HRSA Health Center Program

BUREAU OF PRIMARY HEALTH CARE

Health Center Program Site Visit Protocol

Last updated: May 27, 2021

Table of Contents

INTRODUCTION

Purpose

The purpose of Health Resources and Services Administration (HRSA) site visits[1] is to support the effective oversight of the Health Center Program. Operational Site Visits (OSVs) provide an objective assessment and verification of the status of each Health Center Program awardee or look-alike's compliance with the statutory and regulatory requirements of the Health Center Program. In addition, HRSA conducts site visits to assess and verify look-alike initial designation applicants for eligibility and compliance with Health Center Program requirements to inform initial designation determinations. For the purposes of this document, the term "health center" refers to entities that apply for or receive a federal award under section 330 of the Public Health Service (PHS) Act (including section 330 (e), (g), (h) and (i)), section 330 subrecipients, and organizations designated as look-alikes.

HRSA uses the Health Center Program Compliance Manual ("Compliance Manual") as the basis for determining whether health centers have demonstrated compliance with the statutory and regulatory requirements of the Health Center Program. The Health Center Program Site Visit Protocol (SVP) is the tool for assessing compliance with Health Center Program requirements during OSVs. The SVP is designed to provide HRSA the information necessary to perform its oversight responsibilities using a standard and transparent methodology that aligns with the Compliance Manual. In addition to assessing compliance with all Health Center Program requirements, the SVP also includes a section for identification, as applicable, of promising practices.

During the OSV, at the health center's request, the site visit team may share recommendations or limited technical assistance on various areas of health center operations that fall outside the scope of the compliance review. Such recommendations/technical assistance information will not be included in the final site visit report.

HRSA conducts OSVs at least once per project/designation period. For health centers with a 1-year project/designation period, the OSV will take place 2–4 months into the project/designation period. For health centers with a 3-year project/designation period, the OSV will take place 14–18 months into the project/designation period. HRSA strongly encourages all health centers to review and utilize the Compliance Manual, the SVP, and all other site visit resources to prepare for site visits and to help regularly assess and assure ongoing compliance with the Health

[1] The U.S. Department of Health and Human Services (HHS) Uniform Administrative Requirements (45 CFR 75.342) permit HRSA to "make site visits, as warranted by program needs." In addition, 45 CFR 75.364 states that, "The HHS awarding agency, Inspectors General, the Comptroller General of the United States, and the pass-through entity, or any of their authorized representatives, must have the right of access to any documents, papers, or other records of the non-federal entity which are pertinent to the federal award, in order to make audits, examinations, excerpts, and transcripts. The right also includes timely and reasonable access to the non-federal entity's personnel for the purpose of interview and discussion related to such documents."

Center Program. For answers to frequently asked questions (FAQs) and resources to help health centers prepare for site visits, see Site Visit Resources.

Site Visit Report and Compliance Determinations

HRSA develops and shares a site visit report with the health center within 45 days after the site visit. The report conveys the site visit findings and final compliance determinations. In circumstances where HRSA determines that a health center has failed to demonstrate compliance with one or more of the Health Center Program requirements, HRSA will place a condition(s) on the award/designation.[2]

The Federal Tort Claims Act (FTCA) Program also uses the site visit report to support FTCA deeming decisions, and to identify technical assistance needs for FTCA-deemed health centers.[3,4] In circumstances where the site visit report contains FTCA risk and claims management findings that require follow-up, the FTCA Program may develop and share a Corrective Action Plan (CAP) with the health center. The health center is expected to respond to the CAP and address findings before the next FTCA deeming cycle.

Health centers and look-alike initial designation applicants should use the site visit report and the Compliance Manual to understand the compliance findings and to obtain guidance for resolving non-compliance findings.[5] Health centers may contact their HRSA Health Center Program staff primary point-of-contact for additional information regarding compliance findings and submissions in response to conditions.

Site Visit Protocol Structure

Each Compliance Manual chapter that addresses Health Center Program requirements has a corresponding section in the SVP. Similar to the Compliance Manual, the SVP also contains a section on the FTCA Program risk management and claims management requirements.

Each of these SVP sections contains the following components:

- ***Statute and Regulations*:** The supporting statute and regulations for the associated program requirements. Each section also includes a link to the Related Considerations in the Compliance Manual.

---

[2] For additional information on how HRSA pursues remedies for non-compliance, including progressive action, see Health Center Program Compliance Manual, Chapter 2: Health Center Program Oversight.
[3] Unresolved Health Center Program conditions related to clinical staffing and/or quality improvement/assurance, requirements that apply to both Health Center Program and FTCA deeming, may impact FTCA deeming if they are not resolved by the time that HRSA makes annual FTCA deeming decisions.
[4] Health centers that have questions regarding the FTCA Program or FTCA deeming requirements may contact Health Center Program Support or call 1–877–464–4772.
[5] Look-alike initial designation applicants must be compliant with all Health Center Program requirements at the time of application and should refer to the look-alike Initial Designation application for further guidance on how HRSA will address findings of non-compliance at a pre-designation OSV.

- ***Primary and Secondary Reviewers*:** The member of the site visit team who serves as the primary reviewer for that section, based on expertise (governance/administrative, fiscal, or clinical), and an optional or suggested secondary reviewer who may add expertise and assistance as needed. The site visit team confers and works together on compliance assessments.

- ***Document Checklist for Health Center Staff*:** The list of documents a health center provides to the site visit team prior to the site visit.[6] Documents are to be provided **at least 2 weeks prior to the start of the site visit.** [7] HRSA may provide additional guidance prior to the site visit regarding preparation or document submission.
    - In cases where a sample (for example, sample of patient records) is referenced in the list of documents to be provided by the health center, **the health center is expected to provide (or "pull") the sample**.
        - When the SVP allows for a range in the sample size, the health center should take into account its size and complexity when determining sample size.
        - The health center should provide samples that are representative of its current Health Center Program project operations.
        - If the sample provided by the health center is not sufficient to allow the HRSA site visit team to assess the program requirement, the team may complete additional sampling in coordination with the health center.
    - ***Documents not provided by the close of the first day of the site visit will not be considered in the compliance assessment by the site visit team.***

- ***Demonstrating Compliance Elements*:** The elements from the Compliance Manual that describe how health centers would demonstrate their compliance with the applicable Health Center Program requirements.[8]

- ***Site Visit Team Methodology*:** The methods a site visit team uses to assess compliance with the corresponding demonstrating compliance elements. Methods

---

[6] Site visit teams, including consultants, are authorized representatives of HRSA and thus may review a health center's policies and procedures, financial or clinical records, and other relevant documents, in order to assess and verify compliance with Health Center Program and FTCA deeming requirements. Site visit teams are also subject to confidentiality standards, including Health Insurance Portability and Accountability Act (HIPAA). Consultants who violate such standards are in violation of their contract, and could be subject to Title 18, United States Code, Section 641. While it is permissible for health centers to request that HRSA staff and/or consultants sign additional confidentiality statements, this should be communicated prior to the site visit to avoid any disruption or delay in the site visit process.
[7] Health centers may choose to provide samples of patient records prior to or during the site visit. If patient records will be provided during the site visit, this should be communicated prior to the site visit to avoid any disruption or delay in the site visit process.
[8] A small subset of elements are not assessed during a site visit because HRSA assesses them by other means (for example, competitive application review, look-alike Renewal Designation application review, HRSA Division of Grants Management Office (DGMO) review).

include but are not limited to reviews of policies and procedures, samples of files and records, site tours, and interviews.[9] All documentation provided to the site visit team, whether by HRSA or by the health center, are available to the entire site visit team and can be used for any portion of the site visit.

