Table of Contents

regulations.[8] These requirements form the foundation of the Health Center Program and support the core mission of this innovative and successful model of primary care.

Health Center Program non-regulatory policy issuances that remain in effect after the issuance of this Compliance Manual are listed in Appendix A. With the exception of these policies, the Compliance Manual supersedes other previous Health Center Program non-regulatory policy issuances (Policy Information Notices (PINs), Program Assistance Letters (PALs), Regional Office Memoranda, Regional Program Guidance memoranda, and other non-regulatory materials) related to compliance or eligibility requirements. In case of any conflict between a provision of the Compliance Manual and other HRSA-disseminated non-regulatory materials related to compliance and/or eligibility requirements, the provisions of this Manual control. Such previously published issuances include, but are not limited to:

- **PIN 1994-07:** Migrant Voucher Program Guidance
- **PINs 1997-27 and 1998-24**: Affiliation Agreements of Community & Migrant Health Centers and Amendment to PIN 1997-27 Regarding Affiliation Agreements of Community and Migrant Health Centers
- **PINs 2001-16 and 2002-22**: Credentialing and Privileging of Health Center Practitioners and Clarification of BPHC Credentialing & Privileging Policy Outlined in PIN 2001-16
- **PAL 2006-01:** Dual Status-Health Centers that are both FQHC Look-Alikes and Section 330 Grantees
- **PIN 2010-01:** Confirming Public Agency Status under the Health Center Program and FQHC Look-Alike Program
- **PIN 2014-01**: Health Center Program Governance
- **PIN 2014-02**: Sliding Fee Discount and Related Billing and Collections Program Requirements
- **PAL 2014-08**: Health Center Program Requirements Oversight
- **PAL 2014-11**: Applicability of PAL 2014-08: Health Center Program Requirements Oversight to Look-Alikes

The Compliance Manual serves as the policy foundation for HRSA's eligibility and compliance-related determinations and review processes for the Health Center Program. HRSA will update or amend the Compliance Manual as needed to provide further clarification of program policies.

Structure of the Health Center Program Compliance Manual

Chapters in the Compliance Manual are generally organized as follows:

- **Authority**: Lists the applicable statutory and regulatory citations for the chapter.[9]

[8] Section 330 of the PHS Act (42 U.S.C. §254b), as amended, 42 CFR Part 51c and 42 CFR Part 56 for Community and Migrant Health Centers, respectively, and 45 CFR Part 75.

- **Requirements**: States the statutory and regulatory requirements.

- **Demonstrating Compliance**: Describes how health centers would demonstrate to HRSA their compliance with the **Requirements** by fulfilling all elements in this section.

  ***Note**: Health centers that fail to demonstrate compliance as described in this Manual will receive a condition of award/designation. In responding to such conditions, health centers could demonstrate their compliance to HRSA either by submitting documentation as described in the Demonstrating Compliance sections of the Manual or by the health center proposing an alternative means of demonstrating compliance with the specified Requirements, which would include submitting an explanation and documentation that explicitly demonstrates compliance. All responses to conditions are subject to review and approval by HRSA (see Chapter 2: Health Center Program Oversight).*

- **Related Considerations**: Describes areas where health centers have discretion or that may be useful for health centers to consider when implementing a requirement. While specific examples are provided, they are not intended to be an all-inclusive list.

Additional Health Center Responsibilities

In addition to the requirements included in this Compliance Manual, organizations receiving Health Center Program federal awards, including subrecipients, are also subject to other applicable award-related statutory, regulatory, and policy requirements (see 45 CFR Part 75 and the U.S. Department of Health and Human Services (HHS) Grants Policy Statement (GPS), Funding Opportunity Announcements (FOAs),[10] and Notices of Award (NoAs)).[11] As such, the Compliance Manual does not constitute an exhaustive listing of all terms and conditions stated in FOAs, NoAs, and other applicable laws, regulations, and policies.

Health centers (including look-alikes) may be subject to the distinct statutory, regulatory, and policy requirements of other Federal programs such as, but not limited to:

- FQHC status under Titles XVIII (Medicare) and XIX (Medicaid) of the Social Security Act;
- The 340B Drug Pricing Program;
- The National Health Service Corps (NHSC) Program; and

[9] These citations include requirements under the Uniform Administrative Requirement for all HHS awards (45 CFR Part 75) which are applicable as stated in the Health Center Program's regulations (42 CFR 51c.113 and 42 CFR 56.114).

[10] Individual FOAs may contain specific additional terms and conditions of award beyond those identified in this Manual.

[11] Further grants policy information may be found in the HHS Grants Policy Statement and the HRSA SF-424 Application Guide Please see http://www.hrsa.gov/grants/index.html for more information.

- The Health Center FTCA Program (with the exception of the deeming requirements included in this Manual).

Each health center is responsible for maintaining its operations in compliance with **all** Health Center Program requirements and all other applicable federal, state, and local laws and regulations.[12] This includes but is not limited to those protecting public welfare, the environment and prohibiting discrimination; state facility and licensing laws; state scope of practice laws; Centers for Medicare and Medicaid Services (CMS) Conditions for Coverage for FQHCs;[13] and State Medicaid requirements. In fulfilling all of these oversight and compliance responsibilities, a health center may wish to consult its private legal counsel. Health centers may also direct questions to the designated points of contact for these programs.

[12] 42 CFR 51c.304(d)(3)(v).
[13] 42 CFR Part 491.

Chapter 1: Health Center Program Eligibility

Organizations applying for funding or designation under the Health Center Program must demonstrate that they are eligible organizations under the Health Center Program statute and regulations. Specifically, organizations applying for funding as health centers or designation as look-alikes must be private non-profit entities or public agencies.[1] Organizations applying for look-alike designation are subject to certain additional statutory eligibility requirements, as described below.[2] The means by which organizations would demonstrate their eligibility to HRSA are outlined below.

In addition to the eligibility requirements described in this Chapter, organizations may be required to comply with certain additional eligibility requirements described in funding opportunity announcements or look-alike application instructions in order to receive funding or look-alike designation.

Non-Profit Organizations

An organization would demonstrate that it is a private non-profit entity by submitting one of the following types of documentation:

- A copy of a currently valid IRS tax exemption certificate.
- A statement from a state taxing body, state attorney general, or other appropriate state official certifying that the applicant organization has a non-profit status and that none of the net earnings accrue to any private shareholders or individuals.
- A certified copy of the organization's official certificate of incorporation or similar document (for example, articles of incorporation) showing the state or tribal seal that clearly establishes nonprofit status.
- Any of these items for a state or local office of a national parent organization and a statement signed by the parent organization that the applicant organization is a local non-profit affiliate.

Public Agency Organizations

An organization would demonstrate that it is a public agency by submitting one of the following types of documentation:

[1] Section 330(e)(1)(A) of the PHS Act, 42 CFR 51c.103, and 42 CFR 56.103.
[2] Sections 1861(aa)(4)(b) and 1905(l)(2)(B) of the Social Security Act.

- A current dated letter affirming the organization's status as a State, territorial, county, city, or municipal government; a health department organized at the State, territory, county, city or municipal level; or a subdivision or municipality of a United States (U.S.) affiliated sovereign State formally associated with the U.S. (for example, Republic of Palau).

- A copy of the law that created the organization and that grants one or more sovereign powers (for example, the power to tax, eminent domain, police power) to the organization (for example, a public hospital district).

- A ruling from the State Attorney General affirming the legal status of an entity as either a political subdivision or instrumentality of the State (for example, a public university).

- A "letter ruling" which provides a positive written determination by the Internal Revenue Service of the organization's exempt status as an instrumentality under Internal Revenue Code section 115.

Tribal or Urban Indian organizations, as defined under the Indian Self-Determination Act or the Indian Health Care Improvement Act,[3] are eligible to apply for Health Center Program funding or designation and would demonstrate their eligibility by providing documentation of such status.

Additional Eligibility Requirements for Look-Alike Designation

In addition to demonstrating that it is either a private non-profit entity or a public agency, an organization applying for look-alike designation must demonstrate that it satisfies all of the following requirements:

1. It is currently delivering primary health services to patients within the service area.

2. It is not owned, controlled, or operated by another entity. Specifically, the organization applying for look-alike designation:
    a. **Owns and controls** the organization's assets and liabilities (for example, the organization does not have a sole corporate member, is not a subsidiary of another organization), and as such will be able to ensure that the benefits that accrue through look-alike designation are distributed to the health center project (for example, Federally Qualified Health Center reimbursement, 340B Drug Pricing income); and
    b. **Operates** the health center project. At a minimum, the look-alike applicant organization demonstrates that it maintains a Project Director/Chief Executive Officer who will carry out independent, day to day oversight of health center

[3] Per section 330(k)(3)(H), tribal or urban Indian organizations are exempt from the governance requirements.

activities on behalf of the governing board of the applicant organization, in particular for those activities provided via contract.

3. It is not currently receiving funding as a Health Center Program Federal award recipient.[4]

   Organizations will not be permitted to apply for "dual status," whereby an organization receives both a Federal award under section 330 and look-alike designation.

[4] Health centers may not maintain or obtain look-alike designation if they are already receiving a Federal award under section 330 of the Public Health Service Act. See: Section 1905(l)(2)(B) of the Social Security Act: "The term "Federally-qualified health center" means an entity which … (i) is receiving a grant under section 254b of this title…or (ii)(I) is receiving funding from such a grant under a contract with the recipient of such a grant, and (II) meets the requirements to receive a grant under section 254b of this title…or (iii) based on the recommendation of the Health Resources and Services Administration within the Public Health Service, is determined by the Secretary to meet the requirements for receiving such a grant, including requirements of the Secretary that an entity may not be owned, controlled, or operated by another entity."

Chapter 2: Health Center Program Oversight

Health centers must comply with all Health Center Program requirements and other applicable federal statutes, regulations, and the terms and conditions of their award or look-alike designation.[1] In keeping with the Health Resources and Services Administration (HRSA)/Bureau of Primary Health Care's (BPHC) oversight responsibilities, HRSA/BPHC monitors and supports health centers in successfully maintaining compliance with these requirements.

The purpose of this chapter is to:

- Set forth HRSA/BPHC's oversight process, which was developed to support the monitoring of Health Center Program requirements and to assist health centers in their efforts to maintain compliance with these requirements.
- Describe when and how HRSA pursues remedies for non-compliance, including taking enforcement action(s) in cases where health centers fail to comply with Health Center Program requirements as well as with other applicable federal statutes, regulations, and the terms and conditions of the award or look-alike designation.
- Clarify when and how compliance status with program requirements and past performance[2] is taken into consideration when making award or designation decisions.

HRSA/BPHC's Progressive Action process is implemented through its Electronic Handbooks (EHB) system. The EHB system facilitates the tracking of compliance with program conditions placed on a health center's award (for Health Center Program federal award recipients) or designation (for Health Center Program look-alikes).[3] This system also communicates these conditions through Notices of Award (NoAs) or Notices of Look-Alike Designation (NLDs), documents the health center's response to these conditions, and documents removal of these conditions when appropriate.[4]

This chapter supersedes Program Assistance Letter (PAL) 2014-08: Health Center Program Oversight[5] and PAL 2014-11: Applicability of PAL 2014-08: Health Center Program Requirements Oversight to Look-Alikes.

---

[1] Section 330 of the Public Health Service (PHS) Act (42 U.S.C. 254b), as amended, 42 CFR Part 51c and 42 CFR Part 56 for Community and Migrant Health Centers, respectively, and 45 CFR Part 75.

[2] 42 CFR 51c.305 and 45 CFR 75.205(c)(3).

[3] Throughout this document, requirements or conditions of award are "requirements of federal designation" for organizations designated by HRSA as look-alikes (see section 1861(aa)(4)(B) and section 1905(l)(2)(B) of the Social Security Act), which must also meet all of the requirements of the Health Center Program.

[4] In the EHB, a health center's response to a condition of award/designation is referred to as a "submission". The removal or lifting of a condition occurs once a submission that adequately addresses the required corrective action has been reviewed, approved by HRSA, and marked as "met" within the EHB.

[5] PAL 2014-08 superseded PAL 2010-01, "Enhancements to Support Health Center Program Requirements Monitoring," which was issued April 8, 2010.

Program Oversight

United States (U.S.) Department of Health and Human Services (HHS) grants regulations, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (Uniform Regulations)[6] require HRSA to "manage and administer the federal award in a manner so as to ensure that federal funding is expended and associated programs are implemented in full accordance with U.S. statutory and public policy requirements, including, but not limited to, those protecting public welfare, the environment, and prohibiting discrimination."[7]

Consistent with applicable law and HRSA's program oversight responsibilities, health centers are assessed for compliance with these requirements and are provided an opportunity to remedy areas of non-compliance whenever reasonably possible. Immediate enforcement action will only be taken against health centers that do not comply with applicable requirements in limited circumstances further addressed below.

HRSA may impose specific award conditions[8] if an applicant or recipient/designee:

- Demonstrates undue risk in such areas as:
    - Financial stability;
    - Quality of management systems and ability to meet required management standards;
    - History of performance, specifically the applicant's record in managing previous federal awards (timeliness of compliance with applicable reporting requirements and conformance to the terms and conditions of previous federal awards);
    - Findings from reports and audits; and
    - Ability to effectively implement statutory, regulatory, or other requirements imposed on non-federal entities;
- Has a history of failure to comply with the general or specific terms and conditions of a federal award/designation;
- Fails to meet expected performance goals; or
- Is not otherwise responsible.[9]

[6] 2 CFR Part 200.
[7] 45 CFR 75.300.
[8] 45 CFR 75.207(a). For example, in accordance with federal regulations (45 CFR 75.207 "Specific award conditions"), HRSA may impose special restrictive conditions on a federal award based on risk factors. Such factors may include, but are not limited to, a health center's financial stability and quality of management systems. One such condition is "Restricted Drawdown". When a federal award recipient is placed on restricted drawdown, all drawdowns of federal funds from the Payment Management System (PMS) must have approval of HRSA's Office of Federal Assistance Management, Division of Grants Management Operations, and must comply with all applicable requirements before funds are drawn.
[9] 45 CFR 75.207(a)(4).

Specific award conditions may include, but are not limited to, the following:[10]

- Requiring payments as reimbursements rather than advance payments;
- Withholding authority to proceed to the next phase of the project until receipt of evidence of acceptable performance within a given period of performance;
- Requiring additional, more detailed financial reports;
- Requiring additional project monitoring;
- Requiring the non-federal entity to obtain technical or management assistance; or
- Establishing additional prior approvals.

If it is determined that noncompliance cannot be remedied by imposing such additional conditions, one or more of the following actions may be taken as appropriate in the circumstances:

- Temporarily withhold cash payments pending further action;
- Disallow all or part of the cost of the activity or action not in compliance;
- Wholly or partly suspend award activities or terminate the federal award;[11]
- Initiate suspension or debarment proceedings;[12]
- Withhold further federal awards for the project or program; or
- Take other remedies that may be legally available.

Progressive Action Overview

In circumstances where a health center is determined to be non-compliant with one or more of the Health Center Program requirements, a condition(s) will be placed on the award/designation, which will follow the Progressive Action policy and process. Non-compliance with program requirements is most often determined based on findings from the review of the Service Area Competition (SAC)/Renewal of Designation (RD) application, a site visit, other compliance-related activities, or through other means.[13] Program conditions placed on the health center's award or look-alike designation describe the:

[10] 45 CFR 75.207(b).

[11] *Termination* means the ending of a federal award, in whole or in part at any time prior to the planned end of period of performance [project period] (45 CFR 75.2).

[12] *Suspension of award activities* means an action by HRSA requiring the recipient to cease all activities on the award pending corrective action by the recipient, including restricting the ability to draw down any funds associated with the federal award (45 CFR 75.375) and is a separate action from suspension under HHS regulations (2 CFR Part 376) (45 CFR 75.2). Health Center Program look-alikes will receive formal notification of de-designation as they do not receive federal funding.

[13] HRSA may also assess compliance with requirements through audit data, UDS or similar performance reports, Medicare/Medicaid reports, external accreditation, or other federal, state, or local findings or reports as applicable, and may conduct onsite verification of compliance at any point within a project/designation period or prior to any final funding/designation decisions.

