points in service areas with existing Health Center Program award recipients may weaken the sustainability of the existing award recipients. One commenter asked if allowing an existing health center into another's service area would create unnecessary competition. One commenter suggested that HRSA could strengthen the requirement by more clearly defining the terms "substantial evidence" and "moderate proof of health care gaps."

HRSA Response
HRSA recognizes both supporting and opposing comments related to this factor. HRSA declines to edit the language in Section 6.B, factor c. The language in the policy allows for unique situations where two closely located sites may be appropriate, while upholding HRSA's statutory and regulatory duty to ensure limited federal award funds and resources are used efficiently and effectively to provide services to the greatest number of individuals in the catchment area, consistent with section 330(k)(2)(C) of the Public Health Service (PHS) Act (42 U.S.C. 254b) and 42 CFR Section 51c.305. HRSA also notes that each factor is not necessarily a determining factor, and HRSA will review each request on a case-by-case basis.

Issue: Site Distant from Existing Sites

Comments
Sixty-seven commenters suggested that the distribution of the population in a service area and the availability of services across sites drives the need for new sites that HRSA would consider to be "significantly distant" from the health center's nearest site. These commenters asked that HRSA take into consideration a health center's justification for the location of these proposed sites instead of strictly applying the 15 miles (urban)/30 miles (rural) rule in Section 6.B, factor d.

Three commenters expressed that the restriction on a proposed site located 15 or 30 miles from a health center's closest existing site (for urban and rural areas, respectively) may harm patient access and the expansion of care. One commenter expressed that areas without any health centers lack institutional capacity to create a new health center and would be better served by an existing health center, even if it is further away. One commenter stated that bus routes or public transit lines may make a location greater than 15 miles away in an urban area appropriate for a new site. This commenter also noted that it is not uncommon in rural areas for distances of 45 miles or more between towns that support the same health center or critical access hospital.

HRSA Response
HRSA added language to the Scope Manual Section 6.B stating that a health center may submit additional information or documentation for HRSA's consideration. The language in the policy addresses HRSA's statutory and regulatory responsibility to ensure limited federal award funds

and resources are used efficiently and effectively to provide access to as many underserved people as possible, consistent with section 330(k)(2)(C) of the Public Health Service (PHS) Act (42 U.S.C. 254b) and 42 CFR Section 51c.305. HRSA also notes that each factor in Section 6.B is not necessarily a determining factor, and HRSA will review each request on a case-by-case basis. HRSA has also updated Section 6.B, factor d from referring to the distance from a health center's "closest existing site" to "the health center's service area," providing greater flexibility especially for a health center in a rural area with a larger service area.

Issue: Other Data Sets to Demonstrate Need

Comments

One commenter expressed concern that HRSA does not capture data on the number of low-income patients served by non-health centers, limiting a health center's ability to grow. They asked that HRSA allow health centers to submit their own data for met and unmet needs scores. The commenter recommended that BPHC partner with the Bureau of Health Workforce (BHW) for low-income population data.

HRSA Response

HRSA appreciates this feedback and refers the commenter to Health Center Program Compliance Manual Chapter 3: Needs Assessment. HRSA added language to the Scope Manual stating that a health center may submit additional information or documentation for HRSA's consideration.

Issue: Pre-Approval of New Sites

Comments

One commenter suggested that the current process for approving new service sites is misaligned with that undertaken by health centers to develop new sites. To make better use of health centers' efforts to develop new sites (and prevent the denial of sites for which health centers have invested significant resources in developing), the commenter suggested that HRSA offer new sites a pre-approval process that could be initiated several years before the health center plans to open the new site.

HRSA Response

HRSA appreciates that the development of new sites entails significant resources. However, HRSA declines to add a pre-approval process to the Scope Manual.

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

Issue: Compliance with Other Requirements for Co-Location Model

Comments

Seventy-three commenters expressed concern over requirements for co-located service sites. Sixty-one commenters requested HRSA add language clarifying that a health center can comply with both HRSA Health Center Program requirements and other federal, state and local legal requirements applicable to the particular co-location model, provided that such other

requirements do not conflict with Health Center Program requirements. Fifty-five commenters requested clarification on board approval requirements when a site is co-located with another organization. Fifty-three commenters specifically requested HRSA add a footnote and language to Section 6.C, criterion b, recognizing that school districts may be regulated by state or local rules as well as have agreements between the state and local jurisdiction, which may specify locations, hours, services/service provisions. Five commenters indicated the importance of co-located service sites.

HRSA Response
HRSA acknowledges these concerns and added footnote 88, recognizing that a health center is required to comply with federal, state, and local requirements, including requirements for operating within a school location, provided that the health center also complies with the Health Center Program requirements.

Issue: Clarify Co-Location Requirements

Comments
Two commenters requested specific clarification about the requirements for co-located sites. One commenter requested clarification on whether spaces leased in schools or housing complexes are considered co-located sites, and one commenter expressed concern over co-location at a hospital.