- ***Site Visit Findings*:** The site visit team's responses to the series of questions based on the related methodologies. These findings are included in the health center's site visit report and form the basis for determining whether a health center has demonstrated compliance with Health Center Program requirements.

[9] Interviews with health center staff are intended to supplement and assist the site visit team in its review of policies, procedures, and other documentation.

NEEDS ASSESSMENT

Primary Reviewer: Governance/Administrative Expert
Secondary Reviewer: Clinical Expert

Authority: *Section 330(k)(2) and Section 330(k)(3)(J) of the Public Health Service (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)*

Related Considerations

Document Checklist for Health Center Staff

- ☐ Service area reports or analysis documentation.
- ☐ Most recent needs assessment and documentation (for example, studies, resources, reports) used to develop the needs assessment.

Demonstrating Compliance

Element a: Service Area Identification and Annual Review

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).]*

Note: *HRSA assesses whether the health center has demonstrated compliance with the portion of element "a" in brackets through HRSA's review of the health center's competing continuation application (Service Area Competition (SAC) or Renewal of Designation (RD)). No review of this portion of element "a" related to determining the consistency of service area ZIP codes and patient origin data is required through the site visit.*

Site Visit Team Methodology

- Interview Project Director/CEO and other key management staff regarding service area analysis process.
- Review health center's Form 5B: Service Sites.

[1] Also referred to as "catchment area" in the Health Center Program implementing regulation in 42 CFR 51c.102.

Site Visit Findings

1. Does the health center utilize patient origin data from its most current UDS report when recording or updating ZIP codes on its Form 5B site entries?
   ☐ YES ☐ NO

   If No, an explanation is required (for example, Form 5B ZIP codes reflect newer data available to the health center):

   _____

2. Is this service area review process completed at least annually?

   ***Note**: The annual review of a health center's service area may be conducted in a number of ways (for example, as part of submission of a competitive application or as a "stand-alone" activity during the year, such as review of annual UDS patient origin data or other data on where patients reside).*
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

Element b: Update of Needs Assessment

The health center completes or updates a needs assessment of the current or proposed population at least once every 3 years,[2] for the purposes of informing and improving the delivery of health center services. The needs assessment utilizes the most recently available data[3] 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, occupation, transience, 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

[2] Compliance may be demonstrated based on the information included in a Service Area Competition (SAC) or a Renewal of Designation (RD) application. Note that in the case of a Notice of Funding Opportunity for a New Access Point or Expanded Services grant, HRSA may specify application-specific requirements for demonstrating an applicant has consulted with the appropriate agencies and providers consistent with Section 330(k)(2)(D) of the PHS Act. Such application-specific requirements may require a completed or updated needs assessment more recent than that which was provided in an applicant's SAC or RD application.

[3] 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.

- 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).

Site Visit Team Methodology

- Review most recent needs assessment and documentation (for example, studies, resources, reports) used to develop the needs assessment.
- Interview Project Director/CEO and other key management staff regarding utilization of needs assessment(s).

Site Visit Findings

3. Does the health center complete or update a needs assessment of the current population at least once every 3 years?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

4. Is the needs assessment based on the most recently available data for the service area and, if applicable, special populations?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

5. Does the needs assessment address all of the following:

   - Factors associated with access to care and health care utilization (for example, geography, transportation, occupation, transience, 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).

   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

6. Was the health center able to provide at least one example of how it utilized the results of its needs assessment(s) to inform and improve the delivery of health center services?

   ***Note**: If the health center is part of a larger organization (for example, a health department, mental health or social service agency), consider whether the needs*

assessment(s) provides data that are relevant and specific enough to inform the delivery of health center services.
☐ YES ☐ NO

If No, an explanation is required:

_____

REQUIRED AND ADDITIONAL HEALTH SERVICES

Primary Reviewer: Clinical Expert
Secondary Reviewer: Fiscal Expert

Note: *The Fiscal Expert also reviews the contracts/agreements and arrangements to support the Clinical Expert with the assessment of scope of project accuracy for element "a."*

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

Related Considerations

Document Checklist for Health Center Staff

- ☐ For services delivered via Column I of the health center's current Form 5A: Services Provided, provide a list of service sites to be toured. Sites selected are those where the majority of services are provided directly by the health center. If the health center has more than one service site, the list must include at least two health center service sites.
- ☐ For health centers with Column II services, health center internal procedures that address documentation of information in the patient's health center record for any contracted service(s) that occur at a location(s) other than a health center Form 5B in-scope site (for example, lab results, x-ray results).
- ☐ For health centers with Column III services, operating procedures for tracking and managing referred services.
- ☐ If a Column I service(s) cannot be verified through the site tours, provide documentation of service(s) provision in a current patient record.[1]
- ☐ For services delivered via Column II of the health center's current Form 5A (whether or not the service is also delivered via Column I and/or Column III):

  Contracts/Agreements:
  - **At least one but no more than three** written contracts/agreements for EACH Required and EACH Additional Service.
  - To assist in the review, the health center should flag all relevant provisions within contracts/agreements related to:
    - How the service will be documented in the patient's health center record; and
    - How the health center will pay for the service.

  Note: *The same sample of contracts/agreements is to be utilized for the review of Required and Additional Health Services, Clinical Staffing, and Sliding Fee Discount Program. The sampling methodologies for Required and Additional Health Services*

[1] Health centers may choose to provide samples of patient records prior to or during the site visit. If patient records will be provided during the site visit, this should be communicated prior to the site visit to avoid any disruption or delay in the site visit process.

are different from Contracts and Subawards and Conflict of Interest, although they may result in some overlap in the contracts/agreements.

Patient Records:

- Three to five health center patient records for patients who have received required and additional health services (**as specified in the methodology under demonstrating compliance element "a"**) in the past 24 months from a contracted provider(s)/organization(s).

☐ For services delivered via Column III of the health center's current Form 5A (whether or not the service is also delivered via Column I and/or Column II):

Referral Arrangements:

- **At least one but no more than three** written referral arrangements for EACH Required and EACH Additional Service.
- To assist in the review, the health center should flag all relevant provisions within referral arrangements related to:
  - 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).

  If these provisions are not present within the referral arrangements, provide additional documentation (for example, health center standard operating procedures) that contain those provisions.

Note: *The same sample of referral arrangements is to be utilized for the review of Required and Additional Health Services, Clinical Staffing, and Sliding Fee Discount Program.*

Patient Records:

- Three to five health center patient records for patients who have received a required and additional service(s) (**as specified in the methodology under demonstrating compliance element "a"**) in the past 24 months from a referral provider(s)/organization(s). Ensure each record clearly documents the patient's entire referral process, from initial referral to receipt of care and follow-up by the health center.

