HRSA Health Center Program

BUREAU OF PRIMARY HEALTH CARE

Summary of Comments and HRSA Responses on the Draft Health Center Program Compliance Manual

UPDATE: The Bipartisan Budget Act of 2018 amended Section 330 of the Public Health Service Act (42 U.S.C. 254b), which is the authorizing statute of the Health Center Program. HRSA/BPHC has revised the Health Center Program Compliance Manual (Compliance Manual), originally issued in August 2017, as well as related materials to reflect the amended statute. Comments and response summaries marked with an asterisk and in italics no longer reflect current Compliance Manual language. Refer to the revised Health Center Program statute for current statutory language and detail on all statutory amendments.

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Summary of Comments and HRSA Responses on the Draft Compliance Manual

The Health Resources and Services Administration (HRSA) announced the availability of the draft Health Center Program Compliance Manual for public comment in the Federal Register on September 6, 2016. (81 Fed. Reg. 61224). Written comments were accepted until November 22, 2016. The purpose of the Compliance Manual is to provide a consolidated resource to assist health centers in understanding and demonstrating compliance with Health Center Program requirements. Individuals and groups submitted over 700 comments regarding the draft Compliance Manual. After thorough review and consideration of all comments received, HRSA made a substantial number of changes to the Compliance Manual to incorporate suggestions and requests for further clarification. Below is a summary of comments for each corresponding section and chapter and HRSA's responses to these comments. Please note that minor editorial changes may have been incorporated into the Compliance Manual that are not specifically mentioned below.

Introduction

Applicability

Issue: FQHC Reimbursement Rates

Comments

Two commenters suggested removing the phrase "FQHC reimbursement rates" and corresponding footnote to avoid implying that HRSA is creating standards for Medicaid/Medicare FQHC reimbursement rate eligibility, since it is not under HRSA's purview.

HRSA Response

HRSA has clarified in the Compliance Manual that health centers are eligible for FQHC reimbursement rates as a result of their Health Center Program funding or designation. HRSA is not creating standards for Medicaid/Medicare FQHC reimbursement and also notes that these programs have separate sets of requirements. Information about Medicaid/Medicare FQHC reimbursement is available from resources and materials published by the Centers for Medicare and Medicaid Services.

Purpose

Issue: Retain PIN 1994-07: Migrant Voucher Program Guidance

Comments

One commenter suggested retaining PIN 1994-07 or providing an updated Policy Information Notice (PIN).

HRSA Response

HRSA appreciates this comment but declines to accept it. HRSA has reviewed the PIN and has confirmed that subject areas referenced in this PIN that align with statutory and regulatory requirements have been integrated into the Compliance Manual. Therefore, the final Compliance Manual will supersede this PIN in its entirety. In addition, consistent with the Health Center Consolidation Act of 1996, the Compliance Manual affirms that all health centers that receive health center section 330(g) funds and provide access to health care services to migratory or seasonal agricultural workers via vouchers are subject to all section 330(g) program requirements.

Issue: Relevance of PINs 1997-27: Affiliation Agreements of Community and Migrant Health Centers and 1998-24: Amendment to PIN 1997-27

Comments

Twenty-nine commenters suggested retaining PINs 1997-27 and 1998-24 in their entirety to ensure that health centers' governance and day-to-day management remain firmly under the control of their community-based, patient majority boards. In contrast, one commenter suggested that the PINs were not necessary and eroded health center autonomy.

HRSA Response

HRSA has reviewed these PINs to confirm that subject areas referenced in these PINs that are consistent with statutory and regulatory program requirements have been integrated into Chapter 19: Board Authority and Chapter 20: Board Composition. Therefore, the final Compliance Manual will supersede these existing PINs on Affiliation Agreements.

Issue: PIN 2013-01: Health Center Program Budgeting and Accounting Requirements

Comments

One commenter suggested clarification on which elements of the Budgeting and Accounting PIN were not addressed in the Compliance Manual but will remain in effect once the Compliance Manual is finalized.

HRSA Response

HRSA reviewed this PIN and confirmed that the subject areas referenced in this PIN that align with statutory and regulatory requirements have been integrated into the Compliance Manual. Therefore, the final Compliance Manual will supersede PIN 2013-01 in its entirety.

Issue: PINs and PALs Superseded Versus in Effect

Comments

Thirteen commenters suggested that policy interpretations contained in existing PINs and Program Assistance Letters (PALs) remain in effect after the Compliance Manual is finalized, either by incorporating these interpretations into the Compliance Manual or leaving the current PINs/PALs in effect. Twenty-one commenters suggested that the Compliance Manual provide a framework for which PINs and PALs remain in effect. Two commenters made additional suggestions to retain flexibilities and best practices currently in the PINs and PALs proposed to be eliminated.

HRSA Response

HRSA reviewed all existing PINs and PALs to confirm that areas that aligned with statutory and regulatory requirements were integrated into the Compliance Manual consistent with the purpose of the Compliance Manual. HRSA has outlined which PINs and PALs are superseded and those remaining in effect in the Introduction and Appendix A: Health Center Program Non-Regulatory Policy Issuances That Remain in Effect.

Issue: Issuance of New PINs and PALs

Comments

Twenty-three commenters suggested the Compliance Manual state that HRSA maintains the authority to issue new PINs and PALs.

HRSA Response

HRSA is committed to ongoing monitoring of the implementation of the Compliance Manual to identify areas that may necessitate periodic issuances to update or amend the Compliance Manual through a public comment process. In addition, HRSA will continue to explore subject areas for technical assistance.

Issue: Compliance Timelines Specified in Funding Opportunities

Comments

Fourteen commenters suggested providing grant applicants 120 days after the receipt of an award to come into compliance with requirements under the finalized Compliance Manual, as opposed to expecting them to be compliant at the time of application.

HRSA Response

HRSA declines to provide a standard timeline to demonstrate compliance. However, HRSA has and will continue to provide timelines, if applicable, in Notices of Funding Opportunity for new awardees to come into compliance with all program requirements. The Compliance Manual provides clarification in a new footnote within this Introduction that states more clearly that Notices of Funding Opportunity may include specified timelines for awardees to demonstrate compliance with the requirements specified in this Compliance Manual after receipt of the Federal Health Center Program award.

Issue: Due Process Related to Conditions of Award/Designation

Comments

One commenter suggested that HRSA allow health centers some measure of due process prior to a condition being placed on an award/designation.

HRSA Response

Health centers are permitted to provide additional information to HRSA at any point regarding compliance findings. HRSA's progressive action condition process also affords health centers an opportunity to provide responses to HRSA using a consistent structure and timeframe to address or remedy identified areas of non-compliance.

Issue: Summary Document of Changes

Comments

One commenter suggested a summary document of changes and/or clarifications the Compliance Manual has made, when compared to previous policy documents.

HRSA Response

The status of previously issued PINS and PALs is noted in the Introduction and Appendix A.

Additional Responsibilities

Issue: Conflicts between Federal, State, and Local Laws

Comments

One commenter suggested making a note that HRSA requirements and other laws or regulations (e.g., Federal, state, CMS) at times contradict.

HRSA Response

Health centers concerned with their ability to comply with various requirements that appear to be contradictory may wish to consult with their legal counsel.

Issue: Related Programs

Comments

One commenter suggested including chapters or references related to other programs that health centers are eligible to participate in based on being a Health Center Program grantee or look-alike.

HRSA Response

The Additional Health Center Responsibilities section of this chapter includes references to other Federal programs for which health centers are eligible by virtue of their Health Center Program funding or designation. HRSA does not believe additional chapters related to these issues are needed at this time.

Structure of the Compliance Manual

Issue: Align Chapter Numbers with 19 Program Requirement Numbers

Comments

Two commenters suggested a standard approach to the numbering of program requirements in all resources to minimize confusion (specifically, give the Compliance Manual chapters the same numbers as the prior list of 19 Program Requirements).

HRSA Response

The list of 19 Program Requirements were the previous structure for presenting a summary of statutory and regulatory requirements. Because HRSA has integrated requirements related to scope of project into applicable chapters of the Compliance Manual, there is one less chapter (18 versus 19 as indicated in Chapters 3-20). Therefore, aligning with the old numbering is not feasible.

Chapter 1: Health Center Program Eligibility

Issue: Co-applicant Eligibility

Comments

One commenter asked HRSA to clarify the eligibility of public agency applicants using a co-applicant governing board model and to provide guidance for maintaining those agreements.

HRSA Response

Public agency applicants are permitted to utilize a co-applicant governance structure for the purposes of meeting Health Center Program governance requirements. For further information on the applicability of governance requirements for health centers with co-applicant structures, please see Chapter 19: Board Authority and Chapter 20: Board Composition.

Issue: Clarity on Legislative Authority for Tribal and Urban Indian Programs to Apply for Section 330 Funds

Comments

Ten commenters requested greater prominence and clarity around Tribal and Urban Indian programs and their eligibility to apply for Health Center Program funding.

HRSA Response

HRSA added a new section to the Eligibility Chapter to clarify that Tribal and Urban Indian Organizations are eligible to apply to the Health Center Program for funding or designation and that such applicants will demonstrate eligibility by submitting documentation as described in the sections of Chapter 1 describing requirements for non-profit or public agency organizations, as applicable.

Issue: Eliminate “Income” in Context of the 340B Drug Pricing Program

Comments

Six commenters suggested eliminating the reference to “income” in the context of the 340B Program. Two of these commenters stated that either savings or benefits more accurately represents the way in which health centers and other covered entities benefit under the program.

HRSA Response

HRSA concurred with the suggestion to delete the reference to “income” and changed the reference to 340B Drug Pricing.

Issue: Sole Corporate Member and Look-Alike Status

Comments

One commenter stated the belief that having a sole corporate member does not necessarily preclude a 501(c)(3) organization from meeting all of the HRSA look-alike eligibility requirements, and that aligning with like-minded organizations is key to health center survival and better outcomes for patients.

HRSA Response

The Compliance Manual reiterates that look-alikes must satisfy the statutory requirement of not being owned, controlled or operated by another organization (Sections 1861(aa)(4)(b) and 1905(l)(2)(B) of the Social Security Act). HRSA recognizes the importance of creating strategic partnerships with other organizations in the service area and supports health centers in these efforts in a manner consistent with the statutory requirement.

Issue: Elimination of Dual Grantee/Look-Alike Status

Comments

Twelve commenters requested that HRSA not prohibit health centers from applying and receiving approval for dual grantee/look-alike status. Seven of these commenters stated that the elimination of dual status has potential to limit access and opportunities for expansion of services in some cases. Two of these commenters requested that HRSA clarify what will happen to organizations that currently have dual status and provide guidance on how this will impact them. And one commenter requested that HRSA make provisions to grandfather such dual status health centers.

HRSA Response

HRSA has clarified that health centers that currently have "dual-status" will be permitted to submit Service Area Competition or Renewal of Designation applications that would maintain such status. HRSA further clarified that, going forward, applications for Federal award funding or look-alike designation that would result in the applicant organizations becoming "dual-status" will no longer be approved. Notices of Funding Opportunity and initial designation instructions for look-alikes will contain specific details regarding how health centers would demonstrate that they meet this requirement. HRSA believes that opportunities for health centers to add new sites through changes in scope and applications for new access points, as appropriations allow, will support expanding access to underserved communities and populations.

Chapter 2: Health Center Program Oversight

Program Oversight

Issue: Evaluation of Performance Goals

Comments

Sixteen commenters suggested clarification of (1) the types of expected performance goals that, if unmet, could result in conditions of award and (2) how performance against those goals should be evaluated. Five commenters requested clarification on how these goals will be established, documented, and communicated to health centers.

HRSA Response

HRSA has drafted the Compliance Manual in such a way as to identify the program requirements that could lead to conditions on a grant award. In addition, there are other requirements that apply to grant awards, for example those found in the Uniform Administrative Rules (grants regulations), Notices of Funding Opportunity (NOFO), and the notices of grant award. Identification of the full range of potential conditions is beyond the scope of this Compliance Manual. To the extent that HRSA has performance goals for health centers, they would be prescribed in the terms or conditions of the Federal award or

designation. In addition, HRSA may impose special restrictive conditions on a Federal award based on identified risk factors. Such factors may include, but are not limited to, a health center's financial stability and quality of its financial management systems.

Issue: The Joint Commission and NCQA PCMH Program Criteria

Comments

There were seven comments suggesting that HRSA incorporate Joint Commission and Patient-Centered Medical Home (PCMH) standards into its program criteria.

HRSA Response

HRSA recognizes the value of the Joint Commission and National Committee for Quality Assurance (NCQA) PCMH programs. However, these criteria are not directly related to demonstrating compliance with Health Center Program statutory and regulatory requirements.

Issue: Role of HRSA Staff

Comments

One commenter suggested clarification of roles for "HRSA, HRSA site visit reviewers, and project officers."

HRSA Response

Clarification of roles for HRSA is beyond the scope of the Compliance Manual. A health center's primary program point of contact regarding the Health Center Program project is the project officer identified on the health center's Notice of Award or Notice of Look-Alike Designation.

Issue: Guidelines from DGMO on Restricted Draw Down

Comments

One commenter suggested including guidelines from HRSA's Division of Grants Management Operations (DGMO) outlining the approval process for drawdowns when Federal award recipients are placed on restricted drawdown. Another commenter suggested clarification on "requiring payments as reimbursements rather than advance payments" and asked about the process for how this occurs.

HRSA Response

DGMO communicates specific instructions directly to impacted health centers when drawdown restrictions are placed on Federal award funds. Such grants management processes are outside the scope of this Compliance Manual.

Issue: Supersedes PINs and PALs

Comments

One commenter suggested referencing PINs and PALs that this chapter supersedes and requests the same process for the other chapters.

HRSA Response

HRSA has provided a consolidated list of all PINs and PALs that will be superseded by the Compliance Manual in the Introduction Chapter and a listing of PINs and PALs that remain in effect in the Appendix. As these PINs and PALs in most cases include content that is addressed in various chapters within the Compliance Manual, HRSA has elected to present this list in one location.

Progressive Action Overview

Issue: Specify Conditions without an Implementation Phase

Comments

Fourteen commenters suggested that the Compliance Manual clarify which conditions will not be subject to a 120-day implementation phase or the initial phase of a 90-day response time.

HRSA Response
All conditions will continue to include an initial 90-day response time to address a non-compliance finding through progressive action. HRSA has added a footnote in this chapter to clarify that conditions afford a 120-day Implementation Phase when a HRSA-approved corrective action plan would require additional time for the health center to implement related programmatic and organizational changes. The condition language in the Notice of Award specifies both the required response timeline and the applicable progressive action phase, including when an associated implementation phase is applied.

Issue: Site Visit Guide

Comments
Two commenters suggested clarification on whether the Site Visit Guide will be revised to no longer refer to PINs that the Compliance Manual will be superseding.
HRSA Response
The Site Visit Guide will be updated to align with the Compliance Manual, and references to superseded PINs will be removed.

Progressive Action Process

Issue: Alternative Means and Reconsideration of Initial Finding of Non-Compliance

Comments
Thirty-five commenters suggested health centers be able to demonstrate alternative means of demonstrating compliance with requirements before a condition is applied. Fourteen commenters suggested a process for reconsidering an initial finding of noncompliance that resulted in a condition. One commenter suggested formalizing and implementing the rapid resolution process.
HRSA Response
HRSA has considered these suggestions and has determined that it will utilize the established progressive action process, as described in the Compliance Manual, to allow health centers the opportunity to formally present alternative means for demonstrating compliance in response to a condition placed on an award. HRSA believes that following this existing progressive action submission process will ensure appropriate notice to health centers, as well as HRSA's full and fair consideration of any proposed alternative, documentation of such reviews, and communication to the requesting health center regarding the results of such reviews.

Issue: Reconsideration of Conditions Due to Inaccuracy of Non-Compliance Finding

Comments
One commenter suggested that, once a condition is imposed, HRSA explicitly state that reconsideration of the condition due to inaccuracy of the non-compliance finding is an available option.
HRSA Response
The Oversight chapter describes that imposed conditions will outline the method and timeline for submitting responses to conditions. Health centers may inform HRSA at any time when they have questions or concerns regarding HRSA's actions in response to compliance assessments.

Issue: Appeals

Comments
Two commenters suggested that HRSA include language stating that health centers may appeal a condition they believe to be unwarranted and describing how such an appeal process would work.

HRSA Response
Because a progressive action condition is not an enforcement action, an appeal process is not applicable. As noted above, health centers may inform HRSA at any time when they have questions or concerns regarding HRSA's actions in response to compliance assessments.

Issue: Effective Date for Compliance Manual and Site Visit Guide

Comments
Three commenters suggested clarification of the relationship between the Compliance Manual and the current Site Visit Guide during the period between the finalization of the Compliance Manual and the publishing of the revised Site Visit Protocol.

HRSA Response
HRSA is creating a new Site Visit Protocol that will replace the Site Visit Guide and which will align with the Compliance Manual. When this updated protocol is released, HRSA will also provide an implementation plan and timeline for its use in the field.

Issue: Applying and Removing Conditions

Comments
One commenter suggested clarification on how determinations of compliance or noncompliance are made.

HRSA Response
The Demonstrating Compliance section within each of the respective chapters in the Compliance Manual provides the basis for how HRSA will make its compliance assessments.

Immediate Enforcement Actions

Issue: Public Health or Welfare Concerns

Comments
One commenter suggested that HRSA provide clarification regarding how HRSA will perform assessments related to immediate enforcement actions. Another commenter suggested clarification on the guidance concerning patient safety and immediate enforcement actions.

HRSA Response
Chapter 2 of the Compliance Manual provides examples of when HRSA may take immediate enforcement actions, including those related to imminent patient safety concerns. Such decisions may be based on findings or actions taken by other organizations or governing bodies that oversee health care facilities and/or the delivery of health care services within their jurisdiction.

Issue: Include TA from PCAs and NCAs

Comments
Two commenters suggested that HRSA add Primary Care Associations (PCAs) and National Cooperative Agreements (NCAs) to the list of resources available to assist health centers with compliance with program requirements.

HRSA Response
HRSA utilizes its BPHC Primary Care Digest and its website to provide various technical assistance resources and to describe how health centers can access opportunities for technical assistance, including those available through PCAs and NCAs. The Primary Care Digest is a weekly electronic newsletter containing updates and information of interest to the health center community. Sign up to receive it here: https://public.govdelivery.com/accounts/USHHSHRSA/subscriber/new?topic_id=USHHSHRSA_118.

Chapter 3: Needs Assessment

**Issue: Needs Assessment Presentation, Content, and Frequency*

Comments

Six commenters requested additional information on how the needs assessment should be presented, how formal it should be, and what information it should contain. In addition, they asked about whether synthesizing data from a Service Area Competition (SAC) or other application would suffice and whether a community wide needs assessment that a number of entities partner to create would be acceptable. Twenty-three commenters requested information about the frequency of the needs assessment.

HRSA Response

Chapter 3 of the Compliance Manual has been modified to specifically state that health centers have flexibility in how they conduct and present their needs assessment. In addition, HRSA has clarified in the Demonstrating Compliance section that health centers would complete or update a needs assessment of the current or proposed population at least once every three years. As stated in a footnote, compliance may be demonstrated based on the information included in a Service Area Competition or a Renewal of Designation application.

Issue: UDS Zip Code Reporting

Comments

Two commenters asked for additional information regarding the zip codes they must report in UDS and specifically whether zip codes other than those where at least 75 percent of its patients reside are considered not to be in a health center's service area. Another commenter noted that a health center serving unique populations – for example, Orthodox Jews, Chinese immigrants – may serve people from a wide metropolitan area and may, as a result, have difficulty defining their service area within specific geographic boundaries.

HRSA Response

Health centers have flexibility to define their service area consistent with the requirements of the Health Center Program authorizing statute and regulations. The Compliance Manual includes an example of a method for doing this, whereby the health center defines its service area as the zip codes where at least 75 percent of its patient population resides (i.e., utilizing patient origin data). In addition, health centers serving a geographically dispersed population have the discretion to determine how to include patients across multiple zip codes in defining their service area.

Issue: Zip Code and Service Area

Comments

One commenter requested clarification regarding whether a health center serving 75 percent of the population in a zip code would preclude HRSA from approving another health center proposing to serve that area.

HRSA Response

As noted in Appendix A, PIN 2007-09: Service Area Overlap: Policy & Process, will not be superseded by the Compliance Manual. The policies described in PIN 2007-09 guide HRSA in deciding funding and change in scope actions. Service area penetration percentage is one of a number of factors that is analyzed and considered. For more information on how HRSA makes service area overlap determinations, please see PIN 2007-09 (https://bphc.hrsa.gov/programrequirements/policies/pin200709.html) and the Add New Service Site Checklist (https://bphc.hrsa.gov/programrequirements/pdf/addnewservicesite.pdf).

Issue: Referring to Special Populations in the Needs Assessment

Comments

Three commenters suggested the Needs Assessment requirement explicitly address the unique needs of the statutorily identified special populations.

HRSA Response

HRSA has added language in the Compliance Manual to clarify that the health center would demonstrate compliance by ensuring that the needs assessment utilizes the most recently available data for the service area and, if applicable, for special populations.

Chapter 4: Required and Additional Services

Issue: Substantial Proportion of Limited English Proficiency (LEP) Patients

Comments

Eleven commenters recommended that requirements to provide interpretation and translation services apply only to health centers whose patient populations include a "substantial proportion of individuals of limited English-speaking ability." In addition, commenters suggested the following:

- further clarification regarding what constitutes a "substantial" proportion of individuals for interpretation/translation;
- stronger guidance and encouragement to develop plans and make arrangements for interpretation and translation;
- clarification that interpretation and translation services must comply with Federal regulations on interpretation and translation services, regardless of having a substantial proportion of LEP; and
- support for the provision of translation services to allow LEP patients to have reasonable access to health center services.