HRSA Response
The Scope Manual indicates that a co-located site is a service site operated by the health center at a location where another organization also provides services. HRSA does not restrict a health center from operating a co-located site if the service site meets the criteria outlined in this section. Section 6.C provides a non-exhaustive list of examples of co-located sites. In addition, Section 6.C clarifies and provides examples of times when, for the sake of continuity of care, a health center may provide services to its patients at locations that are not service sites, so long as it provides such services on behalf of the health center (and not as a contract service on behalf of another party) and in accordance with Health Center Program requirements. HRSA declines to add "housing complexes" as another example of a possible co-location, because not all housing complexes provide "services," and a service site must provide in-scope services defined under section 330(b) of the Public Health Service (PHS) Act (42 U.S.C. 254b(b)).

D. Service Site Operated by Contractors or Subrecipients

Issue: "Operated Entirely by a Contractor" Definition

Comments
Fifty-seven commenters recommended that HRSA either provide a definition for the term "operated entirely by the contractor" or provide criteria for making such a determination to reduce confusion about this term.

HRSA Response

HRSA appreciates the feedback and added language to Section 6.D to define the term "operated entirely by the contractor." A service site is "contractor-operated" when the contractor has functional control and responsibility over the service site's day-to-day operations, even if there is a mix of directly employed and contracted clinical and other staff such as when the health center has hired an obstetrician or gynecologist that occasionally provides services on behalf of the health center at a contractor-operated site. In contrast, a directly-operated site is one where staff directly employed by the health center have functional control and responsibility over the service site's day-to-day operations.

Issue: Service Site Removal Criteria

Comments

Fifty-one commenters requested that HRSA delete, or move to Chapter 1 or 10, language where HRSA reserves the right to disapprove or remove service sites operated by award recipients, look-alikes, subrecipients, or contractors. Commenters raised concerns that the language appears to broaden application of subrecipient compliance requirements beyond subrecipients, specifically including look-alikes or award recipients, and contractors.

HRSA Response

HRSA appreciates the suggestion and has provided additional information regarding this concept in Chapter 1 and removed it from this section.

Issue: Subrecipients as Contractors

Commenters

Fifty-seven commenters requested that HRSA revise the introductory paragraphs of Section D through Section D.1 so that it distinguishes and separates requirements that are applicable to contractors from those applicable to subrecipients. Additionally, they recommend revisions to reflect that service sites operated by subrecipients would not be operated "on behalf of" the health center.

Fifty-three commenters suggested that subrecipient arrangements are not procurements or purchases and, therefore, federal requirements articulated in 45 CFR Part 75 [now 2 CFR Part 200] should not apply. They asked that HRSA amend Section 6.D, criterion f, which requires compliance with HHS grants regulations, to reflect that these requirements only apply to contractor-operated service sites and to contracts paid with the health center's federal grant funds.

HRSA Response

HRSA clarified distinctions between contractors and subrecipients, including implications for eligibility for Federal Tort Claims Act (FTCA) coverage and other federal benefits. Sections 1861(aa)(4)(A)(ii) and 1905(l)(2)(B)(ii) of the Social Security Act (SSA) allows for the creation of what is known as a "subrecipient" within the Health Center Program when that entity "is receiving funding from such a grant under a contract with the recipient of such a grant." HRSA

recognizes that a health center may use alternate definitions of contracts and subawards for other organizational purposes. However, for the purposes of the Health Center Program scope of project, a health center should use the definitions of contracts and subawards in the Scope Manual to support accurate compliance documentation, which are consistent with the Health Center Program Compliance Manual, the SSA, and HHS grant regulations at 2 CFR Part 200.

Sites within a health center's scope of project must be operated on behalf of the health center, including sites operated by subrecipients. All subawards must comply with all requirements in the Scope Manual.

Issue: Clarification on Footnote Related to 50 Percent Directly-Operated Sites

Comments

Three commenters expressed concern with footnote 93 relating to the requirement that health centers directly operate at least 50 percent of their service sites before proposing a new contractor-operated site. One commenter stated that the process to request an exemption to directly operate the majority of sites is unclear and recommended that this requirement be implemented through the New Access Point application or the Service Area Competition application and that the exemption should be granted for the duration of the applicable project period.

One commenter asked for clarification on this footnote and asked for allowances to be made for subrecipients serving special medically underserved populations. One commenter expressed concern that the requirement for health centers to operate at least 50 percent of its service sites discourages partnerships with local providers and diverts resources from patient care to staffing and facilities. The commenter recommended eliminating the 50 percent threshold and encouraging health centers to subcontract arrangements that enhance patient access to specialized care based on community need.

HRSA Response

HRSA updated the requirement that a health center proposing a new subrecipient- or contractor-operated service site demonstrate at least 50 percent of service sites are directly operated. The requirement now states that a health center must directly operate "at least one" service site before proposing a new subrecipient- or contractor-operated service site. HRSA recognizes that there may be circumstances that justify an exception. As stated in the Scope Manual, such circumstances will be reviewed on a case-by-case basis. HRSA also updated the language in the Scope Manual to clarify that the criteria in Section D will be applied prospectively to proposals that add new contractor- or subrecipient-operated sites. A health center that currently operates all of its service sites via contractors or subrecipients may continue to do so. HRSA declines to include an exemption for sites operated by health centers receiving funding only for special medically underserved populations. However, HRSA notes that the language of footnote 92 exempts a public agency health center using a co-applicant model whose co-applicant is directly providing services, as well as a health center that is funded

or designated to serve only the special medically underserved population of Migratory and Seasonal Agricultural Workers, as defined under section 330(g) of the Public Health Service (PHS) Act (42 U.S.C. 254b).