☐ Sample of key health center documents (for example, materials/application used to assess eligibility for the health center's sliding fee discount program, intake forms for clinical services, instructions for accessing after-hours services) translated for patients with limited English proficiency.

Note: *Refer to the Sampling Review Resource Guide to assist in assembling the samples for Required and Additional Health Services.*

Demonstrating Compliance

Element a: Providing and Documenting Services within Scope of Project

The health center provides access to all services included in its HRSA-approved scope of project[2] (Form 5A: Services Provided) through one or more service delivery methods,[3] as described below:[4]

- ***Direct***: If a required or additional service is provided directly by health center employees[5] or volunteers, 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.
- ***Formal Written Contract/Agreement***:[6] If a required or additional service is provided on behalf of the health center via a formal contract/agreement between the health center and a third party (including a subrecipient),[7] this service is accurately recorded in

---

[2] In accordance with 45 CFR 75.308 (Uniform Administrative Requirements: Revision of Budget and Program Plans), health centers must request prior approval from HRSA for a change in the scope or the objective of the project or program (even if there is no associated budget revision requiring prior written approval). This prior approval requirement applies, among other things, to the addition or deletion of a service within the scope of project. These changes require prior approval from HRSA and must be submitted by the health center as a formal Change in Scope request. Visit the Scope of Project website for further details, including the Form 5A Service Descriptors listed on Form 5A: Services Provided.

[3] The Health Center Program statute states in 42 U.S.C. 254b(a)(1) that health centers may provide services "either through the staff and supporting resources of the center or through contracts or cooperative arrangements." 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 Provided, visit Form 5A Column Descriptors. 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.

[4] See [Health Center Program Compliance Manual] Chapter 9: Sliding Fee Discount Program for more information on sliding fee discount program requirements and how they apply to the various service delivery methods.

[5] For purposes of the HRSA-approved scope of project (Form 5A: Services Provided), 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.

[6] See [Health Center Program Compliance Manual] Chapter 12: Contracts and Subawards for more information on program requirements around contracting.

[7] For purposes of the HRSA-approved scope of project (Form 5A: Services Provided), services provided via "contract/formal agreement" are those provided by practitioners who are not employed by or volunteers of the health center (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 an IRS Form 1099 to report payments to an individual contractor. See the Federal Tort Claims Act (FTCA) Health Center Policy Manual for information about eligibility for FTCA coverage for covered activities by

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, the health center ensures that 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.
- ***Formal Written Referral Arrangement***: If access to 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, the health center ensures that 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).

Site Visit Team Methodology

- In conjunction with the CEO and/or other relevant staff, review the accuracy of the health center's Form 5A: Services Provided.
- Tour sites where the majority of services are provided directly by the health center (Column I) and interview clinical staff during the site tours.
    - If the health center has more than one service site, tour at least two service sites.
    - For any Column I services that cannot be verified through the site tour or through interview(s), review at least one patient record for each service directly provided by the health center (Column I).
- Interview CMO and/or other clinical staff responsible for all service delivery methods (Columns I, II, and III).
- For any service delivered **via Column II (whether or not the service is also delivered via Column I and/or Column III)**:

    Review of Contracts/Agreements:
    - Review **at least one but no more than three** written contracts/agreements for EACH Required and EACH Additional Service. For any required or additional service noted as a Column II service on Form 5A, review at least one written contract. If there is more than one contract for the same service, each contract should be included in the sample, up to a maximum of three contracts. For example:

---

covered individuals, which extends liability protections for eligible "covered individuals," including governing board members and officers, employees, and qualified individual contractors.

[8] For purposes of the HRSA-approved scope of project (Form 5A: Services Provided), access to 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 Provided, visit Form 5A Column Descriptors.

        - Primary Care Services is listed in Column II. The health center maintains four separate contracts for individual contracted providers. The sample should include a maximum of three of these contracts for Primary Care Services.
        - Preventive Dental is listed in Column II. The health center maintains one contract for its preventive dental services. The sample should include one contract for Preventive Dental.
    - Review health center internal procedures that address documentation of information in the patient's health center record for any contracted service(s) that occur at location(s) other than a health center Form 5B in-scope site (for example, lab results, x-ray results).
- For any service delivered **via Column II (whether or not the service is also delivered via Column I and/or Column III):**

    Review of Patient Records:
    - Based on three Required Services and two Additional Services: Review three to five health center patient records for patients who have received these services in the past 24 months from a contracted provider(s)/organization(s). If the same patient has received more than one of these services, the same record can be used for assessing those services. If the health center delivers a service(s) through a subrecipient agreement(s), include patient records from all subrecipients, not to exceed a total of five subrecipients. For a health center with more than five subrecipients, select patient records from the subrecipients that receive the largest amounts of Health Center Program subaward funds.
      Note: *For Column II Services provided by individual contractors who work at a health center Form 5B in-scope site, documentation in the patient record of the services provided would occur in the health center's own patient record system.*
- For any service delivered **via Column III (whether or not the service is also delivered via Column I and/or Column II)**:

    Review of Referral Arrangements:
    - Review **at least one but no more than three** written referral arrangements for EACH Required and EACH Additional Service. For any required or additional service noted as a Column II service on Form 5A, review at least one written contract. If there is more than one referral arrangement for the same service, each written arrangement should be included in the sample, up to a maximum of three written arrangements. For example:
        - Intrapartum Services is listed in Column III. The health center maintains four separate arrangements for these services in various communities in their service area. The sample should include a maximum of three of these written arrangements for Intrapartum Care Services.
        - Diagnostic Laboratory Services is listed in Column III. The health center maintains one referral arrangement with a local hospital to provide these services. The sample should include one written arrangement for Diagnostic Laboratory Services.
- For any service delivered **via Column III (whether or not the service is also delivered via Column I and/or Column II):**

    Review of Patient Records:
    - Based on three Required Services and two Additional Services: Review three to five health center patient records for patients who have received these services in the past 24 months from a referral provider(s)/organization(s). If the same

patient has received more than one of these services, the same record can be used for assessing those services.

Notes:

- *The same sample of contracts/agreements and referral arrangements is to be utilized for the review of Required and Additional Health Services, Clinical Staffing, and Sliding Fee Discount Program.*
- *The sampling methodologies for Required and Additional Health Services are different from Contracts and Subawards and Conflict of Interest, although they may result in some overlap in the contracts/agreements.*
- *The primary focus of this portion of the site visit is to validate the actual provision of the various required and additional services at the time of the Operational Site Visit and to ensure that Form 5A accurately reflects this current provision of services.*
- *The sample provided by the health center should reflect the service(s) that the health center is currently providing.*
- *If the site visit team finds that services reviewed in the sample differ from what is reflected on the health center's Form 5A (for example, a contract or referral arrangement is provided in the sample but is not reflected on the health center's current 5A), the team will still proceed with reviewing the sample and note the discrepancies in their site visit findings. This includes noting if any services are not being conducted within the scope of project (i.e., are other lines of business).*
- *When reviewing the provisions for enabling services (for example, transportation, translation, outreach) provided via Column II or III, compliance is demonstrated even if the related contracts or referral arrangements do not address all of the provisions (for example, documentation in the patient record, follow-up care) required for clinical services (for example, general primary medical care, preventive dental).*
- *Any findings regarding the structure or availability of a health center's sliding fee discount program (SFDP) as it relates to the services listed on Form 5A (for example, health center is providing an additional service directly, but the service is NOT discounted through the health center's SFDP) will be assessed and documented under the Sliding Fee Discount Program section.*
- *Follow-up from hospital admissions or hospital visits will be reviewed in the Continuity of Care and Hospital Admitting section.*