HRSA Response

Health centers are required by law to provide enabling services, including, if a substantial number of the individuals in the population served by a center are of limited English-speaking ability, translation services. For more information, please see the National Standards for Culturally and Linguistically Appropriate Services (CLAS) published by the U.S. Department of Health and Human Services at https://www.thinkculturalhealth.hhs.gov/. Additional cultural/linguistic competency and health literacy tools, resources and definitions are available online at http://www.hrsa.gov/culturalcompetence and http://www.hrsa.gov/healthliteracy.

Issue: Additional Acceptable Strategies

Comments

One commenter requested adding language to the Demonstrating Compliance section of this chapter, specifically:

- Adding a reference to telehealth to the examples of how interpretation and translation services may be provided,
- Adding a reference specifically to training when discussing resources that enable staff to deliver services, and
- Adding the following statement: "*The health center provides required services and is engaged in addressing the social determinants of health as identified in the needs assessment by indicators relevant to its service area and special populations*."

HRSA Response
HRSA has added language to the referenced examples to capture the first two suggestions above, including training and use of high quality video or telephone remote interpreting services. Regarding the suggestion to include an additional bullet in this chapter stating that health centers be engaged in addressing social determinants of health as identified in their needs assessments, this comment goes beyond the scope of this Compliance Manual, but HRSA has addressed the issue of social determinants of health in Chapter 3: Needs Assessment. Specifically, that chapter describes that a health center would demonstrate compliance by addressing within its needs assessment the unique health care needs or characteristics impacting health status, access to, or utilization of, primary care (for example, social factors, the physical environment, cultural/ethnic factors, language needs, housing status).

Issue: Eligibility Assistance versus Outreach Services

Comments
One commenter requested that HRSA clarify the distinction between eligibility assistance and outreach services in the list of required services. Another commenter recommended providing a direct reference to the Form 5A Service Descriptor resource.
HRSA Response
HRSA agrees that eligibility assistance and outreach services are separate and distinct services. The distinctions between these services are further outlined in the Form 5A Service Descriptors resource and a resource link has been added in a footnote in this chapter.

Issue: Assessment of Form 5A: Services Provided and Form 5C: Other Activities/Locations

Comments
One commenter noted that there is not a chapter that separately addresses scope of project and requested clarification that assessment of the accuracy of Forms 5A and 5C is included as a compliance component within Chapter 4.
HRSA Response
This chapter describes how health centers would demonstrate compliance with the requirement to provide all required primary health services and approved additional health services by accurately documenting these on Form 5A: Services Provided. Form 5C: Other Activities/Locations is beyond the scope of the Compliance Manual. Additional information on Form 5C is available on the BPHC Scope of Project website: https://bphc.hrsa.gov/programrequirements/scope.html.

Issue: Clarification on Form 5A: Services Provided, Column III

Comments
Two commenters suggested using standard language in Form 5A: Services Provided, Column III and this Compliance Manual.
HRSA Response
HRSA revised the titles referenced in the Compliance Manual to be consistent when referring to Form 5A: Services Provided, Column III, formal written referral arrangements.

Issue: Documentation of Transportation on Form 5A: Services Provided

Comments
One commenter questioned whether transportation needs to be identified at all on Form 5A: Services Provided.

HRSA Response
Transportation is a required health center service as outlined in the Health Center Program statute (section 330(b)(1) of the PHS Act). Thus, provision of this required service would be documented on Form 5A: Services Provided.

Issue: Tracking Referrals

Comments
One commenter requested clarification on the paragraph addressing "Services Provided to Health Center Patients by Third Parties through Formal Referral," especially with respect to the health center's responsibility for tracking these patients. Another commenter indicated that, while a provision for tracking referrals is included, there is no information about diagnostic services, such as laboratory services, which are also part of the process.
HRSA Response
The Demonstrating Compliance section of this chapter describes how a health center would comply with tracking and referring patients back to the health center for appropriate follow-up care. Specifically, formal written referral arrangements within the scope of the Health Center Program project must describe, at a minimum, the manner by which the referral will be made and managed, and the process for tracking and referring patients back to the health center for appropriate follow-up care. Services provided by a formal written referral arrangement are rendered by the other entity (the referral provider); however, the health center maintains responsibility for the establishment of the referral arrangement(s) for health center patients and any follow-up care subsequent to the referral. Additional technical assistance resources related to tracking referrals and other services are available via BPHC's website on health center quality improvement, available at: https://bphc.hrsa.gov/qualityimprovement/index.html.

Issue: Accessibility Issues

Comments
One commenter made an observation that accessibility for patients with physical disabilities was not mentioned in this chapter.
HRSA Response
The Compliance Manual provides a consolidated resource to assist health centers in understanding and demonstrating compliance specifically with the Health Center Program requirements, as outlined in statute and regulations. In addition to maintaining its operations in compliance with all Health Center Program requirements, each health center is responsible for complying with all other applicable Federal, state, and local laws and regulations (for example, the Americans with Disabilities Act).

Issue: Relation of Chapter 4 to Chapter 12: Contracts and Subawards

Comments
Two commenters recommended including a cross-reference to Chapter 12: Contracts and Subawards.
HRSA Response
Chapter 4 addresses the required and additional services provided by health centers as well as the methods by which they may be delivered. This chapter is not intended to address the broader overall contracting and subaward process that is addressed in Chapter 12: Contracts and Subawards.

Issue: Access to Additional Health Services (Specialty Services)

Comments
One commenter suggested that it would be helpful to have more guidance on how to demonstrate compliance in connection with additional health services that are specialty services. The commenter also

mentioned challenges with having written agreements with the specialists that a patient may need and posed the question as to whether it would be possible to assist with these services without being deemed non-compliant if there is not a written agreement.

HRSA Response

Additional health services, including specialty services, may be provided at the discretion of the health center through either formal or informal arrangements, and are not required services. HRSA acknowledges that there are challenges for health centers in establishing written agreements with specialists and that specialty services are a key component of the provision of care to the patient population. Additional and specialty services may be provided to health center patients through what HRSA refers to as an informal referral arrangement. Such informal arrangements are not considered part of the scope of the Health Center Program project and are therefore not assessed for compliance with Health Center Program requirements.

Issue: Relationship of PIN 2009-02: Specialty Services and Health Centers' Scope of Project to this Compliance Manual

Comments

One commenter questioned whether PIN 2009-02 would be superseded by the details in this chapter and, if so, suggested transforming the PIN into a tool that is provided as a resource alongside other scope of project resources.

HRSA Response

Appendix A to the Compliance Manual notes that PIN 2009-02: Specialty Services and Health Centers' Scope of Project has not been superseded by the Compliance Manual, and is still available on HRSA's scope of project website, available at: https://bphc.hrsa.gov/programrequirements/scope.html.

Issue: Using the Term "Pays For"

Comments

Five commenters suggested not using the term "pays for" when describing different service delivery methods (for example, Column I on Form 5A is described as Direct, health center pays for the service). In contrast, one commenter suggested retaining the term "pays for," stating that this would assist the health center in appropriately categorizing the relationship.

HRSA Response

HRSA has historically used this plain language terminology in its various scope resources when describing the different service delivery methods, and as such, will maintain the 'pays for' terminology.

Issue: Availability of All Services at All Sites

Comments

Fourteen commenters suggested that HRSA explicitly state that health centers are not required to provide all required services at each service site. Several commenters suggested including wording from PIN 2008-01: Defining Scope of Project and Policy for Requesting Changes, which indicates that "Services provided by the grantee are defined for the organization/entity, not by individual site. Not all services must be available at every grantee service site; rather, the patients must have reasonable access to the full complement of services offered by the center as a whole, either directly or through formal established arrangements."

HRSA Response

HRSA has addressed this suggestion by adding language to a footnote in Chapter 6: Accessible Locations and Hours of Operation. Appendix A to the Compliance Manual also notes that PIN 2008-01: Defining Scope of Project and Policy for Requesting Changes, remains in effect.

Issue: Applicability of Policies to Contracted Services

Comments

Seven commenters recommended that the Compliance Manual explicitly state that formal contracts/agreements must specify how the health center's policies and/or procedures will apply, while one commenter viewed it as a positive change that HRSA does not require contracts for services to describe how the health center's policies and procedures apply.

HRSA Response

HRSA has revised language in Chapter 4 of the Compliance Manual to clarify that, if a health center elects to provide services within its scope of project to health center patients via contracts/agreements with a third party (i.e., through a formal contract/agreement), the health center would demonstrate compliance with Health Center Program requirements by ensuring that such contracts/agreements require the third party to comply with applicable and specifically identified Health Center Program requirements. The health center may do this either by specifying the applicability of specific health center policies or procedures that comply with Health Center Program requirements or by including provisions within the contract that incorporate these applicable requirements.

Issue: Request Cross-Reference to Chapter 9: Sliding Fee Discount Program

Comments

Eight commenters recommended including a specific cross-reference to the Chapter 9 requirement that, for in-scope services provided through formal referral arrangements, the agreement must specify that sliding fee discounts will be offered by the referral provider.

HRSA Response

HRSA clarified and repositioned a footnote within this chapter to refer readers to Chapter 9: Sliding Fee Discount Program for more information on sliding fee discount program requirements and their applicability to the various service delivery methods.

Issue: Requirements for Informal Referral Arrangements

Comments

Twelve commenters requested that HRSA state explicitly that informal referral arrangements are not subject to the requirements outlined in this Compliance Manual, with several of these commenters suggesting including this clarification under Related Considerations. Some commenters indicated that many health centers have informal referral arrangements with other providers within the community which are not separately recorded on Form 5A: Services Provided, and thus should not be required to comply with the aforementioned requirements. Two commenters mentioned their concern that without such language, consultants may over-interpret the Compliance Manual requirements.

HRSA Response

HRSA acknowledges the value of informal referral arrangements with other providers in assisting health center patients with receiving a wide array of services within their community outside of the health center's scope of project. Because these services are not provided as part of the health center's approved scope of project, the provision of care through such informal referral arrangements is not addressed in the Demonstrating Compliance section of Chapter 4.

Issue: Including Contractors on Form 5A: Services Provided, Column I

Comments

Fourteen commenters expressed concern with not including independent contractors as providers of direct services, noting that this could impact staffing models and/or correct completion of Form 5A for many health centers.

HRSA Response

HRSA has reviewed Compliance Manual language to ensure that it is consistent with current, long-standing HRSA scope policy and guidance, as well as Notices of Funding Opportunity in this area. The Compliance Manual is not intended to modify existing scope policy or procedures for how to document scope of project on HRSA's forms. Thus, an individual (or independent) contracted provider or a group of contracted providers (e.g. a group practice) would continue to be documented in Column II on Form 5A.

Chapter 5: Clinical Staffing

Issue: Clarify What is Meant by a "Staffing Plan"

Comments

Nine commenters requested that HRSA clarify what is meant by a staffing plan and whether it is different from Form 2: Staffing Profile from the Service Area Competition application. Eight commenters requested that if "staffing plan" is the same as Form 2, HRSA remove language from the Compliance Manual that refers to including "referral providers" in the staffing plan. Seven commenters requested that HRSA indicate what guidance, if any, HRSA has regarding frequency of updates.

HRSA Response

HRSA has removed the term "staffing plan" to avoid the confusion that this terminology created and to provide greater clarity as to how to demonstrate compliance with this requirement. The Compliance Manual language has been updated to refer to health center clinical staff sufficient to provide required and additional services. No reference is made to a Form 2: Staffing Profile in the Demonstrating Compliance section of this chapter.

Issue: Requirement to Consider Needs of Patient Population

Comments

Two commenters requested clarification regarding the need for health centers to consider the patient population demographics, such as adult/child ratio, and disease status, such as diabetes, when determining the clinical staff mix needed to ensure patient access to services. One commenter noted that operational site visit consultants differ greatly in what they deem sufficient for a needs assessment.

HRSA Response

A health center would demonstrate compliance with this requirement by describing a clinical staff mix that is able to meet the health care needs of its patient population. For example, a health center serving a high number of children would demonstrate sufficient staffing to serve this population in providing well child visits, immunizations, and other specific needs of that population. HRSA acknowledges the importance of consistency in assessing compliance in this and other areas included in the Compliance Manual. HRSA plans to address these issues in its updated Site Visit Protocol and in future Notices of Funding Opportunity and application instructions to ensure consistent compliance assessments during site visits and the review of applications.

Issue: Align with Site Visit Guide

Comments

One commenter recommended that the Compliance Manual's language requiring "sufficient staff" be aligned with the Site Visit Guide's language that says "maintain a core staff as necessary."

HRSA Response

The reference to "sufficient staff" within the Requirements section of this chapter is consistent with the Health Center Program regulations at 42 C.F.R. 51c.303(p). The Demonstrating Compliance section of this chapter explains how HRSA would assess compliance in this area. HRSA will update the Site Visit Protocol to align with this language.

Issue: PINs 2001-16 and 2002-22

Comments

One commenter supported the rescission of PIN 2001-16: Credentialing and Privileging of Health Center Practitioners and PIN 2002-22: Clarification of Bureau of Primary Health Care Credentialing and Privileging Policy Outlined in Policy Information Notice 2001-16, saying they are "in some ways outdated." An additional commenter stated the new credentialing and privileging guidelines "are significantly more reasonable than the current expectations." However, one commenter stated that 2002-22 was "an important resource to guide health center staff in the credentialing and privileging process" and requested that HRSA either add to the Compliance Manual or reference separately the 2002-22 table entitled, "Comparative Summary of Requirements for Credentialing and Privileging Licensed or Certified Health Care Practitioners," since it is a helpful resource to guide health center staff through the credentialing and privileging process. Another commenter requested that HRSA further define the credentialing and privileging process.

HRSA Response

While HRSA recognizes that the PIN 2002-22 table may have been useful for some health centers in organizing their credentialing and privileging activities, the Compliance Manual no longer lists all of the elements that are included in the referenced table. Rather, health centers will have flexibility in creating operating procedures that fit the needs of the health center in complying with the requirements of this chapter. In addition, HRSA is exploring the use of a table as a technical assistance tool to accompany the updated Site Visit Protocol.

Issue: Requirements for Other Licensed or Certified Providers (OLCPs)

Comments

Six commenters requested clarification of requirements related to other licensed or certified providers (OLCPs). Four commenters requested clarity as to whether OLCPs are required to have credentials of education and training verified, and, if so, whether primary or secondary sources are required. Two commenters noted that PIN 2002-22 clearly states that OLCPs should be verified using secondary sources, while the Compliance Manual is silent on this. Two commenters requested a distinction be made between credentialing requirements for Licensed Independent Practitioners (LIPs) and OLCPs. One commenter interpreted the Compliance Manual's language to require that all providers be considered LIPs, which would increase the credentialing and privileging workload significantly.

HRSA Response

HRSA added language to the Demonstrating Compliance section of this chapter clarifying that verification of credentials is required for both LIPs and OLCPs. HRSA also clarified that primary source verification is only required for LIPs and that a health center has flexibility with respect to source verifications for OLCPs.

Comments
Two commenters requested clarification on requirements related to Certified Medical Assistants. One commenter requested HRSA eliminate specific reference to Certified Medical Assistants as a provider type in the Compliance Manual given the variability of certification requirements for Medical Assistants (MAs) at the state level. Another commenter asked that HRSA revise the footnote to clarify that HRSA will accept non-certified MAs as eligible health center staff.
HRSA Response
In a footnote that provides examples of "other clinical staff," HRSA has replaced the reference to Certified Medical Assistants with Medical Assistants in response to these comments. In states that require certification of Medical Assistants, such Certified Medical Assistants would be considered OLCPs.

Comments
One commenter requested clarification related to credentialing, privileging, and verification requirements for medical residents and interns, who provide patient care but cannot bill third party payors for services.
HRSA Response
Health centers are responsible for ensuring through their contracts and cooperative arrangements that the entity that is supplying medical residents or interns carries out the responsibilities of credentialing and privileging for those trainees as appropriate. Specifically, HRSA added "training programs" to the Demonstrating Compliance section of this chapter to clarify that such resident or intern programs are considered contracts for providers and therefore credentialing and privileging requirements would be included in the "contract" provisions.

Issue: Primary Source Verification

Comments
Two commenters requested that the Compliance Manual clearly state whether or not primary source verification of licensure and/or certification is required, and, if so, whether it is required for all clinical staff. Two additional commenters recommended HRSA remove requiring primary source verification for credentialing, given differences in initial credentialing and because state credentialing in some cases already requires primary source verification for licensing of LIPs. One commenter requested HRSA more clearly define the differences between primary and secondary source verification.
HRSA Response
HRSA has clarified in the Demonstrating Compliance section of this chapter the applicability of primary source verification for LIPs and OLCPs. Further, a footnote in this chapter notes that in states in which the licensing agency, specialty board or registry conducts primary source verification of education and training, the health center would not be required to duplicate primary source verification when completing the credentialing process.

Issue: Credentialing and Privileging of Contract and/or Referral Providers

Comments
Three commenters requested clarification regarding a health center's responsibility related to credentialing for contract providers, specifically with respect to maintaining files for contracted providers and the need to verify licensures and hospital privileges.
HRSA Response
HRSA reviewed the Demonstrating Compliance section of this chapter and believes it provides sufficient guidance for ensuring that contracted providers are credentialed in accordance with applicable Federal, state, and local laws; and assessed as competent to perform the contracted service through a privileging process. Where a health center is contracting for providers' services, the health center would not be

required to replicate the contractor's credentialing and privileging process for the purposes of verification. Rather, the health center is responsible for ensuring compliance by overseeing all contracts for providers' services consistent with the terms of the contract.

Comments
One commenter asked whether locum tenens providers should be included in the credentialing and privileging process.
HRSA Response
HRSA has clarified, in cases where health centers have contracted with a locum tenens staffing agency, that such health centers would ensure that these providers are: licensed, certified, or registered as verified through a credentialing process, in accordance with applicable Federal, state, and local laws; and assessed as competent to perform the contracted or referred services through a privileging process.

Comments
One commenter requested that HRSA add "…of providers accepting assignments from Migrant Health Voucher Programs" to the end of the Demonstrating Compliance element, "The health center maintains files (for employees, individual contractors and volunteers) or if applicable, contracts with assurances of proper credentialing…"
HRSA Response
HRSA is declining to add the recommended language to the Compliance Manual as health centers utilizing migrant voucher models would demonstrate compliance in the same manner as other health centers. Specifically, HRSA considers the health center to be directly responsible for credentialing and privileging when it contracts with an individual provider. In contrast, when a health center contracts with a group practice or other entity, the language contained in the Demonstrating Compliance section of this chapter related to "contracts with provider organizations" would apply. Since migrant voucher models primarily utilize contracts with provider organizations, the health center would have to ensure that contract provisions address the credentialing and privileging of providers through that organization's own process.

Comments
Seventeen commenters requested that HRSA clarify that health centers may accept assurances from formal referral providers that they have been credentialed, and that health centers are not required to credential these providers themselves. Another commenter requested examples for how to demonstrate compliance with the requirement that health centers ensure providers are competent to perform the referred services.
HRSA Response
The Demonstrating Compliance section of this chapter clarifies that health centers would demonstrate compliance by ensuring that providers of organizations with which formal written referral arrangements are maintained, are licensed, certified, or registered as verified through a credentialing process in accordance with applicable Federal, state, and local laws, and are assessed as competent to perform the referred services through a privileging process.

Issue: Credentialing and Privileging: State Level Verification

Comments
Two commenters support the Compliance Manual's provision allowing health centers to rely on state level verification of education and training where the state licensing board utilizes primary source verification. One commenter requested that HRSA publish or maintain a list of states that do this type of primary source verification.

HRSA Response
Maintaining a list of state licensing boards utilizing primary source verification is beyond the scope of the Compliance Manual and HRSA's current technical assistance activities.

Issue: Credentialing and Privileging: Querying of the National Practitioner Data Bank

Comments
Two commenters requested clarification regarding health center queries of the National Practitioner Data Bank (NPDB) as a source for credentialing.
HRSA Response
HRSA has stated in the Demonstrating Compliance section that a health center may demonstrate compliance with credentialing and privileging requirements, in part, by documenting that it has queried the NPDB for applicable provider classes (e.g., physicians). HRSA has also included links to additional information on the NPDB.

Issue: Credentialing and Privileging: Sampling Files for Documentation Review

Comments
One commenter asked whether the Operational Site Visit Guide would continue to utilize a sampling method to review compliance with credentialing and privileging requirements.
HRSA Response
HRSA will provide information regarding sampling and file documentation in the updated Site Visit Protocol.

Issue: Credentialing and Privileging: Verifying Clinical Competence

Comments
One commenter suggested further defining "verifying clinical competence after initial training" by clearly explaining that verification can be done through supervision and documented in performance evaluations.
HRSA Response
HRSA agrees and has clarified in the Compliance Manual that "supervisory performance reviews" would be an acceptable method for demonstrating compliance with respect to verification of clinical competence.

Issue: Credentialing and Privileging: Basic Life Support Applicability

Comments
One commenter suggested adding "if applicable" to the requirement related to documentation of basic life support skills, to align with the language in PIN 2001-16.
HRSA Response
PIN 2001-16 is superseded by the Compliance Manual. However, HRSA agrees and has added the phrase "as applicable" to this Demonstrating Compliance element to acknowledge that not all aspects of credentialing would apply to all providers, consistent with previous policy.

Issue: Credentialing and Privileging: Role of Board

Comments
Three commenters supported the Compliance Manual's language that leaves determination of approval authority for Credentialing and Privileging to the health center. One commenter specifically requested confirmation that the Compliance Manual intended to allow the health center to choose the individual responsible for credentialing and privileging of providers, stating that this change would make it less

cumbersome for the staff member with hiring authority. Another commenter stated that this language is more flexible than the PIN 2002-22 requirement that the Board approve credentialing and privileging while still allowing for Board involvement as necessary. In contrast, one commenter expressed the opinion that HRSA should continue the current role of the Board in credentialing and privileging, while another commenter recommended that HRSA instead require the Board to approve and identify (via policy or resolution) the individual with authority for credentialing and privileging. One additional commenter requested clarification regarding the Board's role in checking the NPDB.