- Nature of the non-compliant finding and the requirement it relates to;
- Reason why the condition(s) is being imposed;
- Nature of the action(s) needed to remove the condition;
- Time allowed for completing the additional requirement (satisfying the condition(s) through submission of appropriate documentation or specific actions taken), if applicable; and
- Method for requesting reconsideration of the condition, if applicable.

HRSA is committed to assisting health centers with identified areas of non-compliance and to providing reasonable time for these organizations to take necessary corrective actions. Progressive Action is designed to provide a time-phased approach for resolution of compliance issues with program requirements. This Progressive Action process is not intended to address or be used for the oversight and enforcement of all federal requirements that may be applicable to the award or designation, particularly those with implications for patient safety (see Immediate Enforcement Actions below).

Should a health center fail to adequately address conditions through Progressive Action, HRSA may take all available remedies, including terminating all or part of the federal award/designation status before the health center's current project end date.[14] Such action may be accompanied by a competition to identify another organization to carry out a service delivery program consistent with federal requirements.[15]

Progressive Action Process

In circumstances where a health center is determined to be non-compliant with one or more Health Center Program requirements, relevant conditions are placed on the health center's award/designation and communicated through NoAs or NLDs. In responding to such conditions, health centers would demonstrate their compliance by either submitting documentation to HRSA, which demonstrates compliance as described in Chapters 3-20 of this Manual, or by providing an alternative means of demonstrating compliance with the specified requirements, which would include submitting an explanation and documentation that explicitly demonstrates compliance. All responses to conditions are subject to review and approval by HRSA.

The Progressive Action process provides a uniform structure and a time-phased approach for notifying health centers of compliance issues and for receiving health center responses to an identified condition(s) as supported within HRSA's EHB. Through this process, health centers

[14] 45 CFR 75.371 and 45 CFR 75.372.

[15] Health Center Program look-alikes that have had their designation period terminated by HRSA under such circumstances or for which HRSA has not renewed a look-alike designation may reapply for look-alike designation through the initial designation application process at any time.

are able to efficiently and effectively respond to conditions, and HRSA is able to promptly review these responses and proceed to next steps, including removal of conditions, as warranted. In addition, the EHB supports the Progressive Action process by clearly noting condition response deadlines in the health center's EHB task list and providing periodic email reminders to health centers during the condition response timeframe.

The Progressive Action process includes four distinct condition phases (detailed below), structured to provide specified timeframes for health center action and response to demonstrate compliance, either as specified by this Manual or via alternative means. After initial notification of the compliance issue, a health center will be notified via a modified NoA/NLD at each Progressive Action phase as to the acceptability of the response and whether further action is needed. If the health center fails to respond by the specified deadline or HRSA determines that the health center's response does not demonstrate compliance, the health center will be notified and the next Progressive Action phase will be activated.

- Phase One: An initial NoA/NLD is issued detailing the specific area(s) of non-compliance and the condition(s) that must be met in order to demonstrate compliance. Phase One provides ninety (90) days for the health center to submit appropriate documentation that the specified program requirement has been met or that the health center has developed an adequate action plan (see Implementation Phase below) for how its organization will comply with the requirement.[16]
- Phase Two: Phase Two provides a further sixty (60) days for the health center to submit appropriate documentation that the program requirement has been met or that the health center has developed an adequate action plan for how its organization will comply with the requirement (See Implementation Phase below).
- Phase Three: Phase Three provides a further thirty (30) days for the health center to submit appropriate documentation that the program requirement has been met or that the health center has developed an adequate action plan for how its organization will comply with the requirement (See Implementation Phase below).
- Implementation Phase (where applicable): Implementation Phase provides one hundred twenty (120) days for the health center to demonstrate its implementation of a HRSA-approved action plan, including the submission of appropriate documentation that the program requirement has been met,[17] following a satisfactory health center response to develop an adequate action plan in Phase One, Two, or Three.

HRSA recognizes that health centers may need to make programmatic and organizational changes in response to a condition. Therefore, the Progressive Action process is designed to

[16] While most of Health Center Program Progressive Action conditions include a 120-day Implementation Phase, a limited number of conditions do not include an implementation phase. This is because the corrective actions needed to address these conditions would not require a health center to make major programmatic and organizational changes or necessitate documentation of implementation (for example, a condition requiring a health center to provide an updated needs assessment).

[17] *Ibid.*

provide health centers with a reasonable amount of time to take appropriate action in response to a condition and for prompt HRSA review and decision-making. For example, in Phase One, for most conditions, a health center is given 90 days to either demonstrate compliance with the identified program requirement or develop and submit an action plan detailing the steps the health center will implement in order to comply with the requirement. If this plan is approved, a modified NoA/NLD will be issued with an "Implementation Phase" condition notifying the health center that HRSA has approved the action plan and that within 120 days it must submit documentation that compliance with the requirement has been implemented in accordance with the HRSA-approved plan.

Health centers that do not adequately address a condition within the Phase One timeframe (90 days) and/or subsequent Implementation Phase (120 days) will be issued a modified NoA/NLD with a Phase Two condition. This gives the health center an additional 60 days to either demonstrate compliance with the identified program requirement or develop and submit an action plan detailing how the organization will comply with the requirement.

Therefore, conditions in Phase Two (60-day) and Phase Three (30-day)[18] state that if the health center does not adequately address the condition within the allotted timeframe (the last opportunity being Phase 3 (30-day), the organization will be determined to have failed to comply with the terms and conditions of the Health Center Program award or designation. As a result, the health center's current project end date may be shortened through the termination of all or part of the federal award or designation status.

Immediate Enforcement Actions

HRSA may determine that certain findings related to a health center, as a consequence of their nature and/or urgency, cannot be remedied by imposing specific award conditions per the Progressive Action process described above. In such cases, HRSA may take one or more of the following immediate remedies for non-compliance based on the circumstances: [19]

- Temporarily withhold cash payments (from the federal award) pending further action;
- Disallow all or part of the cost of the activity or action not in compliance;
- Wholly or partly suspend award activities or terminate the federal award;
- Initiate suspension or debarment proceedings;
- Withhold further federal awards for the project or program; or
- Take other remedies that may be legally available.

[18] The BPHC website includes a public Health Center Profile for each individual health center that displays data on the status of a health center's compliance with Health Center Program requirements based on the presence of any active 60- and/or 30-day Progressive Action conditions. Please see http://bphc.hrsa.gov/uds/datacenter.aspx?q=d to view individual health center data.

[19] 45 CFR 75.371.

Situations that cannot be remedied through use of the Progressive Action process and that may require HRSA to apply such immediate enforcement actions include:

- Findings that a health center, in responding to the terms or conditions of award/designation, misrepresented the actions it took to correct areas of non-compliance. For example, a site visit reveals that HRSA lifted a Progressive Action condition based on false or misrepresented information submitted by the health center.

- Documented public health or welfare concerns. Examples may include threats to health center patient safety, violations of state scope of practice regulations or guidelines, inappropriate or illegal prescribing practices, lack of appropriate infection control procedures, and occupational or environmental hazards.

- Failure of the health center organization to demonstrate operational capacity to continue or maintain its health center service delivery program. For example, a health center has ceased operations and is no longer providing primary care services or is providing only minimal services.

- A determination that continued funding would not be in the best interest of the Federal Government. For example, a health center organization's inclusion as an excluded entity on the U.S. Department of Health and Human Services Office of Inspector General's List of Excluded Individuals/Entities (LEIE) and/or inclusion on the System for Award Management (SAM) Excluded Parties List System (EPLS),[20] or as an organization that is not qualified per the Federal Awardee Performance and Integrity Information System (FAPIIS).[21]

Program Compliance and Application Review and Selection

Project/designation period length is based on a comprehensive evaluation of the risks to the Health Center Program posed by each applicant if it were to receive an award/designation for a new project or designation period, including an assessment of a health center's compliance with program requirements. Therefore, an existing health center with a history of non-compliance with Health Center Program requirements may be considered by HRSA to pose risk and may be awarded federal funding or designation for a shortened project/designation period as part of the competing continuation/renewal of designation application review process. The specific criteria for determining project period length are further detailed in the applicable SAC FOAs and Look-Alike RD application instructions.

[20] The Government Services Administration administers the SAM EPLS. The SAM is available at https://www.sam.gov.
[21] The FAPIIS is available at https://www.fapiis.gov/fapiis/index.action.

Further, if a current Health Center Program federal award recipient has been awarded two consecutive one-year project periods, based on the project period length criteria associated with program compliance and outlined in the SAC FOA, and a review of the subsequent SAC application would result in a third consecutive one-year project period, HRSA may conclude that this organization cannot consistently carry out the health center project in accordance with Health Center Program requirements. Due to continued unsatisfactory performance in meeting program requirements, this organization's SAC application may not be selected for funding for a third consecutive one-year project period.[22] In such circumstances, HRSA may announce a new competition for the service area, in order to identify an organization that can carry out a service delivery program consistent with Health Center Program requirements.

In addition, a health center's ability to demonstrate compliance with program requirements is critical to ensuring continued federal award support and may, in certain cases, directly impact award decisions for supplemental funding, as outlined in the specific FOA.

Consistent with the approach regarding federal award recipients, HRSA will not renew a Health Center Program look-alike organization's designation if the organization has received two consecutive one-year designation periods and the review of the subsequent RD application would result in a third consecutive one-year designation period. Look-alikes whose designation period has not been renewed may reapply for look-alike designation through the initial designation application process at any time.[23]

Technical Assistance

HRSA is committed to assisting health centers in complying with Health Center Program requirements through the provision of appropriate guidance and technical assistance. HRSA encourages frequent communication between the health center and its designated Project Officer to ensure the development of appropriate and timely responses throughout the phases of the Progressive Action process.

[22] While such organizations may apply to future Health Center Program funding opportunity announcements in accordance with 45 CFR 75.205(c)(3), HRSA may consider factors, including an applicant's history of performance if it is a prior recipient of Federal awards or designation when making competitive awards. These factors include, but are not limited to, unsuccessful Progressive Action condition resolution and current compliance with Health Center Program requirements and regulations.

[23] For more information on the Health Center Program look-alike application process, please see http://www.bphc.hrsa.gov/programopportunities/lookalike/index.html.

Chapter 3: Needs Assessment

Authority

Section 330(k)(2) and Section 330(k)(3)(J) of the PHS Act; and 42 CFR 51c.104(b)(2-3), 42 CFR 51c.303(k), 42 CFR 56.104(b)(2), 42 CFR 56.104(b)(4), and 42 CFR 56.303(k)

Requirements

- The health center must define and annually review the boundaries of the catchment area to be served [service area], including identification of the medically underserved population or populations within the catchment area in order to ensure that the:
    - Size of this area is such that the services to be provided through the center (including any satellite service sites) are available and accessible to the residents of the area promptly and as appropriate;
    - Boundaries of such area conform, to the extent practicable, to relevant boundaries of political subdivisions, school districts, and areas served by Federal and State health and social service programs; and
    - Boundaries of such area eliminate, to the extent possible, barriers resulting from the area's physical characteristics, its residential patterns, its economic and social groupings, and available transportation.

- The health center must assess the need for health services in the catchment area of the center based on the population served or proposed to be served, utilizing, but not limited to, the following factors:
    - Available health resources in relation to the size of the area and its population, including appropriate ratios of primary care physicians in general or family practice, internal medicine, pediatrics, or obstetrics and gynecology to its population;
    - Health indices for the population of the area, such as infant mortality rate;
    - Economic factors affecting the population's access to health services, such as percentage of the population with incomes below the poverty level; and
    - Demographic factors affecting the population's need and demand for health services, such as percentage of the population age 65 and over.

Demonstrating Compliance

A health center would demonstrate compliance with these requirements by fulfilling all of the following:

- The health center identifies and annually reviews its service area[1] based on where current or proposed patient populations reside as documented by the ZIP codes reported on the health center's Form 5B: Service Sites. In addition, these service area ZIP codes are consistent with patient origin data reported by ZIP code in its annual Uniform Data System (UDS) report. For example, the ZIP codes reported on the health center's Form 5B: Service Sites would include the ZIP codes in which at least 75 percent of current health center patients reside as identified in the most recent UDS report.

- The health center completes or updates a needs assessment of the current or proposed population for the purposes of informing and improving the delivery of health center services. The needs assessment utilizes the most recently available data[2] for the service area and, if applicable, special populations and addresses the following:
    - Factors associated with access to care and health care utilization (for example, geography, transportation, unemployment, income level, educational attainment);
    - The most significant causes of morbidity and mortality (for example, diabetes, cardiovascular disease, cancer, low birth weight, behavioral health) as well as any associated health disparities; and
    - Any other unique health care needs or characteristics that impact health status or access to, or utilization of, primary care (for example, social factors, the physical environment, cultural/ethnic factors, language needs, housing status).

Related Considerations

The following points may be useful for health centers to consider when implementing these requirements:

- The health center may choose to include additional indicators relevant to its service area and population and the most appropriate methodologies, tools, and formats for conducting these assessments (for example, quantitative or qualitative data sources, focus groups, patient surveys).

- The health center may choose to include an additional focus on a specific underserved subset of the service area population (for example, low-income individuals; homeless children; lesbian, gay, bisexual, and transgender individuals; persons living with HIV/AIDS; elderly persons), as part of its overall assessment of need in its service area.

[1] Also referred to as "catchment area" in the Health Center Program implementing regulation in 42 CFR 51c.102.
[2] In cases where data are not available for the specific service area or special population, health centers may use extrapolation techniques to make valid estimates using data available for related areas and population groups. Extrapolation is the process of using data that describes one population to estimate data for a comparable population, based on one or more common differentiating demographic characteristics. Where data are not directly available and extrapolation is not feasible, health centers should use the best available data describing the area or population to be served.

Chapter 4: Required and Additional Services

Authority

Section 330(a)-(b), Section 330(h)(2), and Section 330(k)(3)(K) of the PHS Act; and 42 CFR 51c.102(h) and (j), 42 CFR 56.102(l) and (o), and 42 CFR 51c.303(l)

Requirements

- The health center must provide the required primary health services listed in section 330(b)(1).

- A health center that receives a grant or designation under section 330(h) to serve individuals experiencing homelessness must, in addition to these required primary health services, provide substance abuse services.

- The health center may provide additional (supplemental) services that are appropriate to meet the health needs of the population served by the health center, subject to review and approval by HRSA.

- All required and applicable additional services must be provided through one or more service delivery method(s): directly, or through written contracts and/or cooperative arrangements (which may include formal referrals).

- A health center which serves a population that includes a substantial proportion of individuals of limited English-speaking ability must:
    - Develop a plan and make arrangements for interpretation and translation that are responsive to the needs of such populations for providing health center services to the extent practicable in the language and cultural context most appropriate to such individuals; and
    - Provide guidance to appropriate staff members with respect to cultural sensitivities and bridging linguistic and cultural differences.

Demonstrating Compliance

A health center would demonstrate compliance with these requirements by fulfilling all of the following:

- The health center provides access to all services included in its HRSA-approved scope of project[1] (Form 5A: Services Provided) through one or more service delivery methods[2] as described below:[3]

[1] In accordance with 45 CFR 75.308 (Uniform Administrative Requirements), health centers must request prior approval from HRSA for a "Change in the scope or the objective of the project or program (even if there is no

- ***Services Provided Directly by the Health Center***: If a required or additional service is provided directly by the health center, this service is accurately recorded in Column I on Form 5A: Services Provided, reflecting that the health center pays for and bills for direct care. In addition, these services are rendered by health center staff[4] and are discounted in accordance with the health center's sliding fee discount program.[5]

- ***Services Provided to Health Center Patients on Behalf of the Health Center by a Third Party via a Formal Contract/Agreement:***[6] If a required or additional service is provided[7] on behalf of the health center via a formal contract/agreement between the health center and a third party entity (including a subrecipient), this service is accurately recorded in Column II on Form 5A: Services Provided, reflecting that the health center pays for the care provided by the third party via the agreement. In addition, such contractual agreements for services include:
  - How the service will be documented in the patient's health center record; and
  - How the health center will pay for the service.