Site Visit Findings

1. **Form 5A, Column I:**

   - Are all services listed in Column I on the health center's current Form 5A being provided by the health center directly?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   Note: *Select "Not Applicable" if the health center does not offer any services via Column I.*

   If No, an explanation is required, including specifying any missing services:

   _____

2. **Form 5A, Column II:**

   - Does the health center maintain formal written contracts/agreements for services listed in Column II on its current Form 5A?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   - Do the health center's contracts/agreements document how the health center will pay for the service(s)?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   - Do the health center's contracts/agreements or any supporting internal procedures document how information regarding the service(s) will be provided to the health center for inclusion in the patient's health center record?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   - Was the health center able to produce patient records from the past 24 months that document receipt of specific contracted services?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   Note: *Select "Not Applicable" for each of the above questions if the health center does not offer any services via Column II.*

   If No OR Not Applicable was selected for any of the above, an explanation is required providing details on the specific service(s):

   _____

3. **Form 5A, Column III:**

   - Does the health center maintain formal written referral arrangements for services listed in Column III on its current Form 5A?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   - Do the health center's formal written referral arrangements or other documentation (for example, health center standard operating procedures) include provisions that address the manner by which referrals will be made and managed as well as 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)?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   - Is there documentation in the patient record of appropriate follow-up care and information that resulted from these referrals (for example, exchange of patient record information, receipt of lab results)?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   Note: *Select "Not Applicable" for each of the above questions if the health center does not offer any services via Column III.*

If No OR Not Applicable was selected for any of the above, an explanation is required providing details on the specific service(s):

_____

4. Considering the overall scope of project (i.e., all services on Form 5A across the various Columns), were services recorded on Form 5A consistent with how they were offered by the health center at the time of the site visit?
   ☐ YES ☐ NO

5. **If No:** Has the health center submitted a Change in Scope request(s) to HRSA to correct all Form 5A inconsistencies?
   ☐ YES ☐ NO

   If Yes OR No, specify the inconsistency(ies) observed and whether the relevant Change in Scope request(s) has been submitted to HRSA to correct the accuracy of Form 5A:

   _____

Element b: Ensuring Access for Limited English Proficient Patients

Health center patients with limited English proficiency (LEP) are provided with interpretation and translation (for example, through bilingual providers, on-site interpreters, high quality video or telephone remote interpreting services) that enable them to have reasonable access to health center services.

Site Visit Team Methodology

- Review Uniform Data System (UDS) patient demographic data.
- Review sample of translated health center documents.
- Review access to interpretation services (for example, on-site interpreter(s), contract(s) for interpretation services).
- Interview health center clinical leadership and providers regarding patient language needs (for example, most common primary languages spoken by the patient population) and the role of cultural competency in the delivery of health center services (for example, training of front desk and clinical staff in cultural knowledge, attitudes, and beliefs of patient population).

Site Visit Findings

6. Does the health center provide access to interpretation for health center patients with LEP?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

7. Was the health center able to provide an example of a key document (i.e., documents that enable patients to access health center services) currently in use that is translated into different languages for its patient population?
   ☐ YES ☐ NO

If No, an explanation is required:

_____

Element c: Providing Culturally Appropriate Care

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

Site Visit Team Methodology

- Review UDS patient demographic data.
- Review sample of translated health center documents.
- Review access to interpretation services (for example, on-site interpreter(s), contract(s) for interpretation services).
- Interview health center clinical leadership and providers regarding patient language needs (for example, most common primary languages spoken by the patient population) and the role of cultural competency in the delivery of health center services (for example, training of front desk and clinical staff in cultural knowledge, attitudes, and beliefs of patient population).

Site Visit Findings

8. Was the health center able to provide an example of how it delivers services in a manner that is culturally appropriate for its patient population (for example, culturally appropriate health promotion tools)?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

CLINICAL STAFFING

Primary Reviewer: Clinical Expert
Secondary Reviewer: Governance/Administrative Expert (as needed)

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

Related Considerations

Document Checklist for Health Center Staff

- ☐ Credentialing and privileging procedures (including Human Resource procedures, if applicable).
- ☐ Website URL (if applicable).
- ☐ Current clinical staffing profile: name, position, FTE, credential (for example, RN, MD), provider type (licensed independent practitioners (LIP), other licensed or certified practitioners (OLCP), or other clinical staff), hire date. Indicate staff with interpretation/translation capabilities (i.e., bilingual, multilingual).
- ☐ Needs Assessment(s) or related studies or resources.
- ☐ If clinical services are provided via Column II or III, written contracts/agreements and written referral arrangements:
    - **No more than three** contracts with provider organizations. Prioritize contracts for any clinical services that are offered only via Column II.
    - **No more than three** written referral arrangements. Prioritize referral arrangements for any clinical services that are offered only via Column III.

  Notes:
    - *In selecting contracts and referral arrangements, select those that support clinical services (for example, general primary medical care, preventive dental). HRSA recognizes that contracts or referral arrangements for enabling services (for example, transportation, translation, outreach) may not contain provisions for credentialing and privileging.*
    - *The same sample of contracts/agreements is to be utilized for the review of Required and Additional Health Services, Clinical Staffing, and Sliding Fee Discount Program. The sampling methodologies for Clinical Staffing are different from Contracts and Subawards and Conflict of Interest, although they may result in some overlap in the contracts/agreements.*
    - *The same sample of referral arrangements is to be utilized for the review of Required and Additional Health Services, Clinical Staffing, and Sliding Fee Discount Program.*
- ☐ Sample of files for current clinical staff that contain credentialing and privileging information: four to five LIP files; four to five OLCP files; and, only if applicable, two to three files for other clinical staff. For the selected files, include:
    - Representation from different disciplines and sites.
    - Providers directly employed and contracted, in addition to volunteers (if applicable).
    - Providers who do procedures beyond core privileges for their discipline(s).

  - Providers who have been initially credentialed.
  - Providers who have been re-credentialed/re-privileged.
- ☐ Contract or agreement with Credentialing Verification Organization (CVO) or other entity used to perform credentialing functions (such as primary source verification) on behalf of the health center (if applicable).

Demonstrating Compliance

Element a: Staffing to Provide Scope of Services

The health center ensures that it has clinical staff[1] and/or has contracts or formal referral arrangements in place with other providers or provider organizations to carry out all required and additional services included in the HRSA-approved scope of project.[2]

Site Visit Team Methodology

- Interview CMO/Clinical Director and/or equivalent health center leadership regarding scope of services, current clinical staffing, and recruitment and retention process(es).
- Tour at least one to two health center site(s) where the majority of required services are delivered.
- Review current clinical staffing profile.
- Review health center's Form 5A for background and alignment of services with clinical staffing. Refer to Required and Additional Health Services documentation for further details on the staffing for services provided via contracts/agreements and written referral arrangements.