Issue: Remove "Good Cause Justification" from Contractor-Operated Site

Comments

Fifty-three commenters requested HRSA remove the requirement for a "good cause justification" in Section 6.D, criteria d and e.

HRSA Response

HRSA declines to remove the "good cause justification" criterion when adding a contractor-operated or subrecipient-operated site, as the requirement is consistent with HRSA's responsibility to ensure that limited federal award funds and resources are used efficiently and effectively to make services available and accessible to the greatest number of individuals residing in a service area under section 330(k)(2)(C) of the Public Health Service (PHS) Act (42 U.S.C. 254b) and 42 CFR Section 51c.305. HRSA updated the Scope Manual to define "good cause justification" required under Section 6.D, criterion d as "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." Note that HRSA has renumbered "criterion e" in the draft Scope Manual as "criterion d.i" in the Scope Manual.

Issue: Requirements for Contractor-Operated Service Sites

Comments

Fifty-seven commenters expressed concerns over the requirements included in the draft Scope Manual for contracts between health centers and the operators of contractor-operated sites. These commenters asked for more flexibility, requesting that health centers be able to demonstrate compliance through "other means" or "other documentation" rather than only through provisions in the contract.

HRSA Response

HRSA agrees with commenters that other means may be effective in demonstrating compliance. In response, HRSA added language to the Scope Manual in Section 6.D, criterion f indicating that this requirement may be met by including provisions either in the contract to operate the service site or in another document agreed to by both the health center and contractor.

Issue: Board's Role and Other Requirements for Contractor-Operated Sites

Comments

Fifty-five commenters reiterated concerns they made concerning Chapters 1 and 5 and asked that those comments also be considered for Chapter 6 requirements that may impact

contractor and subrecipient operated sites such as: the board's role in approving services provided at a new site, the board's role in approving contracts, criteria for determining when activities are provided "on behalf of" the health center, and maintenance and access to patient records.

Forty-eight commenters requested that HRSA add a qualification or footnote to Section 6.D, criterion a, which states that the site meets all requirements in Chapters 1 and 5. Commenters state that the requirements in Chapter 1.C do not apply to subrecipient-operated sites. This request is due to stated concern that subrecipients do not operate "on behalf of" the health center.

HRSA Response
HRSA refers commenters to the responses to comments in Chapters 1 and 5 and changes incorporated in those chapters and throughout the Scope Manual, as appropriate, including in Chapter 6.

HRSA declines to exempt subrecipient-operated sites from Section 6.D, criterion a. As with any service site included within a health center's scope of project, a subrecipient-operated site must meet all the requirements in Chapters 1, 5, and 6, including that the site is operated on behalf of the health center that received the award from HRSA.

Refer to the Response to Issue: Subrecipients as Contractors for more information.

D.1. Requirements for Service Sites Operated by Subrecipients
HRSA received no comments specific to this subsection.

D.2. Requirements for Service Sites Operated by Contractors that Do Not Meet All Health Center Program Requirements
HRSA received no comments specific to this subsection.

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

In this chapter:

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

A. Adding Temporary Service Sites in Response to Emergency Events

Issue: Add Tribal and Territorial Declarations of Emergencies to Sections A and B

Comments

One commenter recommended that, in addition to local, state, and federal emergency declarations, HRSA should add reference to tribal and territorial emergency declarations.

HRSA Response

HRSA concurs with the commenter and updated Chapter 7, Sections A and B, to reference tribal and territorial emergency declarations.

Issue: Compliance Burden

Comments

One commenter described the challenge of responding meaningfully to the needs of a community during an emergency event while also thoroughly reviewing compliance criteria.

HRSA Response

HRSA recognizes the challenges of both responding to community needs and Health Center Program compliance criteria during an emergency. In 2022, HRSA streamlined key processes, which are detailed in the updated Program Assistance Letter (PAL) 2020-05: Requesting a Change in Scope to Add Temporary Service Sites in Response to Emergency Events (PDF). This PAL is referenced in Chapter 7.

Issue: Temporary Service Sites for Emergencies

Comments

Seventy-four commenters expressed support that health centers may add temporary service sites in response to emergency events. They highlighted the critical role that health centers play in their local communities and that the Scope Manual will allow them to provide critical services to effectively respond to emergency events.

HRSA Response

HRSA thanks commenters for their support.