---

associated budget revision requiring prior written approval)." This prior approval requirement applies, among other things, to the addition or deletion of a service. These changes require prior approval from HRSA and must be submitted by the health center as a formal change in scope request. Please see http://www.bphc.hrsa.gov/programrequirements/scope.html for further details on scope of project.

[2] Other Health Center Program requirements apply when providing services through contractual agreements and formal referral arrangements. Such requirements are addressed in other chapters of the Manual where applicable.

[3] The Health Center Program statute states that health centers may provide services "either through the staff and supporting resources of the center or through contracts or cooperative arrangements." 42 U.S.C. 254b(a)(1) The Health Center Program Compliance Manual utilizes the terms "Formal Written Contract/Agreement" and "Formal Written Referral Arrangement" to refer to such "contracts or cooperative arrangements." For more information on documenting service delivery methods within the HRSA-approved scope of project on Form 5A: Services, please see: http://bphc.hrsa.gov/programrequirements/scope/form5acolumndescriptors.pdf.

[4] For purposes of the HRSA-approved scope of project (Form 5A), services provided "directly" are those provided by employees and volunteers. HRSA/BPHC utilizes Internal Revenue Service (IRS) definitions to differentiate contractors and employees. Typically, an employee receives a salary on a regular basis and a W-2 from the health center with applicable taxes and benefit contributions withheld along with coverage for unemployment compensation.

[5] For more information on sliding fee discount programs, please see Sliding Fee Discount Program.

[6] For more information on program requirements around contracting, please see Contracts and Subawards.

[7] For purposes of the HRSA-approved scope of project (Form 5A) services provided via "contract/formal agreement" are those provided by third parties (for example, an individual provider with whom the health center has a contract; a group practice with which the health center has a contract; a locum tenens staffing agency with which the health center contracts; a subrecipient organization). Typically, a health center will issue a Form 1099 to an individual contractor. Please see the FTCA Health Center Policy Manual for information about eligibility for FTCA coverage for covered individuals [governing board members and officers, employees, and qualified individual contractors].

- ***Services Provided to Health Center Patients by Third Parties through Formal Referral Arrangements***: If a required or additional service is provided and billed for by a third party with which the health center has a formal referral arrangement, this service is accurately recorded in Column III on Form 5A: Services Provided, reflecting that the health center is responsible for the act of referral for health center patients and any follow-up care for these patients provided by the health center subsequent to the referral.[8] In addition, such formal referral arrangements for services, at a minimum, address:
  - The manner by which referrals will be made and managed; and
  - The process for tracking and referring patients back to the health center for appropriate follow-up care (for example, exchange of patient record information, receipt of lab results).

- Health center patients with limited English proficiency are provided with interpretation and translation (for example, through bilingual providers, on-site interpreters, language telephone line) that enables them to have reasonable access to health center services.

- The health center makes arrangements and/or provides resources that enable its staff to deliver services in a manner that is culturally sensitive and bridges linguistic and cultural differences.

Related Considerations

The following points may be useful for health centers to consider when implementing these requirements:

- The health center governing board determines which, if any, additional health services to offer in order to meet the health needs of the population served by the health center (subject to review and approval by HRSA).

- The health center determines how to make services accessible in a culturally and linguistically appropriate manner,[9] based on its patient population.

[8] For purposes of the HRSA-approved scope of project (Form 5A), services provided via "formal referral arrangements" are those referred by the health center but provided and billed for by a third party. Although the service itself is not included within the HRSA-approved scope of project, the act of referral and any follow-up care provided by the health center subsequent to the referral are considered to be part of the health center's HRSA-approved scope of project. For more information on documenting service delivery methods within the HRSA-approved scope of project on Form 5A: Services, please see: http://bphc.hrsa.gov/programrequirements/scope/form5acolumndescriptors.pdf

[9] HRSA programs serve culturally and linguistically diverse communities that are not just defined by race or ethnicity, but also socio-economic status, sexual orientation, gender identity, physical and mental ability, age, and other factors. Organizational behaviors, practices, attitudes, and policies across all HRSA-supported entities respect and respond to the cultural diversity of communities, clients, and students served. HRSA is committed to ensuring access to quality health care for all. Quality care means access to services, information, and materials

- The health center determines the level or intensity of Required and Additional Services, as well as the method for delivering these services, based on factors such as the needs of the population served, demonstrated unmet need in the community, provider staffing, and collaborative arrangements.

- The health center may, through policies and operating procedures, prioritize the availability of additional services within the approved scope of project to individuals who utilize the health center as their primary care medical home.

---

delivered by competent providers in a manner that factors in the language needs, health literacy, culture, and diversity of the populations served. Quality also means that data collection instruments used should adhere to culturally competent and linguistically appropriate norms. For additional information and guidance, 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.

Chapter 5: Clinical Staffing

Authority

Sections 330(a)(1), (b)(1)-(2), and (k)(3)(I)(ii)(II)-(III) of the PHS Act; and 42 CFR 51c.303(a), 42 CFR 51c.303(p), 42 CFR 56.303(a), and 42 CFR 56.303(p)

Requirements

- The health center must provide the required primary and approved additional health services[1] of the center through staff, including staff supported through contracts or cooperative arrangements.

- The health center must have sufficient staff so that such services are available and accessible promptly, as appropriate, and in a manner which will assure continuity of service to the residents of the center's catchment area.

- The health center must utilize staff, including those supported through contracts or cooperative arrangements, that are qualified by training and experience to carry out the activities of the center.

Demonstrating Compliance

A health center would demonstrate compliance with these requirements by fulfilling all of the following:

- The health center's staffing plan ensures that clinical[2] and related support staff are in place to carry out all required and additional services included in the HRSA-approved scope of project.[3] This staffing plan may include the use of contracted providers and/or referral providers.

- The health center has considered the size, demographics, and health needs (for example, large number of children served, high prevalence of diabetes) of its patient

[1] These terms are defined in section 330(b) of the Public Health Service Act.
[2] Clinical staff includes licensed independent practitioners (for example, Physician, Dentist, Physician Assistant, Nurse Practitioner), other licensed or certified practitioners (for example, Registered Nurse, Licensed Practical Nurse, Certified Medical Assistant, Registered Dietitian), and other clinical staff providing services on behalf of the health center.
[3] Health centers seeking coverage for themselves and their providers under the Health Center FTCA Program should review the statutory and policy requirements for coverage, as discussed in the Health Center FTCA Policy Manual.

population in determining the number and mix of clinical staff necessary to ensure reasonable patient access to health center services.

- The health center has operating procedures for the initial and recurring review (for example, every two years) of credentials for all clinical staff members who are health center employees, individual contractors, or volunteers. These credentialing procedures would ensure verification of all of the following:
    - Current licensure, registration, or certification;
    - Education and training for initial credentialing, using primary sources for licensed independent practitioners;[4]
    - Completion of a query through the National Practitioner Databank (NPDB);[5]
    - Clinical staff member's identity for initial credentialing using a government issued picture identification;
    - Drug Enforcement Administration registration (if applicable); and
    - Current documentation of Basic Life Support skills.

- The health center has operating procedures for the initial granting and renewal (for example, every two years) of privileges for clinical staff members who are health center employees, individual contractors, or volunteers. These privileging procedures would address all of the following:
    - Verification of health fitness, including physical and mental health status, immunization and communicable disease status,[6] and any impairments that may interfere with the safe and effective provision of care permitted under the requested clinical privileges;
    - Verification of current clinical competence via reference reviews, training, and education for initial privileging, and via peer review or other comparable methods for renewal of privileges; and
    - Criteria and processes for modifying or removing privileges based on the outcomes of clinical competence assessments.

- The health center maintains files or records for its clinical staff (employees, individual contractors, and volunteers) that contain documentation of licensure and credentialing verification and recording of privileges, consistent with operating procedures.

[4] This does not require the health center to obtain primary source verification in cases where the state licensing board utilizes primary source verification.
[5] The NPDB is an electronic information repository created by Congress. It contains information on medical malpractice payments and certain adverse actions related to health care practitioners, entities, providers, and suppliers. For more information, please visit http://www.npdb.hrsa.gov.
[6] The CDC and many states have standards for immunization and communicable disease status. The CDC standards are available at http://www.cdc.gov/vaccines/adults/rec-vac/hcw.html.

- The health center's contracts with provider organizations (for example, group practices, staffing agencies) and formal, written referral agreements with other provider organizations, contain provisions that:
    - Ensure that the providers are licensed, certified, or registered as verified through a credentialing process, in accordance with applicable federal, state, and local laws; and
    - Ensure that the providers are assessed as competent to perform the contracted or referred services through a privileging process.

Related Considerations

The following points may be useful for health centers to consider when implementing these requirements:

- The health center determines the composition of its staffing plan (for example, use of nurse practitioners, physician assistants, certified nurse midwives) and staffing levels (for example, full- and/or part-time staff).

- The health center determines who has approval authority for credentialing and privileging of clinical staff.

- The health center determines how credentialing will be implemented (for example, a health center may contract with a credentials verification organization (CVO) to perform credentialing activities or it may have its own staff conduct credentialing).

- The health center determines how it assesses clinical competence for purposes of privileging (for example, a health center may utilize peer review conducted by its own providers or may contract with another organization to conduct peer review).

- The health center determines (consistent with its established privileging criteria) whether to deny, modify, or remove privileges; whether to use an appeals process in conjunction with such determinations; and whether to implement corrective action plans in conjunction with the denial, modification, or removal of privileges.

Chapter 6: Accessible Locations and Hours of Operation

Authority

Section 330(k)(3)(A) of the PHS Act; and 42 CFR 51c.303(a) and 42 CFR 56.303(a)

Requirements

- The required primary health services of the health center must be available and accessible in the catchment [service] area of the center promptly, as appropriate, and in a manner which assures continuity of service to the patient population.

Demonstrating Compliance

A health center would demonstrate compliance with these requirements by fulfilling all of the following:

- The health center's service site(s) are accessible to the patient population relative to where this population lives or works (for example, at migrant camps for health centers targeting agricultural workers, in areas immediately accessible to public housing for health centers targeting public housing residents). Specifically, the health center has considered the following factors to ensure the accessibility of its sites:
    - Access barriers (for example, barriers resulting from the area's physical characteristics, residential patterns, or economic and social groupings); and
    - Distance and time taken for patients to travel to or between service sites in order to access the health center's full range of in-scope services.

- The health center's total number and scheduled hours of operation of its service sites are responsive to patient needs by facilitating their ability to schedule appointments and access services[1] (for example, a health center service site might offer extended evening hours 3 days a week based on input or feedback from patients who cannot miss work for appointments during normal business hours).

- The health center accurately records the sites in its HRSA-approved scope of project[2] on its Form 5B: Service Sites in the HRSA's Electronic Handbooks (EHB).

[1] Services refer to services which are included in the HRSA-approved scope of project as documented on Form 5A: Services Provided. For further details on scope of project, including Form 5A service and column descriptors please see http://www.bphc.hrsa.gov/programrequirements/scope.html.

[2] In accordance with 45 CFR 75.308(c)(1)(i), health centers must request prior approval from HRSA for a "Change in the scope or the objective of the project or program (even if there is no associated budget revision requiring prior

Related Considerations

The following points may be useful for health centers to consider when implementing these requirements:

- The health center determines which methods to use for obtaining patient input on the accessibility of its service sites and hours of operation (for example, annual survey, focus groups, input from patient board members).

- The health center determines how to support patient access to the various service sites included within its HRSA-approved scope of project (for example, provide patient transportation between service sites, use mobile service sites).

written approval)." This prior approval requirement applies to the addition, deletion, or replacement of a service site. These changes require prior approval from HRSA and must be submitted by the health center as a formal change in scope request. For further details on scope of project, please see http://www.bphc.hrsa.gov/programrequirements/scope.html.

Chapter 7: Coverage for Medical Emergencies During and After Hours

Authority

Section 330(b)(1)(A)(IV) and Section 330(k)(3)(A) of the PHS Act; and 42 CFR 51c.102(h)(4), 42 CFR 56.102(l)(4), 42 CFR 51c.303(a), and 42 CFR 56.303(a)

Requirements

- To assure continuity of the required primary health services of the center, the health center must have:
  - Provisions for promptly responding to patient medical emergencies during the health center's regularly scheduled hours; and
  - Clearly defined arrangements for promptly responding to patient medical emergencies after the health center's regularly scheduled hours.

Demonstrating Compliance

A health center would demonstrate compliance with these requirements by fulfilling all of the following:

- The health center has the clinical capacity to respond to patient medical emergencies[1] at all health center service sites (as documented on Form 5B: Service Sites) during the health center's regularly scheduled hours of operation[2] by having at least one staff member certified in basic life support skills present at each HRSA-approved service site.

- The health center has and follows its applicable operating procedures when responding to patient medical emergencies during regularly scheduled hours of operation.

- The health center has after-hours coverage operating procedures, which may include other formal arrangements[3] with non-health center providers/entities, that ensure:
  - Coverage is provided via telephone or face-to-face by an individual with the qualification and training necessary to exercise professional judgment in assessing a health center patient's need for emergency medical care;[4]

[1] Medical emergencies include those related to physical, oral, behavioral, or other emergent health needs.
[2] See Accessible Location and Hours of Operation for more information on Hours of Operation.
[3] See Contracts, Subawards, and Other Formal Agreements for more information on oversight over such arrangements.
[4] *Ibid*.

  - Coverage includes the ability to refer patients either to a licensed independent practitioner for further consultation or to locations such as emergency rooms or urgent care facilities for further assessment or immediate care as needed; and
  - Patients, including those with limited English proficiency,[5] are informed of and are able to access after-hours coverage, and after-hours coverage information or instructions are provided in the language(s), literacy levels, and formats accessible to the health center's patient population.

- The health center has documentation of after-hours calls and any necessary follow-up resulting from such calls for the purposes of continuity of care.[6]

Related Considerations

The following points may be useful for health centers to consider when implementing these requirements:

- The health center determines the means by which it provides after-hours coverage. Examples include: 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,[7] or "nurse call" lines.

- The health center determines how to make patients aware of the availability of, and procedures for, accessing professional coverage after hours. Examples include after-hours instructions that are: posted on the door of all health center service sites, explained as part of the initial patient registration process, noted on the health center's website, or provided as patient handouts, brochures, or cards.

[5] Under Section 602 of Title VI of the Civil Rights Act and the Department of Health and Human Services implementing regulations (45 C.F.R. Section 80.3(b)(2)), recipients of federal financial assistance, including health centers, must take reasonable steps to ensure meaningful access to their programs, services, and activities by eligible Limited English Proficient (LEP) persons. For further guidance on translating vital documents for LEP, please see http://www.hhs.gov/ocr/civilrights/resources/laws/summaryguidance.html.

[6] For more information on continuity of care, please see Continuity of Care and Hospital Admitting.

[7] Health centers that are deemed under the Federal Tort Claims Act (FTCA) should ensure that they are familiar with the applicable restrictions on FTCA coverage for services provided to non-health center patients. Please review the FTCA Health Center Policy Manual for further information.

Chapter 8: Continuity of Care and Hospital Admitting

Authority

Section 330(k)(3)(A) and 330(k)(3)(L) of the PHS Act; and 42 CFR 51.c.303(a) and 42 CFR 56.303(a)

Requirements

- The health center must provide the required primary health services of the center so that such services are available and accessible promptly, as appropriate, and in a manner which will assure continuity of service to patients within the center's catchment area (service area).

- The health center must develop an ongoing referral relationship with one or more hospitals for the purposes of continuity of service, including, where appropriate, the provision of care to health center patients by health center providers in the hospital setting, such as hospital admissions or rounding by health center providers.

Demonstrating Compliance

A health center would demonstrate compliance with these requirements by fulfilling all of the following:

- The health center has:
    - Provider[1] employment contracts or other appropriate documentation that address the delivery of care in a hospital setting to health center patients, including hospital admitting for those health center providers who have such privileges; and/or
    - Formal arrangements between the health center and non-health center provider(s) or entity(ies) (for example, hospital, hospitalists, obstetrics group practice) that address health center patient admissions.