Site Visit Findings

1. Does the health center's current clinical staffing makeup (for example, employees, volunteers, contracted and referral providers) enable it to carry out the approved scope of project (i.e., the list of Required and Additional services on Form 5A)?
   ☐ YES ☐ NO

   If No, an explanation is required specifying what staffing is lacking and for which services:

   _____

[1] 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, registered dietitian, certified medical assistant), and other clinical staff providing services on behalf of the health center (for example, medical assistants or community health workers in states, territories or jurisdictions that do not require licensure or certification).
[2] Health centers seeking coverage for themselves and their providers under the Health Center Federal Tort Claims Act (FTCA) Medical Malpractice Program should review the statutory and policy requirements for coverage, as discussed in the FTCA Health Center Policy Manual.

Element b: Staffing to Ensure Reasonable Patient Access

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

Site Visit Team Methodology

- Interview CMO/Clinical Director and/or equivalent health center leadership (for example, Dental Director, Pharmacist) regarding how the number and mix of clinical staff support patient access.
- Review health center's needs assessment documentation and Uniform Data System (UDS) Summary Report (number of patients served annually, patient demographics, primary diagnosis, and clinical quality and outcome measures).
- Assess the type and range of services provided through review of the health center's Form 5A and other resources as appropriate (for example, website, health center presentation during the Entrance Conference, observation during site visit tour(s), and interviews with clinical leadership).

Site Visit Findings

2. Was the health center able to provide one to two examples of how the mix (for example, pediatric and adult providers) and number (for example, full or part time staff, use of contracted providers) of clinical staff is responsive to the size, demographics, and needs of its patient population?
   ☐ YES ☐ NO

   If No, an explanation is required specifying why the example(s) did not show how the mix and number of clinical staff are responsive to the health center's patient population:

   _____

3. Given the number of patients served annually (based on most recent UDS), is the number and mix of current staff (considering the overall scope of project—i.e., all sites and all service delivery methods) sufficient to ensure reasonable patient access to health center services?
   ☐ YES ☐ NO

   If No, an explanation is required, including specific examples of why there is not reasonable patient access to health center services:

   _____

Element c: Procedures for Review of Credentials

The health center has operating procedures for the initial and recurring review (for example, every 2 years) of credentials for all clinical staff members (licensed independent practitioners (LIPs), other licensed or certified practitioners (OLCPs), and other clinical staff providing services on behalf of the health center) who are health center employees, individual contractors,

or volunteers. These credentialing procedures would ensure verification of the following, as applicable:

- Current licensure, registration, or certification using a primary source;
- Education and training for initial credentialing, using:
  - Primary sources for LIPs;[3]
  - Primary or other sources (as determined by the health center) for OLCPs and any other clinical staff;
- Completion of a query through the National Practitioner Data Bank (NPDB);[4]
- Clinical staff member's identity for initial credentialing using a government-issued picture identification;
- Drug Enforcement Administration (DEA) registration; and
- Current documentation of basic life support training.

Site Visit Team Methodology

- Review the health center's credentialing procedures (including Human Resource procedures, if applicable) for LIPs and OLCPs.
- If the health center utilizes other clinical staff who do not require licensure or certification to provide services on behalf of the health center (for example, non-certified medical/dental assistants, community health representatives, case managers), review the health center's credentialing procedures for those other clinical staff.
- Review any contracts the health center has with CVOs (if applicable).
- Interview the individual(s) who conduct or have responsibility for the credentialing of clinical staff to determine:
  - Whether education and training for LIPs is confirmed through:
    - Primary source verification obtained by the health center, or
    - The state licensing body, because the state licensing body conducts primary source verification of education and training for LIPs.
  - The health center's method(s) for tracking timelines for the recurring review of credentials of existing providers as well as tracking of date-sensitive credentials (such as professional licenses, DEA registration) to ensure currency.

Notes:

- *If a health center does not have "other clinical staff," the health center does not have to include such staff in its operating procedures.*
- *The health center determines whether to have separate credentialing processes for LIPs versus other provider types. For example, the health center determines what specific aspects of the credentialing process (such as verification of current licensure, registration, or certification) might not apply to "other clinical staff."*
- *For OLCPs and any other clinical staff, the health center determines the sources used for verification of education and/or training. In states in which the licensing agency,*

[3] In states in which the licensing agency, specialty board or registry conducts primary source verification of education and training, the health center would not be required to duplicate primary source verification when completing the credentialing process.
[4] The NPDB is an electronic information repository authorized 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, visit National Practitioner Data Bank.

specialty board, or registry conducts primary source verification of education and training, the health center may consider the state's primary verification of state licensure or board certification to be adequate verification of education and training.

Site Visit Findings

4. **Initial Credentialing Only:** Do the health center's credentialing procedures require verification of the following for all clinical staff, as applicable, upon hire:

   - Clinical staff member's identity using a government-issued picture identification?
     ☐ YES ☐ NO

   - Verification by the health center or the state (licensing agency, specialty board, or registry) of the education and training of LIPs using a primary source?
     ☐ YES ☐ NO

   - Verification of the education and/or training of OLCPs and, as applicable, other clinical staff using a primary or secondary source, as determined by the health center?
     ☐ YES ☐ NO

   Note: *Clinical staff are health center employees, individual contractors, or volunteers and include LIPs, OLCPs and other clinical staff.*

   If No was selected for any of the above, an explanation is required:

   _____

5. **Initial and Recurring Credentialing Procedures:** Do the health center's credentialing procedures require verification of the following for all clinical staff upon hire AND on a recurring basis:

   - Current licensure, registration, or certification using a primary source for LIPs and OLCPs?
     ☐ YES ☐ NO

   - Completion of a query through the NPDB?
     ☐ YES ☐ NO

   - DEA registration (as applicable)?
     ☐ YES ☐ NO

   - Current documentation of basic life support training (or comparable training completed through licensure or certification)?
     ☐ YES ☐ NO

   Note: *Clinical staff are health center employees, individual contractors, or volunteers and include LIPs, OLCPs and other clinical staff.*

   If No was selected for any of the above, an explanation is required:

   _____

Element d: Procedures for Review of Privileges

The health center has operating procedures for the initial granting and renewal (for example, every 2 years) of privileges for clinical staff members (LIPs, OLCPs, and other clinical staff providing services on behalf of the health center) who are health center employees, individual contractors, or volunteers. These privileging procedures would address the following:

- Verification of fitness for duty, immunization, and communicable disease status;[5]
- For initial privileging, verification of current clinical competence via training, education, and, as available, reference reviews;
- For renewal of privileges, verification of current clinical competence via peer review or other comparable methods (for example, supervisory performance reviews); and
- Process for denying, modifying or removing privileges based on assessments of clinical competence and/or fitness for duty.

Site Visit Team Methodology

- Review the health center's privileging procedures (including Human Resource procedures, if applicable) for LIPs, OLCPs, and other clinical staff providing services on behalf of the health center to assess procedures for: verification of fitness for duty and immunization and communicable disease status; clinical competence; and modification or removal of privileges.
- Interview individual(s) or committee that completes or has approval authority for privileging of clinical staff to determine:
    - How fitness for duty, immunization, and communicable disease status are verified;
    - How clinical competence is assessed for initial granting of privileges;
    - How clinical competence is assessed for renewal of clinical privileges; and
    - What the health center's processes are for modifying or removing privileges.