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

Issue: Remove Service Area Limitations for Temporary Sites

Comments

Sixty-one commenters requested that HRSA not include a rigid geographic service area limitation within the proposed temporary service site criteria, which will impact effective and expedient response, overwhelm emergency rooms, and limit essential community collaboration during catastrophic incidents. Fifty-five commenters recommended that HRSA allow health centers to establish temporary sites in response to emergency events on a case-by-case basis. The commenters recommended that HRSA strike reference to service area limitation and broaden the scope of Section B. If HRSA retains "adjacent" language, thirty-nine commenters recommended modifying the definition to align with PIN 2024-05, which defines adjacent to include local political subdivisions and not just ZIP Code Tabulation Areas (ZCTAs).

HRSA Response

HRSA appreciates the need for flexibility during declared emergencies, such as the ability to establish a temporary site beyond the health center's service area or adjacent ZIP Codes. HRSA declines to remove all geographic restrictions, consistent with the requirement under section 330(a)(1) of the Public Health Service (PHS) Act (42 U.S.C. 254b) that a health center provide services within a service area. 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. Refer to footnote 106. The definition of "adjacent" has been updated to align with PIN 2024-05.

Please note that HRSA has updated the Scope Manual to refer to ZIP Codes instead of ZCTAs.

Issue: Supersede PAL 2020-05 Requesting a Change in Scope to Add Temporary Service Sites in Response to Emergency Events

Comments

Sixty-one commenters requested that the Scope Manual supersede Program Assistance Letter (PAL) 2020-05: Requesting a Change in Scope to Add Temporary Service Sites in Response to Emergency Events (PDF). Commenters highlighted the importance of having clear guidance from HRSA for health centers to reference in times of emergencies and expressed concern that having multiple guidance documents for temporary service sites in response to declared emergencies may lead to confusion. Commenters urged HRSA to consolidate PAL 2020-05 into the proposed Scope Manual.

HRSA Response

HRSA appreciates the concerns and recommendations. In the Scope Manual, HRSA articulates policy regarding a health center's scope of project, whereas PAL 2020-05 describes the process

for requesting changes in scope during emergencies. Though HRSA declines to consolidate these documents, PAL 2020-05 will be updated as necessary to align with the Scope Manual.

Issue: Include “Ad-Hoc" Language

Comments

Fifty commenters requested that, in the interest of needed flexibility, temporary service sites established in response to declared emergencies be allowed to offer services on an ad-hoc basis, rather than only on a regularly scheduled basis.

HRSA Response

HRSA agrees that temporary emergency sites should not be required to offer services on a regularly scheduled basis, and the Scope Manual includes language allowing for services at these sites on an ad-hoc basis. Refer to Section 5.B, criterion f and footnotes 69 and 70.

Chapter 8: Providers, Patients, and Visits

In this chapter:

A. Providers
B. Patients and Visits

A. Providers

Issue: Add Behavioral Health and Pharmacy Providers

Comments

Two commenters suggested adding behavioral health providers, such as Licensed Clinical Psychologists and Licensed Clinical Social Workers, and pharmacists to the list of types of providers given the emphasis on expanding behavioral health services.

HRSA Response

HRSA concurs and added these provider types to the list of examples found in the Scope Manual in Section 8.A.

B. Patients and Visits

Issue: Revise Telehealth Language

Comments

Sixty-seven commenters noted that the proposed language in Section 8.B is inconsistent with Section 4.B, criterion d. These commenters requested a minor revision to the proposed criterion that establishes a patient-provider relationship by adding after the language "An individual receives an in-scope service either in-person or via telehealth," the phrase "consistent with Chapter 4: Services Provided via Telehealth."

One commenter requested that the criteria be extended to case management and care coordination services rendered telephonically.

One commenter requested clarification if new patients can be established via telehealth versus a Form 5B: Sites location.

HRSA Response

HRSA updated Section 4.B, criterion d, to address the inconsistency in the draft Scope Manual. HRSA declines to add the proposed language, as the Scope Manual states that a patient may be established via telehealth if the patient is physically located in or a resident of the health center's service area or an adjacent area at the time of the service.

Issue: No Capacity to Provide In-Scope Services

Comments

One commenter expressed concern regarding the requirement that all health center patients must have access to all in-scope services, specifically when a specific service is at provider capacity within the health center or has a regional shortage of providers.

HRSA Response
HRSA recognizes that a health center may have capacity limitations for providing certain services. HRSA added footnote 32 in Section 3.A clarifying that when a health center provides a service and needs to establish a waiting list due to high need, the health center would be compliant with Health Center Program requirements if it meets all the criteria described in the Scope Manual.

Issue: Patient-Provider Relationship

Comments
Two commenters requested HRSA expand on what aspects of scope of project require a patient-provider relationship.

One commenter requested HRSA remove the patient's physical location requirement to establish a patient-provider relationship.

HRSA Response
HRSA updated this section to clarify that an individual becomes a health center patient when the health center patient-provider relationship is established. Therefore, any reference in the Scope Manual to a health center patient uses the definition of "established health center patient" now included in Section 8.B. HRSA updated the patient's physical location requirement for establishing a patient-provider relationship to refer to either the patient's "physical location" or "residency," which is required under section 330(a)(1) of the Public Health Service (PHS) Act (42 U.S.C. 254b(a)(1)). HRSA has also created more flexibility in where a patient may be located by updating the definition of "adjacent to" the service area to align with other HRSA guidance. Refer to Section 4.B, Footnote 46.