HRSA Response

HRSA intended for the Compliance Manual to allow a health center to choose the individual staff person responsible for credentialing and privileging of providers. The Compliance Manual also clarified that Board approval for credentialing and privileging is not applicable for demonstrating compliance nor does the Board have a role in checking the NPDB as part of credentialing and privileging.

Comments

One commenter recommended that the Board's role in complying with clinical staffing requirements be described in Chapter 19: Board Authority as well as in the applicable Chapter (in this case -- Chapter 5).

HRSA Response

The Compliance Manual specifies all board responsibilities and authorities in Chapter 19: Board Authority. These authorities are not repeated in any other chapters, including Chapter 5: Clinical Staffing, to ensure clarity as to when and how compliance with Board authority requirements would be demonstrated. However, the Compliance Manual does not outline a specific role for the governing board in the implementation of operating procedures with respect to credentialing and privileging.

Issue: Credentialing and Privileging: Peer Review

Comments

One commenter recommended adding the term "and/or" to the following sentence: "Verification of current clinical competence via reference reviews, training and[/or] education for initial privileging, and via peer review or other comparable methods for renewal of privileges."

HRSA Response

HRSA has revised the Compliance Manual language to provide the requested clarity. This language reads "via training, education, and as available, reference reviews" to clarify that health centers verify training and education in all cases and reference reviews, when available.

Comments

One commenter asked if HRSA had more guidance on peer review, such as the number of charts and frequency, asking specifically if one chart annually per provider is acceptable.

HRSA Response

HRSA has provided health centers with flexibility to set guidance for methods of conducting peer review, including determining how they assess clinical competence and fitness for duty, as described in Related Considerations section of this chapter.

Issue: Credentialing and Privileging: Appeals Process

Comments

One commenter requested confirmation that an appeals process for privileges is no longer required for LIPs.

HRSA Response
HRSA clarified in the Related Considerations section of this chapter that a health center determines whether to use an appeals process, confirming that an appeals process for privileges for LIPs is not a Health Center Program requirement.

Issue: Credentialing and Privileging: Verification of Fitness for Duty

Comments
Seventeen commenters requested that HRSA remove the new requirement to verify clinicians' "mental health status." Sixteen commenters requested that if this requirement remains, HRSA provide examples of acceptable methods of verification. Another commenter recommended that the Compliance Manual specify that "self-declaration" be considered allowable documentation for the verification of fitness for duty.
HRSA Response
HRSA has removed references to physical and mental health status verification to avoid confusion created by this reference and instead clarified that health centers may demonstrate compliance by verifying providers' fitness for duty, which relates to their fitness to perform health services. HRSA also clarified in the Related Considerations section of this chapter that a health center has flexibility in how the health center assesses the fitness for duty of its providers for the purpose of privileging them to provide medical care to its patients.

Chapter 6: Accessible Locations and Hours of Operations

Issue: Expectations to Measure Accessibility of Sites, Including Time and Distance

Comments
Seventeen commenters requested clarification regarding if and how health centers would document factors impacting accessibility of sites, including how to measure time and distance and how to take into consideration available transportation options and the remoteness of a given community being served. Three commenters suggested that if there is flexibility in defining and addressing such factors, a statement explicitly reflecting such flexibility be included in the Compliance Manual.
HRSA Response
In response to these comments, HRSA has clarified that health centers have flexibility in how they document such factors. Specifically, HRSA has added a new Related Consideration stating that it is up to individual health centers to determine how to measure and consider distance and travel time to or between health center sites when assessing impact on patient access to health center services.

Issue: Examples of Special Populations and Accessibility of Sites

Comments
One commenter suggested including an example for the homeless population with respect to ensuring the health center's service sites are accessible to the patient population relative to where this population lives or works, adding to the examples already provided for agricultural workers and public housing residents.
HRSA Response
As requested, HRSA has expanded the set of examples of special populations, including one for health centers serving individuals experiencing homelessness.

Issue: Accuracy of Form 5B: Service Sites

Comments

One commenter requested clarification regarding how the assessment and accuracy of Form 5B fits within compliance with Chapter 6 (Accessible Locations and Hours of Operation), when this form has been used in the past to assess scope of project.

HRSA Response

HRSA has integrated components of scope of project into relevant chapters of the Compliance Manual. Chapter 6 addresses the recording of service sites within the HRSA-approved scope of project. Health centers are responsible for ensuring accurate documentation of their current HRSA-approved scope of project on Form 5B: Service Sites, and attesting to such within their applications for continued Health Center Program funding or designation.

Chapter 7: Coverage for Medical Emergencies During and After Hours

Issue: Demonstrating Coverage for Emergencies during Hours

Comments

Two commenters suggested clarification regarding the level of patient emergency care health centers would need to be able to address during normal hours of operation. One commenter noted that this is a new requirement and health centers are not set up to be an emergency room. Eleven commenters suggested replacing the term “basic life support skills” with a clinical standard that is broadly understood (for example, "Basic Life Support" (BLS) from the American Heart Association as BLS is a generally recognized term). Another commenter recommended outlining the requirements for clinical training and equipment necessary to meet this standard. Three commenters suggested clarification of how health centers will demonstrate they have basic life support certified staff at each location.

HRSA Response

HRSA does not believe that coverage for emergencies during normal business hours is a new requirement, as the provision of “emergency medical services” is a statutorily required primary health service under section 330(b)(1)(A)(IV) of the PHS Act. In applying this requirement, HRSA is requiring that health centers have the capability to respond to patient medical emergencies during and after hours, not that they provide emergency room services. In this chapter, HRSA has updated language and provided greater clarity that health centers would demonstrate compliance with this requirement by having at least one staff member “trained and certified in basic life support” present at each HRSA-approved service site in order to ensure the health center maintains the clinical capacity to respond to patient medical emergencies at all health center service sites during the health center’s regularly scheduled hours of operation and provides certain emergency-related information after regular business hours.

Issue: Behavioral Health Only Sites

Comments

One commenter suggested clarification as to whether behavioral health only sites need to have a staff member who is certified in basic life support skills.

HRSA Response

HRSA has clarified that health centers would demonstrate compliance with the requirements of this chapter by having at least one staff member trained and certified in basic life support present at each HRSA-approved service site to ensure the health center has the clinical capacity to respond to patient medical emergencies at all health center service sites during the health center’s regularly scheduled hours of operation. This includes service sites providing only behavioral health services.

Issue: After Hours Coverage

Comments

One commenter suggested that HRSA clarify what is meant by providing instructions for health center patients who may need to access care after hours since posting information on the door of service sites could create confusion that services are available after hours to non-health center patients. A commenter suggested providing examples of how a health center would make a patient aware of how to access after-hours coverage (e.g., "calling the main line for instructions").

HRSA Response

HRSA has provided clarification regarding where health centers have discretion in the Related Considerations section of this chapter. Individual health centers determine how to make patients aware of the availability of, and procedures for, accessing after-hours coverage. Some examples for health center options for posting after-hours information include: after-hours instructions integrated into the automated message on the health center's main phone line, signs posted on the door of all health center service sites, information provided as part of the initial patient registration process, postings on the health center's website, and information provided as patient brochures. If a health center feels that posting such information on the door of service sites would create confusion for non-health center patients, it has discretion to use other method(s) to inform its patients of the availability of care after hours.

Issue: Triage Services

Comments

One commenter suggested that requiring a nurse triage service would be cost-prohibitive for many health centers. Another commenter requested clarification about whether health centers are still able to use triage services to field calls.

HRSA Response

HRSA has clarified that health centers have discretion in determining the means by which after-hours coverage is provided to health center patients, including whether an after-hours nurse triage service is appropriate. For example, telephone coverage by health center providers, primary care services after hours to address urgent medical conditions on an extended or 24-hour basis at certain service sites, after-hours phone coverage arrangements with other community providers, or nurse call lines and other after-hours coverage options may be utilized. The examples are provided only as illustrative options for health centers to consider.

Issue: Rural and Frontier Area Considerations

Comments

One commenter suggested the utilization of Medicare Payment Advisory Commission's (MedPAC) Policy Option 2 which was designed for a community that is too small to support a 24-hour emergency department. The option suggests a primary care clinic that would be open 8-12 hours a day with an adjacent ambulance service operating 24 hours a day seven days a week.

HRSA Response

This commenter's suggestion is outside the scope of the Compliance Manual, the purpose of which is to address Health Center Program requirements and how health centers would demonstrate compliance with those requirements.

Chapter 8: Continuity of Care and Hospital Admitting

Issue: Requiring Primary Health Services to be Accessible "Promptly"

Comments

One commenter asked to remove the word "promptly" from the first requirement bullet that primary health services be available and accessible "promptly," explaining that health centers are currently using a variety of ways to measure access, which may be impacted by a number of factors outside the health center's control, including shortage of providers.

HRSA Response

HRSA declines to remove the word "promptly" from the Requirements section of this chapter because it is included in the statutory language. However, please note that the word "promptly" applies to the availability and accessibility of required primary health services and is therefore addressed in Chapter 6: Accessible Locations and Hours of Operation.

Issue: Provider Contract Contents

Comments

One commenter asked for clarification regarding what type of provider employment contract provisions addressing care in a hospital setting would be required.

HRSA Response

HRSA has clarified within the Demonstrating Compliance section of this chapter that this chapter addresses provider admitting privileges, which may be outlined in a contract, but it does not prescribe the content of provider employment contracts.

Issue: Informal Unwritten Referrals

Comments

Twenty-two commenters asked HRSA to explicitly state whether unwritten, informal hospital referral relationships are adequate to demonstrate compliance with this chapter. One commenter specifically requested that HRSA consider accepting informal agreements.

HRSA Response

The Compliance Manual describes how a health center would demonstrate compliance with the requirements of this chapter by documenting its ability to admit patients to one or more hospitals. Unwritten, informal hospital referral relationships are not included in this chapter as a way to demonstrate compliance.

Issue: Challenges Related to Rural and Migrant Voucher Referrals

Comments

Three commenters noted challenges associated with convincing the local hospital to agree to allow direct admitting by health center providers. Although the access to hospitals was acknowledged as a continuity of care issue, commenters noted the difficulties associated with small rural hospitals declining to update long-standing Memoranda of Understanding (MOU), or in cases where migrant voucher patients are scattered throughout a large geographic area.

HRSA Response

HRSA recognizes that frontier, rural, and special population-only health centers face unique challenges in addressing continuity of care. This chapter affords health centers flexibility with respect to how the health center documents its ability to admit health center patients to one or more hospitals.

Issue: Hospital Admissions and Follow-up

Comments

One commenter noted it may be difficult for either the health center or HRSA to access hospital patient records for the purposes of receiving notification of patient hospitalization, receipt and recording of medical information, and follow-up actions by health center staff, when appropriate.

HRSA Response

HRSA acknowledges the challenge related to notification and has eliminated from the Demonstrating Compliance section of this chapter reference to health centers ensuring notification from hospitals when a health center patient is hospitalized or visits a hospital emergency department. In addition, the health center has discretion in how it receives discharge follow-up information. The health center would follow its own procedures with respect to documenting follow-up actions by health center staff when appropriate. HRSA does not plan to assess a health center's compliance with Continuity of Care and Hospital Admitting Health Center Program requirements through the review of hospital patient records.

Issue: Extra Resources Needed for Continuity of Care

Comments

One commenter requested that HRSA acknowledge that a health center would need additional resources in order to increase efforts in the areas of discharge planning and tracking.

HRSA Response

Although HRSA acknowledges the challenges associated with tracking patient discharges and associated follow-up care for the purposes of continuity of care in the provision of required primary health services, this is a Health Center Program statutory requirement and does not reflect a new policy.

Issue: Define Continuity of Care

Comments

One commenter asked for a definition of continuity of care, giving the example that is cited in the current Site Visit Guide, which lists specifics such as hospitalization, discharge, and patient tracking. The Compliance Manual states only that referral agreements must be established for ongoing "continuity of care."

HRSA Response

HRSA has provided examples in the Demonstrating Compliance section of this chapter that address continuity of care as it pertains to hospital admitting and discharge. In addition, the Related Considerations section addresses the flexibility afforded to health centers in determining how to perform patient tracking. HRSA will align the updated Site Visit Protocol with the content of the final Compliance Manual.

Issue: Referrals to the ER

Comments

One commenter requested clarity regarding whether it is acceptable when demonstrating compliance with this chapter that the health center's hospital evaluation and admission plan is to always refer patients to the ER for evaluation and possible admission by a designated group of hospitalists.

HRSA Response

Health centers would demonstrate compliance with this requirement by maintaining referral arrangements with a hospital for use in appropriate circumstances. HRSA allows health centers the flexibility to determine how they set up their admission agreements with hospitals and the procedures associated with admitting health center patients under such an agreement.

Issue: Sliding Fee Scale Application to Hospital Services

Comments

Fifteen commenters requested clarification that formal arrangements with hospitals for admission and hospitalization of health center patients do not require sliding fee discounts for services provided within the hospital to health center patients. In addition, commenters noted that requiring a sliding fee discount to be part of the formal arrangements will limit health center flexibility in obtaining other discounts for their patients; will not allow them to make their referral decisions based on quality of care; and will impact other options such as subsidizing the cost of referral to a hospital and the hospital's services.

HRSA Response

The hospital arrangements outlined in this chapter relate to the requirement that health centers ensure continuity of care by facilitating the admission of patients to one or more hospitals. HRSA has clarified for the commenters that only in-scope services provided to a health center patient in a hospital setting on behalf of the health center would be subject to the sliding fee discount program requirements. As such, services provided by the hospital or other non-health center providers in the hospital would not be subject to sliding fee discount program requirements.

Issue: ER and Hospital Admission Tracking

Comments

Twenty-one commenters requested that HRSA encourage – but not require – health centers to receive notification from hospitals when a health center patient seeks care from an emergency room (ER) or is admitted to an emergency department or hospital. Additional commenters noted that requiring health center notification when a health center patient seeks care from an ER or is admitted to an emergency department or hospital could be difficult to obtain due to privacy laws, EHR systems limitations, patients seeking care outside the health center's service area or with hospitals with which the health center does not have an agreement, and the burden on understaffed rural hospitals.

HRSA Response

HRSA acknowledges the challenges noted by these commenters, and in response, has eliminated from the Demonstrating Compliance section of this chapter reference to health centers ensuring notification from hospitals when a health center patient is hospitalized or visits a hospital emergency department.

Chapter 9: Sliding Fee Discount Program

Issue: Nominal Charges

Comments

Two commenters requested clarification as to whether the Compliance Manual is removing the Sliding Fee Discount Program (SFDP) requirement that the nominal charge must be a fixed flat fee.

HRSA Response

HRSA's intention was not to change or remove this requirement and, for clarity, has reinstated the term "flat" into the corresponding Demonstrating Compliance element. This terminology also is consistent with language previously included in PIN 2014-02: Sliding Fee Discount and Related Billing and Collections Program Requirements.

Comments

One commenter requested clarification regarding whether a health center may both provide a 100 percent discount and apply a nominal charge for patients with family incomes at or below 100 percent of the Federal Poverty Guidelines (FPG).

HRSA Response
As indicated in the Requirements section of this chapter, a health center may elect to have a full discount or a nominal charge for services for individuals and families with incomes at or below 100 percent of the current FPG. If a health center is applying a nominal charge, then it is not actually providing a full discount, and thus a health center may not both provide a 100 percent discount and apply a nominal charge.

Comments
One commenter requested that HRSA add language indicating that nominal charges are not intended to create a payment threshold for patients to receive care and that nominal charges are not minimum fees, minimum charges or a co-pay. This commenter also requested that HRSA include examples provided in PIN 2014-02 and that the final Compliance Manual language indicate that the examples are not exhaustive.
HRSA Response
HRSA has added a footnote to the chapter indicating that nominal charges are not "minimum fees," "minimum charges," or "co-pays," using language from PIN 2014-02. HRSA also revised the Demonstrating Compliance element to state that a full discount is provided for individuals and families with annual incomes at or below 100 percent of the current FPG, unless a health center elects to have a nominal charge which would be less than the fee paid by a patient in the first sliding fee discount pay class above 100 percent of the FPG. In addition, a non-exhaustive list of examples for gathering input from patients as to what is considered "nominal" from the patient perspective was added to the chapter.

Comments
One commenter expressed the view that any nominal charge is perceived as a barrier to care by patients at or below 100 percent FPG, and suggested that assessing whether a fee is a barrier to care only be required when the nominal charge is judged to be exceptionally high or unreasonable.
HRSA Response
The purpose of the sliding fee discount program is to assure access to health care services regardless of ability to pay. HRSA has revised the Compliance Manual to include more information regarding evaluations of the health center's SFDP, including any nominal charge.

Issue: Multiple Nominal Charges

Comments
One commenter requested that HRSA clarify the ability to have different nominal charges for patients that are identified as being part of a "special population."
HRSA Response
HRSA recognizes, consistent with requirements in Federal statute and regulations, that eligibility for sliding fee discounts is to be based solely on income and family size, not on whether patients are identified as being part of a "special population" or any other demographic category, and therefore, declines to accept this request for revision to the Compliance Manual.

Comments
Two commenters requested additional clarity on whether health centers may use multiple nominal charges within each SFDS.
HRSA Response
HRSA has provided clarification on this point in the Related Considerations section, indicating that the health center determines whether to establish additional aspects of its sliding fee discount program,

such as determining whether or not to establish a nominal charge and whether to establish different nominal charges if the health center elects to establish multiple SFDSs. The Demonstrating Compliance section allows for "a nominal charge" for each SFDS, but does not allow for multiple nominal charges within a single SFDS.

Comments

One commenter requested that HRSA include language providing additional flexibility in structuring SFDSs in cases of complex services that may require multiple visits and therefore higher charges (for example, complex dental procedures). In addition, the commenter stated that such additional flexibility may assist health centers in providing these additional services in a fiscally sustainable manner.

HRSA Response

The provision of all services within a health center's scope of project must comply with SFDS requirements as outlined in Health Center Program statute and regulations and summarized in this chapter. HRSA recognizes that the financial sustainability of the project is a major factor for the health center's consideration when determining whether to offer additional services, such as complex dental procedures, within the approved scope of project.

Issue: Multiple Sliding Fee Discount Schedules

Comments

Thirteen commenters recommended revising the example of distinct, permissible SFDSs to clarify that different SFDSs can be based on either broad service types (such as medical, dental, behavioral health) or distinct sub-categories within such service types (such as distinguishing between preventive and restorative dental).

HRSA Response

For clarification, HRSA has revised the Demonstrating Compliance element to read, consistent with the comment, "… for example, having separate SFDSs for broad service types such as medical and dental or distinct subcategories of service types such as preventive dental and additional dental services." This also is consistent with language that was previously included in PIN 2014-02 (superseded by the Compliance Manual).

Comments

Two commenters recommended revising the examples of permissible sliding fee discount schedules to clarify that health centers may be required to have different SFDSs under other grant programs (for example, Title X and Ryan White).

HRSA Response

This Compliance Manual is intended to address only the SFDS requirements of the Health Center Program. As indicated in the Related Considerations section of Chapter 16: Billing and Collections, if a health center has a funding source (other than a Health Center Program award) that subsidizes or covers all or part of the fees for certain services for specific patients (in accordance with the terms and conditions of such funding sources), the health center may use such funding source (for example, Ryan White Part C grant funds) to support discounts greater than those available through the health center's sliding fee discount schedule, including providing discounts to patients above 200 percent of the Federal Poverty Guidelines (FPG). This is an example of how a health center might demonstrate compliance with SFDS requirements of the Health Center Program and use another funding source.

Comments
Two commenters requested that the Compliance Manual identify some of the characteristics which may not be used to set separate SFDSs (i.e., subpopulations, specific sites such as mobile vans, residence of a patient).
HRSA Response
As indicated in the chapter of the Compliance Manual, separate sliding fee discount schedules may be based on services and/or service delivery method and no other factors and must apply uniformly to all patients based on income and family size and no other factors. HRSA has provided additional examples in the Demonstrating Compliance section, and the Related Considerations section gives information about what remains within the health center's discretion.

Comments
Two commenters expressed concern that not being able to have multiple SFDSs could limit the utilization of certain services, such as behavioral health.
HRSA Response
HRSA has clarified in the Demonstrating Compliance section that health centers may elect to have multiple SFDSs for services or service delivery methods. The SFDS examples provided in the chapter are not exhaustive.

Comments
One commenter asked for clarity as to whether it is allowable to have varying percentage discounts or varying degrees of changes in discount across multiple SFDSs.
HRSA Response
The Compliance Manual allows health centers flexibility in establishing multiple SFDSs as long as each follows the Demonstrating Compliance elements of this chapter. The structural requirements would apply to each SFDS the health center establishes.

Issue: Fee Schedule Covering Costs
Comments
One commenter suggested that HRSA's paraphrasing of statutory language on this topic is confusing. Specifically, the commenter suggested that the phrase in the statute regarding the fee schedule being "designed to cover its costs" should be stated as such in this chapter.
HRSA Response
HRSA has reviewed its language to ensure that it is consistent with Health Center Program statute and regulations. Specifically, section 330(k)(3)(G) of the PHS Act includes the following language, which is reflected in the Requirements section of this chapter: The health center must prepare "a schedule of fees or payments for the provision of its services consistent with locally prevailing rates or charges and designed to cover its reasonable costs of operation…"

Issue: Staff Training
Comments
One commenter requested additional clarification on what would constitute training being provided to staff, as described in PIN 2014-02 (superseded by the Compliance Manual), and what forms of documentation would be sufficient to satisfy the requirement.

HRSA Response
Staff training is not a Health Center Program requirement, as it is at the discretion of the health center to determine how best to train its staff on the implementation of the sliding fee discount program. The

Compliance Manual does not identify documentation regarding staff training as a means of demonstrating compliance with this chapter's requirements.

Issue: Waiving Charges

Comments

One commenter requested clarification as to whether the waiver provision is applicable to all patients or just those who qualify for the sliding fee schedule, explaining that some health center SFDS policies permit fees to be waived when patients are faced with extraordinary circumstances or other hardship circumstances. Another commenter requested that HRSA explain the absence of a specific reference to the waiving of charges.