Note: *If a health center does not have "other clinical staff," the health center does not have to include such staff in its operating procedures.*

Site Visit Findings

6. Do the health center's operating procedures address both the initial granting and renewal of privileges for all clinical staff (LIPs, OLCPs, and other clinical staff who are health center employees, individual contractors, or volunteers)?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

[5] The CDC has published recommendations and many states have their own recommendations or standards for provider immunization and communicable disease screening. For more information about CDC recommendations, visit CDC: Recommended Vaccines for Healthcare Workers.

7. Do the health center's privileging procedures require verification of fitness for duty for all clinical staff upon hire and on a recurring basis?

   Note: *Clinical staff are health center employees, individual contractors, or volunteers and include LIPs, OLCPs and other clinical staff.*
   ☐ YES ☐ NO

   If Yes OR No was selected, an explanation is required, including specifying how the health center has verified fitness for duty to ensure all clinical staff have the physical and cognitive ability to safely perform their duties:

   _____

8. Do the health center's privileging procedures require verification of the following for all clinical staff upon hire and on a recurring basis:

   - Immunization and communicable disease status?
     ☐ YES ☐ NO

   - Current clinical competence?
     ☐ YES ☐ NO

   Note: *Clinical staff are health center employees, individual contractors, or volunteers and include LIPs, OLCPs and other clinical staff.*

   If No was selected for any of the above, an explanation is required:

   _____

9. Does the health center have criteria and processes for modifying or removing privileges based on the outcomes of clinical competence assessments?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

Element e: Credentialing and Privileging Records

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

Site Visit Team Methodology

- Interview health center staff regarding credentialing and privileging records.
- Review sample of files for current clinical staff that contain credentialing and privileging information (as defined by the health center in its operating procedures): four to five LIP files; four to five OLCP files; and, only if applicable, two to three files for other clinical staff.
- Conduct the review of the file sample together with the health center individual(s) responsible for maintaining credentialing and privileging documentation.

Note: *Please utilize the Credentialing and Privileging File Review Resource to assist in this review and for examples of documentation methods and sources.*

Site Visit Findings

10. Based on the review of the sample of current clinical staff files, did the files contain up-to-date (as defined by the health center in its operating procedures) documentation of licensure and credentialing of these clinical staff (employees, individual contractors, and volunteers)?
☐ YES ☐ NO

    If No, an explanation is required:

    _____

11. Based on the review of the sample of current clinical staff files, did the files contain up-to-date (as defined by the health center in its operating procedures) documentation of privileging decisions (for example, an up-to-date privileging list for each provider) for these clinical staff (employees, individual contractors, and volunteers)?
☐ YES ☐ NO

    If No, an explanation is required:

    _____

Element f: Credentialing and Privileging of Contracted or Referral Providers

If the health center has contracts with provider organizations (for example, group practices, locum tenens staffing agencies, training programs) or formal, written referral agreements with other provider organizations that provide services within its scope of project, the health center ensures[6] that such providers are:

- Licensed, certified, or registered as verified through a credentialing process, in accordance with applicable federal, state, and local laws; and
- Competent and fit to perform the contracted or referred services, as assessed through a privileging process.

Site Visit Team Methodology

- Interview health center staff involved in overseeing and managing services provided via contracts and/or referral arrangements regarding related credentialing and privileging processes.
- Review **no more than three** contracts with provider organizations. Prioritize the review of any clinical services that are offered only via Column II.
- Review **no more than three** written referral arrangements. Prioritize the review of any clinical services that are offered only via Column III.

[6] This may be done, for example, through provisions in contracts and cooperative arrangements with such organizations or health center review of the organizations' credentialing and privileging processes.

Notes:

- *The same sample of contracts/agreements and referral arrangements is to be utilized for the review of Required and Additional Health Services, Clinical Staffing, and Sliding Fee Discount Program. The sampling methodologies for Clinical Staffing are different from Contracts and Subawards and Conflict of Interest, although they may result in some overlap in the contracts/agreements.*
- *In selecting contracts and referral arrangements, select those that support clinical services (for example, general primary medical care, preventive dental). HRSA recognizes that contracts or referral arrangements for enabling services (for example, transportation, translation, outreach) may not contain provisions for credentialing and privileging.*
- *If possible, conduct the review of the contract(s)/agreement(s), referral arrangement(s), or related documentation together with health center staff involved in overseeing and managing clinical services provided via contracts and/or referral arrangements.*
- *Examples of demonstrating credentialing and privileging for contracted or referral providers could include assurance that the health center has reviewed:*
    - *The contracted organization's credentialing and privileging processes for providers, such as physicians, pharmacists, and dentists;*
    - *The contracted organization's documentation from a nationally recognized accreditation organization; or*
    - *The contracted laboratory's documentation of Clinical Laboratory Improvement Amendments (CLIA) compliance.*

Site Visit Findings

12. Was the health center able to ensure through provisions in contracts or through other means (for example, the contracted organization provides the health center with documentation of Joint Commission accreditation) that contracted services (Form 5A, Column II) are provided by organizations that:

    - Verify provider licensure, certification, or registration through a credentialing process?
      ☐ YES ☐ NO ☐ NOT APPLICABLE

    - Verify providers are competent and fit to perform the contracted service(s) through a privileging process?
      ☐ YES ☐ NO ☐ NOT APPLICABLE

    Notes:
    - *Select "Not Applicable" if the health center does not offer any clinical services via Column II.*
    - *For Column II services that involve a contract with provider organization(s), the credentialing and privileging process for the provider(s) may either be conducted by the provider organization(s) or may be conducted by the health center. Individual contractors are credentialed and privileged by the health center (see demonstrating compliance element "c").*

    If No was selected for any of the above, an explanation is required:

    _____

13. Was the health center able to ensure through provisions in written referral arrangements or through other means (for example, the referral organization provides the health center with documentation of Joint Commission accreditation) that referred services (Form 5A, Column III) are provided by organizations that:

    - Verify provider licensure, certification, or registration through a credentialing process?
      ☐ YES ☐ NO ☐ NOT APPLICABLE

    - Verify providers are competent and fit to perform the referred service(s) through a privileging process?
      ☐ YES ☐ NO ☐ NOT APPLICABLE

    Notes:
    - *Select "Not Applicable" if the health center does not offer any clinical services via Column III.*
    - *In all cases for Column III services, the credentialing and privileging process for providers is external (i.e., conducted by the referral provider/organization).*

    If No was selected for any of the above, an explanation is required:

    _____

ACCESSIBLE LOCATIONS AND HOURS OF OPERATION

Primary Reviewer: Governance/Administrative Expert
Secondary Reviewer: Clinical Expert

Authority: *Section 330(k)(3)(A) of the Public Health Service (PHS) Act; and 42 CFR 51c.303(a) and 42 CFR 56.303(a)*

Related Considerations

Document Checklist for Health Center Staff

- ☐ List of health center sites, including site addresses, hours of operation by site, and information on what general services (for example, medical, oral health, behavioral health) are offered at each service site.
  Note: *These may be presented in separate documents or as references to health center websites.*
- ☐ Uniform Data System (UDS) Mapper Service Area Map (if updated since last application submission to HRSA).
- ☐ Patient satisfaction surveys or other forms of patient input.
- ☐ Needs assessment(s) or related studies or resources.