Issue: Additional Flexibilities to Establish Patients

Comments
Three commenters requested more flexibility to establish a new health center patient. Two commenters requested that HRSA remove geographic restrictions from the draft Scope Manual. Both commenters expressed concerns about HRSA determining when a patient-provider relationship is established.

One commenter requested an exception for patients with mobility limitations to HRSA's requirement that, to become "established patients," they must receive services within or adjacent to a health center's designated service area. The commenter requested flexibility to allow health centers to provide individuals outside of these areas with access to specialized services that may not be widely available.

HRSA Response
HRSA appreciates the comments. This section of the Scope Manual strikes a balance between providing a health center with flexibility to address patient needs with the Health Center Program's authorizing statute, under section 330(a)(1) of the Public Health Service (PHS) Act (42 U.S.C. 254b(a)(1)), which ties the services provided by a health center to a geographic service area, or "catchment area." The geographic restrictions found in the Scope Manual reflect this statutory approach and will remain in the final policy. Therefore, HRSA declines to update the policy as requested. HRSA notes that the definition of a patient-provider relationship included in the Scope Manual applies only to the health center scope of project.

Issue: Group Visits

Comments
One commenter encouraged HRSA to more clearly define group visits in the "Visits" subsection, with a potential cross reference in the "Providers" subsection. The commenter noted that group visits have proven health benefits, can be conducted in-person or through telehealth modalities, and will likely rise in prominence to support emerging wellness and chronic disease management policy priorities, including the Make America Healthy Again initiative.

HRSA Response
HRSA concurs and added footnote 114, clarifying that a group visit may establish a patient-provider relationship, so long as the visit meets all other applicable Health Center Program compliance requirements. A health center should confirm a group visit meets other applicable state and third-party payor requirements, including any from Centers for Medicare & Medicaid Services. These include important billing and reimbursement considerations separate from the scope of the Scope Manual.

Issue: Remove Section 8.B Defining a Patient-Provider Relationship

Comments
One commenter recommended that HRSA remove Section B from Chapter 8, which defines, in the context of the Scope Manual, when the patient-provider relationship is established. The commenter suggested that HRSA lacks the statutory authority to set geographical location requirements and suggested that this definition will have implications beyond the Scope Manual.

HRSA Response
HRSA appreciates the feedback but declines to remove Section 8.B, since the Scope Manual follows and is consistent with the statutory authority of the Health Center Program under section 330(a)(1) of the Public Health Service (PHS) Act (42 U.S.C. 254b (a)(1)).

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

Issue: Listing Other Service Site Locations

Comments

Seventy-five commenters expressed support for HRSA no longer requiring health centers to list the various locations where they serve established patients, other than on Form 5B: Sites, and they applaud this change since it removes an unnecessary operational burden of documenting these activities in Form 5C: Other Activities/Locations.

HRSA Response

HRSA strives to minimize administrative burden for health centers and thanks the commenters for their support.

Issue: Clarify Established Health Center Patient Definition

Comments

One commenter urged HRSA to develop a unified definition of an established health center patient across all aspects of the Health Center Program.

HRSA Response

HRSA appreciates the recommendation and has added a definition of an established health center patient to Section 8.B. An individual is considered a health center patient when a patient-provider relationship is established at a health center. HRSA added footnote 111 in Section 8.B clarifying that this definition is only for the health center scope of project and that other parts of HRSA or health center-related benefit programs may have different definitions of a “patient.”

Issue: Senior Assisted Living

Comments

Sixty-nine commenters requested clarification as to whether health centers may serve established patients at non-service sites locations if criteria 1, 2, and 3 in Chapter 9 are met. Commenters provided the example of senior communities and assisted living facilities and asked for clarification if rounding at these non-service site locations would also be considered in-scope. One commenter requested that HRSA confirm whether consolidating "other locations" into Form 5B: Sites (Form 5B) was intended to maximize access and flexibility. One commenter requested clarification on whether health centers can provide services anywhere—for example, street medicine and in a nursing home—so long as they are an established health center patient.

HRSA Response

HRSA appreciates this request for clarification. If a service meets the criteria 1, 2, and 3 in Chapter 9, a health center may provide that service to an established health center patient at a location other than a health center service site without additional documentation on Form 5B, including, for example, in a senior community or assisted living facility. HRSA updated the Introduction, Section B. "Purpose" to clarify that examples throughout the Scope Manual are not an exhaustive list. HRSA does not intend to consolidate the former Form 5C: Other Activities/Locations into Form 5B.

Issue: Oppose Established Health Center Patient Distinction

Comments

One commenter expressed concern regarding the Scope Manual's distinction between established health center patients and other individuals when services are provided outside of HRSA-approved service sites. The commenter requested that HRSA clarify that a health center may deliver in-scope services on behalf of the health center to individuals, even if they are not established patients of the health center, by meeting criteria 1, 2, and 3 in Chapter 9.

HRSA Response

HRSA appreciates the concern and recommendation. While established patients may be seen outside of a health center service site consistent with criteria 1, 2, and 3 in Chapter 9, all individuals may receive in-scope services at locations other than a health center service site consistent with criteria a-e in Chapter 9. HRSA declines to add the requested language.