HRSA Response

HRSA has added a footnote to this chapter referring readers to Chapter 16: Billing and Collections for more information on waiving or reducing charges due to a patient's inability to pay and has also updated language in Chapter 16 to provide greater clarity.

Issue: Annual Re-Assessment

Comments

One commenter requested clarification as to whether the Compliance Manual is eliminating the requirement for annual re-assessment of patient eligibility.

HRSA Response

HRSA added an element to the Related Considerations section to clarify that health centers determine how and with what frequency to re-assess patient eligibility for the sliding fee discount program.

Issue: SFDS for Formal Referral Arrangements

Comments

Thirteen commenters suggested the SFDS requirements only apply to formal referral arrangements when the only way in which an in-scope service is provided is through a formal referral arrangement. Commenters stated that there is difficulty in finding specialty providers to offer the same or better discounts than health centers which can negatively impact access to care for patients. One commenter requested that the Compliance Manual allow a health center to demonstrate compliance by documenting a good faith effort to secure an agreement that meets the outlined requirements.

HRSA Response

HRSA declines to revise the Compliance Manual in response to these comments as health centers have the option of providing services through formal written referral arrangements or through informal arrangements. When providing services through formal referral arrangements, the health center ensures that fees for such services are either discounted as described in element "c" of the Demonstrating Compliance section of this chapter, or discounted in a manner such that: individuals and families with incomes above 100 percent of the current FPG and at or below 200 percent of the FPG receive an equal or greater discount for these services than if the health center's SFDS were applied to the referral provider's fee schedule; and individuals and families at or below 100 percent of the FPG receive a full discount or a nominal charge for these services.

Comments

Eleven commenters requested HRSA state explicitly that health centers are permitted to subsidize the cost of services provided by formal referral arrangement to ensure that patient charges and discounts adhere to SFDS rules.

HRSA Response
The Compliance Manual outlines how the SFDS requirements apply to each of the service delivery methods listed on Form 5A: Services Provided. As described in PIN 2008-01 (which remains in effect), formal written referral arrangements are provided and paid for by another entity. The Compliance Manual is not intended to supersede existing scope policy.

Comments
Eleven commenters requested HRSA state explicitly that discounts offered by formal referral providers are compliant, even if they do not meet the SFDS structural requirements in the Compliance Manual, provided that they offer discounts equivalent to or greater than the health center's discounts.
HRSA Response
HRSA is continuing policy outlined in PIN 2014-02 (superseded by the Compliance Manual) that when providing services through formal referral arrangements, the health center has flexibility as long as it ensures that fees for such services are either discounted as described in element "c" of the Demonstrating Compliance section of this chapter, or discounted in a manner such that: individuals and families with incomes above 100 percent of the current FPG and at or below 200 percent of the FPG receive an equal or greater discount for these services than if the health center's SFDS were applied to the referral provider's fee schedule; and individuals and families at or below 100 percent of the FPG receive a full discount or a nominal charge for these services.

Comments
One commenter asked whether the section on Demonstrating Compliance for formal referral arrangements should be interpreted to mean that such discounts would be structured in the manner described within this chapter or within other parts of the Compliance Manual.
HRSA Response
HRSA has revised the language in this chapter to clarify specifically which Demonstrating Compliance element is applicable.

Comments
One commenter asked whether the examples provided in this chapter are suggestions or requirements.
HRSA Response
The examples provided in the Demonstrating Compliance section of each chapter of the Compliance Manual are examples of how a health center would demonstrate compliance with the requirements of that chapter. The examples provided in the Related Considerations section of each chapter are examples of areas where health centers have flexibility in implementing a given requirement.

Comments
One commenter asked how these SFDS policy requirements will be interpreted and implemented by HRSA staff (i.e., what will the internal control mechanism be for policy application and interpretation?).
HRSA Response
HRSA staff will assess compliance with the Health Center Program requirements as set forth in the final Compliance Manual.

Comments
One commenter suggested including as an example in the Related Considerations section a health center that provides all services via Columns II and III (for example, migrant health centers operating a voucher program) so that reviewers recognize it is possible to run a program using only these service delivery methods. The commenter also requested that HRSA clarify whether a health center providing

services in this manner needs to have a schedule of fees or payments as indicated in the Requirements section, since it seems that some requirements related to providing direct services via Column I would not be applicable.

HRSA Response

Health centers may determine the service delivery method to be used for the provision of all required and additional services as long as the requirements of the Health Center Program have been met. Health centers using models that deliver all services via Columns II and III would demonstrate compliance by meeting all requirements outlined in this chapter. The service delivery method historically referred to as a migrant voucher is considered in the Compliance Manual to be a contract model that provides services via Column II, and the Demonstrating Compliance section outlines how the requirements would apply to each service delivery method. HRSA declines to provide specific examples in this area.

Issue: SFDS for Contracted Services

Comments

Ten commenters requested eliminating the detailed, required contractual language regarding the application of the SFDS, since it could be interpreted to indicate that contractors will bill and be paid by patients based on such discount schedules. Some commenters cited concerns that it is already extremely difficult for health centers to negotiate contracts without this additional requirement.

HRSA Response

HRSA has revised the Compliance Manual to remove the details about contractual language and clarifies instead that health centers are responsible for ensuring that fees for services provided via contractual agreements are discounted in accordance with SFDS requirements.

Issue: Discounts for Privately-Insured Patients

Comments

Nine commenters suggested clarifying that privately-insured patients who qualify for the SFDS must pay no more than what they would have paid under the SFDS (unless required otherwise by contracts). One commenter requested requiring the sliding fee policy to specify the method to be used to discount services to insured patients.

HRSA Response

HRSA has provided additional clarifying language in this Demonstrating Compliance element in response to the comments received. The language now specifically reflects that privately-insured patients who qualify for the SFDS would pay no more than they would have paid under their applicable SFDS pay class, as long as this is not precluded or prohibited by the applicable insurance contract.

Issue: Patients at All Incomes Accessing Services

Comments

One commenter requested clarification as to how a health center would demonstrate that patients at or below 100 percent FPG are accessing services, specifically the type of assessment and level of access that would demonstrate compliance.

HRSA Response

HRSA provided additional guidance in the Demonstrating Compliance section to clarify that health centers would demonstrate compliance by evaluating the effectiveness of their sliding fee discount program in reducing financial barriers to care. The Compliance Manual has been revised to provide examples of data sources, in addition to utilization data, that may be used in this evaluation, such as

patient satisfaction surveys, focus groups, or surveys of patients at various income levels. HRSA declines to further specify the level of access that would demonstrate compliance.

Issue: Measure of Literacy

Comments

One commenter requested that HRSA identify an appropriate literacy level for informing patients of the availability of sliding fee discounts, for example the 5th grade reading level.

HRSA Response

HRSA included literacy levels as one example for health centers to consider in informing patients of the availability of sliding fee discounts. HRSA recognizes that health centers may utilize a variety of mechanisms as they deem appropriate for informing patients of the availability of sliding fee discounts.

Issue: Discounts between 101 and 200 Percent FPG

Comments

One commenter asked for clarity regarding whether the percentage discount has to increase across the various slide levels.

HRSA Response

HRSA clarified in the Demonstrating Compliance section that partial discounts under the health center's SFDS adjust in accordance with income based on gradations in income levels that include at least three discount pay classes. By definition, adjustments of partial discounts require increases across the various slide categories. Therefore, the percentage discount across discount pay classes may not remain at a constant value.

Comments

One commenter suggested adding language to the Compliance Manual explicitly allowing section 330(h) grantees to slide discounts to zero between 101 percent and 200 percent FPG with board approval.

HRSA Response

Health centers must have a gradation of discounts for income levels between 101-200 percent FPG, and it would not be permissible to provide a full discount for patients above 100 percent FPG. However, the Related Considerations section of the chapter notes health center discretion and flexibility when it comes to the determination of income and family size, including whether to consider the characteristics of its patient population in defining these terms. HRSA has added a specific example of considering the availability of income documentation for individuals experiencing homelessness in response to this comment.

Comments

One commenter requested including text indicating that fees paid by patients below 100 percent FPG cannot be higher than the lowest fees paid by patients above 100 percent FPG, as stated in the Health Center Site Visit Guide.

HRSA Response

In response to the comment received, HRSA has added clarification to this Demonstrating Compliance element, stating that "the health center's SFDS(s) is structured consistent with board-approved policy and ensures that a full discount is provided for individuals and families with annual incomes at or below 100 percent of the current FPG, unless a health center elects to have a nominal charge, which would be less than the fee paid by a patient in the first sliding fee discount pay class above 100 percent of the FPG."

Issue: Verification of Income

Comments

One commenter suggested explicitly stating whether health centers are required to request and retain physical proof of income from patients to verify sliding fee scale eligibility, and stating that if aligned with board-approved policies, self-declaration is sufficient.

HRSA Response

HRSA has added language in the Related Considerations section of this chapter in response to this comment, clarifying that health centers have flexibility in determining how to document income (which may include permitting self-declaration of income) and family size in health center records.

Issue: Minimum Number of Discount Classes

Comments

Three commenters recommended specifically stating the minimum number of discount classes between 101 and 200 percent FPG. One commenter recommended a minimum of two discount classes, stating that it would be simpler and have no material effect on either the patient or the health center. Another commenter requested clarification that the 3-5 levels cited in the Compliance Manual is an example, not a requirement.

HRSA Response

HRSA has added clarifying language to the Demonstrating Compliance section of this chapter indicating that at least three discount pay classes that adjust in accordance with income based on gradations in income levels above 100 percent and at or below 200 percent of the current Federal Poverty Guidelines would demonstrate compliance. This language is consistent with policy previously outlined in PIN 2014-02 (superseded by the Compliance Manual).

Issue: Definition of Family

Comments

One commenter recommended changing “family” to “group” and defining “group” as the family or household members whose income is factored into the eligibility determination.

HRSA Response

The language in the Compliance Manual reflects Health Center Program regulations and also provides discretion to health centers in how they define a “family,” as addressed in the Related Considerations section of this chapter. For additional clarity, HRSA has removed the term “household” from this section of the Compliance Manual.

Issue: Patient Utilization Expectation

Comments

One commenter requested clarification of HRSA’s expectations regarding demonstrating the ability of sliding fee patients to access services.

HRSA Response

HRSA has clarified in the Demonstrating Compliance section of this chapter that the health center evaluates, at least once every three years, its sliding fee discount program. At a minimum, this evaluation would document the rate at which patients within each discount pay class, as well as those at or below 100 percent of the FPG, are accessing health center services.

Issue: Frequency of Evaluation

Comments

Fourteen commenters suggested clarifying whether there is a standard for how frequently health centers must evaluate the effectiveness of their SFDSs. Two commenters suggested a 3-year interval, as stated in the current Site Visit Guide, is an appropriate timeframe.

HRSA Response

HRSA has provided clarification that the health center would demonstrate compliance by assessing SFDSs at least once every three years. This standard aligns with similar timelines for assessment in other sections of the Compliance Manual (for example, needs assessment is at least once every three years and the board is required to assess policies in the same timeframe).

Issue: Payment Incentives

Comments

Eleven commenters suggested adding language about optional payment incentives (such as prompt pay and cash discounts) from PIN 2014-02 (superseded) to this chapter of the Compliance Manual. One commenter recommended that HRSA add language recognizing that health centers may elect to offer incentives through board-approved billing and collections policies, consistent with Chapter 16. Three commenters expressed confusion over whether HRSA has removed the option of adopting payment incentives, such as prompt payment and cash payment discounts.

HRSA Response

HRSA declines to add language regarding optional payment incentives to this chapter, noting that these are addressed in the Demonstrating Compliance section of Chapter 16: Billing and Collections. In response to these commenters, however, HRSA added the term “cash payment incentives” in the appropriate section of Chapter 16.

Issue: Methods of Evaluation

Comments

Three commenters suggested specifying the types of methods or standard evaluation measures that might be used to evaluate whether the sliding fee discount program is effective in reducing financial barriers to care (for example, patient satisfaction surveys, focus groups, specific surveys for nominal charge patients).

HRSA Response

HRSA has added examples to the Demonstrating Compliance section of this chapter regarding how a health center might utilize additional data to evaluate the effectiveness of their SFDS programs in reducing financial barriers to care. Such examples include gathering data from patient satisfaction surveys, focus groups, or surveying patients at various income levels.

Issue: PIN 2014-02

Comments

Twelve commenters requested clarification on the status of nominal charge requirements from PIN 2014-02. Ten commenters requested that HRSA not rescind PIN 2014-02, or consider instead indicating which parts of the PIN are superseded, or using the PIN as a complementary guidance resource.

HRSA Response

PIN 2014-02 will be superseded by the Compliance Manual. HRSA has updated language in this chapter as well as in Chapter 16: Billings and Collections that clarifies the sliding fee and related billing requirements, as requested. In addition, more examples have been included to assist with clarification.

Issue: Discounts Above 200 Percent FPG

Comments

Eleven commenters requested that, in addition to the footnote included in Chapter 16, HRSA state in the main text that health centers may offer discounts to patients above 200 percent FPG if the health center has access to other grants or subsidies that support patient care. For contractual arrangements, a commenter stated that some health centers partner with hospitals and specialty groups that have charitable care policies going beyond 200 percent FPG.

HRSA Response

HRSA declines to update this chapter as requested, as this issue is a billing issue and, as such, has been addressed in Chapter 16: Billing and Collections. A footnote in this chapter provides a cross reference to language in Chapter 16 for health centers that have access to other grants or subsidies that provide funding for health care services to health center patients. Specifically, a Related Consideration in Chapter 16 states the following: "If a health center has a funding source that subsidizes or covers all or part of the fees for certain services for specific patients (in accordance with the terms and conditions of such funding sources), the health center may use such funding sources to support discounts greater than those available through the health center's sliding fee discount program," including providing discounts to patients above 200 percent of the Federal Poverty Guidelines.

Chapter 10: Quality Improvement and Assurance

Issue: Clarify "Clinical Management Issues"

Comments

Seven commenters requested that HRSA replace the term "clinical services and management" with "clinical services and clinical management" to clarify that QI/QA plans are limited to clinical management issues. An additional commenter asked for clarification about how broad "management" should be read and asked for examples.

HRSA Response

HRSA added clarifying language to this chapter to reflect, as requested by commenters, that this requirement applies only to clinical management.

Issue: Authorized Individual to Oversee QI/QA

Comments

Six commenters recommended expanding the definition of the "authorized individual" who conducts the assessment of utilization/quality of services to include staff other than physicians or under the supervision of physicians (such as "other mid-level providers," or "other licensed health care professionals or other staff designated by the Chief Medical Officer"). An additional commenter requested clarification as to whether the list was illustrative or exhaustive. Three commenters noted an inconsistency between the Requirements and the Related Considerations language in this chapter, suggesting either removing language from the Requirements section or changing the language from "physicians and other licensed health care professionals" to "qualified health center staff." Another commenter supported the flexibility of allowing someone with an MPH or MHA to fill this position.

HRSA Response

The Compliance Manual does not use or define the term "authorized individual." As with other chapters in the Compliance Manual, the Requirements section lists Health Center Program requirements as they appear in statute and regulations, while the Demonstrating Compliance section describes how HRSA will assess health center compliance with these requirements. With respect to this requirement, there are two distinct aspects: 1) a health center designates an individual to oversee the QI/QA program (HRSA

has clarified in the Demonstrating Compliance section of this chapter that this individual need not be a clinician); and 2) a health center physician or other licensed health care professional conducts QI/QA assessments (HRSA also clarifies in this section that this aspect of the requirement is distinct from overseeing the QI/QA program). HRSA has reviewed language in all sections of this chapter to improve clarity and ensure consistency when describing the responsibilities of the individual overseeing the implementation of the QI/QA program.

Issue: Conducting Assessment of Utilization and Quality of Services

Comments

One commenter requested clarification as to whether these "periodic assessments" refers specifically to peer review. Another commenter asked for guidance on how a health center assesses utilization and quality of services "proposed to be provided" (as opposed to already being provided). A third commenter was confused by what was perceived as an expansion of the requirement to conduct periodic assessments and expressed concern regarding time constraints and budgets related to achieving these increased objectives.

HRSA Response

HRSA updated and reordered language in this chapter to provide greater clarity regarding elements of a "QI/QA program" and what is part of "QI/QA assessments," which must be conducted by a clinician. The language in the Requirements section regarding services "proposed to be provided" cannot be altered as it is statutory language. However, HRSA has clarified how health centers will demonstrate compliance with this requirement by eliminating the word "proposed" in the Demonstrating Compliance section of this chapter and has also further clarified other aspects of what constitutes a QI/QA program. The requirement to conduct periodic assessments is not a new or expanded requirement, as it is stated explicitly in Health Center Program regulations.

Issue: Access to Patient Records During HRSA Reviews

Comments

One commenter recommended adding to the discussion of protected health information, a description of the access that "HRSA reviewers" should have when assessing sites for compliance.

HRSA Response

HRSA has the authority to audit health centers and review patient records under 45 CFR Part 75. The operational Site Visit Guide also includes language regarding HRSA reviewer access to records.

Issue: Operational Site Visits and Methods of Documentation

Comments

One commenter expressed concern that the current Compliance Manual language does not include specific information on documenting an evaluation of the QI/QA program, which may allow for inconsistent review of the program during site visits. The commenter recommends that the Compliance Manual address methods of documentation, such as "minutes of QI/QA meeting including summaries of QI activities demonstrating attempts to improve patient care," and that the Compliance Manual discuss how the QI/QA program relates to UDS or other measures.

HRSA Response

HRSA declines to address the methods of documenting an evaluation of the health center's QI/QA program in the Compliance Manual. However, the Site Visit Protocol will be aligned with this Compliance Manual and will provide information regarding what documentation will be reviewed, which will support consistent evaluations of health center QI/QA programs.

Issue: Alignment of UDS Reporting Requirements with Evidence-Based Clinical Guidelines

Comments

One commenter stated that the clinical quality measures in UDS do not adhere to current evidence-based clinical guidelines, standards of care, and standards of practice. The commenter recommended that HRSA update UDS clinical quality measures to better adhere to current guidelines, and that HRSA clearly indicate in the Compliance Manual if the UDS clinical quality measure reporting requirements should be included along with the current evidence-based clinical guidelines, standards of care, and standards of practice.

HRSA Response

The Compliance Manual does not specifically cover UDS reporting, which is intended to measure health center activity and impact on clinical outcomes. The data to be reported in UDS undergoes regular updates, and HRSA accepts comments upon proposed UDS changes during the process of updating UDS forms. Please note that this chapter's Demonstrating Compliance section states that a health center may demonstrate compliance with the requirements of this chapter by implementing procedures that providers adhere to evidence based guidelines, standards of care, and standards of practice.

Issue: Provide References for Standards

Comments

One commenter requested that HRSA provide in this chapter a footnote for each of the following that includes a citation to a resource where health centers may refer to standards: site reviews, periodic assessments, utilization and quality of services, peer reviews, and clinical measures outcomes.

HRSA Response

HRSA declines to provide further definitions or clarifying information beyond what is contained in the Demonstrating Compliance section of this chapter. The Compliance Manual provides health centers with flexibility to establish standards within the limits of the requirements.

Issue: Systems and Process for Safeguarding Patient Data

Comments

One commenter requested clarification of how to demonstrate compliance with the "systems and procedures for protecting the confidentiality of patient information." Specifically, the commenter asks whether this is shown via written policies and procedures or whether it will be assessed in another way.

HRSA Response

HRSA does not prescribe the method by which a health center would demonstrate compliance with this requirement. HRSA has clarified the language in the Demonstrating Compliance section of this chapter to explain that the health center would demonstrate compliance with this requirement by implementing a system as required by regulations at 42 CFR 51c.303(b). In addition, while outside the scope of the Compliance Manual, health centers must comply with Federal, state, and local laws and regulations related to the confidentiality of patient records.

Issue: Retrievable Health Record

Comments

Two commenters requested clarification on the definition of a "retrievable health record." Another commenter asked how a health center would demonstrate that each patient has a retrievable health record.

HRSA Response
Health centers would demonstrate that they have a retrievable health record by accessing patient information as needed for patient care, audit, or other purposes. HRSA will provide additional information on how this will be assessed on site in the Site Visit Protocol.

Issue: Frequency of Periodic QI/QA Assessments

Comments
One commenter requested more specificity regarding HRSA's expectations on the frequency of "periodic QI/QA assessments" and what documentation would satisfy the requirement.
HRSA Response
HRSA has clarified language in this chapter to describe the frequency of "periodic assessments" to be "at least on a quarterly basis."

Issue: Frequency of Policy Review

Comments
One commenter requested this chapter include a once-every-three-years reassessment period for Quality Improvement/Assurance policies, which would align with the frequency for reviewing policies referenced in Chapter 19: Board Authority.
HRSA Response
HRSA declines to include a reference to frequency of policy assessments in this chapter. However, Chapter 19 speaks to the governing board's role in setting and reviewing health center policy, which would include evaluating at least once every 3 years any board-approved policies related to a Quality Improvement/Assurance Program.

Issue: Modifying Services Based on Findings

Comments
One commenter requested further definition of expectations related to the Demonstrating Compliance bullet that reads, "A process for modifying the provision of health services based on the findings of QI/QA assessments, as appropriate."
HRSA Response
HRSA has modified language in this bullet to explain that health centers demonstrate compliance by showing how QI/QA assessments of utilization and quality impact and/or modify the provision of in scope health services to health center patients (for example, with the goal of improving health outcomes).

Issue: Patient Satisfaction and Grievance Process

Comments
One commenter requested clarification regarding changes to patient satisfaction and grievance procedures, specifically requesting that HRSA outline protocols and timelines.
HRSA Response
HRSA has considered this request and concludes that allowing health centers flexibility to design protocols and procedures that are appropriate for their particular patient population, including any protocols and procedures regarding patient satisfaction or grievances, is consistent with Health Center Program statutory and regulatory requirements.