- The health center has internal operating procedures and, if applicable, related provisions in its formal arrangements with non-health center provider(s) or entity(ies)

[1] In addition to physicians, various provider types may have admitting privileges, if applicable, based on scope of practice in their State (for example, Nurse Practitioners, Certified Nurse Midwives).

that address the following areas for patients who are hospitalized as inpatients or who visit a hospital's emergency department:[2]
    - Notification to the health center of a patient's hospitalization or emergency department visit and of patient discharge;
    - Receipt and recording of medical information from non-health center providers/hospitals, such as discharge follow-up instructions and laboratory, radiology, or other results; and
    - Follow-up actions by health center staff, when appropriate.

- The health center follows its operating procedures and written agreements as documented by:
    - Receipt and recording of notifications to the health center of patient hospitalization or emergency department visits and of patient discharges;
    - Receipt and recording of medical information from non-health center providers, such as discharge follow-up instructions and laboratory, radiology, or other results; and
    - Evidence of follow-up actions taken by health center staff based on the information received, when appropriate.

Related Considerations

The following points may be useful for health centers to consider when implementing these requirements:

- The health center determines the number and type(s) of hospitals with which its providers will have admitting arrangements based on the services included in the HRSA-approved scope of project (Form 5A: Services Provided), the patient population served, and the service area.

- The health center determines whether the most appropriate means for hospital admitting is to use its own providers, have formal arrangements with non-health center providers, or both.

- The health center determines the most appropriate formats and mechanisms for discharge planning and tracking (for example, use of community-wide shared electronic health record, patient hospitalization tracking log).

[2] Health center patients may enter a hospital setting through a variety of means such as a visit to the Emergency Department (ED), an ED visit that resulted in an inpatient hospital admission, or a health center patient admission to a unit of the hospital such as labor and delivery.

Chapter 9: Sliding Fee Discount Program

Authority

Section 330(k)(3)(G) of the PHS Act; and 42 CFR 51c.303(f), 42 CFR 51c.303(g), 42 CFR 51c.303(u), 42 CFR 56.303(f), 42 CFR 56.303(g), and 42 CFR 56.303(u)

Requirements

- The health center must operate in a manner such that no patient shall be denied service due to an individual's inability to pay.

- 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 and must prepare a corresponding schedule of discounts [sliding fee discount schedule] to be applied to the payment of such fees or payments, by which discounts are adjusted on the basis of the patient's ability to pay.

- The health center must establish systems for [sliding fee] eligibility determination.

- The health center's schedule of discounts must provide for:
    - A full discount to individuals and families with annual incomes at or below those set forth in the most recent Federal Poverty Guidelines (FPG) [100 percent of the FPG], except that nominal charges for service may be collected from such individuals and families where imposition of such fees is consistent with project goals; and
    - No discount to individuals and families with annual incomes greater than twice those set forth in such Guidelines [200 percent of the FPG].

Demonstrating Compliance

A health center would demonstrate compliance with these requirements by fulfilling all of the following:

- The health center has a sliding fee discount program[1] that applies to all required and additional services[2] within the HRSA-approved scope of project, for which there are distinct fees.

[1] A health center's sliding fee discount program consists of a schedule of discounts applied to the fee schedule which adjusts fees based on the patient's ability to pay and also includes the related policies and procedures for determining sliding fee eligibility and applying sliding fee discounts.

- The health center has board-approved policies for its sliding fee discount program that apply uniformly to all patients and address the following areas:
    - Assessment of all patients for sliding fee discount eligibility based only on income and family size (in accordance with the FPG);
    - Definitions of, and requirements for, verifying income[3] and family size;
    - The manner in which the health center's sliding fee discount schedule(s) (SFDS(s)) will be structured in order to ensure that patient charges are adjusted based on ability to pay; and
    - *Only applicable to health centers that choose to have a nominal charge for patients at or below 100 percent of the FPG*: The setting of the nominal charge(s) at a level that would be nominal from the perspective of the patient and would not reflect the actual cost of the service being provided.

- For health centers that choose to have more than one SFDS, these SFDSs would be based on services (for example, having separate SFDSs for medical and dental services) or service delivery methods (for example, having separate SFDSs for services provided directly by the health center and for services provided via formal written contract) and no other factors.

- The health center has operating procedures for and records of assessing/re-assessing patients for income and family size (unless the patient declines/refuses to be assessed) consistent with board-approved policies.

- The health center has mechanisms for informing patients of the availability of sliding fee discounts (for example, using materials in language(s) and literacy levels appropriate for the patient population).

- The health center evaluates its sliding fee discount program to ensure its effectiveness in reducing financial barriers to care and to identify and implement changes as needed.

- The health center's SFDS(s) is structured consistent with board-approved policy and provides discounts as follows:
    - 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.

---

[2] For more information on requirements around services within the scope of the project, please see Required and Additional Services.

[3] Earnings over a given period of time used to support an individual/household unit based on a set of criteria of inclusions and exclusions. Income is distinguished from assets, as assets are a fixed economic resource while income is comprised of earnings.

  - Partial discounts are provided for individuals and families with incomes above 100 percent of the current FPG and at or below 200 percent of the current FPG that adjust in accordance with income (for example, three (3) to five (5) discount pay classes based on gradations in income levels above 100 percent of the FPG and at or below 200 percent of the FPG).[4]
  - No discounts are provided to individuals and families with annual incomes above 200 percent of the current FPG.[5]

- For services provided directly by the health center (Form 5A: Services Provided, Column I), the health center has records that show it provides sliding fee discounts in accordance with its established SFDS(s).

- For services provided via contractual agreements (Form 5A: Services Provided, Column II), the health center's contracts/agreements contain provisions for sliding fee discounts as follows:
  - 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.
  - Partial discounts are provided for individuals and families with incomes above 100 percent of the current FPG and at or below 200 percent of the current FPG that adjust in accordance with income (for example, three (3) to five (5) discount pay classes based on gradations in income levels above 100 percent of the FPG and at or below 200 percent of the FPG).
  - No discounts are provided to individuals and families with annual incomes above 200 percent of the current FPG.

- For services provided via formal referral arrangements (Form 5A: Services Provided, Column III), the health center has ensured that the referral provider either offers sliding fee discounts as described above or offers greater discounts to patients such that:
  - Patients at or below 200 percent of the FPG receive a greater discount for these services than if the health center's SFDS was applied to the referral provider's fee schedule; and
  - Patients at or below 100 percent of the FPG receive no charge or only a nominal charge for these services.

- The health center's SFDS(s) has incorporated the most recent FPG.

---

[4] For example, a SFDS with discount pay classes of 101 percent up to 125 percent of the FPG, 126 percent to 150 percent of the FPG, 151 percent to 175 percent of the FPG, 176 percent to 200 percent of the FPG, and over 200 percent of the FPG would have four discount pay classes between 101 percent and 200 percent of the FPG.

[5] Please see Billing and Collections, if the health center has access to other grants or subsidies that support patient care.

- The health center's patients, including those at or below 100 percent of the FPG are accessing health center services, regardless of discount pay class (for example, patient utilization data shows that patients at all income levels are accessing health center services).

- Subject to potential legal and contractual restrictions,[6] health center patients with third-party coverage who are also eligible for sliding fee discounts are provided with any applicable sliding fee discounts.[7]

Related Considerations

The following points may be useful for health centers to consider when implementing these requirements:

- The health center determines whether to establish additional aspects of its sliding fee discount program, such as:
    - Providing alternative mechanisms for determining SFDS eligibility (for example, self-declaration, streamlined eligibility renewal);
    - Identifying as ineligible for SFDS individuals who refuse to provide income and family size;
    - Establishing multiple SFDSs (for example, separate SFDSs for medical services and dental services); or
    - Determining whether or not to establish a nominal charge and whether to establish different nominal charges for different services.

- The health center determines how to define "family/household" and "income" and associated verification requirements for SFDS eligibility, taking into consideration the characteristics of its patient population (for example, individuals experiencing homelessness) and service areas (for example, areas with high cost of living).

- The health center determines how to make patients aware of sliding fee discounts (for example, signage, registration process).

- The health center determines:

[6] Such limitations may be specified by applicable federal and state law for Medicare and Medicaid or terms and conditions of private payor contracts.

[7] For example, an insured patient receives a health center service for which the health center has established a fee of $80, per its fee schedule. Based on the patient's insurance plan, the co-pay would be $60 for this service. The health center also has determined, through an assessment of income and family size, that the patient's income is 150 percent of the FPG and thus qualifies for the health center's SFDS. Under the SFDS, a patient with an income at 150 percent of the FPG would receive a 50 percent discount of the $80 fee, resulting in a charge of $40 for this service. Rather than the $60 co-pay, the health center would charge the patient no more than $40 out-of-pocket, consistent with its SFDS, as long as this is not precluded by the insurance contract.

  - What income range to establish for each discount pay class; and
  - What method to use for discounting fees (for example, percentage of fee, fixed/flat fee per discount pay class).

- For in-scope services provided through formal referral arrangements (Form 5A: Services Provided, Column III), the health center determines whether to enter into formal referral agreements with organizations that may also provide discounts to patients with incomes above 200 percent of the FPG.

Chapter 10: Quality Improvement/Assurance

Authority

Section 330(k)(3)(C) of the PHS Act; and 42 CFR 51c.110, 42 CFR 51c.303(b), 42 CFR 51c.303(c), 42 CFR 51c.304(d)(3)(iv-vi), 42 CFR 56.111, 42 CFR 56.303(b), 42 CFR 56.303(c), and 42 CFR 56.304(d)(4)(v-vii)

Requirements

- The health center must have an ongoing quality improvement/assurance (QI/QA) system that includes clinical services and management and maintains the confidentiality of patient records.

- The health center's ongoing quality improvement/assurance system must provide for all of the following:
    - Organizational arrangements, including a focus of responsibility, to support the quality assurance program and the provision of high quality patient care; and
    - Periodic assessment of the appropriateness of the utilization of services and the quality of services provided or proposed to be provided to individuals served by the center. Such assessments must:
        - Be conducted by physicians or by other licensed health professionals under the supervision of physicians;
        - Be based on the systematic collection and evaluation of patient records;
        - Assess patient satisfaction, achievement of project objectives, and include a process for hearing and resolving patient grievances; and
        - Identify and document the necessity for change in the provision of services by the center and result in the institution of such change, where indicated.

- The health center must maintain the confidentiality of patient records, including all information as to personal facts and circumstances obtained by the health center staff about recipients of services. Specifically, the health center must not divulge such information without the individual's consent except as may be required by law or as may be necessary to provide service to the individual or to provide for medical audits by the Secretary of HHS or her designee with appropriate safeguards for confidentiality of patient records.

Demonstrating Compliance

A health center would demonstrate compliance with these requirements by fulfilling all of the following:

- The health center has board-approved policies that establish a QI/QA program.[1]

- The health center's operating procedures address all of the following:
  - Adherence to current evidence-based clinical guidelines, standards of care, and standards of practice, as applicable;
  - A process for identifying, analyzing, and addressing patient safety and adverse events and for implementing follow-up actions, as necessary;
  - A process for assessing patient satisfaction;
  - A process for hearing and resolving patient grievances;
  - Production and sharing of reports on QI/QA to support decision-making and oversight by key management staff and the governing board regarding the provision of health center services;
  - Completion of periodic (for example, quarterly) QI/QA assessments; and
  - A process for modifying the provision of health center services based on the findings of QI/QA assessments, as appropriate.

- The health center's physicians or other licensed health care professionals conduct QI/QA assessments using data systematically collected from patient records.

- The health center's QI/QA program assesses the following:
  - The quality of health center services;
  - Patient satisfaction and the outcomes of patient grievance processes;
  - The utilization of health center services, consistent with evidence-based guidelines; and
  - The status of activities around any safety and adverse events, including follow-up actions, as appropriate.

- The health center designates an individual(s) to oversee the QI/QA program. This individual's responsibilities would include, but not be limited to ensuring the implementation of QI/QA operating procedures and completion of QI/QA assessments, monitoring QI/QA outcomes, and updating QI/QA operating procedures.

- The health center maintains a retrievable health record (for example, the health center has implemented a certified Electronic Health Record)[2] for each patient, the format and content of which is consistent with both federal and state laws and requirements.

[1] For more information on the health center governing board's role in approving policies please see Board Authority.

- The health center has systems and procedures for protecting the confidentiality of patient information and safeguarding this information against loss, destruction, or unauthorized use, consistent with federal and state requirements.

Related Considerations

The following points may be useful for health centers to consider when implementing these requirements:

- The health center determines whether the position designated with responsibility for the QI/QA program (for example, Clinical Director, QI Director) is full-time, part-time, or combined with another position and whether it is filled by an employee or via contract.

- The health center determines whether the position designated with responsibility for the QI/QA program is filled by a physician, other licensed health care professional (for example, registered nurse, nurse practitioner), or other qualified individual (for example, an individual with a Master of Public Health or a Master of Healthcare Administration).

- The health center determines which QI/QA methodology or methodologies to use.

- The health center determines the type of patient health record system that it will use.

- The health center determines the format, content, and focus of QI/QA reports.

[2] CMS and the Office of the National Coordinator for Health Information Technology (ONC) have established standards and other criteria for structured data that Electronic Health Records (EHRs) must use in order to qualify for CMS incentive programs. For health centers that participate in these CMS Incentive Programs, further information is available at https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Certification.html.

Chapter 11: Key Management Staff

Authority

Section 330(k)(3)(I)(i) of the PHS Act; 42 CFR 51c.104(b)(4), 42 CFR 51c.303(p), 42 CFR 56.104(b)(5), and 42 CFR 56.303(p); and 45 CFR 75.308(c)(1)(ii)(iii)

Requirements

- The health center must have position descriptions for key personnel [key management] that set forth training and experience qualifications necessary to carry out the activities of the health center.

- The health center must maintain sufficient key personnel [key management] to carry out the activities of the health center.

- The health center must request prior approval from HRSA for a change in the key person [Project Director/Chief Executive Officer (CEO)] specified in the Federal Health Center Program award or Health Center Program look-alike designation.

Demonstrating Compliance

***A health center would demonstrate compliance with these requirements by fulfilling all of the following*:**

- The health center has determined the makeup of its key management staff[1] and the percentage of time dedicated to the health center project for each position, as necessary to carry out the HRSA-approved scope of project.

- The health center has identified the training and experience qualifications for each key management staff position in position descriptions.

- The health center has implemented a process for filling open key management positions (for example, vacancy announcements have been published and reflect the identified qualifications).

[1] Examples of key management staff may include Project Director/CEO, Clinical Director/Chief Medical Officer, Chief Financial Officer, Chief Operating Officer, Nursing/Health Services Director, or Chief Information Officer.

- The health center's Project Director/CEO[2] reports to the health center's governing board and is responsible for overseeing other key management staff in carrying out the day-to-day activities necessary to fulfill the HRSA-approved scope of project.

- If there has been a post-award change in the Project Director/CEO position,[3] the health center requested and received prior approval from HRSA.

Related Considerations

The following points may be useful for health centers to consider when implementing these requirements:

- The health center determines whether to directly employ or contract for the Project Director/CEO or other key management staff positions.[4]

[2] While the position title of the key person specified in the award/designation may vary, for the purposes of the Health Center Program, this Chapter will utilize the term "Project Director/CEO" when referring to this key person. Under 45 CFR 75.2, the term "Principal Investigator/Program Director (PI/PD)" means the individual(s) designated by the recipient to direct the project or program being supported by the grant. The PI/PD is responsible and accountable to officials of the recipient organization for the proper conduct of the project, program, or activity. For the purposes of the Health Center Program, "Project Director/CEO" is synonymous with the term "PI/PD."

[3] Such changes include situations in which the current health center Project Director/CEO will be disengaged from involvement in the project for any continuous period for more than 3 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)].

[4] Contracting for the CEO and/or the entire key management team inclusive of the CEO requires prior approval from HRSA. For more information please see Contracts and Subawards.

Chapter 12: Contracts and Subawards

Authority

Section 330(k)(3)(I) and Section 330(q) of the PHS Act; 42 CFR 51c.113, 42 CFR 56.114, 42 CFR 51c.303(t), and 42 CFR 56.303(t); 45 CFR Part 75 Subpart D; and Section 1861(aa)(4)(A)(ii) and Section 1905(l)(2)(B)(ii) of the Social Security Act

Requirements

General

- Health center contracts and other agreements (including subawards) with other providers for the provision of health services within the scope of project must include a schedule of rates and method of payment for such services.