Issue: Remove Geographic Restriction from Portable Care, Outreach, and Individual Emergencies

Comments

Sixty-nine commenters requested that HRSA strike Chapter 9 criterion c, which states the service is provided within the health center's service area so that it does not apply to "portable care and outreach" and "individual emergencies." Commenters stated that this geographic restriction language is inconsistent with the Federal Tort Claims Act (FTCA) regulations at 42 CFR § 6.6(e)(4). Resulting out-of-scope activities would create problems with malpractice insurance and service access consequences for health centers seeking to serve the highest needs of the most underserved and vulnerable patients, who often experience significant barriers to accessing care through scheduled visits to traditional service sites.

One commenter sought clarification as to whether specific common mobile service team primary care and behavioral health activities, provided to patients through home visits or in community-based assisted living facilities, would be covered under criterion e. The commenter suggested that HRSA could revise criterion e to more clearly reflect these considerations.

One commenter voiced concern that Chapter 9, criterion c, "service is provided within the health center's service area", would create undue burden for health centers who serve target populations like homeless individuals, migratory and seasonal agricultural workers, and those

living with HIV. The commenter expressed concern that this language addresses service area overlap rather than what is best for patients who may need care outside of their service area.

One commenter recommended that a health center be allowed to provide non-emergency services to individuals who are not established patients not only within the health center's service area, as stated in criterion c, but also in Zip Code Tabulation Areas (ZCTAs) contiguous to the health center's service area.

HRSA Response
HRSA appreciates the feedback related to malpractice risk and added "certain individual emergencies" to criterion c to align with the FTCA regulations. While HRSA has deleted criterion c for clarity, the Scope Manual will limit portable clinical care and outreach to within the health center's service area. This is reflected in criterion e.i. A health center should ensure that its service area reflects and includes the locations where its patient population is located, regardless of whether those patients are served at service sites or through portable clinical care. Where a health center identifies a high need area outside of its current service area, the health center may consider expanding its service area through addition of a new service site. Refer to Chapter 6, Sections A and B.

HRSA confirms that mobile service teams may be considered a type of "portable care" under criterion e, so long as it meets all the criteria listed in Chapter 9. On the other hand, home visits are in-scope when used to provide an in-scope service to an established health center patient, and, therefore, would not be included in criterion e. Refer instead to criteria 1, 2, and 3.

Please note that HRSA has updated the Scope Manual to refer to ZIP Codes instead of ZCTAs.

Issue: School-Based Clinics

Comments
Sixty-eight commenters recommended that HRSA modify criteria e to include school-based clinics and school-linked clinics to be consistent with regulation and long-standing HRSA policy. The draft Scope Manual's description of "portable care and outreach" does not include "school-based clinics" or "school-linked clinics," both of which are included as types of "community-wide interventions" in the Federal Tort Claims Act (FTCA) regulations at 42 CFR § 6.6(e)(4)(i), and are also incorporated into current HRSA policy, per PIN 2008-01.

HRSA Response
HRSA declines to add a separate item to Chapter 9, criterion e for "school-based clinics" or "school-linked clinics" and notes that PIN 2008-01 does not include these as separate activities under section III.B.1.g, "Other Activities." Rather, PIN 2008-01 includes "schools" as a possible location where certain types of portable care or outreach may occur, and this policy continues that guidance.

Issue: Proposed Rounding Creates Burden

Comments

One commenter expressed concern that making hospital rounds “contingent” on the employment contract would create an administrative burden, referring to Chapter 9, criterion e.ii. They requested that rounding be considered in-scope if it is simply “included” in the employment contract.

HRSA Response

HRSA notes that criterion e.ii does not use the word “contingent,” but rather “condition,” which is consistent with the language used in the FTCA regulations at 42 CFR § 6.6(e)(4)(ii). HRSA declines to make this change that would create language inconsistent with the cited regulation.

Issue: Clarify In-Scope Hospital-Related Coverage

Comments

Four commenters asked that HRSA clarify how the criteria in Section 8.B, which explains how to establish a health center patient relationship applies to hospital-related activities discussed in Chapter 9. Three commenters requested clarification on how services provided within a hospital must be documented and the criteria to establish new patients under "hospital-related activities." Specifically, commenters asked if hospital rounds and on-call coverage would be considered in-scope if they are not a condition of employment for a health center. One commenter requested the inclusion of examples for allowable hospital-related activities provided to non-established health center patients. The commenter provided the examples of obstetrical and gynecological surgeries and podiatric surgeries as common specialties that may arise for health centers in hospital settings and asked for examples related to outreach, services, and care.

HRSA Response

A health center must ensure that an in-scope service provided at a location other than a service site to an individual who is not an established patient meets the criteria a-e in Chapter 9. Under criterion e.ii, hospital-related activities such as rounding and on-call coverage are not considered in-scope if they are not documented as a condition of the provider’s employment.