Demonstrating Compliance

Element a: Accessible Service Sites

The health center's service site(s) are accessible to the patient population relative to where this population lives or works (for example, in areas immediately accessible to public housing for health centers targeting public housing residents, or in shelters for health centers targeting individuals experiencing homelessness, or at migrant camps for health centers targeting agricultural workers). Specifically, the health center considers 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.

Site Visit Team Methodology

- Review Service Area Map.
- Review needs assessment(s) or related studies or resources.

- Review status of any special populations funding or designation.
- Interview health center staff and board members, walking through considerations either for one to two sites already in scope OR a site added to scope within the past 12 months.

Site Visit Findings

1. Does the health center take the following factors, including those specific to special population(s) (if applicable), into consideration in determining where to locate its sites:

   - Access barriers (for example, the health center has considered the ways patients access health center sites)?
     ☐ YES ☐ NO

   - 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 (for example, if some in-scope services are located only at certain sites, the health center facilitates access to these services for the entire patient population)?
     ☐ YES ☐ NO

   If No was selected for any of the above, an explanation is required:

   _____

Element b: Accessible Hours of Operation

The health center's total number and scheduled hours of operation across its service sites are responsive to patient needs by facilitating the ability to schedule appointments and access the health center's full range of services within the HRSA-approved scope of project[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).

Site Visit Team Methodology

- Review health center's Form 5B to assess overall range of hours of operation and addresses of sites.
- Review needs assessment(s) or related studies or resources.
- Review patient satisfaction surveys or other forms of patient input.
- Interview relevant health center staff and board members to have them provide one to two examples of how hours are responsive to patient need.

[1] Services provided by a health center are defined at the awardee/designee level, not by individual site. Thus, not all services must be available at every health center service site; rather, health center patients must have reasonable access to the full complement of services offered by the center as a whole, either directly or through formal written established arrangements. Visit the Scope of Project website for further details, including services and column descriptors listed on Form 5A: Services Provided.

Site Visit Findings

2. Has the health center taken patient needs into consideration in setting the hours of operation of its sites (for example, within available resources, the hours correspond to most requested appointment times or align with the most in-demand services)?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

Element c: Accurate Documentation of Sites within Scope of Project

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

Site Visit Team Methodology

- Review health center's Form 5B.
- Review latest list of site addresses provided by health center and compare to those sites listed on the most current Form 5B in the EHBs.
- Interview relevant health center staff.

Note: *The primary focus of this portion of the site visit is to validate the active service sites of the health center, noting any inaccuracy(ies) on Form 5B accordingly in the site visit finding question.*

Site Visit Findings

3. Does the health center's Form 5B need to have any site(s) added or removed?
   ☐ YES ☐ NO

4. **If Yes:** Has the health center submitted a Change in Scope request(s) to HRSA to correct Form 5B?
   ☐ YES ☐ NO

   If Yes OR No, specify the inconsistency(ies) observed and whether the relevant Change in Scope request(s) has been submitted to HRSA to correct Form 5B:

   _____

[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 written approval)." This prior approval requirement applies to the addition or deletion 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. Visit the Scope of Project website for further details.

COVERAGE FOR MEDICAL EMERGENCIES DURING AND AFTER HOURS

Primary Reviewer: Clinical Expert
Secondary Reviewer: TBD

Authority: *Section 330(b)(1)(A)(IV) and Section 330(k)(3)(A) of the Public Health Service (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)*

Related Considerations

Document Checklist for Health Center Staff

- ☐ Operating procedures for addressing medical emergencies during health center's hours of operation.
- ☐ Operating procedures for responding to patient medical emergencies after hours.
- ☐ Staffing schedules for up to five service delivery sites that identify the individual(s) with current certification in basic life support at each site.
- ☐ Provider on-call schedules and answering service contract (if applicable; for health centers whose own providers cover after-hours calls).
- ☐ Written arrangements with non-health center providers/entities (for example, formal agreements with other community providers, "nurse call" lines) for after-hours coverage (if applicable; for health centers that utilize non-health center providers).
- ☐ List of service delivery sites with names of at least one individual (clinical or non-clinical staff member) at each site trained and certified in basic life support, including a copy of that individual's current certification (for example, credentialing file for licensed independent practitioner or other licensed or certified practitioner, certification of training if non-clinical staff).
- ☐ Instructions or information provided to patients for accessing after-hours coverage.
- ☐ Three samples of after-hours clinical advice documentation in the patient record[1] (for example, screenshots selected by the health center), including associated documentation of follow-up.
  Note: *The samples will be based on after-hours calls that necessitated follow-up by the health center. If the health center has fewer than three after-hours calls that required follow-up, the health center will make up the difference with after-hours call documentation that did not require follow-up.*
- ☐ Documentation demonstrating systems/methods of tracking, recording, and storing of after-hours coverage interactions (for example, log of patient calls) and, if applicable, related follow-up.

[1] Health centers may choose to provide samples of patient records prior to or during the site visit. If patient records will be provided during the site visit, this should be communicated prior to the site visit to avoid any disruption or delay in the site visit process.

Demonstrating Compliance

Element a: Clinical Capacity for Responding to Emergencies During Hours of Operation

The health center has at least one staff member trained and certified in basic life support present at each HRSA-approved service site (as documented on Form 5B: Service Sites) to ensure the health center has the clinical capacity to respond to patient medical emergencies[2] during the health center's regularly-scheduled hours of operation.[3]

Site Visit Team Methodology

- Interview health center clinical leadership.
- Review operating procedures for provisions that ensure that all service delivery sites have at least one individual per site present during the health center's regularly-scheduled hours of operation to respond to patient medical emergencies.
- Using staffing schedules for up to five service delivery sites, request that clinical leadership identify the individual(s) with current certification in basic life support present at each site during the health center's regularly-scheduled hours of operation.

Site Visit Findings

1. Was there documentation that the health center ensures at least one staff member (clinical or non-clinical) trained and certified in basic life support is present at each HRSA-approved service delivery site to respond to patient medical emergencies during the health center's regularly-scheduled hours of operation?
   ☐ YES ☐ NO

   If No, an explanation is required, including stating what, if any, provisions the health center has in place to respond to patient medical emergencies during regularly-scheduled hours of operation at its site(s):

   _____

Element b: Procedures for Responding to Emergencies During Hours of Operation

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

---

[2] Medical emergencies may, for example, include those related to physical, oral, behavioral, or other emergent health needs.
[3] See [Health Center Program Compliance Manual] Chapter 6: Accessible Location and Hours of Operation for more information on hours of operation.

Site Visit Team Methodology

- Review health center's operating procedures for responding to medical emergencies.
- Interview CMO, Clinical Director, and/or equivalent leadership regarding how the health center HAS or WOULD follow its operating procedure when responding to a patient emergency.