- The health center must determine[1] whether an individual agreement that will result in disbursement of Federal funds will be carried out through a contract or a subaward and structure the agreement accordingly.[2]

- The health center must request and receive approval from HRSA to subaward or to contract for work[3] under the Federal award.

- The health center must retain financial records, supporting documents, statistical records, and all other records pertinent to the Health Center Program project (including those related to contracts or subawards) for a period of three years from the date of the submission of the final expenditures report to HHS (or to the Federal award recipient in the case of a subrecipient).

- The health center must be responsible, in accordance with good administrative practice and sound business judgment, for the settlement of all contractual and administrative

[1] Per 45 CFR 75.351(c): "In determining whether an agreement between a pass-through entity [Health Center Program awardee] and another non-Federal entity casts the latter as a subrecipient or a contractor, the substance of the relationship is more important than the form of the agreement. All of the characteristics listed above [see 45 CFR 351(a) and (b)] may not be present in all cases, and the pass-through entity [Health Center Program awardee] must use judgment in classifying each agreement as a subaward or a procurement contract."
[2] Specifically, the purpose of a subaward is to carry out a portion of the Federal award and creates a Federal assistance relationship with the subrecipient, while the purpose of a contract is to obtain goods or services for the health center 's own use and creates a procurement relationship with the contractor.
[3] This does not apply to the acquisition of supplies, material, equipment, or general support services. However, it does apply to the delivery of health care services under the Federal award.

issues arising out of procurements. These issues include, but are not limited to, source evaluation, protests, disputes, and claims.[4]

Contracts: Procurement and Monitoring

- The health center must use its own documented procurement procedures which reflect applicable State, local, and tribal laws and regulations, provided that the procurements conform to applicable Federal law and the standards identified in 45 CFR Part 75.

- The health center must perform a cost or price analysis in connection with every procurement action in excess of the Simplified Acquisition Threshold.[5]

- The health center must conduct all procurement transactions in a manner that provides full and open competition consistent with the standards of 45 CFR 75.328. Procurements by non-competitive proposals[6] are allowable only when:
    - The item is available only from a single source;
    - The public exigency or emergency for the requirement will not permit a delay resulting from competitive solicitation;
    - The non-competitive proposal is specifically authorized by HRSA (or, in the case of a subrecipient, the Federal award recipient) in response to a written request from the Federal award recipient or subrecipient; or
    - Competition is determined to be inadequate after soliciting a number of sources.

- The health center must oversee contractors to ensure their performance is in accordance with the terms, conditions, and specifications of their contracts and to assure compliance with applicable Federal requirements.

Subawards: Monitoring and Management

- The health center awardee must make documented, case-by-case determinations[7] whether the agreement it makes for the disbursement of Federal program funds casts

[4] These standards do not relieve the non-Federal entity of any contractual responsibilities under its contracts. HRSA will not substitute its judgment for that of the non-Federal entity unless the matter is primarily a Federal concern. Violations of law will be referred to the local, tribal, state, or Federal authority having proper jurisdiction.
[5] *Simplified acquisition threshold* means the dollar amount below which a non-Federal entity may purchase property or services using small purchase methods. Non-Federal entities adopt small purchase procedures in order to expedite the purchase of items costing less than the simplified acquisition threshold. 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. The acquisition threshold is periodically adjusted for inflation.
[6] As defined by 45 CFR 75.329(f), procurement by "noncompetitive proposals" is procurement through solicitation of a proposal from only one source.
[7] Per 45 CFR 75.351(c), please note that the "substance of the relationship is more important than the form of the agreement. All of the characteristics listed above [see 45 CFR 351(a) and (b)] may not be present in all cases, and

the party receiving the funds in the role of a subrecipient, consistent with the characteristics outlined in 45 CFR 75.351. In addition, the health center must identify subawards as such to the subrecipient, and provide all applicable information to the subrecipient as described in 45 CFR 75.352(a)(1). If any of the data elements contained in 45 CFR 75.352(a)(1) change, the health center must include the change(s) in a subsequent subaward modification.

- The health center must ensure that, at the time of making a subaward, each subrecipient which is a subawardee of Federal funds complies with all applicable requirements specified in the Federal award (including those found in section 330 of the PHS Act, implementing program regulations, Health Center Federal Tort Claims Act (FTCA) Program requirements[8] (where applicable), and grants regulations in 45 CFR Part 75).

- The health center must monitor the ongoing activities of the subrecipient which is a subawardee to ensure that the subaward is used for authorized purposes and that the subrecipient maintains compliance with all applicable requirements specified in the Federal award (including those found in section 330 of the PHS Act, implementing program regulations, Health Center FTCA Program requirements (where applicable), and grants regulations in 45 CFR Part 75).

Demonstrating Compliance

A health center would demonstrate compliance with these requirements by fulfilling all of the following:

General

- The health center's contracts and subawards that support the HRSA-approved scope of project include provisions that address the following:
    - Mechanisms for the health center to monitor contractor or subrecipient performance;
    - Requirements for the contractor or subrecipient to provide data necessary to meet the recipient's applicable federal financial and programmatic reporting requirements, as well as provisions addressing record retention and access, audit, and property management;[9]
    - The specific activities or services to be performed or goods to be provided;

---

the pass-through entity [Health Center Program awardee] must use judgment in classifying each agreement as a subaward or a procurement contract."

[8] For further requirements related to the Health Center FTCA Program, please see the Federal Torts Claim Act Health Center Policy Manual at: http://bphc.hrsa.gov/ftca/pdf/ftcahcpolicymanualpdf.pdf.

[9] For further guidance on these requirements, please see the HHS Grants Policy Statement, at http://www.hrsa.gov/grants/hhsgrantspolicy.pdf.

  - Requirements that all costs directly attributable to the federal grant are allowable consistent with Federal Cost Principles;[10]
  - The integration of applicable requirements of the Health Center Program (for example, sliding fee discounts, credentialing and privileging); and
  - The applicability of distinct statutory, regulatory, and policy requirements for health centers that participate in other Federal programs associated with their HRSA-approved scope of project (for example, FTCA coverage, reimbursement as a Federally Qualified Health Center (FQHC) under Medicare/ Medicaid/ Children's Health Insurance Program, 340B Program drug discount pricing as an FQHC).

- If the health center has arrangements with a contractor or subrecipient to perform substantive programmatic work,[11] the health center requested and received prior approval from HRSA as documented by:
  - An approved competing continuation/renewal of designation application or other competitive application, which included such an arrangement; or
  - An approved post-award request for such arrangements submitted within the project period (for example, change in scope).

- The health center retains final subrecipient agreements, contracts, and related records consistent with federal document maintenance requirements.[12]

Contracts: Procurement and Monitoring

- The health center has written procurement procedures that comply with federal procurement standards.

- The health center has procurement records that include the rationale for method of procurement, selection of contract type, contractor selection or rejection, and the basis for the contract price. This would include documentation related to noncompetitive procurements.

- The health center has access to contractor records and reports related to health center activities in order to ensure that all activities and reporting requirements are being carried out in accordance with the provisions and timelines of the related contract (for example, performance goals are achieved, Uniform Data System (UDS) data is submitted by appropriate deadlines, funds are used for authorized purposes).

[10] See 45 CFR 75 Subpart E: Cost Principles.
[11] This includes, but is not limited to, all subrecipient arrangements and contracting for the majority of core primary care services, or CEO/Project Director, or both.
[12] See 45 CFR 75.361 for HHS retention requirements for records.

Subawards: Monitoring and Management

- If the health center makes subawards, it monitors the activities of the subrecipient to ensure that the subaward is used for authorized purposes and that the subrecipient maintains compliance with all applicable requirements specified in the Federal award (including those found in section 330 of the PHS Act, implementing program regulations, Health Center Federal Tort Claims Act (FTCA) Program requirements (where applicable), and grants regulations in 45 CFR Part 75). Specifically, the health center's monitoring of the subrecipient includes:
    - Reviewing financial and performance reports required by the health center in order to ensure performance goals are achieved, UDS data is submitted by appropriate deadlines, and funds are used for authorized purposes;
    - Ensuring that the subrecipient takes timely and appropriate action on all deficiencies pertaining to the health center subaward which may be identified through audits, on-site reviews, and other means; and
    - Issuing a management decision for audit findings pertaining to the subaward.

Related Considerations

The following points may be useful for health centers to consider when implementing these requirements:

- The health center determines the methods it will utilize to monitor subrecipient compliance and performance with Health Center Program requirements. Such monitoring could include:
    - Receiving/reviewing copies of the subrecipient governing board's meeting minutes;
    - Performing site visits;
    - Conducting regular check-in calls and updates regarding program requirements or new Health Center Program policies;
    - Receiving/reviewing the subrecipient's annual audit;
    - Conducting periodic joint meetings between the two entities' boards, or between the health center's key management staff and the subrecipient's board;
    - Receiving/reviewing periodic written reports from the subrecipient; or
    - Sharing data and creating systems for the sharing of financial and medical records for the purpose of health center data reporting.

- The health center determines the methods it will utilize to monitor contractor activities and performance. Such monitoring could include:
    - Periodic evaluations of contractor performance (for example, results from reviews of invoices and records, reports from staff of contractor activity) that are shared with the board and management staff; and

  - Documentation at the time of contract completion or renewal that the contractor has met terms, conditions, and specifications of the contract.

- The health center determines the methods it will utilize to settle any contractual or administrative issues arising out of procurements, with respect to contracts or subawards. These issues include, but are not limited to, source evaluation, protests, disputes, and claims.

Chapter 13: Conflict of Interest

Authority

Section 330(a)(1) and 330(k)(3)(D) of the PHS Act; 42 CFR 51.113 and 42 CFR 56.114; and 45 CFR 75.327

Requirements

- The health center must maintain written standards of conduct covering conflicts of interest[1] and governing the actions of its employees engaged in the selection, award, or administration of contracts that comply with all applicable federal requirements.

- No employee, officer, or agent[2] of the health center may participate in the selection, award, or administration of a contract supported by a Federal award if he or she has a real or apparent conflict of interest.

- Officers, employees, and agents of the health center may neither solicit nor accept gratuities, favors, or anything of monetary value from contractors or parties to subcontracts.

- The health center's standards of conduct must provide for disciplinary actions to be applied for violations of such standards by officers, employees, or agents of the health center.

- If the health center has a parent, affiliate, or subsidiary organization[3] that is not a State, local government, or Indian tribe, the health center also must maintain written standards of conduct covering organizational conflicts of interest.

Demonstrating Compliance

A health center would demonstrate compliance with these requirements by fulfilling all of the following:

---

[1] A conflict of interest arises when the employee, officer, or agent, any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of the parties indicated herein, has a financial or other interest in or a tangible personal benefit from a firm considered for a contract. See: 45 CFR 75.327(c)1.

[2] An agent of the health center includes, but is not limited to, an employee, officer, governing board member, or contractor acting on behalf of the health center.

[3] This would include a subrecipient or contractor.

- The health center has and implements written standards of conduct applicable to all health center employees, officers, and agents regarding the selection, award, or administration of contracts that:
    - Require written disclosure of any conflicts of interest related to procurements;
    - Prohibit individuals with actual or apparent conflicts of interest from participating in the selection, award, or administration of the contract;[4]
    - Restrict health center employees, officers, and agents from soliciting or accepting gratuities, favors, or anything of monetary value from contractors or parties to sub-agreements (including subrecipients or affiliation organizations); and
    - Enforce disciplinary actions on health center employees, board members, and agents for violating these standards.

- If the health center has a parent, affiliate, subsidiary, or subrecipient organization (that is not a State, local government, or Indian tribe), the health center has and implements written standards of conduct covering organizational conflicts of interest[5] that might arise when conducting a procurement action involving a related organization. These standards of conduct require:
    - Written disclosure of conflicts of interest that arise in procurements from a related organization; and
    - Avoidance and mitigation of any identified actual or apparent conflicts during the procurement process.

- The health center has mechanisms or procedures for informing its employees, officers, and agents of the health center's standards of conduct covering conflicts of interest, including organizational conflicts of interest, and governing their actions with respect to the selection, award and administration of contracts.

- In cases where a conflict of interest was identified, the health center's procurement records document adherence to its standards of conduct (for example, an employee whose family member was competing for a health center contract was not permitted to participate in the selection, award, or administration of that contract).

[4] This includes, but is not limited to, prohibiting board members that are employees or contractors of a subrecipient of the health center from participating in the selection, award, or administration of that subaward. This also includes prohibiting board members who are employees of an organization that contracts with the health center from participating in the selection, award, or administration of that contract.

[5] Organizational conflicts of interest mean that because of relationships with a parent company, affiliate, or subsidiary organization, the health center is unable or appears to be unable to be impartial in conducting a procurement action involving a related organization. See: 45 CFR 75.327(c)(2).

Related Considerations

The following points may be useful for health centers to consider when implementing these requirements:

- The health center determines the appropriate methods for board members, agents, and employees to disclose actual or apparent conflicts of interest when implementing federal requirements incorporated as terms and conditions of the federal award.

- The health center determines how to inform its employees, board members, individual contractors and agents about the health center's standards of conduct (for example, bylaws, staff manuals, disclosure forms/statements, employee and board orientations or trainings).

- The health center determines whether to establish additional standards of conduct that are not addressed by federal requirements.

- The health center sets standards for when a financial interest is not substantial or a gift is an unsolicited item of nominal value.

Chapter 14: Collaborative Relationships

Authority

Section 330(k)(3)(B) of the PHS Act; and 42 CFR 51c.303(n), 42 CFR 56.303(n), and 42 CFR 51c.305(h)

Requirements

- The health center has made and must continue to make every reasonable effort to establish and maintain collaborative relationships with other health care providers in the health center's catchment area [service area].

- To the extent possible, the health center must coordinate and integrate project activities with the activities of other Federally funded, as well as State and local, health services delivery projects and programs serving the same population.

Demonstrating Compliance

A health center would demonstrate compliance with these requirements by fulfilling all of the following:

- The health center documents its efforts to coordinate and integrate activities with other providers or programs in the service area (for example, social service organizations, specialty practices, hospitals) in order to support patient:
    - Continuity of care across community providers; and
    - Access to services that are beyond the scope or capacity of the health center.

- The health center documents its efforts to collaborate with other primary care providers serving similar patient populations in the service area (at a minimum, this would include establishing and maintaining relationships with other health centers in the service area).

- If the health center expands[1,2] its HRSA-approved scope of project:
    - The health center obtains letters or other appropriate documents specific to the request or application that describe areas of coordination or collaboration with

[1] Expanding the HRSA-approved scope of project may occur by adding sites or services through change in scope requests, New Access Point competitive applications, or other supplemental funding applications.
[2] Additional requirements for documented collaboration may apply based on specific funding opportunity announcements, Notices of Award, look-alike designation instructions, or other federal statutes, regulations, or policies.

providers serving similar patient populations in the service area (for example, health centers, rural health clinics, critical access hospitals, health departments, other providers); or

- If such letters or documents cannot be obtained from such providers, the health center documents the process it utilized to attempt to obtain support for the specific request or application proposal.

Related Considerations

The following points may be useful for health centers to consider when implementing these requirements:

- The health center determines how to document collaborations with providers and organizations in its service area (for example, through a contract or a Memorandum of Agreement, letters of support, membership on a city-wide community health planning council).

Chapter 15: Financial Management and Accounting Systems

Authority

Sections 330(e)(5)(D), 330(k)(3)(D), and 330(q) of the PHS Act; 42 CFR 51c.113, 42 CFR 56.114, 42 CFR 51c.303(d), and 42 CFR 56.303(d); and 45 CFR Part 75 Subparts D, E and F

Requirements

- The health center must maintain effective control over, and accountability for, all funds, property, and other assets in order to adequately safeguard all such assets and ensure that they are used solely for authorized purposes.

- The health center must develop and utilize financial management and control systems in accordance with sound financial management procedures which ensure at a minimum:
    - The fiscal integrity of grant financial transactions and reports; and
    - Ongoing compliance with Federal statutes, regulations, and the terms and conditions of the Health Center Program award or designation.