An individual becomes an established health center patient under the criteria outlined in Chapter 8, Section B, “Patients and Visits.” Hospital-related activities covered by Chapter 9, criterion e.ii will not typically result in establishing a patient-provider relationship for the purposes of the Health Center Program scope of project, as they do not usually result in the health center establishing and maintaining a health record for that individual, as required by Section 8.B, criterion c.

A non-health center patient receiving a scheduled surgery from a health center provider would not be considered in-scope, as it does not meet the criteria in Chapter 9. Such activity falls

outside of the call or coverage activities covered by Chapter 9, criterion e.ii. HRSA therefore declines to add the requested examples to the policy.

Issue: Emergency Response Activities

Comments

Sixty-eight commenters applauded HRSA's proposed policy that emergency response activities, Chapter 9, criterion e.iv, including opening limited-service sites, may occur on an ad-hoc basis, rather than the Ch. 7 requirement that emergency response activities happen on a regularly scheduled basis.

HRSA Response

HRSA thanks commenters for their support of the updated emergency response policy. HRSA updated Section 5.B, criterion f to clarify that the "regularly scheduled basis" requirement does not apply to emergency temporary sites. Please refer to Chapter 7, section B.

Issue: Clarify Services to Non-Established Health Center Patients

Comments

Two commenters requested clarification about whether services provided to establish a new patient-provider relationship at a location that is not a HRSA-approved service site would qualify as within the health center's scope of project.

HRSA Response

HRSA confirms that, as stated in the Scope Manual, services provided to a non-established health center patient at a location other than an approved service site may be considered in-scope if it meets the requirements listed in Chapter 9. A patient-provider relationship will be established and an individual will become an established health center patient when the criteria in Section 8.B are met.

Issue: Documenting Activities in the Absence of Form 5C

Comments

Three commenters requested more alignment of categories of "other health center activities" between criteria found in this section of the Scope Manual, and Form 5C: Other Activities/Locations (Form 5C) as it currently exists, including additional guidance on how to document activities outside the health center once Form 5C is no longer in use. One commenter requested HRSA reference Form 5C to highlight the differences between Forms 5A, 5B, and 5C. One commenter requested HRSA clarify if currently listed other activities and locations on Form 5C are still considered in-scope if Form 5C goes away.

HRSA Response

HRSA is discontinuing Form 5C. The previous Form 5C categories have been merged into the five activity types listed in Chapter 9 criterion e. For example, "Portable Care and Outreach"

includes the statement that "Such 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." These activities do not need to be approved by HRSA and do not require formal documentation. It is the responsibility of a health center to ensure that the "other activities" that were previously documented on Form 5C meet all the criteria in Chapter 9. If the activities currently listed in Form 5C meet the requirements in Chapter 9, they will be considered in-scope.

Issue: Home Visits

Comments

Two commenters recommended that, if HRSA finalizes an "established patient" requirement for services outside of a HRSA-approved service site, home visits be included in this section as one of the five categories of acceptable in-scope services for non-established patients outside of a service site.

HRSA Response

Home visits are in-scope when used to provide an in-scope service to an established health center patient and are covered by Chapter 9, criteria 1, 2, and 3. Therefore, home visits should not be considered "portable care."

Chapter 10: Changes in Scope of Project

In this chapter:

A. Overview
B. Changes to Services or Sites
C. Special Medically Underserved Population-Only Health Centers Adding a New Statutory Population
D. Additional Scope of Project Information and Resources

A. Overview

Issue: Change in Scope (CIS) to Remove Sites or Services

Comments

One commenter noted that "removal of a site or service" is not listed as a type of change in scope of project that requires prior approval from HRSA in this section.

HRSA Response

HRSA appreciates the comment and revised language in Section 10.A to address situations where removal of a site or service requires prior approval. Please note that removal of a site or service is also discussed in Section 10.B.

Issue: HRSA Overreach and Statutory Authority

Comments

One commenter noted that the Public Health Service Act (42 U.S.C. 254b) sections cited in the Definition of Scope of Project do not provide HRSA the stated authority to require prior approval for scope of project changes, stating that sections 330(k)(3) and (H)(ii) provide the health center governing board oversight authority, not HRSA. The commenter stated that HRSA prior approval for minor scope of project changes, including modified hours and temporary site additions, lead to health centers being slow to respond to patient needs, particularly in emergencies. The commenter also stated that if HRSA requires health centers to seek prior approval for any project change when no extra funding is requested by the health center, the scenario creates conflict between who has the authority to oversee proposed changes, HRSA or the Board, and can cause delays in meeting the needs of the community. The commenter recommended limiting HRSA's authority to verify that the governing board approved the proposed change.

HRSA Response

HRSA acknowledges these concerns but disagrees with the assertions regarding HRSA's authority. The Scope Manual provides a health center with flexibility to operate in accordance with the specific interests and needs of the health center's community and patient population. In accordance with sections 330(k)(3) and (H)(ii) of the Public Health Service (PHS) Act (42 U.S.C. 254b) and 2 CFR § 200.308, HRSA has a statutory and regulatory responsibility to monitor

compliance, including prior approvals. By accepting a Health Center Program grant award or look-alike designation, a health center agrees to the terms and conditions of the award or designation and to HHS grants regulations under 2 CFR Part 200, which includes agreeing to follow HRSA scope of project policy, including HRSA-managed prior approval processes.