Issue: Board's Role

Comments

One commenter requested HRSA create an appendix or website that lists all the policies and operating procedures that require Board approval. Another commenter requests that this chapter list any elements that HRSA expects to be found in board minutes.

HRSA Response

HRSA addresses in Chapter 19: Board Authority the list of health center policies that require Board approval. Beyond that, the Compliance Manual's Demonstrating Compliance sections do not reference Board minutes as the single means by which a health center would demonstrate compliance with Health Center Program requirements.

Issue: Timeline for Implementing Related Considerations

Comments

One commenter requested HRSA clarify a timeline for the implementation of "the requirements outlined under 'Related Considerations.'"

HRSA Response

Please note that the Related Considerations sections are not requirements. Rather, they are clarifications as to where a health center has discretion in the manner in which it elects to implement requirements. Therefore, there are no timelines associated with implementing any Related Considerations.

Chapter 11: Key Management Staff

**Issue: Contracting for the CEO Position*

Comments

Eighteen commenters recommended that HRSA not permit health centers to contract for their CEO, even with the reference to the required prior approval from HRSA. Of these commenters, one stated that a contractual CEO could have an impact on the health center operations and places a huge burden on the governing board. Two commenters recommended that contracting for the CEO should only be allowed under unusual circumstances requiring case-by-case approval. Six commenters expressed a different point of view, stating they supported the flexibility of allowing a health center to use a contractor for the CEO position, especially in recognition of how difficult it is to fill these positions with qualified individuals and for interim circumstances. One commenter recommended that HRSA permit CEOs to work under a contractual agreement basis, if approved to do so by the Health Center Board.

HRSA Response

As suggested by many of these commenters, HRSA added language to its Related Considerations section that clarifies that the health center's governing board determines the circumstances where it may be appropriate and necessary to contract for the Project Director/CEO position rather than directly employ this individual. As stated in several chapters of this Compliance Manual where this topic is referenced, a health center decision to contract for the Project Director/CEO falls under the category of substantive programmatic work and therefore requires HRSA approval.

**Issue: Language in a Contract for a CEO*

Comments

One commenter recommended that specific language be included in a contract for CEO that states that the health center retains full authority over the individual including selecting, evaluating, and removing such an individual.

HRSA Response

HRSA has added a footnote in Chapter 11 that addresses this suggestion. The footnote directs readers to Chapter 19: Board Authority, which includes the requirement regarding the selection and dismissal of the Project Director/CEO.

Issue: Full-time Status of CEO

Comments

Twenty-one commenters suggested requiring that health center CEOs work full-time for the health center. Of these commenters, three requested clarity as to whether the CEO is required to work full-time for the health center. Three commenters suggested that, if the CEO is required to work full-time, HRSA differentiate between the CEO and other key management regarding permitted flexibilities to work either full- or part-time for the health center.

HRSA Response

HRSA has clarified that it is the health center's governing board that determines when a less than full time Project Director/CEO position is sufficient to oversee the day-to day activities of the HRSA-approved scope of project. This flexibility also applies to the other key management positions.

Issue: Assessing Sufficient Key Personnel

Comments

One commenter recommended clarifying what constitutes sufficient key personnel and suggested that it be based upon job function rather than title. In addition, it was further suggested that HRSA specifically clarify the health center's responsibilities with respect to determining position titles and how key management functions are distributed among management staff.

HRSA Response

HRSA has clarified in the Demonstrating Compliance section that the health center is responsible for determining the makeup and distribution of functions among its key management staff as well as the percentage of time dedicated to the health center, as necessary to carry out the HRSA-approved scope of project. In addition, HRSA has clarified in the Related Considerations that the health center has flexibility in determining the specific key management position titles and distribution of functions for its key management staff.

Issue: Process for Filling Open Key Management Positions

Comments

One commenter requested clarification regarding what documentation HRSA requires of the health center's attempts to fill open key management positions. Another commenter expressed a view that HRSA's progressive action process does not allow sufficient time or flexibility for a health center to address a noncompliance finding with respect to filling key staff roles.

HRSA Response

Based on program statute and regulation, health centers are required to maintain sufficient key management staff to carry out the activities of the health center. HRSA clarified in this chapter that health centers would demonstrate compliance with this requirement by documenting their process for filling any vacant key management positions. The progressive action process provides health centers a time-phased opportunity to demonstrate compliance, which in this case would include documenting the health center's process for filling vacancies. Please see Chapter 2: Health Center Program Oversight for further details on the progressive action process.

**Issue: Prior Approval for Contracting for Key Management Staff*

Comments

Ten commenters requested that HRSA clarify whether prior approval is required when contracting for key management positions other than the CEO. Two commenters recommended that a footnote be revised to address HRSA's prior approval requirements in this area and that it specifically include contracting for additional specific management team members, in particular the CFO and CMO. One commenter expressed concerns that contracting for the entire management team with an outside organization could allow the organization to have undue influence and control over the health center.

HRSA Response

HRSA has restated that it is the health center's governing board that determines the circumstances whereby it may be appropriate and necessary to contract for the Project Director/CEO position rather than directly employing this individual. Regarding HRSA's prior approval requirement, it includes either contracting for the Project Director/CEO or for the entire key management team (inclusive of the Project Director/CEO), as these scenarios are considered to be a transfer of substantive programmatic work. For more information on this subject, please refer to Chapter 12: Contracts and Subawards.

Issue: Clarify Prior Approval Requirements for a Change in Key Management Staff

Comments

Three commenters stated that it is the CEO's responsibility to hire key management staff and health centers should not be required to seek HRSA approval prior to hiring. One commenter recommended that a health center be required only to notify HRSA of a change in the key person within ten days rather than needing to seek prior approval.

HRSA Response

According to 45 CFR 75.308, HRSA's prior approval is required for a change in Project Director/CEO. This approval is tied to HRSA's responsibility to ensure that significant revisions to approved program plans contained in funding applications maintain the awardee's capacity to carry out the Health Center Program project.

Issue: Prior Approval Process Timeline

Comments

Two commenters requested an expedited or interim prior approval process to accommodate issues in rural areas where there is high turnover and in emergency situations where there is a need to quickly and efficiently fill these positions.

HRSA Response

HRSA follows the HHS regulation in 45 CFR 75.308(c)(1)(ii) and (iii), which does not allow for an expedited or interim approval process. In this chapter, HRSA describes when a health center must submit for prior approval a change in the Project Director/CEO position. These changes would include situations in which the current health center Project Director/CEO is disengaged from involvement in the project for any continuous period for more than three months or will reduce time devoted to the project by 25 percent or more from the level that was approved at the time of award [see: 45 CFR 75.308(c)(1)(ii) and (iii)]. Health centers are encouraged to discuss any pending changes and timelines with their BPHC Project Officer, including urgent situations.

Issue: Clarification of Key Management Staff Examples

Comments

One commenter suggested that HRSA clarify whether the examples of key management staff listed in a footnote are required or recommended and that HRSA consider including a Chief Administrative Officer title as an alternative to a Chief Operating Officer.

HRSA Response

HRSA has clarified in this chapter that the list of key management staff contains examples and, as such, is not intended to be an exhaustive list of all position titles.

Issue: Require Residency Requirement for Health Center CEO

Comments

One commenter suggested requiring that the CEO reside in the same state as the health center.

HRSA Response

As the Health Center Program statute and regulations do not include a residency requirement for a health center's Project Director/CEO, there is no Health Center Program requirement that a health center Project Director/CEO reside in the same state as the health center.

Issue: Requirements for Health Center Position Descriptions

Comments

One commenter suggested that health center key management position descriptions be required to define the functions and responsibilities in addition to training and experience.

HRSA Response

HRSA has added language in the Demonstrating Compliance section of this chapter that the health center not only document the training and experience qualifications, but also the duties or functions for each key management staff position (for example, in position descriptions).

Issue: Combined Roles of Key Management Staff

Comments

Two commenters supported allowing combined key management positions, especially with respect to the CEO and CFO based on the size and complexity of the health center.

HRSA Response

HRSA has further clarified in the Related Considerations section of this chapter that health centers may determine the key management position titles appropriate for their health center and how health center functions are distributed among its key management staff positions (for example, determining in a smaller health center whether it is appropriate to combine the Project Director/CEO and CFO functions).

Chapter 12: Contracts and Subawards

Issue: Requirements for Contracts versus Subawards

Comments

Nine commenters suggested removing the General sections from this chapter to avoid confusion regarding the applicability of requirements with respect to contracts and subawards. The commenters suggested that all relevant provisions be included in the appropriate subsections of Contracts or Subawards.

HRSA Response
HRSA has restructured this chapter to remove the General section and include all applicable language in each of the distinct subsections for Contracts and Subawards.

**Issue: Prior Approval for Substantial Programmatic Work*

Comments
Fifteen commenters suggested clarification that the requirement for HRSA prior approval of contracts for the delivery of health care services under the Federal award applies only to those contracts for substantial programmatic work. Of these commenters, two specifically requested clarification regarding whether prior approval is needed for contracts for non-CEO key management positions and for contracts involving the majority of primary care providers.

HRSA Response
HRSA has clarified in the Contracts: Procurement and Monitoring section and in other sections of the Compliance Manual that contracting for the Project Director/CEO or for the entire key management team requires prior approval from HRSA, because this is considered to be a transfer of substantive programmatic work under the Federal award. For the purposes of the Health Center Program, contracting for substantive programmatic work includes contracting for the following: Project Director/CEO; entire key management team; or majority of health care providers through an arrangement with a single entity. Please note that substantive programmatic work may be further defined within a specific HRSA Notice of Funding Opportunity or application instructions.

**Issue: Prior Approval for Contracts*

Comments
Three commenters suggested rephrasing the Demonstrating Compliance bullet that discusses HRSA "prior approval" for certain contracts, specifically to clarify whether this would apply to a) on-site services, including leasing of staff; b) off-site clinical services, such as hospitalists or lab services; c) facility expenses; and d) operational expenses such as supplies, material, equipment, and general support services.

HRSA Response
For the purposes of the Health Center Program, contracting for substantive programmatic work would not include the acquisition of supplies, material, equipment, or general support services. However, it does apply to contracting for the following: Project Director/CEO; entire key management team; or majority of health care providers with a single entity. Please note that substantive programmatic work may be further defined within HRSA Notices of Funding Opportunity or application instructions, as applicable.

Issue: Interpretation of New Requirements

Comments
One commenter suggested training for site visit reviewers on new requirements that were not incorporated into the Site Visit Guide for consistent interpretation.

HRSA Response
HRSA agrees with this comment and will take it into consideration in future updating of the Site Visit Protocol.

Issue: Part 75 Uniform Administrative Requirements for All Contracts

Comments
Seventeen commenters suggested clarification that Part 75 Uniform Administrative Requirements (including but not limited to procurement requirements) do not apply to contracts for which payment is made only with non-grant funds (i.e., program income or other operational funding). Two additional

commenters suggested that instead of “all procurement transactions” the wording be changed to “transactions purchased with Federal funds” must use full and open competition consistent with 45 CFR 75.328.

HRSA Response

HRSA has incorporated this clarification into the Contracts: Procurement and Monitoring section of this chapter. Specifically, the language clarifies that the procurement requirements contained in 45 CFR Part 75 apply to all procurement transactions paid for in whole or in part under the Federal award.

Issue: Procurement Requirements

Comments

Two commenters suggested clarification as to whether the cost or price analysis in connection with procurement actions must be documented and retained, and if so, for what period of time (i.e. the duration of the contract). Two additional commenters suggested adding compliance with Federal procurements to the OMB compliance supplement.

HRSA Response

HRSA declines to further clarify this, as HRSA has reviewed language in the Demonstrating Compliance section in this chapter and determined that it reflects the requirement that health centers retain contracts for goods and services and related procurement records, consistent with Federal document maintenance requirements. The Demonstrating Compliance section also includes a footnote referring to grants regulations at 45 CFR 75.361 for HHS retention requirements for records. Regarding the conduct of the cost or price analysis tied to procurement transactions, the health center is required to conduct all procurement transactions paid for in whole or in part by the Federal award in a manner that provides full and open competition consistent with the standards of 45 CFR 75.328. The Demonstrating Compliance section of this chapter further clarifies that the health center’s procurement records would be the basis for documenting any required cost or price analysis. The suggestion that this topic area be addressed via the OMB compliance supplement is outside the scope of the Compliance Manual. However, health centers should note that auditors generally test for compliance with HHS procurement regulations as part of their annual audit review process.

Issue: Align with CIS Checklists

Comments

One commenter suggested that the more specific language in the Change in Scope (CIS) module of EHB (e.g., details in an agreement, such as contracts with a specialist) be included in the Compliance Manual for continuity and clarity of expectations since there should not be additional requirements included in the CIS checklists that are not included in the Compliance Manual.

HRSA Response

HRSA declines to make this suggested revision. While the Compliance Manual contains Health Center Program requirements applicable to all health centers, the CIS module requests specific information from each health center that is relevant to fully understanding its proposal for the purposes of making a prior approval decision regarding the request to change its scope of project.

Issue: Procurement Guidelines for Capital Development Projects

Comments

One commenter suggested clarification on the applicability of the types of standards applicable to capital development projects (for example, if a health center contracts with a general contractor, would that entity be held to Federal funds procurement guidelines). In addition, the commenter requested clarity as to whether the standards are applicable only when Federal dollars are being utilized.

HRSA Response

HRSA refers the commenter to 45 CFR Part 75 and the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf). Federal funds procurement standards apply to contractors when Federal dollars are used in whole or in part. HRSA has included the link to the Grants Policy Statement in a footnote in the Demonstrating Compliance section of this chapter. In addition, HRSA notes that some capital development projects have been authorized and funded by specifically applicable laws with associated requirements beyond those found in the Health Center Program statute and regulations.

Issue: Simplified Acquisition Threshold

Comments

One commenter suggested identifying the current acquisition threshold.

HRSA Response

The Requirements section of this chapter includes a footnote stating that the *simplified acquisition threshold* refers to the dollar amount below which a non-Federal entity may purchase property or services using small purchase methods. The simplified acquisition threshold is set by the Federal Acquisition Regulation at 48 CFR subpart 2.1 and in accordance with 41 U.S.C. 1908. HRSA has not added the current threshold to the Compliance Manual since the acquisition threshold is periodically adjusted for inflation.

Subawards

Issue: Subrecipient Compliance with FTCA Requirements

Comments

Eight commenters suggested deleting the requirement for health centers to ensure subrecipient compliance with FTCA requirements at the time the subaward is made and/or clarifying which specific FTCA requirements a health center must monitor with respect to its subrecipients.

HRSA Response

HRSA has removed the FTCA requirement language from this bullet in response to this comment.

Demonstrating Compliance

Issue: Redundancy of Agreements in Other Chapters

Comments

One commenter suggested removing duplication with formal written agreements that are referenced in other chapters of the Compliance Manual, such as Required and Additional Services, Continuity of Care and Hospital Admitting, and Sliding Fee Discount Program.

HRSA Response

HRSA concurs with this suggestion and has made appropriate adjustments to the language in the Compliance Manual to ensure that various chapters within the Compliance Manual that reference contracts speak specifically to the unique requirements contained in each of those chapters.

Contracts

Issue: Oversight

Comments

One commenter suggested clarification on health centers overseeing contractors since this is in the current Site Visit Guide and is subject to a range of interpretation.

HRSA Response

HRSA will be updating the Site Visit Protocol to align with the final Compliance Manual. As HRSA has stated in the Related Considerations section of this chapter, the health center has the discretion to

determine the methods it will utilize to monitor its contractors' activities and performance, as long as such methods comply with 45 CFR Part 75.

Subawards

Issue: Monitoring and Management

Comments

Two commenters suggested clarification as to what would be an acceptable process for monitoring subrecipient compliance with Federal guidelines, including frequency and documentation that verifies compliance. An additional two commenters also suggested clarification regarding the required frequency of subrecipient reviews as well as the level of detail needed within subrecipient budgets.

HRSA Response

HRSA addresses these questions within the Related Considerations section of this chapter, including the provision of examples. It is the health center awardee that determines the methods it will utilize to monitor subrecipient compliance and performance with Health Center Program requirements, including the manner in which it requests budget information, consistent with the requirements of 45 CFR Part 75.

Issue: UDS Report

Comments

Two commenters suggested the Uniform Data System (UDS) Manual specify how subrecipient data are to be reported. One commenter suggested having health centers formally identify subrecipients to BPHC.

HRSA Response

The contents of the UDS Manual are beyond the scope of the Compliance Manual.

Issue: Audit Findings

Comments

One commenter suggested clarification on issuing a management decision for audit findings pertaining to subawards.

HRSA Response

The Demonstrating Compliance section describes that the health center awardee is responsible for monitoring the activities of subrecipients to ensure that subawards are used for authorized purposes and that subrecipients comply with all applicable requirements specified in the Federal award (including those found in section 330 of the PHS Act, implementing program regulations and grants regulations in 45 CFR Part 75). HRSA added a footnote to clarify that "per 45 CFR 75.521, the management decision [issued by the health center to the subrecipient] must clearly state whether or not the audit finding with respect to use of Federal funds is sustained, the reasons for the decision, and the expected auditee action to repay disallowed costs, make financial adjustments, or take other action."

Issue: Development of a Subrecipient and Contracting PIN

Comments

One commenter suggested developing a subrecipient and contracting PIN with significantly more detail to support compliance expectations and interpretations.

HRSA Response

HRSA declines this suggestion, as it intends for the Compliance Manual to serve as HRSA's primary resource for identifying applicable program requirements, including those outlined in this chapter, and for providing information as to how health centers would demonstrate compliance with these

requirements.

Related Considerations

Issue: Create Separation for Subaward versus Contract

Comments

Two commenters suggested creating separate sub-sections under Related Considerations to address contracts and subawards.

HRSA Response

HRSA declines to accept this suggestion since each of the Related Considerations bullets specifically identifies its applicability to either subrecipients or to contracts.

Chapter 13: Conflict of Interest

Issue: Citation Reference

Comments

One commenter stated that they were unable to find the language for 42 CFR 51c.113 and requested that HRSA provide the language. In addition, the commenter requested that HRSA add a reference to 45 CFR 75.112.

HRSA Response

HRSA confirmed that 42 CFR 51c.113 is accessible through the HRSA website. In addition, HRSA further reviewed 45 CFR 75.112 and noted that it is does not apply directly to health centers as written. Therefore, no changes were made to the citations in this chapter.

Issue: Ensure Provisions Apply to All Health Center Board Members

Comments

Twenty-one commenters asked HRSA to add the term “board member” to the Requirements and Demonstrating Compliance sections where “officer” is listed so that it is clear the conflict of interest provisions apply to all members of the board.

HRSA Response

HRSA has modified language throughout this chapter to clarify that the conflict of interest requirements apply to board members.

Issue: Conflict of Interest Challenges in Rural Areas

Comments

One commenter noted that the conflict of interest provisions surrounding board members overseeing contracts can sometimes create barriers for rural and frontier health centers securing contracts. For example, if a health center board member owns the only cleaning business in town and recuses himself from the selection of the award for such a contract, the commenter requested clarity regarding whether he would also be banned from managing the company seeking the contract.

HRSA Response

In cases such as the one described here, the affected health center board member(s) would be required to recuse himself only from participating in his capacity as a board member in the health center’s contracting decisions related to the entity with which the board member has a real or apparent conflict of interest. There would be no requirement that the board member cease operating a private company, nor would the company be restricted from competing for health center contracts as long as the health center (including the board member) acted in accordance with the health center’s procurement procedures and those procedures comply with applicable 45 CFR Part 75 requirements.

Issue: Clarity Requested Regarding a Health Center's Gift Policy

Comments

Two commenters asked for clarification on accepting or soliciting gifts from contractors and whether this is applicable to conferences with door prizes, gifts from vendor booths, or winnings from an auction. Another commenter asked to add the word "material" to the phrase "monetary value" when banning gifts from contractors and to let the health center define "material" in its gift acceptance policy. Eight commenters asked HRSA to allow health center officers, employees, or agents to accept unsolicited gifts from contractors if they are of nominal value (two specifically referenced the provision of lunches as an example). An additional three commenters asked for a definition or examples of nominal value. One commenter also noted differences between various sections of the Compliance Manual related to nominal value. One commenter requested clarification on the gift ban as in one place the chapter seems to ban all gifts from contractors and in another part of the chapter it says health centers may set standards for when a financial interest isn't substantial or a gift is of unsolicited nominal value. This commenter also suggested that the phrase "personal gain" be inserted in the Demonstrating Compliance section about soliciting and accepting things from contractors, which would allow the health center to fundraise from contractors. One commenter noted that allowing nominal value gifts conflicts with the fourth bullet in Related Considerations allowing the health center to set standards defining nominal value. One commenter also asked for clarity regarding discipline for any breaches.

HRSA Response

With respect to this set of comments, HRSA has clarified that, with reference to Health Center Program requirements, and to the extent not foreclosed by other agency or Federal requirements, health centers have flexibility to decide whether to establish standards that would allow employees to accept nominal value gifts, including what constitutes a nominal value gift. HRSA has also added a footnote within the Demonstrating Compliance section of this chapter to clarify that health centers are permitted an exception to the restriction against accepting anything of "monetary value" where the gift is of "nominal value." This exception is further described in the Related Considerations section of this chapter. Health centers may wish to consult private legal counsel regarding discipline or remedies for any breaches of conflict of interest standards. In addition, HRSA has added clarifying language to the Compliance Manual stating that gifts or fundraising donations to the health center from contractors are acceptable if consistent with health center policy, while gifts for "private financial gain" of persons associated with the health center are not.

Issue: Add Appearance of Conflict when Documenting Adherence

Comments

One commenter requested that language regarding the appearance of conflict be added to the Demonstrating Compliance section making it clear that a health center would document adherence to its conflict of interest standards in its procurement records in order to ensure that conflict policies have been applied regardless of whether an actual conflict was identified.

HRSA Response

HRSA has added specific language to the Compliance Manual clarifying that conflict of interest standards apply to both real and apparent conflicts of interest.