- The health center's financial management system must specifically identify in its accounts all Federal awards, including Federal awards made under the Health Center Program, received and expended and the Federal programs under which they were received. This financial management system must also provide for all of the following:
    - Accurate, current, and complete disclosure of the financial results of each Federal award or program in accordance with the reporting requirements; (see 45 CFR 75.341 and 75.342).
    - Records that identify the source (receipt) and application (expenditure) of funds for federally-funded activities. These records must contain information pertaining to Federal awards, authorizations, obligations, unobligated balances, assets, expenditures, income, and interest, and be supported by source documentation;
    - Written procedures to implement Federal Payment Management System requirements; and (see 45 CFR 75.305.)
    - Written procedures for assuring that costs under the award are allowable in accordance with the terms and conditions of the Federal award and with the Federal Cost Principles. (see 45 CFR Part 75 Subpart E.)

- The health center must provide for and submit an independent annual financial audit that is conducted in accordance with Generally Accepted Accounting Principles (GAAP) and the applicable requirements prescribed in 45 CFR Part 75 Subpart F. The health

center must promptly follow up and take corrective action on audit findings, including preparation of a summary schedule of prior audit findings and a corrective action plan in accordance with 45 CFR 75.511.

- The health center must use any non-grant funds as permitted under section 330, and may use such funds for such other purposes as are not specifically prohibited under section 330 if such use furthers the objectives of the [health center] project.

Demonstrating Compliance

A health center would demonstrate compliance with these requirements by fulfilling all of the following

- The health center has and utilizes a financial management and internal control system that reflects GAAP for private non-profit health centers or Government Accounting Standards Board (GASB) principles for public agency health centers[1] and ensures at a minimum:
    - Health center expenditures are consistent with the HRSA-approved total budget[2] and with any additional applicable HRSA approvals that have been requested and received;[3]
    - Effective control over, and accountability for, all funds, property, and other assets associated with the Health Center Program project;
    - Safeguards all assets to assure they are used solely for authorized purposes in accordance with the terms and conditions of the Health Center Program award/designation; and
    - Capacity to track the financial performance of the health center, including identification of trends or conditions that may warrant action by the organization to maintain financial stability.

- The health center's financial management system is able to account for all Federal award(s) (including Federal awards made under the Health Center Program) in order to

[1] GAAP and GASB are used as defined in 45 CFR Part 75.

[2] A health center's "total budget" includes the Health Center Program federal award funds and all other sources of revenue in support of the HRSA-approved health center scope of project (Federal and Non-Federal Share). For additional detail please see Budget.

[3] Per 45 CFR 75.308, post-award, federal award recipients are required to report significant deviations from budget or project scope or objective, and request prior approvals from HHS awarding agencies for budget and program plan revisions (re-budgeting). "Re-budgeting, or moving funds between direct cost budget categories in an approved budget, is considered significant when cumulative transfers for a single budget period exceeds 25 percent of the total approved budget (inclusive of direct and indirect costs and federal funds and required matching or cost sharing). The base used for determining significant re-budgeting excludes carryover balances but includes any amounts awarded as supplements."

identify the source[4] (receipt) and application (expenditure) of funds for federally-funded activities. Specifically, the health center's financial records contain information and related source documentation pertaining to authorizations, obligations, unobligated balances, assets, expenditures, income, and interest under the Federal award(s).

- The health center has written procedures for:
  - Implementing the Federal Payment Management System requirements in 45 CFR 75.305; and
  - Assuring that costs expended under the award are allowable in accordance with the terms and conditions of the Federal award and with the Federal Cost Principles[5] in 45 CFR Part 75 Subpart E.

- If a health center expends **less than $750,000 in award funds from all federal sources** during its fiscal year, the health center ensures that an annual independent financial audit is conducted and submitted in accordance with generally accepted accounting principles and ensures that subsequent audits demonstrate corrective actions have been taken to address all findings, questioned costs, reportable conditions, and material weaknesses cited in the previous audit report, if applicable.

- If a health center expends **$750,000 or more in award funds from all federal sources** during its fiscal year, the health center ensures a single or program-specific audit is conducted and submitted for that year in accordance with the provisions of 45 CFR Part 75, Subpart F: Audit Requirements and ensures that subsequent audits demonstrate corrective actions have been taken to address all findings, questioned costs, reportable conditions, and material weaknesses cited in the previous audit report, if applicable.

- The health center can document that 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[6] were utilized to further the objectives of the project by benefiting the current or proposed patient population and were not utilized for purposes that are specifically prohibited by the Health Center Program.

Related Considerations

The following points may be useful for health centers to consider when implementing these requirements:

---

[4] Federal program and federal award identification would include, as applicable, the Catalog of Federal Domestic Assistance (CFDA) title and number, federal award identification number and year, name of the HHS awarding agency, and name of the pass-through entity, if any.

[5] The cost principles are set forth in 45 CFR Part 75, Subpart E.

[6] A health center's "total budget" includes the Health Center Program federal award funds and all other sources of revenue in support of the HRSA-approved health center scope of project (Federal and Non-Federal Share). For additional detail please see Budget.

- The health center determines which accounting software and related systems to use for financial management.

- The health center determines the type, frequency and format of financial reports used to support the board and the key management staff's ability to carry out its oversight responsibilities.

- The health center determines which specific actions to take in response to negative financial trending and its method for monitoring the results of those actions.

Chapter 16: Billing and Collections

Authority

Section 330(k)(3)(E), (F), and (G) of the PHS Act; and 42 CFR 51c.303(e), (f), and (g) and 42 CFR 56.303(e), (f), and (g)

Requirements

- The health center must prepare a schedule of fees for the provision of its services consistent with locally prevailing rates or charges and designed to cover its reasonable costs of operation.

- The health center must assure that any fees or payments required by the center for health care services will be reduced or waived in order to assure that no patient will be denied such services due to an individual's inability to pay for such services.

- The health center must establish systems for eligibility determination and for billing and collections [with respect to third party payors].

- The health center must make every reasonable effort to enter into contractual or other arrangements to collect reimbursement of its costs with the appropriate agency(s) of the State which administers or supervises the administration of:
  - A State Medicaid plan approved under title XIX of the Social Security Act (SSA) [42 U.S.C. 1396, et seq.] for the payment of all or a part of the center's costs in providing health services to persons who are eligible for such assistance; and
  - the Children's Health Insurance Program (CHIP) under title XXI of the SSA [42 U.S.C. 1397aa, et seq.] with respect to individuals who are State children's health insurance program beneficiaries.

- The health center must make and continue to make every reasonable effort to collect appropriate reimbursement for its costs on the basis of the full amount of fees and payments for health center services without application of any discount when providing health services to persons who are entitled to:
  - Medicare coverage under title XVIII of the SSA [42 U.S.C. 1395 et seq.];
  - Medicaid coverage under a State plan approved under title XIX of the SSA [42 U.S.C. 1396 et seq.]; or
  - Assistance for medical expenses under any other public assistance program (for example, CHIP), grant program, or private health insurance or benefit program.

- The health center must make and continue to make every reasonable effort to secure payment for services from patients, in accordance with health center fee schedules and the corresponding schedule of discounts.

Demonstrating Compliance

A health center would demonstrate compliance with these requirements by fulfilling all of the following:

- The health center has 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.

- The health center uses data on locally prevailing rates and actual health center costs to develop and update its fee schedule.

- The health center participates in Medicaid, CHIP, Medicare, and as appropriate, other public or private assistance programs or health insurance.

- The health center has systems, which may include operating procedures, for billing and collections that address:
    - Educating patients on insurance and, if applicable, related third-party coverage options available to them;
    - Billing Medicare, Medicaid, CHIP, and other public and private assistance programs or insurance in a timely manner, as applicable;[1]
    - Requesting applicable payments from patients, while ensuring that no patient is denied service based on inability to pay;[2] and
    - If applicable, incorporating additional elements such as payment plans, grace periods, and prompt payment incentives.

- The health center has billing records that show claims are submitted in a timely and accurate manner to the third party payor sources with which it participates (Medicaid, CHIP, Medicare, and other public and private insurance) in order to collect reimbursement for its costs in providing health services consistent with the terms of such contracts and other arrangements.

- The health center has and utilizes board-approved policies and operating procedures that address the waiving or reducing of amounts owed by patients due to a patient's specific circumstances related to inability to pay.

---

[1] For information on Federal Tort Claims Act (FTCA) coverage in cases where health centers are using alternate billing arrangements in which the covered provider is billing directly for services provided to covered entity patients, please refer to the FTCA Policy Manual, Section I.E: Eligibility and Coverage, Coverage Under Alternate Billing Arrangements.

[2] Health centers may provide a full discount to individuals and families with annual incomes at or below 100 percent of the Federal Poverty Guidelines (FPG). Please see Sliding Fee Discount Program for more information. In addition, health centers may waive payments in order to assure that no patient will be denied such services due to an individual's inability to pay for such services.

- 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;[3] and
    - Makes reasonable efforts to collect such amounts owed from patients.

- If a health center provides supplies or equipment that are related to, but not included in the service itself as part of prevailing standards of care (for example, eyeglasses, prescription drugs, including those purchased under discount programs, dentures) and charges patients for these items, the health center informs patients of such charges ("out of pocket costs") prior to the time of service.[4]

- If a health center elects to limit or deny services based on a patient's refusal to pay, the health center has a board-approved policy that distinguishes between refusal to pay and inability to pay.

Related Considerations

The following points may be useful for health centers to consider when implementing these requirements:

- The health center determines whether to charge a single fee for related health center services, medically-related supplies, and/or equipment. Examples include, but are not limited to, charging a single fee for a well-child visit and the immunizations provided during that visit or combining all prenatal care visits and labs into a single fee.

- The health center determines whether to participate in a specific insurance plan based on its patient population and the costs and benefits of such participation.

- 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 charge such fees to that funding source (for example, Ryan White Part C grant) rather than to the patient.[5]

- If a health center elects to provide its patients access to supplies or equipment (for example, eyeglasses, prescription drugs, dentures) that are related to, but not included

[3] For more information on the sliding fee discount schedule please see Sliding Fee Discount Program.
[4] For related information on revenue generated from such charges please see Financial Management and Accounting Systems.
[5] Health centers that have questions on the appropriate use of other federal, state, local, or private funds should refer to those program sources for additional guidance.

in, the service itself as part of prevailing standards of care, the health center determines how to charge its patients for such supplies or equipment (for example, flat discounts, at cost, sliding fee discounts).

Chapter 17: Budget

Authority

Section 330(e)(5)(A) and Section 330(k)(3)(I)(i) of the PHS Act; and 45 CFR 75.308(a) and 45 CFR 75 Subpart E

Requirements

- The health center must develop an overall project plan and annual budget that:
  - Identifies the projected costs of the Health Center Program project;
  - Identifies the projected costs to be supported by Federal Health Center Program funds, consistent with Federal Cost Principles[1] and any other requirements or restrictions on the use of Federal funding; and
  - Includes all other non-Federal revenue sources that will support the Health Center Program project, including:
    - State, local, and other operational funding; and
    - Fees, premiums, and third-party reimbursements which the health center may reasonably be expected to receive for its operation of Health Center Program project.

- The health center must submit this budget annually by a date specified by HRSA for approval through the Federal award or designation process.

Demonstrating Compliance

A health center would demonstrate compliance with these requirements by fulfilling all of the following:

- The health center develops and submits to HRSA (for new or continued funding or designation from HRSA) an annual operating budget, also referred to as a "total budget,"[2,3] that reflects projected costs and revenues necessary to support the health center's proposed or HRSA-approved scope of project.

[1] Please see 45 CFR Part 75 Subpart E: Cost Principles.
[2] A health center's "total budget" includes the Health Center Program federal award funds and all other sources of revenue in support of the HRSA-approved health center scope of project (Federal and Non-Federal Share).
[3] Any aspects of the requirement that relate to the use of Health Center Program federal award funds are not applicable to look-alikes.

- In addition to the Federal Health Center Program award, the health center's annual operating budget includes all other projected revenue sources that will support the health center project, specifically:
    - Fees, premiums, and third-party reimbursements and payments that are generated from the delivery of services;
    - Revenues from state, local, or other federal grants or contracts (for example, Ryan White, Healthy Start);
    - Private support or income generated from contributions; and
    - Any other funding expected to be received for purposes of supporting the health center project.

- The health center's annual operating budget identifies the portion of projected costs to be supported by the federal Health Center Program award. Any proposed costs supported by the federal award are consistent with the Federal Cost Principles[4] and the terms and conditions[5] of the award.

- If the health center organization operates or conducts other lines of business (i.e. activities that are not part of the HRSA-approved scope of project), the costs of these other activities are not included in the annual operating budget for the health center project.[6]

Related Considerations

The following points may be useful for health centers to consider when implementing these requirements:

- The health center determines how to allocate projected costs between federal Health Center Program award funds, consistent with Federal requirements, and non-Federal award funds within the annual operating budget.

[4] Please see 45 CFR Part 75 Subpart E: Cost Principles.
[5] For example, health centers may not use HHS federal award funds to support salary levels above the salary limitations on federal awards.
[6] As these other lines of business are not included in the health center's total budget, they are not subject to Health Center Program requirements and not eligible for related Health Center Program benefits (for example, reimbursement as a FQHC under Medicare/Medicaid/ CHIP, 340B Program eligibility, FTCA coverage).

Chapter 18: Program Monitoring and Data Reporting Systems

Authority

Section 330(k)(3)(I)(ii) of the PHS Act; 42 CFR 51c.303(j) and 42 CFR 56.303(j); and 45 CFR 75.342(a) and (b)

Requirements

- The health center must establish systems for monitoring program performance to ensure:
  - Oversight of the operations of the Federal award-supported activities in compliance with applicable Federal requirements;
  - Performance expectations are being achieved; and
  - Areas for improvement in program outcomes and productivity [efficiency and effectiveness] are identified.

- The health center must compile and report data and other information to HRSA, as it may require, relating to:
  - Costs of health center operations;
  - Patterns of health center service utilization;
  - Availability, accessibility, and acceptability of health center services; and
  - Other matters relating to operations of the Health Center Program project, as required.

- The health center must submit required data and information to HRSA in a timely manner and with such frequency as prescribed by HRSA.

Demonstrating Compliance

A health center would demonstrate compliance with these requirements by fulfilling all of the following:

- The health center has a system in place for monitoring program performance to ensure oversight of the operations of the Federal award-supported activities in compliance with applicable Federal requirements and that performance expectations are being achieved. Specifically:
  - The health center has a system in place to collect and organize data related to the HRSA-approved scope of project, as required to meet HHS reporting requirements, including those data elements for UDS reporting; and

  - The health center submits timely, accurate, and complete UDS reports in accordance with HRSA instructions and submits any other required HHS and Health Center Program reports.

- The health center produces data-based reports on patient service utilization and trends and patterns in the patient population[1], as necessary to inform and support decision making and oversight by the health center's key management staff and the governing board.

Related Considerations

The following points may be useful for health centers to consider when implementing these requirements:

- In fulfilling HRSA reporting obligations, the health center determines the type of data system(s) it will utilize based on its needs and the size and complexity of the health center's operations (for example, type of Electronic Health Record software, use of practice management system).

- The health center determines the number, format, and types of reports the system generates to support governing board and key management staff internal decision making.

[1] Examples of data health centers may analyze as part of such reports may include patient access to and satisfaction with health center services, patient demographics, quality of care indicators, and health outcomes.

Chapter 19: Board Authority

Authority

Section 330(k)(3)(H) of the PHS Act; 42 CFR 51c.303(i), 42 CFR 56.303(i), 42 CFR 51c.304(d), and 42 CFR 56.304(d); and 45 CFR 75.507(b)(2)

Requirements[1]

- The health center must establish a governing board[2] that has specific responsibility for oversight of the Health Center Program project.

- The health center governing board must develop bylaws which specify the responsibilities of the board with respect to the conduct of the health center.

- The health center governing board must assure that the center is operated in compliance with applicable Federal, State, and local laws and regulations.

- The health center governing board must hold monthly meetings[3,4] and record in meeting minutes the board's attendance, key actions, and decisions.

- The health center governing board must approve the selection and termination/dismissal of the health center's Project Director/Chief Executive Officer (CEO).