B. Changes to Services or Sites

Issue: Tying New Sites to Specific Unmet Need

Comments

One commenter suggested that adding service sites should be tied to meeting a specific and proven unmet need in the service area. For example, a new service site with an unmet need for behavioral health services does not prove a general need for all health center services and should not permit other services to be added without the proof of unmet for those services.

HRSA Response

HRSA appreciates the suggestion for addressing specific unmet need. However, as addressed in Section 6.B, HRSA does not consider specific proposed services when assessing unmet need. To add a new service site, a health center must show that there is overall unmet need, rather than unmet need for individual services like behavioral health, consistent with the health center statute that does not look at unmet need by specific services. Refer to section 330 of the Public Health Service (PHS) Act (42 U.S.C. 254b). Therefore, HRSA declines to edit this section as requested.

Issue: Scope Adjustment

Comments

Sixty-eight commenters requested clarification as to whether HRSA intends to use the current scope adjustment process when health centers add or remove “other” non-service sites, rather than the more intensive change in scope process.

HRSA Response

HRSA will continue to use a scope adjustment process where appropriate. Additional information related to scope adjustment may be found on Scope of Project Resources.

Issue: Update Additional Service and HRSA Systems

Comments

One commenter recommended moving the footnote related to HRSA systems into the main text. The commenter also requested HRSA clarify what “update an additional service” means, specifically whether it refers to a scope adjustment or a formal Change in Scope request, and especially as it relates to the documentation of specialty services.

HRSA Response

HRSA concurs and moved the specified footnote to the body of the section. Regarding when a scope adjustment or a formal Change in Scope request must be made, please refer to Scope of Project Resources, including the Scope Adjustment Request Checklist (PDF).

Issue: Change in Scope (CIS) Process and Communication Improvements

Comments

One commenter asked that HRSA establish an FAQ page of questions submitted from health centers to the BPHC Contact Form. They also asked that HRSA establish an option to anonymously submit questions to the BPHC Contact Form. They voiced concern that health centers do not ask questions through the contact form because it is not anonymous.

HRSA Response

HRSA thanks the commenter for this additional information and concern. HRSA is committed to delivering exceptional customer service. HRSA will take this suggestion into consideration for future updates to the BPHC Contact Form.

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

HRSA received no comments specific to this section.

D. Additional Scope of Project Information and Resources

HRSA received no comments specific to this section.

Glossary

Issue: Patient-Provider Relationship

Comments

Two commenters urged HRSA to remove “where a patient is from” and "distance from the health center” from the definition for “patient-provider relationship.”

HRSA Response

Consistent with the final policy in the Scope Manual, HRSA declines to make this edit, as it is consistent with the tying of a health center’s scope of project to a geographical service area under section 330(a)(1) of the Public Health Service (PHS) Act (42 U.S.C. 254b).

General Comments

Issue: Conduct Cost-Benefit Analysis of All Proposed Requirements

Comments

One commenter recommended a comprehensive cost-benefit analysis, with the elimination of any requirements that impose high costs without clear benefits, to protect patient care resources.

HRSA Response

HRSA appreciates the feedback. HRSA and HHS conduct oversight related to Health Center Program costs and benefits, consistent with Federal law.

Issue: Consolidate Forms 5A and 5B

Comments

One commenter noted that HRSA mandates multiple forms for documenting services and sites, which they believe increases administrative costs and diverts resources from patient care. Smaller health centers have less ability to meet duplicative reporting requirements due to smaller staff sizes and limited technological infrastructure. The commenter recommended consolidating Forms 5A: Services Provided and 5B: Sites into a single, streamlined reporting process and requests that HRSA provide federal grants to support technology upgrades for smaller health centers.

HRSA Response

HRSA appreciates the recommendation. To support burden reduction, HRSA has discontinued Form 5C: Other Activities/Locations and the need for health centers to document in-scope activities allowable under Chapter 9 of the Scope Manual. HRSA strives to minimize administrative burden for health centers while ensuring that the agency has the information (such as that currently captured on Forms 5A and 5B) to perform the oversight responsibilities required under the Health Center Program authorized by section 330 of the Public Health Service (PHS) Act (42 U.S.C. 254b).

Issue: Administrative Burden

Comments

Four commenters requested that HRSA consider how the Scope Manual may increase administrative burden for health center staff and leadership. One commenter expressed concern about the requirements for contracted services delivered through Column II and Column III cooperative arrangements. The commentor expressed that the requirements could dissuade partners from renegotiating contacts, limiting services to patients.

HRSA Response

The Scope Manual balances reducing health center administrative burden and regulatory responsibility to ensure appropriate distribution of resources across the country under sections

330(k)(2) and (k)(3)(J) of the Public Health Service Act (42 U.S.C. 254b) and 42 CFR Section 51c.305. The Scope Manual eliminates some documentation requests for health centers entirely, such as the discontinuance of Form 5C: Other Activities/Locations.