Issue: Flexibility in Reporting Conflicts

Comments

One commenter requested that HRSA allow health centers to determine when, how, and the frequency with which conflicts should be reported by health center employees, board members, and agents.

HRSA Response

HRSA has modified language in the Compliance Manual to clarify that health centers generally have flexibility regarding how they ensure that conflicts are reported by health center employees, board members, and agents.

Issue: Board Approval of Conflict of Interest Policy

Comments

One commenter requested clarification regarding whether the board has to approve the conflict of interest policy.

HRSA Response

HRSA notes that Chapter 19 of the Compliance Manual speaks to Board Authority, including the requirement for health center boards to establish and approve specific program policies related to conduct of the health center's operations, including those related to financial management and accounting systems and personnel. Such policies may include conflict of interest policies as they impact board members; however, health centers may choose to adopt standards of conduct, including conflict of interest provisions, in operating procedures that do not require board approval.

Issue: Replacing Program Requirement 19

Comments

One commenter asked if this chapter would replace Program Requirement 19 as it is currently described in the summary of 19 "Key Health Center Program Requirements."

HRSA Response

The 19 program requirements that appear on the website are the currently referenced summary of the Health Center Program statutory and regulatory requirements. The Compliance Manual, when issued in final, will replace this summary as the updated Health Center Program requirements.

Issue: Remove "Contractor" from the Definition of "Agent"

Comments

Six commenters asked HRSA to remove the word "contractor" from the definition of agent in a footnote of this chapter.

HRSA Response

HRSA has not adopted this request, as contractors may be agents of the health center in certain circumstances, and has clarified the relevant footnote that defines an "agent" to apply to those contractors who act on behalf of the health center.

Issue: Remove "Contractors" from the Footnote on Organizational Conflicts

Comments

Five commenters asked HRSA to remove the word "contractors" from the footnote addressing organizational conflicts of interest.

HRSA Response

HRSA has reviewed this footnote related to organizational conflicts and determined that contractors are not referenced in that footnote.

Issue: Written Disclosures of Conflicts of Interest

Comments

Seven commenters asked HRSA to require written disclosures of both actual and apparent conflicts of interest.

HRSA Response

HRSA has modified this chapter to clarify that the requirement for written disclosure of conflicts of interest applies to both real and apparent conflicts of interest.

Issue: Standards Apply when Federal Funds are Involved

Comments

Six commenters requested that HRSA clarify that written standards of conduct apply to the selection, award, or administration of contracts [procurement procedures] paid for in whole, or in part, with HHS grant funds. Four additional commenters asked that a clear statement be included stating that standards of conduct should reference the health center's procurement policies and procedures.

HRSA Response

HRSA has added language to the Compliance Manual clarifying that conflict of interest standards apply to the selection, award and administration of contracts that are paid for in whole or in part by the Federal Award. In addition, these standards are applicable to all health center employees, officers, board members and agents.

Chapter 14: Collaborative Relationships

Issue: Collaboration with Homeless and Social Service Organizations

Comments

One commenter suggested specifically including reference to the homelessness service system in addition to referencing social service organizations. Another commenter suggested including additional references to other organizations that address social determinants of health as providers or programs in the service area with which health centers should document their efforts to coordinate and integrate activities.

HRSA Response

HRSA recognizes that the Compliance Manual does not provide an exhaustive list of organizations with which health centers could collaborate, nor does HRSA intend to limit collaboration by the examples provided. Many organizations fall under the category of "social service agencies," and the examples listed are many of those most commonly connected to health centers' patient populations. However, as requested, HRSA added text to include organizations that serve special populations.

Issue: Definition of "Nearby" and "Service Area"

Comments

One commenter requested a definition of the terms "nearby" and "service area."

HRSA Response

The term "nearby" is not used in the Compliance Manual, while "service area" is included in the Glossary section of the Compliance Manual.

Issue: Linkage Agreements

Comments

One commenter questioned whether "collaborative relationships" are to be construed as "Linkage Agreements" to further extend the primary health care services offered by health centers.

HRSA Response
HRSA has modified language to clarify that this chapter's reference to collaborative relationships is not about the service delivery methods used for specific health center services. Rather, the focus of this chapter is on broader community collaboration and the role health centers play in community-wide efforts to support the patient population and address population health.

**Issue: Need for Clarity on Documentation*

Comments
Seventeen commenters requested clarification on HRSA's expectation regarding documentation of health centers' efforts to collaborate with other community providers and programs. Another commenter suggested that this section overlaps with Form 5A, Column III (Formal Written Referral Arrangements) and requested additional guidance regarding how collaboration should be documented by health centers, as opposed to services recorded on Form 5A: Services Provided. One additional commenter suggested inserting "key" to the following sentence: "The health center documents its [key] efforts to coordinate and integrate activities with other providers or programs in the service area…" explaining that with a multitude of collaborations and partnerships, focusing on the key efforts assures a more efficient focus of documentation efforts.

HRSA Response
HRSA acknowledges that the format and type of documentation of collaboration is determined by the health center and may vary by health center. HRSA will ask health centers to respond to specific questions and describe these collaborative efforts in future competitive funding/designation applications. HRSA also recognizes that health centers may provide some services through formal written referral arrangements, as documented on Form 5A; however, this chapter is intended to address collaboration for the purposes of access to care and services that are beyond what the health center would have documented on its Form 5A. With respect to the request for insertion of the term "key," HRSA believes that guidance has been provided as to how health centers would demonstrate compliance with this program requirement including documenting, "at a minimum," its establishment and maintenance of relationships with other health centers in the service area.

Issue: Letters of Support

Comments
Thirteen commenters suggested removing or qualifying the expectation that letters of support from providers serving similar patient populations in the service area address areas of coordination or collaboration, citing concerns that in highly competitive markets, it is not unusual for hospitals, health systems, integrated networks, or corporate organizations to be unwilling to partner or collaborate with health centers.

HRSA Response
HRSA has modified elements of the Demonstrating Compliance section in this chapter to clarify that health centers document their attempts to collaborate with providers serving similar populations when proposing to expand their scope of project. Additionally, HRSA has clarified that where a health center is unable to secure letters of support, the health center would document the process it used to attempt to collaborate with other providers.

Chapter 15: Financial Management and Accounting Systems

Issue: Results of Each Federal Award or Program

Comments

Two commenters requested clarification as to what constitutes "accurate, current, and complete disclosure of financial results" of "each" Federal award or program. Specifically, the commenters asked whether a health center that has a Health Center Program grant award and receives supplemental awards (for example, oral health, substance abuse) needs to categorize those supplemental awards separately, and whether it is required that this information is captured in "specific general ledger accounts" or whether a "subsidiary ledger," such as an Excel spreadsheet, may be used.

HRSA Response

As noted in the Compliance Manual, the health center would demonstrate compliance with this requirement by its ability to account for all Federal award(s) (including the Federal award made under the Health Center Program). If additional tracking is required, Supplemental Notices of Award would contain such terms or conditions. In addition, as noted in Related Considerations, the health center determines which accounting software and related systems to use for financial management.

Issue: Use of Non-Grant Funds

Comments

One commenter requested clarification of the phrase "must use" within the sentence "The health center must use any non-grant funds as permitted under section 330…" The commenter specifically requested clarification regarding the timeframe for using such funds and approved uses.

HRSA Response

A health center board may set policy defining parameters and timeframes for using such non-grant funds within the statutory text and may wish to consult accounting and/or financial professionals. HRSA interprets the statute to permit health centers flexibility in setting this policy so long as such uses further the objectives of the Health Center Program project and are not specifically prohibited.

Issue: Office of the Inspector General (OIG) Compliance Programs for Small Group Physician Practices

Comments

One commenter recommended addressing whether health centers should implement a corporate compliance program as outlined in *OIG Compliance Programs for Individual and Small Group Physician Practices* (65 Fed. Reg. 59434 (October 5, 2000)). The commenter requests that the Compliance Manual point to these regulations and state whether they apply to health centers. This comment applies to both Chapters 15 and 18.

HRSA Response

OIG Compliance Programs for Individual and Small Group Physician Practices provides voluntary guidance regarding corporate compliance programs. HRSA encourages health centers to consider implementing such a program, but does not require implementation of this guidance.

Issue: Board Role

Comments

One commenter recommended that the Compliance Manual state that the Board has authority for determining "accounting software, reports and responses to negative trends."

HRSA Response
The Related Considerations section of this chapter states that the health center has flexibility in determining whether the health center board or staff will be delegated this authority. Please also see clarification in a footnote in Chapter 19 regarding development of policies and procedures by the health center board and staff.

Issue: Excess Income

Comments
Two commenters requested clarification of the last Demonstrating Compliance bullet of this chapter that requires documentation of "any non-grant funds generated from health center activities in excess of what is necessary to support the HRSA-approved total health center project budget." Specifically, the commenters ask whether such excess income: 1) is defined differently than how it has been defined on the Notices of Award, which currently identify such excess income as an Unobligated Balance (UOB); 2) may be used for capital expansions; and 3) may be used for programs outside of scope, if such programs benefit the patient population. One commenter requested that if capital or out-of-scope programs cannot use such excess income, the Compliance Manual explicitly state that such uses are prohibited.
HRSA Response
Direction regarding how to report excess grant income on a grantee's Federal Financial Report and requesting carryover of heath centers' UOB is beyond the scope of the Compliance Manual. Grantees should consult with their Grants Management Specialist regarding such requests. As outlined in the Compliance Manual, health centers have flexibility with regard to use of non-grant funds as long as such uses further the objectives of the Health Center Program project and are not specifically prohibited. Non-grant funds in excess of what is necessary to support the HRSA-approved total Health Center Program project budget may be utilized to fund out-of-scope programs, as long as the use furthers the objective of the Health Center Program project by benefitting the current or proposed patient population and is not specifically prohibited.

Issue: Reporting Program Income

Comments
One commenter asked whether a health center's failure to report all of its program income relating to the health center grant would impact future HRSA funding decisions.
HRSA Response
The bases of HRSA funding decisions and any relation to reporting of program income are governed by 45 CFR Part 75 and provisions of the HHS Grants Policy Statement, as well as the applicable Notices of Funding Opportunity and terms and conditions of award. Therefore, determinations of the kind sought by this commenter are beyond the scope of this Compliance Manual.

Issue: PIN 2013-01

Comments
Nine commenters requested that HRSA explain which elements of PIN 2013-01: Health Center Budgeting and Accounting Requirements are not addressed in this Compliance Manual but will remain in effect once the Compliance Manual is finalized.
HRSA Response
HRSA has reviewed this PIN to ensure that all elements have been addressed in the Compliance Manual. HRSA has clarified that PIN 2013-01 will be superseded in its entirety by the Compliance Manual.

Issue: Include Citation to 45 CFR 75.302

Comments

Seven commenters requested that HRSA add a citation to 45 CFR 75.302 in the applicable Requirements, stating that this regulation is the key regulatory requirement for financial management systems under the grant management regulations.

HRSA Response

HRSA has updated the Compliance Manual language in this chapter to include a citation to 45 CFR 75.302.

Issue: Clarify the Intent of the Reference to 45 CFR 75.305

Comments

Eight commenters requested that HRSA revise the Requirements section of this chapter to reflect the language at 45 CFR 75.305(b)(1), regarding drawing down Federal funds, more specifically by stating either: (a) "Written procedures to minimize the time elapsing between the transfer of funds from the Department of Health and Human Services and disbursement by the non-Federal entity" or (b) "Policies and, as necessary, procedures to facilitate compliance with advance payment requirements set forth in 45 CFR 75.305."

HRSA Response

HRSA has updated the Compliance Manual to align with 45 CFR 75.305 to state, "Written procedures that minimize the time elapsing between the transfer of Federal award funds from HHS and the disbursement of these funds by the health center."

Issue: Federal Payment Management System

Comments

Two commenters requested more guidance regarding policy requirements related to the "Payment Management System."

HRSA Response

HRSA recognizes that the phrase "Federal Payment Management System" was unclear, and has removed this language, clarifying that this requirement is about procedures for drawing down Federal funds. More information regarding accessing Federal funds is available in 45 CFR 75.305.

Issue: Non-Grant Funds and Federal Cost Principles

Comments

Fourteen commenters requested that HRSA revise the Requirements section to make clear that expenditures of program income funds ("non-grant funds") by Federally-funded health centers are not subject to the Federal Cost Principles, as follows: *"The health center's financial management system must... provide for... Written procedures for assuring that expenditures of Federal funds are allowable in accordance with the terms and conditions of the Federal award and with the Federal Cost Principles."*

HRSA Response

HRSA has updated the Compliance Manual language to reflect that the Federal Cost Principles apply to "expenditures of Federal funds," and not to expenditure of non-grant funds.

Issue: Single Audit Act and Section 330(q)

Comments

Eleven commenters recommended that HRSA consult HHS before imposing the audit requirement on health centers that expend less than $750,000 of Federal award funding in a fiscal year.

HRSA Response
HRSA has removed the audit requirement for health centers expending less than $750,000 of Federal award funding in a fiscal year, as the Single Audit Act supersedes the Public Health Service Act audit requirements set forth in section 330(q).

Chapter 16: Billing and Collections

Issue: Fee Schedule Based on Locally Prevailing Rates

Comments
One commenter requested additional guidance regarding how to prepare a schedule of fees consistent with locally prevailing rates or charges.
HRSA Response
HRSA further reviewed Health Center Program statute and regulations for requirements in this area and concluded that health centers have flexibility in establishing their schedule of fees, specifically in how they determine consistency with locally prevailing rates or charges. Health centers may wish to consult with their private legal counsel or medical billing experts on any further considerations.

Issue: Application of the SFDP to Supplies and Equipment Including Prescription Drugs

Comments
Twelve commenters requested that HRSA delete prescription drugs from the list of examples of "supplies and equipment" and instead categorize them as part of required services, subject to sliding fee discount requirements. In contrast, two commenters supported maintaining prescription drugs as an example under "supplies and equipment" to ensure flexibility and greater financial benefit for health centers, which enables them to pass on these savings by serving additional patients. One commenter strongly supported HRSA's related consideration element providing health center discretion in electing to decide how to charge its patients for supplies and equipment.
HRSA Response
HRSA considered the views expressed by these commenters and maintains its policy, outlined in PIN 2014-02: Sliding Fee Discount and Related Billing and Collections Program Requirements (superseded by the Compliance Manual), that supplies and equipment (including prescription drugs) that are related to, but not included in the service itself as part of prevailing standards of care, are not services that are subject to Health Center Program sliding fee discount program requirements. However, if a health center elects to provide supplies and equipment and to charge patients for them, the health center would demonstrate compliance with the requirements of this chapter by informing patients of any charges prior to the time of service. As HRSA believes that providing such supplies and equipment greatly benefits a health center's patients, HRSA has elected to maintain flexibility for health centers in determining whether and how to make these items accessible to their patients.

Issue: Clarify and Provide Additional Examples of Supplies and Equipment

Comments
Five commenters suggested that HRSA provide additional examples of supplies and equipment. Four commenters asked if all "dental reference lab costs," pharmaceuticals, medications, vaccines, and eyeglasses fall into the supplies and equipment category. One of these commenters requested clarification as to what the statement "related to but not included in the service itself as part of the prevailing standards of care" means. Another commenter requested that, if some or all of the cost of the supplies and equipment are to be passed on to the patient, HRSA require that the health center inform patients of the cost of the service (including whether multiple visits are involved in provision of the

service) as distinct from the cost of the supplies and equipment. Six commenters suggested adding language to this chapter indicating that different discounting rules apply to "Supplies and Equipment" than to services. One commenter suggested including additional detail from PIN 2014-02 related to gathering information on locally prevailing charges and reasonable costs.

HRSA Response

HRSA reviewed this chapter of the Compliance Manual and believes it includes as examples the most common supplies and equipment items. Supplies or equipment that are related to, but not included in the service itself as part of prevailing standards of care, include items such as eyeglasses, prescription drugs, and dentures, which differ from supplies and equipment that are included in a service as part of prevailing standards of care and are reflected in the fee schedule, such as casting materials and bandages. HRSA also added a new Related Consideration to clarify that the health center has discretion in determining how to consider both locally prevailing charges and actual costs for services when setting its fee schedule, as well as the data used to determine locally prevailing charges. HRSA declines to revise the Compliance Manual to limit the flexibility afforded to health centers regarding how they inform patients of the cost of a service as distinct from the cost of supplies and equipment, as discussed in this chapter.

Issue: Require SFDS for Labs, Vaccines, and X-rays

Comments

One commenter requested clarification as to whether laboratory testing, vaccines, and x-rays must be included on the SFDS.

HRSA Response

Health centers must provide the required services described in statute and regulations which include, but are not limited to diagnostic laboratory, diagnostic radiology and immunizations. In addition, a health center sliding fee discount program must apply to all required and additional services within the HRSA-approved scope of project for which there are a distinct set of fees. For further information on how health centers record services as part of the scope of project, refer to the Form 5A Service Descriptors at: https://bphc.hrsa.gov/programrequirements/scope/form5aservicedescriptors.pdf.

Issue: SFDS Supply Costs and Dentures

Comments

One commenter requested clarification regarding which supply costs, such as dentures, may be passed through to patients at or below 100 percent FPG or to patients at various levels of the SFDS above 100 percent and up to 200 percent FPG. Another commenter requested clarification regarding the applicability of SFDS to Form 5A services that typically include non-service costs [supplies/equipment].

HRSA Response

If a health center elects to provide its patients access to supplies or equipment (for example dentures) that are related to, but not included in, the service itself as part of prevailing standards of care, the health center determines how to charge its patients for such supplies and equipment (for example, flat discounts, at cost, sliding fee discounts). Health centers are required to have a sliding fee discount program that applies to all required and additional services within the HRSA-approved scope of project (as reflected on Form 5A) for which there are a distinct set of fees, including services that typically include non-service costs as part of prevailing standards of care. For more information, see the footnote related to this topic in the Demonstrating Compliance section of this chapter.

Issue: Charges Reflect Care Provided

Comments

One commenter requested that HRSA add language to assure that a health center's charges accurately reflect the care provided, that the care was appropriate for the patient's presenting condition, and that health centers monitor and audit documentation to compare it to the billed charge.

HRSA Response

HRSA declines to add language beyond what is in the Demonstrating Compliance section of this chapter, including the request to add a requirement that health centers monitor and audit documentation. Specifically, health centers are required to have a fee schedule for services that are within the HRSA-approved scope of project and that are typically billed for in the local health care market. They must also have billing records or other forms of documentation reflecting that the health center charges patients for health center services provided in accordance with its fee schedule and, if applicable, the sliding fee discount schedule, and that they make reasonable efforts to collect such amounts owed from patients. For further information with respect to assuring that health center services are provided consistent with prevailing standards of care, please see Chapter 10: Quality Improvement/Assurance.

Issue: Differentiating between Refusal to Pay and Inability to Pay Policy

Comments

Two commenters suggested HRSA provide a definition for both refusal to pay and inability to pay to ensure consistency and clarity regarding health center policies addressing these topics. One commenter suggested explicitly stating what considerations and changes should be made to the health center's collections policy to address the topics of refusal to pay and inability to pay.

HRSA Response

Health centers are required to make and continue to make every reasonable effort to secure from patients payment for services in accordance with the fee schedule and corresponding schedule of discounts. See Chapter 9: Sliding Fee Discount Program for detailed information regarding determining a patient's ability to pay. In the Demonstrating Compliance section of Chapter 16, HRSA expanded language describing how compliance would be demonstrated in cases where a health center elects to limit or deny services based on a patient's refusal to pay. In such cases, health centers have discretion in defining the term "refusal to pay" in the context of billing and collections. In these instances, the health center would have a board-approved policy that defines refusal to pay as well as a process for making reasonable efforts to collect prior to limiting or denying services. HRSA has provided additional clarity within the Related Considerations section by stating that when a health center has such a policy, the health center may also determine how and when patients may be permitted to rejoin the practice.

Issue: Timely Billing and Collections

Comments

One commenter requested that HRSA explicitly state whether verbal requests for payment at the time of a subsequent visit are sufficient to be considered in compliance with timely follow-up. Another commenter noted a difference between reasonable effort and efficiency in billing and collection and asked if billing efficiency is performance improvement.

HRSA Response

The only reference in this chapter to having billing records that show that claims are submitted in a timely manner is in reference to third party payor sources with which the health center participates. Specifically, the Compliance Manual addresses under the Demonstrating Compliance section of this chapter that health centers would demonstrate compliance by having billing records that show claims are submitted in a timely and accurate manner to third party payor sources with which it participates. In

addition, with respect to charging patients, the Compliance Manual states that the health center has billing records or other forms of documentation that reflect that the health center charges patients in accordance with its fee schedule and, if applicable, the sliding fee discount schedule and makes reasonable efforts to collect such amounts owed from patients. Verbal requests for payment from patients would need to be documented in the billing record.

Issue: Utilizing Cash/Prompt Pay Incentives and Factors to Implement these Incentives

Comments

Ten commenters suggested providing a reference to cash payment incentives, or prompt pay arrangements, as well as guidance to health centers considering these practices regarding factors to consider when implementing such incentives. Another commenter made the suggestion that prompt pay discounts would be considered reasonable as long as the discount approximates the estimated cost of collection.

HRSA Response

HRSA has clarified within the Demonstrating Compliance section of this chapter that in cases where a health center elects to offer additional billing options or payment methods, such as payment plans, grace periods, or prompt or cash payment incentives, the health center would demonstrate compliance by having operating procedures for implementing these options and for ensuring they are accessible to all patients regardless of income level or sliding fee discount pay class.

Issue: Perceived Best Practice for Bad Debt

Comments

One commenter suggested that if a board does not want to engage a collection agency, there should be a formula whereby grant funds are reduced by the amount of "bad debt" a health center writes off.

HRSA Response

This comment is beyond the scope of the Compliance Manual.

Issue: Migrant Voucher Programs and Billing

Comments

One commenter requested that HRSA include language in the Related Considerations section of this chapter that addresses migrant voucher programs where services are often not provided directly and therefore the health center does not bill third party insurers.