- The health center governing board must have authority for establishing or adopting policies for the conduct of the health center project and for updating these policies when needed. Specifically, the health center governing board must have authority for:
    - Adopting policy for financial management practices and a system to ensure accountability for center resources (unless already established by the public

[1] The governing board of a health center operated by Indian tribes, tribal groups, or Indian organizations under the Indian Self-Determination Act or Urban Indian Organizations under the Indian Health Care Improvement Act is exempt from the specific board authority requirements discussed in this chapter. Section 330(k)(3)(H) of the PHS Act.

[2] For public agencies that elect to have a co-applicant, these authorities and functions apply to the co-applicant board.

[3] Where geography or other circumstances make monthly, in-person participation in board meetings burdensome, monthly meetings may be conducted by telephone or other means of electronic communication where all parties can both listen and speak to all other parties.

[4] Boards of organizations receiving funding/look-alike designation only under section 330(g) may meet less than once a month during periods of the year, as specified in the bylaws, where monthly meetings are not practical due to health center patient migration out of the area. 42 CFR 56.304(d)(2).

agency as the Federal award or designation recipient), including periodically reviewing the financial status of the health center and the results of the annual audit to ensure appropriate follow-up actions are taken;[5]
  - Adopting policy for eligibility for services including criteria for partial payment schedules [sliding fee discount program];
  - Establishing and maintaining general personnel policies for the health center (unless already established by the public agency as the Federal award or designation recipient), including those addressing selection and dismissal procedures, salary and benefit scales, employee grievance procedures, and equal opportunity practices; and
  - Adopting health care policies including quality-of-care audit procedures.

- The health center governing board must adopt health care policies including the:
  - Scope and availability of services to be provided within the Health Center Program project, including decisions to subaward or contract for a substantial portion of the services;[6,7]
  - Service site location(s);[8] and
  - Hours of operation of service sites.

- The health center governing board must review and approve the annual Health Center Program project budget.[9]

- The health center must develop its overall plan for the health center project under the direction of the governing board.

- The health center governing board must provide direction for long-range planning, including but not limited to identifying health center priorities and adopting a three-year plan for financial management and capital expenditures.

- The health center governing board must assess the achievement of project objectives through evaluation of health center activities, including service utilization patterns, productivity [efficiency and effectiveness] of the center, and patient satisfaction.

- The health center governing board must ensure that a process is developed for hearing and resolving patient grievances.

---

[5] For more information on the related requirements, please see Financial Management and Accounting Systems.
[6] For more information on the requirements associated with providing services within the HRSA-approved scope of project, please see Required and Additional Services.
[7] For more information on the requirements associated with such arrangements, please see Contracts and Subawards.
[8] For more information on the requirements associated with health center service sites and hours of operation, please see Accessible Locations and Hours of Operation.
[9] For more information on the requirements of the Health Center Program project budget, please see Budget.

Demonstrating Compliance

A health center would demonstrate compliance with these requirements by fulfilling all of the following:

- The health center's organizational structure, articles of incorporation, bylaws, and other relevant documents ensure the health center governing board maintains the authority for oversight of the health center project, specifically:
    - The organizational structure and documents do not allow for any other individual, entity or committee (including, but not limited to, an executive committee authorized by the board) to reserve or have approval/veto power over the health center board with regard to the required authorities and functions;
    - In cases where a health center collaborates with other entities in fulfilling the health center's HRSA-approved scope of project, such collaboration or agreements with the other entities do not restrict or infringe upon the health center board's required authorities and functions; and
    - For public agencies with a co-applicant board, the health center has a co-applicant agreement that delegates the required authorities and functions to the co-applicant board and delineates the roles and responsibilities of the public agency and the co-applicant in carrying out the health center project.

- The health center's articles of incorporation, bylaws, or other relevant documents outline the following required authorities and responsibilities of the governing board:
    - Holding monthly meetings;
    - Approving the selection (and termination or dismissal, as appropriate) of the health center's Project Director/CEO;
    - Approving the health center's annual budget and applications;
    - Approving health center services and the location and hours of operation of health center sites;
    - Evaluating the performance of the health center;
    - Establishing or adopting policy related to the operations of the health center; and
    - Assuring the health center operates in compliance with applicable Federal, State, and local laws and regulations.

- The health center's board minutes and other relevant documents confirm that the board exercises, without restriction, the following authorities and functions:
    - Holding monthly meetings;
    - Approving the selection of, evaluating and, if necessary, approving the dismissal or termination of the Project Director/CEO from the health center project;

  - Approving applications related to the health center project, including approving the annual budget, which outlines the proposed uses of both Federal Health Center Program award and non-Federal resources and revenue;
  - Approving health center project's sites, hours of operation and services, including subawarding or contracting for a substantial portion of the health center's services;
  - Monitoring the financial status of the health center, including reviewing the results of the annual audit, and ensuring appropriate follow-up actions are taken;
  - Conducting long-range planning at least once every three years, which at a minimum results in financial management and capital expenditure plans; and
  - Evaluating the performance of the health center based on quality assurance/quality improvement assessments and other information received from health center management,[10] and ensuring appropriate follow-up actions are taken regarding:
    - Achievement of project objectives;
    - Service utilization patterns;
    - Quality of care;
    - Efficiency and effectiveness of the center; and
    - Patient satisfaction, including addressing any patient grievances.

- The health center board has adopted, evaluated at least once every three years, and, as needed, approved updates to policies in the following areas: Sliding Fee Discount Program, Quality Improvement/Assurance Program, and Billing and Collections.

- The health center board has adopted, evaluated at least once every three years, and, as needed, approved updates to Financial Management and Personnel policies. However, in cases where a public agency is the recipient of the Health Center Program Federal award or designation, the public agency may establish and retain the authority to adopt and approve financial management and personnel policies.

Related Considerations

The following points may be useful for health centers to consider when implementing these requirements:

- The health center board determines how to carry out required responsibilities, functions, and authorities in areas such as the following:

[10] For more information related to the production of reports associated with these topics, please see Program Data Reporting Systems, Financial Management and Accounting Systems, and Quality Improvement/Assurance Program.

  - Whether to establish standing committees, including the number and type of such committees (for example, executive, finance, quality improvement, personnel, planning).
  - Whether to seek input or assistance from other organizations or subject matter experts (for example, joint committees for health centers that collaborate closely with other organizations, consultants, community leaders).

- The health center board determines the format of its long-range planning.

- For public agencies with co-applicant boards, the co-applicant board and the public agency determine how to collaborate in carrying out the health center project (for example, shared project assessment, public agency participation on board committees, joint preparation of grant applications).

Chapter 20: Board Composition

Authority

Section 330(k)(3)(H) of the PHS Act; and 42 CFR 51c.304 and 42 CFR 56.304

Requirements[1,2]

- The health center's governing board must consist of at least 9 and no more than 25 members.[3]

- The majority [at least 51 percent] of the health center board members must be patients[4] served by the health center. These health center patient board members must, as a group, represent the individuals who are served by the health center in terms of demographic factors, such as race, ethnicity, and gender.

- Non-patient health center board members must be representative of the community served by the health center and must be selected for their expertise in relevant subject areas, such as community affairs, local government, finance and banking, legal affairs, trade unions, and other commercial and industrial concerns, or social service agencies within the community.

- Of the non-patient health center board members, no more than one-half may derive more than 10 percent of their annual income from the health care industry.[5]

- A health center board member may not be an employee of the center, or spouse or child, parent, brother or sister by blood or marriage of such an employee. [6] The project director may be a non-voting, ex-officio member of the board.

---

[1] The governing board of a health center operated by Indian tribes, tribal groups, or Indian organizations under the Indian Self-Determination Act or Urban Indian Organizations under the Indian Health Care Improvement Act is exempt from the specific board composition requirements discussed in this document. Section 330(k)(3)(H) of the PHS Act.

[2] For public agencies that elect to have a co-applicant, these board composition requirements apply to the co-applicant board.

[3] 42 CFR 51c.304(a) and 42 CFR 56.304(a) permit that the requirement regarding board size may be waived by the Secretary for good cause shown. HRSA will not grant such waivers except where the health center has demonstrated to HRSA an inability to meet the requirement.

[4] Patient board members are also often referred to as "user" or "consumer" board members. However, for the purposes of this chapter, only the term "patient" or "non-patient" board member will be used for ease of reference.

[5] Per the regulations in 42 CFR 56.304, for health centers funded/look-alike designated solely under section 330(g) of the PHS Act, no more than two-thirds of the non-patient board members may derive more than 10 percent of their annual income from the health care industry.

- The health center bylaws or other internal governing rules must prescribe the process for selection and removal of all governing board members. This selection process must ensure that the governing board is representative of the health center patient population. Such process of selection in the bylaws or other rules is subject to approval by HRSA.

- In cases where a health center receives section 330(g), 330(h) and/or 330(i) funding or designation and does not receive any section 330(e) funding/designation, the health center may request approval from HRSA for a waiver of the patient majority board composition governance requirement by showing good cause.

Demonstrating Compliance

A health center would demonstrate compliance with these requirements by fulfilling all of the following:

- The health center has bylaws or other relevant documents that specify the process for ongoing selection and removal of board members. This board member selection and removal process does not permit any other entity, committee or individual (other than the board) to select either the board chair or the majority of health center board members,[7] including a majority of the non-patient board members.[8]

- The health center has bylaws or other relevant documents that require the board to be composed as follows:
    - Board size is at least 9 and no more than 25 members,[9] with either a specific number or a range of board members prescribed;

---

[6] While no board member may be an employee of the health center, 42 CFR 51c.107 permits the health center to use Federal award funds to reimburse board members for these limited purposes: 1) reasonable expenses actually incurred by reason of their participation in board activities; or 2) wages lost by reason of participation in the activities of such board members if the member is from a family with an annual family income less than $10,000 or if the member is a single person with an annual income less than $7,000. For section 330(g)-only funded/look-alike designated health centers, 42 CFR 56.108 permits the use of grant funds for certain limited reimbursement of board members as follows: 1) for reasonable expenses actually incurred by reason of their participation in board activities; 2) for wages lost by reason of participation in the activities of such board members. Health centers may wish to consult with their legal counsel and auditor on applicable state law regarding reimbursement restrictions for non-profit board members and implications for IRS tax-exempt status.

[7] An outside entity may only remove a board member who has been selected by that entity as an organizational representative to the governing board.

[8] For example, if the health center has an agreement with another organization, the agreement does not permit that organization to select either the chair or a majority of the health center board.

[9] For the purposes of the Health Center Program, the term "board member" refers only to voting members of the board.

- At least 51 percent of board members are patients served by the health center. For the purposes of board composition, a patient is an individual who has received at least one service in the past 24 months that generated a health center visit, where both the service and the site where the service was received are within the HRSA-approved scope of project;
- Patient members of the board, as a group, reasonably represent the individuals who are served by the health center in terms of demographic factors, such as race, ethnicity, and gender;
- Non-patient members are representative of the community served by the health center or the health center's service area;
- Non-patient members are selected to provide relevant expertise and skills such as:
  - Community affairs;
  - Local government;
  - Finance and banking;
  - Legal affairs;
  - Trade unions and other commercial and industrial concerns; and
  - Social services;
- No more than one-half of non-patient board members derive more than 10 percent of their annual income from the health care industry; and
- Health center employees,[10] individual contractors working for the health center, and immediate family members (i.e. spouses, children, parents, or siblings through blood, adoption, or marriage) of employees may not be health center board members.

- The health center has bylaws or other relevant documents[11] requiring a quorum of not less than 51 percent of board members (absent a different quorum requirement in state law).

- The health center has documentation that the board is composed of:
  - At least 9 and no more than 25 members;
  - A patient[12] majority (at least 51 percent). For the purposes of board composition, a patient is an individual who has received at least one service in the past 24 months that generated a health center visit, where both the service

[10] In the case of public agencies with co-applicant boards, this includes employees or immediate family members of either the co-applicant organization or of the public agency component in which the health center project is located (for example, employees within the same department, division, or agency).
[11] State law may specify whether quorum standards should be outlined in bylaws or articles of incorporation.
[12] A legal guardian of a patient who is a dependent child or adult, a person who has legal authority to make health care decisions on behalf of a patient, or a legal sponsor of an immigrant patient may also be considered a patient of the health center for purposes of board representation. Students who are health center patients may participate as board members subject to state laws applicable to such non-profit board members.

and the site where the service was received are within the HRSA-approved scope of project;
- Patient board members who as a group are representative of its patient population in terms of demographic factors, such as race, ethnicity, and gender, consistent with the demographics reported in the health center's UDS report;[13]
- Representative(s) from or for each of the funded/designated special population(s)[14] for those health centers that receive any funding/look-alike designation under one or more of the special populations section 330 subparts, 330(g), (h), and/or (i); and
- As applicable, non-patient board members:
  - Who are representative of the community in which the health center is located, either by living or working in the community, or by having a demonstrable connection to the community;
  - With relevant skills and expertise in areas such as community affairs, local government, finance and banking, legal affairs, trade unions, other commercial and industrial concerns, or social services within the community; and
  - Of whom no more than 50 percent earn more than 10 percent of their annual income from the health care industry.[15]

- The health center verifies periodically (for example, annually or during the selection or renewal of board member terms) that the governing board does not include members who are current employees of the health center, immediate family members of current health center employees, or individual contractors currently working for the health center.

- Health centers requesting a waiver of the patient majority board composition requirements present to HRSA for review and approval:
  - "Good cause" that justifies the need for the waiver by documenting:
    - The unique characteristics of the population (homeless, migratory or seasonal agricultural worker, and/or public housing patient population) or service area that create an undue hardship in recruiting a patient majority; and

[13] For health centers that do not yet have a UDS report, this would be assessed based on demographic data included in the health center's application.
[14] Representation could include advocates for the health center's 330 (g), (h), or (i) patient population (for example, those who have personally experienced being a member of, have expertise about, or work closely with the current special population). Such advocate board members would count as "patient" board members only if they meet the patient definition.
[15] For example, in a 9 member board with 5 patient board members, there could be 4 non-patient board members. In this case, no more than 2 non-patient board members could earn more than 10% of their income from the health care industry.

        - Its attempts to recruit a majority of special population board members and why these attempts have not been successful; and
    - Strategies that will ensure patient participation and input in the direction and ongoing governance of the organization by addressing the following elements:
        - Collection and documentation of input from the special population(s);
        - Communication of special population input directly to the health center governing board; and
        - Incorporation of special population input into key areas, including but not limited to: selecting health center services; [16] setting hours of operation of health center sites;[17] defining budget priorities;[18] evaluating the organization's progress in meeting goals, including patient satisfaction;[19] and assessing the effectiveness of the sliding fee discount program.[20]

- For health centers with approved waivers, the health center has board minutes or other documentation that demonstrates how special population patient input is utilized in making governing board decisions in key areas as addressed in the health center's waiver request.

Related Considerations

The following points may be useful for health centers to consider when implementing these requirements:

- Within the range of 9 to 25 board members, the health center determines the appropriate board size for its organization.

- In addition to race, ethnicity, and gender, which are examples listed in the regulations, the health center determines which relevant demographic or geographic factors to consider when selecting patient or non-patient board members.

- In cases where language or literacy may present a barrier to board members' evaluation of written materials, the health center determines how to make accommodations to ensure the meaningful participation of such board members.

[16] For more information on providing services within the HRSA-approved scope of project, please see Required and Additional Services.
[17] For more information on health center service sites and hours of operation, please see Accessible Locations and Hours of Operation.
[18] For more information on the health center project budget, please see Budget.
[19] For more information on the health center board's required authorities, please see Board Authority.
[20] For more information on requirements for health center sliding fee discount programs, please see Sliding Fee Discount Program.

- The health center board determines whether to include non-voting, ex-officio members such as the Project Director/Chief Executive Officer (CEO) or community members on the board, consistent with what is permitted under other applicable laws.

- For health centers with a HRSA-approved waiver, the health center board determines which strategies[21] to use for receiving input from the special population and ensuring the special population's participation in the direction and ongoing governance of the health center.

[21] For example, a health center could utilize an advisory council of special population representatives, could conduct regular focus groups with the special population, or could have one or more patients from the special population serving on the board.