HRSA Response

In cases where health centers utilize contractual arrangements to deliver services, as is the case with health centers that utilize vouchers for care for migratory agricultural workers, such health centers must provide proper oversight over these contracts, the requirements for which are laid out in Chapter 12: Contracts and Subawards. These oversight requirements include ensuring that the billing and collections requirements set forth in this chapter are met.

Issue: Billing Responsibility for Contracts/Agreements

Comments

Seven commenters requested clarification as to whether the health center is generally responsible for billing for services provided by a third party via a formal contract/agreement (Form 5A, Column II), subject to limitations in law. In addition, three commenters recommended adding a statement recognizing the health center as the billing entity, and stating that billing of and collections from third party payors and patients must be conducted consistent with the health center's applicable policies and procedures (which would include the health center's SFDP policies and procedures).

HRSA Response
HRSA has clarified in the Demonstrating Compliance section of this chapter that a health center would demonstrate compliance by having billing records that show claims were submitted in a timely and accurate manner to the third party payor sources with which it participates or from which it receives reimbursement (Medicaid, CHIP, Medicare, and other public and private insurance) for the purposes of collecting reimbursement for its costs in providing health services consistent with the terms of such contracts and other arrangements. The health center is responsible for ensuring that such billing records include services provided through a formal written contract/agreement (Form 5A, Column II), subject to limitations in law, as well as services provided directly (Form 5A Column I). In addition, the Demonstrating Compliance section states that such billing records or other documentation reflect the application of the health center's SFDP policies and procedures.

Chapter 17: Budget

Issue: Request to Supersede PIN 2013-01: Health Center Budgeting and Accounting Requirements

Comments
One commenter suggested superseding the Budget and Accounting PIN or clearly indicating which areas of this chapter are supplemented by information included within the PIN.
HRSA Response
HRSA concurs with this comment and has included this PIN in the list of PINs superseded by the Compliance Manual.

Issue: Clarification of Project Plan

Comments
One commenter requested clarification of the term "project plan" because it can be interpreted as a number of different documents.
HRSA Response
HRSA concurs with this comment and has removed the phrase "overall project plan" from this chapter to avoid potential confusion.

Issue: Federal Award Costs

Comments
One commenter suggested the language that "any proposed costs supported by the Federal award are consistent with the Federal Cost Principles" be used consistently throughout the Manual.
HRSA Response
HRSA accepts this comment and has included clarifying language to ensure consistent references to the Federal Cost Principles throughout the document.

Issue: Budget Submission Requirements

Comments
Two commenters suggested clarification that health centers with the same fiscal year and grant budget period are not required to submit a separate organizational budget from the HRSA grant application budget.

HRSA Response
The Compliance Manual articulates the requirements that health centers must develop and annually submit a budget that identifies the projected costs of the Health Center Program project to be submitted by a date specified by HRSA for approval through the Federal award or designation process. HRSA declines to make further edits in response to this comment. The Compliance draft Manual did not use the term "organizational" but instead used the term "operating" budget; HRSA has removed the word "operating" from this chapter to provide clarity.

Chapter 18: Program Monitoring and Data Reporting Systems

Issue: Measuring Health Center Performance

Comments
One commenter requested guidance on how a health center's performance will be measured. Specifically, the commenter requested clarification on how health centers will be measured against the requirements in the Compliance Manual, the Site Visit Guide, and/or the still-in-effect PINs.
HRSA Response
The purpose of the Compliance Manual is to clarify how health centers will demonstrate compliance with Health Center Program requirements, not to set forth specific performance measures. Accordingly, HRSA has included clarifying language in this chapter to reference to demonstrating compliance rather than assessing performance. As a primary tool for assessing compliance, the Site Visit Guide will be aligned with the Compliance Manual.

Issue: UDS Data Accuracy

Comments
One commenter noted that it seems new to require accurate reporting of UDS data.
HRSA Response
Health centers have always been required to submit accurate UDS data reports.

Chapter 19: Board Authority

Issue: Board's Role with Policies and Procedures

Comments
One commenter sought confirmation that the requirement in PIN 2002-22: Clarification of Bureau of Primary Health Care Credentialing and Privileging Policy Outlined in Policy Information Notice 2001-16 for the board to approve the credentialing/privileging of all LIPs or delegation of this responsibility to the CEO and/or CMO is missing from the Compliance Manual.
HRSA Response
PIN 2002-22 is superseded by the Compliance Manual as stated in the Introduction. As stated in Chapter 5: Clinical Staffing, the health center has flexibility to determine who has approval authority for credentialing and privileging of its clinical staff.

Comments
One commenter recommended that any areas where HRSA requires the board's involvement in determining how to comply with requirements be included within this chapter, as well as the chapter it most applies to.

HRSA Response
This chapter outlines the required authorities and responsibilities of the governing board, and the Demonstrating Compliance section describes areas where the board is required to approve health center policies. The Related Considerations section of this chapter discusses areas where the health center board has discretion regarding how to carry out its required responsibilities, functions and authorities.

Comments
Three commenters suggested maintaining a list of all the policies and operating procedures that are required to be Board-approved.
HRSA Response
The last two elements of the Demonstrating Compliance section in Chapter 19 list the specific areas where the health center board is responsible for adopting, evaluating, and as needed, approving policies. In addition, HRSA has added a footnote to this chapter indicating that the governing board of a health center is generally responsible for establishing and/or approving policies that govern health center operations, while the health center's staff is generally responsible for implementing and ensuring adherence to these policies through operating procedures.

Issue: Board Self-Assessment
Comments
One commenter suggested providing guidance on whether board self-assessments are required and the frequency of such assessments.
HRSA Response
The Health Center Program requirements do not include a requirement for board self-assessments, as these are within the discretion of the health center.

Issue: Quality-of-Care Audit Procedure Terminology
Comments
One commenter requested that the phrase "quality-of-care audit procedure" be either removed or replaced with a commonly understood clinical term.
HRSA Response
The phrase "quality-of-care audit procedure" reflects the existing Health Center Program regulatory language (see 42 CFR 51c.304d). The Demonstrating Compliance section of this chapter provides further details including the board's role in evaluating the performance of the health center based on quality assurance/quality improvement assessments.

Issue: Board-Approved Documents
Comments
Three commenters made suggestions related to board-approved documents: One commenter requested adding a footnote under every bullet stating either that it "must be motioned by the board" or that it "does not need motion by board"; one commenter requested not to require board approval of the organizational operating procedures; and one commenter supported the Compliance Manual's clarity requiring the board to approve credentialing/privileging, quality improvement, sliding fee, and billing and collection policies at least every 3 years.
HRSA Response
The Demonstrating Compliance section of this chapter outlines the health center policies that require health center board approval. HRSA provided additional clarification in a footnote, indicating that the

governing board of a health center is generally responsible for establishing, and/or approving policies governing health center operations, while the health center's staff is generally responsible for implementing and ensuring adherence to these policies through operating procedures. HRSA has not specified the means by which the board approval must be documented, as such process issues are within the discretion of the health center to decide.

Issue: Monthly Meeting

Comments

Three commenters responded to the monthly meeting requirement: One commenter suggested softening the wording surrounding the term "monthly" in regards to meeting frequency (e.g., a Board that meets in early and late July but not in August would not be out of compliance). One commenter requested HRSA explicitly state whether the board can choose to schedule an "off" month due to vacations. One commenter asked if a monthly meeting would meet the monthly meeting requirement if it were held without a quorum.

HRSA Response

Since the monthly meeting requirement is explicit in both statute and regulation, HRSA did not alter the Requirements section of this Chapter. HRSA further clarified in the Demonstrating Compliance section that the health center's board minutes and other relevant documentation confirm that the board exercises, without restriction, the authority to hold monthly meetings where a quorum is present to ensure the board has the ability to exercise its required authorities and functions.

Issue: Public Entities and PIN 2014-01: Health Center Program Governance

Comments

Fourteen commenters recommended maintaining the guidance on the public entity model by incorporating Section IV of PIN 2014-01 into this Chapter, or otherwise not rescinding the PIN. Two commenters sought clarification on the requirement of public entities to establish co-applicant agreements (as opposed to using bylaws); and one commenter suggested including a footnote to specify which policies the public agency may adopt/approve. One commenter requested clarification that the language in the draft Compliance Manual replaces the detailed wording in PIN 2014-01. One commenter requested clarification if the items required in bylaws in PIN 2014-01 but not included in the draft Compliance Manual are no longer required, or whether this exclusion was an oversight.

HRSA Response

HRSA clarified in the Demonstrating Compliance section, as well as through the addition of a footnote in the same section, that public center governance may be structured in one of two ways – either through a direct arrangement or through a co-applicant arrangement. As the purpose of the Demonstrating Compliance section of each chapter of the Compliance Manual is to describe how health centers would demonstrate compliance to HRSA with respect to program requirements, other guidance on the public entity model would be considered technical assistance in nature.

Issue: Committees

Comments

One commenter asked whether a health center would be non-compliant if its bylaws call for standing committees but they are not active.

HRSA Response
As indicated in Related Considerations, it is up to the health center board to determine whether to establish standing committees. As such, the establishment of standing committees is not considered as part of HRSA's assessment of demonstrating compliance with Health Center Program requirements.

Issue: Bylaws

Comments
Eight commenters requested clarification that bylaws are written operating rules for the board, not the health center. Six commenters requested that if HRSA continues to have expectations of the required provisions of the bylaws beyond the regulatory authorities, that they be stated explicitly in chapter 19.
HRSA Response
HRSA has revised the corresponding Requirements element to clarify that the bylaws address the responsibilities of the board. HRSA will assess compliance with the Health Center Program requirements based on the Demonstrating Compliance elements outlined in this section of the Compliance Manual.

Issue: Capital Expenditure Plans

Comments
Eight commenters suggested that acknowledgement that not all health centers have capital expenditure plans would be helpful.
HRSA Response
HRSA revised the Demonstrating Compliance element to more accurately reflect the board authority and function in conducting long-range/strategic planning, which, at a minimum, addresses financial management and capital expenditure needs, as opposed to capital expenditure plans.

Issue: Financial and Personnel Operating Procedures

Comments
Six commenters suggested explicitly recognizing that while boards are responsible for approving financial management and personnel policies, they are not required or expected to approve operating procedures. Two of these commenters suggested removing the link to Chapter 15 within this chapter.
HRSA Response
HRSA has clarified that the health center board is responsible for adopting, evaluating, and, as needed, approving updates to policies for financial management, accounting systems, and personnel policies. Since operating procedures do not require board approval, HRSA has added a clarifying footnote to the Demonstrating Compliance section to underscore this distinction. HRSA also removed the hyperlink to Chapter 15, per the commenter's suggestions, for further clarification.

Issue: Approving Contracts and Sub-awards

Comments
Eight commenters requested clarification that while the board is required to approve the decision to enter into a contract or sub-award for a substantial portion of the health center's services, it is not required to approve the actual agreement.
HRSA Response
HRSA agrees and has clarified the language in the Demonstrating Compliance element to reflect that the board exercises the authority to approve decisions to subaward or contract for a substantial portion of the health center's services, rather than approves the actual agreement.

Issue: Approval of the Budget

Comments

Six commenters requested a resolution of the inconsistency between the Requirements section (referencing approval of the "Health Center Program project budget") and the Demonstrating Compliance section (referencing approval of the "health center's annual budget"). One commenter recommended revising the reference to the "health center's annual budget" to mirror the regulatory language indicating the board is responsible for approving the "annual Health Center Program project budget."

HRSA Response

HRSA has updated the language in the Demonstrating Compliance section to clarify that board approval only applies to the Health Center Program project budget, as opposed to the health center's annual operating budget.

Issue: Evaluation of the CEO

Comments

Ten commenters suggested including a clarification as to whether the board will continue to be required to evaluate the performance of the Project Director/CEO, and if so, how frequently. One additional commenter asked that public entities with established personnel policies and procedures may retain the evaluation of the CEO with board approval and/or will work with the board in the matter of hiring, evaluation, and dismissal of the CEO.

HRSA Response

HRSA has added a Related Consideration element in response to these comments to clarify that the health center board has discretion in determining how often the Project Director/CEO's performance is evaluated. In cases where the Project Director/CEO is a public employee, evaluation of the Project Director/CEO is subject to the public entity's established general personnel policies, including those addressing selection and dismissal procedures. However, as outlined in Demonstrating Compliance section, HRSA will review documentation that the board exercises its authority in approving the selection of, evaluating and, if necessary, approving the dismissal or termination of the Project Director/CEO from serving as the health center Project Director/CEO.

Issue: Application of Requirements to Special Populations-Only

Comments

Seven commenters requested clarification if and how governance requirements set forth solely in regulations apply to grantees who receive only section 330(h) and/or section 330(i) funds.

HRSA Response

The Compliance Manual does not amend or update Health Center Program regulations. The purpose of the Compliance Manual is to assist health centers in understanding how they would demonstrate compliance with Health Center Program requirements found in section 330 of the Public Health Service Act (42 U.S.C. 254b) and implementing regulations as well as in certain applicable grants regulations. As described in the Introduction and in Chapter 2: Health Center Program Oversight of the Compliance Manual, when a health center (including those who receive only section 330 (h) and/or (i) funding or designation) formally responds to a HRSA assessment that the health center has not demonstrated compliance, the health center may provide explanatory information and documentation that demonstrates compliance with specified requirements in the manner prescribed by the Compliance Manual or via an alternative means for HRSA review and approval.

Issue: Executive Committee

Comments

Twelve commenters requested that the Compliance Manual clarify that the health center board's executive committee may act independently of the full board in time-sensitive situations provided that it acts in a manner consistent with board priorities and bylaws.

HRSA Response

In response to requests for clarity regarding the executive committee's ability to act apart from the full board, HRSA added a footnote to reflect that the executive committee is not precluded from taking action on behalf of the board in time-sensitive scenarios, such as emergencies.

Chapter 20: Board Composition

Issue: Representing Patient Demographics on Board

Comments

One commenter recommended that the Compliance Manual require that all Board members, not just patient members, "reasonably represent the individuals who are served by the health center in terms of demographic factors, such as race, ethnicity, and gender." Another commenter requested that in the Demonstrating Compliance section of this chapter, the word "reasonably" be added before the word "representative," and that the phrase "in terms of demographic factors" be replaced with "reasonably represent the individuals who are served by the health center in terms of race, ethnicity, and sex."

HRSA Response

HRSA notes that the Compliance Manual's language is taken directly from Health Center Program regulations (see 42 CFR 51c.304b) and cannot be altered through the Compliance Manual. However, HRSA clarified in the Related Considerations section of this chapter that health centers have discretion to take additional demographic factors into consideration relative to non-patient board members.

Issue: Define Health Care Industry

Comments

Two commenters requested that the Compliance Manual define and provide criteria for "health care industry." One commenter asked whether this restriction applies only to individuals directly employed by health care delivery organizations or whether it extends to consultants, health insurance carriers, equipment manufacturers, social service agencies, or alternative care providers.

HRSA Response

HRSA has added language to the Related Considerations section of this chapter to further clarify health centers have discretion in how they define "income derived from the health care industry" with respect to board composition.

Issue: Waiver for "Health Care Industry" Limitation for Migrant Voucher Programs

Comments

One commenter requested that the Compliance Manual allow for a waiver of or exception to the limit on Board members who receive 10 percent or more income from the health care industry for Migrant Voucher Programs, including those managed by a PCA. Specifically, the commenter requested a waiver for this composition requirement as long as a majority of the Board is comprised of health center CEOs or staff.

HRSA Response

Health Center Program regulations provide flexibility for migrant health centers, the specifics of which are laid out in a footnote in the Requirements section of this chapter. To summarize, the regulatory

flexibility afforded to migrant health centers is that two-thirds of non-patient board members may have 10 percent or more income derived from the health care industry.

Issue: Ex-Officio

Comments

One commenter requested that the Compliance Manual language add "CEO" to the points about ex-officio board members, as it currently only says "Project Director." Another commenter suggested incorporating a clear explanation for the term ex-officio board member beyond being a non-voting member.

HRSA Response

HRSA has added the term "CEO" to the Compliance Manual language, as requested. In addition, language was added to the Related Considerations section of this chapter to clarify that health centers may appoint other ex-officio board members and may define parameters for such positions beyond being non-voting, subject to state law, as reflected in the Related Considerations section of this chapter.

Issue: Appointing Co-Applicant Board Members

Comments

One commenter recommended extending to public centers with co-applicant boards the restriction on allowing an "other entity, committee, or individual (other than the board) to select either the board chair or a majority of board members." The commenter states that public agencies sometimes attempt to retain control over the appointment of co-applicant board members, which in practice takes away real authority from the board and transforms the board into an advisory board, rather than a governing board.

HRSA Response

The Health Center Program statute and regulations allow for a public entity together with its co-applicant board, as a public center, to meet Health Center Program requirements. Therefore, the public agency in this arrangement is not considered an "other entity," and the restrictions associated with the selection of the majority of board members would not apply. For additional information, please also see the footnote in the Requirements section of this chapter.

Issue: Public Housing Special Population Representative

Comments

One commenter recommended that the Compliance Manual explicitly state that for the purposes of health centers that receive grant funding to serve section 330(i) patients, a special population representative may include recipients of publicly funded housing vouchers, since publicly funded housing vouchers have replaced public housing projects in some parts of the country.

HRSA Response

HRSA declines to make the requested change to the Compliance Manual, as the Health Center Program statute defines the special population eligible to be served under section 330(i) to exclude any individuals living in housing units that receive only Section 8 housing vouchers and no other public housing agency assistance. For additional information, please note that a footnote in the Demonstrating Compliance section of this chapter clarifies that a special population representative for a health center funded or designated to serve both section 330(i) and section 330(e) patients may include advocates for the special population or individuals who formerly met the definitions associated with section 330(i).

Issue: Former Contractors

Comments

One commenter recommended adding the word "current" before contractors to prevent precluding former auditors or other former contractors from serving on a board.

HRSA Response

HRSA has removed reference to contractors from this section of the Compliance Manual.

Issue: Application of Requirements to Special Populations-Only

Comments

Six commenters requested that HRSA clarify if its position has changed regarding whether the regulatory-only requirements apply to health centers that receive only Health Care for the Homeless [section 330(h)] funds and/or Public Housing Primary Care [section 330(i)] funds.

HRSA Response

The Compliance Manual does not amend or update Health Center Program regulations. The purpose of the Compliance Manual is to assist health centers in understanding how they would demonstrate compliance with Health Center Program requirements found in section 330 of the Public Health Service Act (42 U.S.C. 254b) and implementing regulations as well as in certain applicable grants regulations. As described in the Introduction and in Chapter 2 Health Center Program Oversight of the Compliance Manual, when a health center (including those who receive only section 330 (h) and/or (i) funding or designation) formally responds to a HRSA assessment that the health center has not demonstrated compliance, the health center may provide explanatory information and documentation that demonstrates compliance with specified requirements in the manner prescribed by the Compliance Manual or via an alternative means for HRSA review and approval.

Issue: Patient Board Member Eligibility

Comments

Eleven commenters requested that HRSA not require patient Board members to receive an in-scope service at a site that is approved under the HRSA Scope of Project (within the past 24 months). Rather, it was suggested that HRSA use the language from PIN 2014-01: Health Center Program Governance requiring only that such individuals receive at least one in-scope service that generated a health center visit.

HRSA Response

HRSA has reviewed this request and has not removed this language from the Compliance Manual, as the primary role of patient board member representatives is to bring to the board their expertise and experience as patients of the health center. Therefore, HRSA determined the benefit of ensuring these individuals have this level of patient experience outweighs the potential burden of this requirement.

Comments

One commenter recommended adding to the Compliance Manual the following language from PIN 2014-01: "A legal guardian of a patient who is a dependent child or adult, or a legal sponsor of an immigrant, may also be considered a patient for purposes of board representation." Another commenter specifically requested clarification as to whether a board member, who is not a patient, but a family member of a patient, is considered a patient board member for the purposes of the patient majority requirement.

HRSA Response

A footnote in the Demonstrating Compliance section of this chapter includes the language from PIN 2014-01 recognizing legal guardians as patients for purposes of board representation. However, family

members of a patient who are not themselves a patient of the health center and who also do not have legal authority to make health care decisions for their family member are not eligible to serve as patient board members for the purposes of the patient majority requirement.

Issue: Independent versus Individual Contractors and Board Membership

Comments

Eight commenters requested that HRSA delete "Individual Contractors" from the list of individuals precluded from serving on the health center board. At a minimum, HRSA should clarify that the prohibition extends to "Independent Contractors" who comprise part of the health center's core "staff," but not to "Individual Contractors."

HRSA Response

HRSA has removed reference to "contractors" in this section of the Compliance Manual. In addition, HRSA added a footnote clarifying the term "employee" for the purposes of board composition.

Issue: Quorum

Comments

Ten commenters stated that HRSA lacks legal authority to require a 51 percent quorum, and requested that HRSA strike the quorum requirement in its entirety from this section. One commenter supported the quorum requirement as written based on its connection to the requirement that a health center has a patient majority board. Further, the commenter stated that the current Compliance Manual language is clear that state law may dictate the quorum requirement in the event that a conflict exists.

HRSA Response

HRSA reviewed this requirement based on comments provided and decided to remove the 51 percent quorum requirement from the Demonstrating Compliance section of this chapter. Instead, language has been added to the Related Considerations section of Chapter 19: Board Authority clarifying that health centers have flexibility in setting quorum requirements.

Issue: Patient Majority Waiver for Unsuccessful Attempts to Recruit

Comments

Fourteen commenters requested that HRSA include a standard for health centers receiving special population funding under sections F(g), (h), or (i) to measure and document "attempts" to recruit a patient-majority board to objectively determine whether the attempts were unsuccessful. The commenters requested that, if HRSA declines to provide such a standard, it move this requirement to "Related Considerations." The commenters further requested that if HRSA provides the aforementioned standard, it clarify that health centers must demonstrate either "undue hardship" or unsuccessful attempts in recruiting the patient-majority board, rather than both. One commenter expressed support for the 51 percent patient majority board requirement, stating that adequate representation on their health center's board has given them invaluable insight to make more informed decisions.

HRSA Response

HRSA clarified in the Demonstrating Compliance section of this chapter that a health center receiving Health Center Program funding or designation only for special populations (i.e., sections 330(g), (h), and/or (i)) would demonstrate compliance by documenting attempts to recruit a patient majority board within the last three years. HRSA reviewed the request to change "and" to "or" and is declining to change this language as demonstrating unsuccessful attempts at recruiting a patient majority board alone, absent unique characteristics of the patient population that create an undue hardship for recruiting a patient majority board, would be insufficient to justify a waiver of this requirement.

Chapter 21: FTCA Deeming Requirements

Issue: Link to FSHCAA

Comments

One commenter requested that the Compliance Manual spell out FSHCAA (The Federally Supported Health Centers Assistance Act of 1992) and link to the statute.

HRSA Response

HRSA has replaced previous references to the Federally Supported Health Centers Assistance Act of 1992 (FSHCAA) with references to section 224 (g) – (n) and (q) of the Public Health Service (PHS) Act, as applicable. HRSA has provided a direct link within the Compliance Manual to section 224 of the PHS Act.

Issue: Purpose of FTCA Chapter

Comments

One commenter requested clarification as to the purpose of this chapter, and specifically why the Compliance Manual does not just refer readers to the FTCA Health Center Policy Manual. Another commenter recommended that this chapter be modified to serve only as a reference to the FTCA Health Center Policy Manual.

HRSA Response

This chapter of the Compliance Manual describes how a health center demonstrates compliance for the purposes of receiving FTCA deeming. The FTCA Health Center Policy Manual does not address requirements related to assessment of compliance with deeming requirements; rather, it focuses primarily on how FTCA relates to covered entities, individuals, and situations. HRSA intends to review the FTCA Health Center Policy Manual with a view to removing possible redundancies.

Comments

One commenter requested clarification as to whether assessment of compliance with FTCA requirements will now be part of the Health Center Program compliance assessments.

HRSA Response

HRSA is required by law to make annual FTCA deeming determinations based on the entity's demonstrated actions, as set forth in its annual deeming application, in implementing risk management/quality improvement policies and procedures, reviewing and verifying professional credentials, and meeting other qualifications established by law. Health Center Program compliance assessments will continue to occur at the time of Service Area Competition/Renewal of Designation application reviews and operational sites visits. Requirements unique to FTCA will continue to be addressed through FTCA deeming processes.

Issue: Relationship to FTCA Health Center Policy Manual Requirements

Comments

Four commenters expressed concern that this chapter does not align with the requirements of the FTCA Health Center Policy Manual in one or more ways. One commenter stated that the Compliance Manual does not include the totality of the FTCA Health Center Policy Manual, and requested clarification of the status of credentialing and privileging standards. One commenter requested clarification as to how deeming application requirements will be aligned with this chapter.

HRSA Response

The information required to be submitted by health centers in their FTCA deeming applications will be aligned with the Compliance Manual's Chapter 5: Clinical Staffing, Chapter 10: Quality Improvement/Assurance, and Chapter 21: FTCA Deeming Requirements. The FTCA Health Center Policy

Manual will remain in effect, but undergo review to eliminate potential redundancies and references to superseded PINs and will be updated in light of the issuance of the Compliance Manual.

Comments

One commenter expressed concern that the draft Compliance Manual does not include the requirements for tracking referrals, diagnostic services and hospital services, as required by the FTCA Health Center Policy Manual. The commenter further requests that Chapters 5 and 10 specify the documentation necessary to meet these requirements. For example, PIN 2002-22 includes requirements for credentialing Other Licensed or Certified Practitioners (OLCPs) that are not included in Chapter 5 and that are included in the FTCA Health Center Policy Manual. Additionally, Chapter 10 does not provide detailed information regarding what QI/QA documentation is needed on the health center's efforts to improve patient care, nor does it specify what QI/QA reporting goes to the Board in order for the Board to exercise its authority and oversight of patient care and services.

HRSA Response

HRSA did not find the specific language in the FTCA Health Center Policy Manual as referenced by the commenter. However, HRSA has added language to this chapter under the Risk Management heading that specifically addresses how health centers would demonstrate compliance by having operating procedures that address the identification and mitigation of risk including those associated with tracking referrals, diagnostic services and hospital admissions ordered by health center providers. In addition, HRSA added language to Chapter 5: Clinical Staffing to address the credentialing of OLCPs. Chapter 10: Quality Assurance/Improvement has been edited to provide greater clarity around conducting, documenting and reporting of quality assurance/improvement activities.

Issue: Define "Professional Review Organization Findings"

Comments

One commenter requested that the Compliance Manual define the phrase "professional review organization findings" included in the Requirements section of this chapter.

HRSA Response

HRSA interpreted this phrase to refer to findings related to credentialing and privileging requirements in Chapter 5: Clinical Staffing. Various types of organizations, including but not limited to professional review organizations, may provide information, including negative findings pertaining to individual health care practitioners. The NPDB also serves as a resource for accessing such information. For more information, see Chapter 5: Clinical Staffing for how health centers would demonstrate compliance with credentialing and privileging requirements including querying the NPDB.

Issue: Risk Management Assessment and Training

Comments

Two commenters requested more guidance and detail regarding how a health center will document "quarterly risk management assessments."

HRSA Response

While the Compliance Manual states that a health center demonstrates compliance by having a policy requiring "quarterly risk management assessments," HRSA declines to add specificity regarding documentation in this area and instead has added language to the Related Considerations section of this chapter to clarify that health centers have flexibility in determining how to document these quarterly risk management assessments.

Comments

One commenter requested more guidance and detail regarding how a health center will meet the

requirement for risk management training, while another commenter supported the Compliance Manual language that allows health centers flexibility in determining which trainings to require and how to obtain such training.

HRSA Response

HRSA declines to add more detail regarding demonstrating compliance with risk management training. As stated in the Related Considerations section of this chapter, the health center has flexibility to determine what type of risk management training to require for covered individuals and how to obtain this training.

Issue: Annual Reporting to the Board

Comments

One commenter recommended clarifying language in the Risk Management section of Demonstrating Compliance from "Annual reporting to the board of" to "Annual reporting to the *Health Center Board of Directors, which includes…*."

HRSA Response

HRSA edited the language in this section of the chapter in response to this comment.

Issue: Informing Patients Using Plain Language

Comments

One commenter requested clarification as to the documentation a health center would provide to demonstrate compliance with the requirement to inform patients of the health center's FTCA coverage. Another commenter asked whether HRSA recommends that, when meeting the Compliance Manual requirement to "inform patients using plain language that [the health center] is a deemed Federal Public Health Service employee," health centers use the sample wording provided in the footnote of the Demonstrating Compliance section of this chapter.

HRSA Response

HRSA provided in the Demonstrating Compliance section of this chapter several examples of how a health center would demonstrate its compliance with this requirement, including the presence of plain language on its website, promotional materials, and/or within an area of the health center visible to patients. The footnote language in the Demonstrating Compliance section of this chapter provides an example of language that could be used. HRSA also added a Related Consideration describing that each health center has flexibility to determine how to inform patients of its deeming status, with the exception of health centers using volunteer health professionals who must comply with section 224(q) of the PHS Act. Health centers may wish to consult their private legal counsel if they have additional questions or concerns regarding providing notice to patients of FTCA deemed status.

Issue: Delete FTCA Chapter from Compliance Manual or Consolidate FTCA and Section 330 Requirements

Comments

Thirteen commenters requested HRSA limit the Compliance Manual to section 330 requirements and make reference to other health center related program policy documents (for example, FTCA, 340B, NHSC, FQHC) where necessary. The commenters also recommended including the term "section 330" in the title of the Compliance Manual (in place of or in addition to "Health Center Program") to emphasize to readers that this Compliance Manual applies only to that program. In contrast, nine commenters requested that HRSA establish a single consolidated set of requirements and expectations for credentialing and privileging, quality improvement/assurance and risk management that apply to both the health center and FTCA programs. These commenters also requested that HRSA reference these standards in both the Compliance Manual and the FTCA Health Center Policy Manual.

HRSA Response
The Compliance Manual lays out a single set of requirements and ways for health centers to demonstrate compliance with requirements for credentialing and privileging (Chapter 5: Clinical Staffing) and quality improvement/assurance (Chapter 10: Quality Improvement/Assurance) that apply to both the Health Center Program and FTCA deeming. In addition, Chapter 21: FTCA Deeming Requirements describes the FTCA-specific deeming requirements under Risk Management and Claims Management. The Compliance Manual will serve as the resource for assessing compliance with these requirements. In contrast, the FTCA Health Center Policy Manual does not address requirements related to assessment of compliance with deeming requirements, but rather focuses primarily on how FTCA relates to covered entities, individuals, and situations.

Issue: Clarify in Future FTCA Deeming Applications that Only Compliance Manual Requirements Apply

Comments
One commenter expressed concern that the draft Compliance Manual language stating that the annual deeming application Program Assistance Letter (PAL) may contain "additional details regarding documentation" of compliance will allow the PAL to establish significant new expectations. The commenter notes that these PALs have traditionally included a wide range of policies and procedures related to risk management, but that these requirements do not appear in this draft Compliance Manual. The commenter also expressed concern that health centers may incorrectly assume that the Compliance Manual includes all requirements necessary for deeming, even though other requirements appear in PINs 2002-22 and 2001-16, as well as in the FTCA Health Center Policy Manual and annual deeming application PAL.
HRSA Response
The Compliance Manual will serve as HRSA's consolidated resource for both Health Center Program requirements and FTCA deeming requirements. Please note that PINs 2002-22 and 2001-16 will be superseded by the Compliance Manual, and other policy references to these PINs will be updated once the Compliance Manual is issued. In addition, HRSA will align the requirements for the annual FTCA deeming application, which is required to be submitted to and approved by HRSA as a condition of deeming, with the Compliance Manual. As a reminder, the FTCA Health Center Policy Manual will continue to provide FTCA policy guidance that goes beyond the application deeming requirements.

Comments
Nine commenters requested that HRSA ensure that future FTCA deeming application PALs indicate that requirements for deeming are limited to those outlined in the Compliance Manual. Another commenter requested clarification on how updates related to FTCA deeming application will be provided in the future (i.e., whether there will continue to be an annual FTCA deeming application PAL).
HRSA Response
HRSA will align its FTCA deeming application requirements with the Compliance Manual and will continue to specify requirements for annual FTCA deeming applications.

Comments
One commenter requested that the Compliance Manual be revised to include the annual FTCA deeming application.
HRSA Response
The Compliance Manual forms the foundation for what will be requested in the annual FTCA deeming application. FTCA deeming application instructions for health centers will continue to be issued annually.

Comments
One commenter expressed concern that a Health Center Program non-compliance condition could be placed on a health center's award as a result of a finding identified in a FTCA deeming application. The commenter requests that the Compliance Manual clearly state that a "separation of powers" exists regarding who may place Health Center Program conditions related to Chapter 5: Clinical Staffing and Chapter 10: Quality Improvement/Assurance.
HRSA Response
In order to be eligible for FTCA deeming, the health center must demonstrate compliance with the requirements specified in Chapters 5 (credentialing and privileging) and 10 (quality assurance/improvement) as part of the annual deeming application/determination process. As the Compliance Manual specifies, there are requirements within Chapters 5 and 10 that apply to both Health Center Program compliance and FTCA deeming. Therefore, conditions may be applied in relation to findings resulting from reviews associated with either program, and based on other information. A health center's Project Officer will be responsible for initiating any compliance condition resulting from a finding, and FTCA deeming will be based on demonstrated compliance with all FTCA requirements in the areas of quality improvement/assurance, credentialing and privileging, risk management, and claims management.

Issue: Clarify Status of PINs 2001-16 and 2002-22

Comments
Five commenters requested that HRSA clarify the status of the credentialing and privileging standards in PINs 2001-16 and 2002-22. The commenters also requested that HRSA maintain the PIN 2002-22 table entitled "Comparative Summary of Requirements for Credentialing and Privileging Licensed or Certified Health Care Practitioners" either in the Compliance Manual or on the website.
HRSA Response
The Introduction of the Compliance Manual notes that PINs 2001-16 and 2002-22 are superseded. In response to this request, health centers may wish to access technical assistance in this area via resources on the BPHC website.

Issue: Clarify "Mitigating Areas of Highest Risk"

Comments
Five commenters requested HRSA clarify what is meant by mitigating the areas of highest risk "consistent with the HRSA-approved scope of project."
HRSA Response
HRSA has revised the language in this chapter of the Compliance Manual to clarify that the requirement is related to mitigating the health care areas/activities of highest risk and added specific areas of possible high risk for claims activity. HRSA also revised the Compliance Manual to clarify that the health center identifies and mitigates risk "within" the scope of project, rather than using the term "consistent with."

Glossary

Issue: Definitions of Tribal Organization and Urban Indian Organization

Comments
Six commenters suggested that HRSA include the statutory definitions of "tribal organization" and "Urban Indian Organization" in the glossary, linked from Chapter 1: Eligibility.
HRSA Response

The statutes that establish and define tribal organizations and Urban Indian Organizations are specifically cited in Chapter 1 and HRSA has added links to these statutes in footnotes. As a result, HRSA is declining to include them in the Glossary section of the Compliance Manual. In addition, the language in Chapter 1: Eligibility has been revised to more clearly state that tribal organizations are eligible to apply for Health Center Program funding or designation.

Issue: Definition of Migratory and Seasonal Agricultural Workers

Comments

Two commenters suggested that HRSA expand the definition of "Migratory and Seasonal Agricultural Worker" to include aged and disabled agricultural workers and their families, consistent with statute.

HRSA Response

HRSA concurs with this suggestion and has revised the glossary definition of "Migratory and Seasonal Agricultural Worker" as suggested.

Issue: Patient Definition

Comments

One commenter suggested that HRSA include a definition of "patient" in the Compliance Manual, particularly as it applies to patient board members.

HRSA Response

Chapter 20: Board Composition clarifies HRSA's definition of a "patient" in the context of patient board members.

Issue: Use of Catchment Area versus Service Area

Comments

Two commenters requested that the term "service area" be used instead of "catchment area" consistently throughout the Compliance Manual, including in the Glossary.

HRSA Response

The term "catchment area" is used in section 330 of the PHS Act and is therefore included in the Compliance Manual within applicable "Requirements" sections, alongside the more commonly used term, "service area." HRSA has ensured that "service area" and "catchment area" are placed together in the Compliance Manual to alert readers that these terms are used interchangeably. Service Area [Catchment Area] is defined in the Compliance Manual's glossary.

General Comments

Issue: Clarify Effective Date

Comments

Two commenters requested that HRSA clarify when the final Compliance Manual will go into effect.

HRSA Response

The Compliance Manual will become effective upon its release, and this date will be indicated on the document at that time. HRSA will provide a timeframe for issuing updates to all related documents, such as a Site Visit Protocol, that will fully align with the Compliance Manual. Until these documents are updated, HRSA plans to review health center submissions with a view to considering where the Compliance Manual may, in limited instances, conflict with the existing Site Visit Guide; in any case where the Compliance Manual affords greater flexibility, HRSA intends to review the condition submission in light of this Compliance Manual.

Issue: Timing of Final Compliance Manual and New Site Visit Protocol

Comments

Twenty-three commenters requested clarification on how HRSA would make on-site compliance determinations after the Compliance Manual is released, and one commenter requested that the Site Visit Guide be aligned with the new Compliance Manual. Eleven commenters requested that HRSA clarify how OSVs will work during the period between when the Compliance Manual is finalized and the new Site Visit Protocol is released. Ten commenters requested that health centers be provided adequate time to come into compliance with the Compliance Manual and that, specifically, health centers with OSV already scheduled when the Compliance Manual is finalized be evaluated under the current OSV Guide. Two commenters requested clarification regarding what will happen to conditions applied under the current OSV Guide once the Compliance Manual is released, particularly where there is a conflict with the final Compliance Manual.

HRSA Response

HRSA is developing a new Site Visit Protocol that aligns with the content of the Compliance Manual and plans to release the new protocol as soon as possible following finalization of the Compliance Manual. At that time, HRSA will provide information on the effective date for conducting site visits using the new protocol, while including a period of time for health centers to review the new protocol and prepare for site visits using this new tool. In the interim, HRSA plans to review conditions in light of this Compliance Manual; in any case where the Compliance Manual affords greater flexibility, HRSA plans to review the condition submission in the context of this flexibility afforded in the Compliance Manual.

Issue: Related Considerations and New Site Visit Protocol

Comments

One commenter recommended that HRSA clarify how site visit consultants will review sections of the Compliance Manual that state, “the health center determines how.”

HRSA Response

The sections of the Compliance Manual titled “Related Considerations” describe areas where health centers have discretion or that may be useful for health centers to consider when implementing a requirement. As these Related Considerations are not the basis for making compliance assessments, the updated Site Visit Protocol will not include the Related Consideration elements. Therefore, site visit consultants will not be utilizing these Related Consideration provisions to assess compliance. For more information on the structure of the Compliance Manual, see the Introduction to the Compliance Manual.

Issue: FTCA Chapter and New Site Visit Protocol

Comments

One commenter requested clarification of how the FTCA chapter will be incorporated in the Site Visit Protocol.

HRSA Response

For areas where the Health Center Program requirements align with the FTCA Program requirements (i.e., QI/QA and credentialing and privileging), the Site Visit Protocol will include guidance to review the requirements for the purposes of both programs. Unique FTCA requirements such as risk management and claims management are outlined in the FTCA Chapter of the Compliance Manual, and assessing compliance with these FTCA requirements will become an integral part of the new Protocol.

Issue: Training for Site Visit Consultants

Comments

One commenter recommended significant training for site visit consultants on the final Compliance

Manual and Site Visit Protocol to ensure consistent interpretation.

HRSA Response

HRSA will orient consultants as part of the transition to the new Site Visit Protocol, which will be aligned with the Compliance Manual. The updated Protocol is designed to support consistent assessments of Health Center Program requirements, including final compliance determinations made by HRSA.

Issue: Establish Schedule for Future Updates to the Compliance Manual

Comments

Twelve commenters requested that a consistent and predictable (e.g., annual) schedule be established for updating and seeking public comment on the Compliance Manual.

HRSA Response

HRSA plans to review the Compliance Manual on a regular basis and to issue updates for public comment when these reviews indicate the need for revisions.

Issue: Resources to Support Final Compliance Manual

Comments

One commenter recommended pre-testing the Compliance Manual prior to finalization, as well as providing additional resources to support the roll-out of the Compliance Manual.

HRSA Response

The public comment period for the Compliance Manual provided an opportunity for HRSA to receive feedback from the public. In the future, HRSA will be issuing additional documents and resources, such as the Site Visit Protocol, that will be aligned with the Compliance Manual and support its implementation. HRSA does plan to pilot the new Site Visit Protocol prior to its finalization and implementation.

Issue: Spanish Translation

Comments

Two commenters requested that the Compliance Manual be translated into Spanish.

HRSA Response

HRSA appreciates the comment and will explore possible opportunities for translation.

Issue: Overall Public Reaction to the Compliance Manual

Comments

Twelve commenters expressed appreciation for HRSA's work in developing the Compliance Manual. They felt it was a "herculean effort" that streamlined and clarified policy guidance and will ultimately lead to a uniform understanding of program requirements among health centers, OSV reviewers, and NCA and PCA TA partners. In contrast, one commenter did not express support for issuing the Compliance Manual.

HRSA Response

The Compliance Manual was drafted in response to numerous recommendations and requests from stakeholders for increased transparency, clarity, and consistency in HRSA's Health Center Program oversight and FTCA deeming decisions. The purpose of the Compliance Manual is to provide a consolidated resource to assist health centers in understanding and demonstrating compliance with Health Center Program requirements. These requirements have been combined into a single compliance document for ease in understanding and reducing the time health centers must spend demonstrating to HRSA their compliance with statutory and regulatory requirements.

Issue: Scope of Project Requirements

Comments

One commenter suggested including scope of project requirements in the Compliance Manual.

HRSA Response

The Compliance Manual does not supersede existing scope of project policy. For additional information, please see related policy guidance on the scope of project website (https://bphc.hrsa.gov/programrequirements/scope.html).

Issue: Accelerate Timeline for CIS Reviews

Comments

One commenter requested that Change in Scope (CIS) requests that are returned to a health center for a change continue to be reviewed within a 60-day timeframe and that the clock not "re-start" at 60 days upon resubmission of the CIS request.

HRSA Response

The Compliance Manual does not address timelines for submission and review of CIS requests. More information on this topic is available on the BPHC scope of project website (https://bphc.hrsa.gov/programrequirements/scope.html) and in PAL 2014-10: Updated Process for Change in Scope Submission, Review and Approval Timelines.

Issue: Categorizing Shelter Location Types on Form 5B

Comments

One commenter requested the following clarifications: whether PIN 2008-01 remains in effect; how to categorize shelter sites where HCH grantees are providing services on a regular basis or year round; and whether such a site is categorized as an intermittent or permanent site.

HRSA Response

Scope of project policy, including PIN 2008-01: Defining Scope of Project and Policy for Requesting Changes, is not superseded by the Compliance Manual. This is noted in Appendix A of the Compliance Manual. Therefore, this PIN will remain in effect where the public can access additional guidance on site definitions and categories. In addition, the scope web page provides Form 5B: Service Site Instructions to guide health centers on how to record different categories of sites on this form.

Issue: The Joint Commission and NCQA PCMH Program Criteria

Comments

There were eleven comments suggesting that HRSA incorporate Joint Commission and PCMH program criteria into the Compliance Manual and related Site Visit Protocol.

HRSA Response

HRSA recognizes the value of the Joint Commission and NCQA PCMH programs. However, these criteria, as written, do not mirror Health Center Program requirements laid out in statute and regulation and, therefore, cannot be the basis for HRSA's oversight of the Health Center Program.