Chapter 21: Federal Tort Claims Act (FTCA) Deeming Requirements

Authority

Section 224(g)-(n) of the PHS Act (42 U.S.C. 233(g)-(n)); and 42 CFR Part 6

Requirements

In order to obtain deemed Public Health Service employment status under the Federally Supported Health Centers and Assistance Acts of 1992, and 1995 (FSHCAA), for themselves and for their covered individuals, Health Center Program awardees and subrecipients (including those defined as subrecipients under the FTCA program regulations)[1] (hereafter referred to as a "health center" in this chapter) must submit, for approval by HRSA, an annual deeming application that demonstrates it:

- Has implemented appropriate policies and procedures to reduce the risk of malpractice and the risk of lawsuits arising out of any health or health-related functions performed by the health center;
- Has reviewed and verified the professional credentials, references, claims history, fitness, professional review organization findings, and license status of its physicians and other licensed or certified health care practitioners;
- Has no history of claims under FSHCAA or, if such a history exists, fully cooperates with the Attorney General in defending against any such claims, and takes any necessary steps to assure against such claims in the future; and
- Will fully cooperate with the Attorney General and other applicable agencies in providing required information under FSHCAA.

***Note**: A health center's deemed employment status[2] does not imply FTCA coverage in all cases, as health center providers must also comply with statutory individual eligibility requirements,*

[1] *Subrecipient*, as used in this chapter means, as described in 42 CFR 6.2, an entity that receives a Federal award or a contract from a covered entity to provide a full range of health services on behalf of the covered entity. *Covered entity* means an entity as described in 42 CFR 6.3 which has been deemed by the Secretary, in accordance with 42 CFR 6.5, to be covered by 42 CFR Part 6. *Covered individual* means any eligible officer, governing board member, employee, or qualified contractor of a covered entity, subject to the requirements of section 224(g)-(n) of the PHS Act.

[2] Deemed employment status extends to covered individuals based on evidence of their relationship with the covered entity (i.e., officer, governing board member, health center employee, or qualified individual contractor), pursuant to section 224(g)-(n) of the PHS Act 42 U.S.C. 233(g)-(n), and 42 CFR Part 6. Whether a specific activity is covered by the FTCA will also require a determination or certification that the activities at issue occurred within the scope of deemed PHS employment.

and covered actions must be taken within the scope of deemed Public Health Service employment. When FTCA matters become the subject of litigation, the U.S. Department of Justice and the federal courts may assume significant roles in certifying or determining whether or not a given activity falls within the scope of employment for purposes of FTCA coverage. For more information, please review the FTCA Health Center Policy Manual available at: http://www.bphc.hrsa.gov/ftca/healthcenters/healthcenterpolicies.html.

Demonstrating Compliance

While additional details regarding documentation may be identified in the annual deeming application instructions, a health center would demonstrate compliance with the FTCA requirements by documenting in its annual deeming application, in the form and manner prescribed by HRSA consistent with the descriptions below, the following:

Credentialing and Privileging / Quality Improvement and Quality Assurance

- The health center is compliant with all of the credentialing and privileging requirements of Chapter 5: Clinical Staffing and all requirements within Chapter 10: Quality Improvement/Assurance Program prior to the deeming determination.

Risk Management

- The health center has and implements an ongoing risk management program to reduce the risk of adverse outcomes that could result in medical malpractice or other health or health-related litigation. The health center's risk management program contains the elements described below:

    - A risk management policy(ies) that requires the following:
        - Risk management across the full range of health center activities;
        - Health care risk management training for health center staff;
        - Completion of quarterly risk management assessments by the health center; and
        - Annual reporting to the board of: completed risk management activities; status of the health center's performance relative to established risk management goals; and proposed risk management activities that relate and/or respond to identified areas of high organizational risk.

    - Operating procedures that address the following areas for health center services and operations:
        - Identifying and mitigating the areas/activities of highest risk for health center patient safety consistent with the health center's HRSA-approved scope of project;
        - Documenting, analyzing, and addressing clinically-related complaints and "near misses" reported by health center employees, patients, and other

individuals;
- Setting and tracking progress related to annual risk management goals;
- Developing and implementing an annual health care risk management training plan for all staff members based on identified areas/activities of highest clinical risk for the health center (including, but not limited to obstetrical procedures, infection control) and any non-clinical trainings appropriate for health center staff (including HIPAA medical record confidentiality requirements); and
- Completing an annual risk management report for the board and key management staff.

- Provision of reports to the board and key management staff on risk management activities and progress in meeting goals at least annually, and documentation showing that any related follow-up actions have been implemented.

- A health care risk management training plan for all staff members, and documentation showing that such trainings have been completed by the appropriate staff, including all clinical staff, at least annually.

- Designation of an individual(s) (for example, a risk manager) who oversees and coordinates the health center's risk management activities and completes health care risk management training annually.

Claims Management

- The health center has a claims management process for addressing any potential or actual health or health-related claims, including medical malpractice claims, that may be eligible for FTCA coverage. In addition, this process ensures:
  - The preservation of all health center documentation related to any actual or potential claim or complaint (for example, medical records and associated laboratory and x-ray results, billing records, employment records of all involved clinical providers, clinic operating procedures); and
  - That any service of process/summons that the health center or its provider(s) receives relating to any alleged claim or complaint is promptly sent to the HHS, Office of the General Counsel, General Law Division, per the process prescribed by HHS and as further described in the FTCA Health Center Policy Manual.

- The health center has a designated individual(s) who is responsible for the management and processing of claims related activities and serves as the claims point of contact.

- The health center informs patients using plain language that it is a deemed federal Public Health Service employee[3] via its website, promotional materials, and/or within an area(s) of the health center that are visible to patients.

- If a history of claims under the FTCA exists, the health center can document that it:
    - Cooperated with the Attorney General, as further described in the FTCA Health Center Policy Manual; and
    - Implemented steps to mitigate the risk of such claims in the future.

Related Considerations

The following points may be useful for health centers to consider when implementing these requirements:

- The health center determines how to obtain its health care risk management training (for example, through one of HRSA's national cooperative agreements or technical assistance contracts) and which trainings to require for covered individuals and the individual(s) designated with risk management responsibilities (for example, risk manager).

- The health center determines what other types of liability coverage to obtain, such as private "gap" or "tail" insurance, directors and officer insurance, and general liability insurance, for activities that may not be eligible for FTCA coverage.

[3] For example: "This health center receives HHS funding and has federal Public Health Service deemed status with respect to certain health or health-related claims, including medical malpractice claims, for itself and its covered individuals." For more information, please see http://www.bphc.hrsa.gov/ftca/.

Appendix A: Health Center Program Non-Regulatory Policy Issuances That Remain in Effect

The following policy issuances most often referred to as Policy Information Notices (PINs) remain in effect and are not superseded by the Health Center Program Compliance Manual:

PIN 2007-09 Service Area Overlap: Policy and Process
(http://bphc.hrsa.gov/programrequirements/policies/pin200709.html)

PIN 2007-15 Health Center Emergency Management Program Expectations
(http://bphc.hrsa.gov/about/pin200715expectations.html)

PIN 2008-01 Defining Scope of Project and Policy for Requesting Changes
(http://bphc.hrsa.gov/programrequirements/policies/pin200801.html)

PIN 2009-02 Specialty Services and Health Centers' Scope of Project
(http://bphc.hrsa.gov/programrequirements/policies/pin200902purpose.html)

PIN 2009-05 Policy for Special Population-Only Grantees Requesting a Change in Scope to Add a New Target Population
(http://bphc.hrsa.gov/programrequirements/policies/pin200905specialpops.html)

PIN 2013-01 Health Center Program Budgeting and Accounting Requirements
(http://bphc.hrsa.gov/programrequirements/policies/pin201301.html)

The following HRSA/BPHC policy documents and resources also remain in effect and are not superseded by the Health Center Program Compliance Manual:

Federal Tort Claims Act Health Center Policy Manual
(http://bphc.hrsa.gov/ftca/healthcenters/ftcahcpolicymanual.html)

Additional Scope of Project/Change in Scope Resources
(http://bphc.hrsa.gov/programrequirements/scope.html)

Site Visit Guides
(http://bphc.hrsa.gov/programrequirements/svguide.html)

Uniform Data System (UDS) Resources
(http://bphc.hrsa.gov/datareporting/reporting/index.html)

Glossary

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

Awardee (award recipient): *Formerly referred to as "grantee."* A public or nonprofit non-federal organization that carries out the federal award under the Health Center Program as a recipient or subrecipient. (45 CFR 75.2)

Co-Applicant: For public agency health centers only. The established body that serves as the health center's governing board when the public agency determines that it cannot meet the Health Center Program governing board requirements directly. (Section 330(r)(2)(A) of the Public Health Service Act)

Contract: A contract is used for the purpose of obtaining goods and services for the health center's own use and creates a procurement relationship with the contractor. Characteristics indicative of a procurement relationship between the health center and a contractor are when the contractor:

(1) Provides the goods and services within normal business operations;
(2) Provides similar goods or services to many different purchasers;
(3) Normally operates in a competitive environment;
(4) Provides goods or services that are ancillary to the operation of the federal program; and
(5) Is not subject to compliance requirements of the federal program as a result of the agreement, though similar requirements may apply for other reasons. (45 CFR 75.2)

Credentialing: The process of assessing and confirming the license or certification, education, training, and other qualifications of a licensed or certified health care practitioner.

Distinct Fee: A fee for a specific service or set of services, which is typically billed for separately within the local health care market.

EHB: HRSA's Electronic Handbooks: HRSA's Web-based interface for all Health Center Program award or designation management activities.

Federal award (award, federal grant): The federal financial assistance that a non-federal entity receives directly from a federal awarding agency, such as HRSA, or indirectly from a pass-through entity. Unless specified differently in the text, this refers to federal award funding under section 330 of the Public Health Service Act or the "Health Center Program federal award." (45 CFR 75.2)

Federal Poverty Guidelines (FPG): The Federal Poverty Guidelines (FPG) are a simplified version

of the income thresholds used by the U.S. Census Bureau to estimate the number of people living in poverty. The thresholds are annual income levels below which a person or family is considered to be living in poverty. The income threshold increases by a constant amount for each additional family member. They are updated annually in the Federal Register by HHS. (https://aspe.hhs.gov/poverty-guidelines)

Federally Qualified Health Center (FQHC): Includes organizations receiving grants under section 330 of the PHS Act, look-alikes, and certain tribal organizations. (Section 1861(aa)(4)(B) and section 1905(l)(2)(B) of the SSA)

Form 5A: Services Provided: Official documentation of the required and additional services (See Required and Additional Services) and their mode of service delivery included in a health center's HRSA-approved scope of project. This form is contained in the health center's folder in EHB. (http://bphc.hrsa.gov/programrequirements/scope.html)

Form 5B: Service Sites: Official documentation of the service delivery sites (see Service Site) included in a health center's HRSA-approved scope of project. This form is contained in the health center's folder in EHB. (http://bphc.hrsa.gov/programrequirements/scope.html)

Homeless Individual: For the purposes of health centers receiving funding or designation under section 330(h) to serve individuals experiencing homelessness, this also includes residents of permanent supportive housing or other housing programs that are targeted to homeless populations, in the service area. (Section 330(h) of the Public Health Service Act)

Limited English Proficiency (LEP): LEP includes individuals who do not speak English as their primary language and/or who have a limited ability to read, write, speak, or understand English; and who may be eligible to receive language assistance with respect to the particular service, benefit, or encounter. (http://www.hhs.gov/civil-rights/index.html)

Look-Alike: Organizations that do not receive a Health Center Program federal award but are designated by HRSA as meeting Health Center Program requirements. (Section 1861(aa)(4)(B) and section 1905(l)(2)(B) of the SSA)

Migratory and Seasonal Agricultural Worker (MSAW): *Formerly referred to as "Migrant and Seasonal Farmworkers (MSFW)."* For the purposes of health centers receiving funding or designation under section 330(g) to serve migratory and seasonal agricultural workers and their families, these are individuals principally employed in agriculture on a seasonal basis within the last 24 months who establish temporary housing for the purpose of this work. Seasonal agricultural workers are individuals employed in agriculture on a seasonal basis, who are not also migratory. Agriculture refers to farming in all its branches, as defined by the North American Industry Classification System under codes 111, 112, 1151, and 1152. (Section 330(g) of the Public Health Service Act)

Non-federal Entity: A State, local government, Indian tribe, institution of higher education

(IHE), or nonprofit organization that carries out a federal award as a recipient or subrecipient. (45 CFR 75.2)

Pass-Through Entity: A non-federal entity that provides a subaward to a subrecipient to carry out part of a federal program. (45 CFR 75.2)

Primary Source Verification: Verification by the original source of a specific credential to determine the accuracy of a qualification reported by an individual health care practitioner.

Privileging: The process of authorizing a health care practitioner's specific scope and content of patient care services.

Public Housing Residents: For the purpose of health centers receiving funding or designation under section 330(i) to serve residents of public housing and individuals living in areas immediately accessible to public housing, this includes individuals living in public housing agency-developed, owned or assisted low-income housing, including mixed finance projects, but excludes housing units with no public housing agency support other than Section 8 housing vouchers. (Section 330(i) of the Public Health Service Act)

Required Services: Required services are those services that a health center must provide, as defined in Section 330(b)(1) of the Public Health Service Act. (Section 330(a)(1) of the Public Health Service Act)

Scope of Project: Defines the service sites, services, providers, service area(s), and target population included in the HRSA-approved Health Center Program project. (Policy Information Notice 2008-01: Defining Scope of Project and Policy for Requesting Changes)

Service Area (also referred to as a "catchment area"): The precise boundaries, as defined by the health center, of the geographic area to be served under the health center project, including identified medically underserved population or populations within that area. (42 CFR 51c.102)

Service Site: Locations where a health center either directly or through a subrecipient or contractual arrangement provides services and where all of the following conditions are met:

- Health center encounters are generated by documenting in the patients' records face-to-face contacts between patients and providers;
- Providers exercise independent judgment in the provision of services to the patient;
- Services are provided directly by or on behalf of the health center, whose governing board retains control and authority over the provision of the services at the location; and
- Services are provided on a regularly scheduled basis. (Policy Information Notice 2008-01: Defining Scope of Project and Policy for Requesting Changes)

Special Population: Special populations refer to the special medically underserved populations defined within statute under sections 330(g), (h), or (i) of the PHS Act. See definitions for

Migratory and seasonal agricultural workers; Homeless individuals; and Residents of public housing.

Subaward: An award provided by a pass-through entity to a subrecipient for the subrecipient to carry out part of a federal award received by the pass-through entity. It does not include payments to a contractor or payments to an individual that is a beneficiary of a federal program. A subaward may be provided through any form of legal agreement, including an agreement that the pass-through entity considers a contract. See also "Pass-Through Entity." (45 CFR 75.2)

Subrecipient: Per 45 CFR 75.2, a non-federal entity that receives a subaward from a pass-through entity to carry out part of a federal program but does not include an individual that is a beneficiary of such program. A subrecipient may also be a recipient of other federal awards directly from a federal awarding agency.
Characteristics which would lend support to the classification of the non-federal entity as a subrecipient include when the non-federal entity:

(1) Determines who is eligible to receive what federal assistance;
(2) Has its performance measured in relation to whether objectives of a federal program were met;
(3) Has responsibility for programmatic decision making;
(4) Is responsible for adherence to applicable federal program requirements specified in the federal award; and
(5) In accordance with its agreement, uses the federal funds to carry out a program for a public purpose specified in authorizing statute, as opposed to providing goods or services for the benefit of the pass-through entity. (45 CFR 75.2)

Uniform Data System (UDS): The UDS is a core set of information appropriate for reviewing the operation and performance of health centers. The UDS annually collects a variety of information, including patient demographics, services provided, staffing, clinical indicators, utilization rates, costs, and revenues.
(http://bphc.hrsa.gov/datareporting/reporting/index.html)

Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (45 CFR Part 75): *Sometimes referred to as the "HHS grant regulations."* Final requirements for federal awards to non-federal entities located in Title 2 of the Code of Federal Regulations as adopted by HHS at 45 CFR Part 75. These requirements supersede and streamline requirements from previous OMB Circulars A-21, A-87, A-110, and A-122 ; Circulars A-89, A-102, and A-133; and the guidance in Circular A-50 on Single Audit Act follow-up. (45 CFR Part 75)