Site Visit Findings

2. Were you able to confirm that the health center has operating procedures for responding to patient medical emergencies during the health center's regularly-scheduled hours of operation?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

3. Was the health center able to describe how it either has responded to or is prepared to respond to (for example, staff training or drills on use of procedures) patient medical emergencies during regularly-scheduled hours of operation?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

Element c: Procedures or Arrangements for After-Hours Coverage

The health center has after-hours coverage operating procedures, which may include formal arrangements[4] 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;
- 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 (LEP),[5] are informed of and are able to access after-hours coverage, based on receiving after-hours coverage

---

[4] See [Health Center Program Compliance Manual] Chapter 12: Contracts and Subawards for more information on oversight over such arrangements.

[5] Under Section 602 of Title VI of the Civil Rights Act and the Department of Health and Human Services implementing regulations (45 CFR 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. Visit Office of Civil Rights: Guidance to Federal Financial Assistance Recipients Regarding Title VI and the Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons - Summary for further guidance on translating vital documents for LEP persons.

information and instructions in the language(s), literacy levels, and formats appropriate to the health center's patient population needs.

Site Visit Team Methodology

- Review the health center's operating procedures or, if applicable, other documentation of arrangements for responding to patient medical emergencies after hours.
- Review provider on-call schedules and answering service contract (if applicable).
- Review instructions or information provided to patients for accessing after-hours coverage.
- Using contact information for after-hours coverage (for example, phone number provided by front desk staff, on signage, in brochures, on health center's website), call the health center once the health center is closed.
- Interview CMO, Clinical Director, and/or equivalent health center leadership and, if applicable, outreach or front desk staff regarding methods of informing patients of after-hours coverage.

Site Visit Findings

4. Does the health center have written operating procedures or other documented arrangements for responding to patient medical emergencies after hours?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

5. Based on the interview with clinical leadership and/or front desk staff, is information provided to patients at all health center service sites (as listed on Form 5B) on how to access after-hours coverage?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

6. Has the health center addressed barriers that patients might face in attempting to utilize the health center's after-hours coverage? This would include barriers due to LEP or literacy levels.
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

7. Did the results from the call made to the health center after hours confirm the following:

   - You were connected to an individual with the qualification and training necessary to exercise professional judgment to address an after-hours call?
     ☐ YES ☐ NO

- This individual can refer patients to a covering licensed independent practitioner for further consultation or to locations such as emergency rooms or urgent care facilities for further assessment or immediate care?
  ☐ YES ☐ NO

- Provisions are in place for calls received from patients with LEP?
  ☐ YES ☐ NO

If No was selected for any of the above, an explanation is required:

_____

Element d: After-Hours Call Documentation

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]

Site Visit Team Methodology

- Interview CMO, Clinical Director, and/or equivalent health center leadership.
- Review the health center's operating procedures or, if applicable, other documentation of arrangements (for example, contract with nurse call line) for responding to patient medical emergencies after hours.
- Review three samples of after-hours documentation within the patient record (a screenshot of the record is also acceptable) provided by the health center, including associated documentation of follow-up. The samples will be based on after-hours calls that necessitated follow-up by the health center.
  Note: *If the health center has fewer than three after-hours calls that required follow-up, the health center will make up the difference with after-hours call documentation that did not require follow-up.*
- Review documentation or systems/methods for tracking, recording, and storing after-hours call coverage interactions and, if applicable, related follow-up.

Site Visit Findings

8. Does the health center document after-hours calls or, if no such calls have been received, does the health center have the capacity to document such calls?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

9. Does the health center (based on review of systems or the sample of records) provide the necessary follow-up, based on the nature of after-hours calls (for example, health center contacts the patient within a prescribed number of days to check in on the patient's condition, schedule an appointment)?

---

[6] See [Health Center Program Compliance Manual] Chapter 8: Continuity of Care and Hospital Admitting for more information on continuity of care.

Note: *For health centers that had no after-hours calls that required follow-up (for example, a newly-funded health center that has just started its operations), a review of operating procedures and results of the interview(s) with health center staff can be used when responding to this question.*

☐ YES ☐ NO

If No, an explanation is required:

_____

CONTINUITY OF CARE AND HOSPITAL ADMITTING

Primary Reviewer: Clinical Expert
Secondary Reviewer: N/A

Authority: *Section 330(k)(3)(A) and 330(k)(3)(L) of the Public Health Service (PHS) Act; and 42 CFR 51.c.303(a) and 42 CFR 56.303(a)*

Related Considerations

Document Checklist for Health Center Staff

- ☐ Health center's internal operating procedures and/or documentation from arrangements with non-health center provider(s) for tracking of patient hospitalization and continuity of care.
- ☐ Documentation of EITHER:
  - Provider hospital admitting privileges (for example, hospital staff membership, provider employee contracts) that address delivery of care in a hospital setting to health center patients by health center providers; OR
  - Formal arrangements with provider(s) or entity(ies) that address health center patient hospital admissions (for example, transfer agreement(s), supporting procedures, or other documentation of inpatient care coordination with the health center).
- ☐ Sample of 5–10 health center patient records[1] (for example, using live navigation of the Electronic Health Records (EHR), screenshots from the EHR, or actual records if the records are not electronic/EHR records) for patients who were hospitalized or who had Emergency Department (ED) visits within the past 12 months. Ensure each record clearly documents the health center's entire hospitalization tracking process, from admission and follow-up through closure.

Demonstrating Compliance

Element a: Documentation of Hospital Admitting Privileges or Arrangements

The health center has documentation of:

[1] Health centers may choose to provide samples of patient records prior to or during the site visit. If patient records will be provided during the site visit, this should be communicated prior to the site visit to avoid any disruption or delay in the site visit process.

- Health center provider[2] hospital admitting privileges (for example, provider employment contracts or other files indicate the provider(s) has admitting privileges at one or more hospitals); and/or
- Formal arrangements between the health center and one or more hospitals or entities (for example, hospitalists, obstetrics hospitalist practices) for the purposes of hospital admission of health center patients.

Site Visit Team Methodology

- Interview health center clinical leadership (for example, CMO, Clinical Director) on processes for ensuring continuity of care for patients that require inpatient hospitalization.
- Review documentation of EITHER:
    - Provider hospital admitting privileges that address delivery of care in a hospital setting to health center patients by health center providers; OR
    - Formal arrangements with non-health center provider(s) or entity(ies) (for example, hospitalists) that address hospital admissions of health center patients.

Site Visit Findings

1. Does the health center have:

    - Documentation of hospital admitting privileges (if select health center providers assume responsibility for admitting and following hospitalized patients); or
    - Formal arrangements with non-health center provider(s) or entity(ies) (such as a hospital, hospitalist group, or obstetrics practice) that address health center patient hospital admissions?

    ☐ YES ☐ NO

    If Yes OR No, an explanation is required specifying the health center's arrangement(s) for hospital admissions:

    _____

Element b: Procedures for Hospitalized Patients

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) that address the following areas for patients who are hospitalized as inpatients or who visit a hospital's emergency department (ED):[3]

- Receipt and recording of medical information related to the hospital or ED visit, such as discharge follow-up instructions and laboratory, radiology, or other results; and

---

[2] 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).
[3] Health center patients may be admitted to a hospital setting through a variety of means (for example, a visit to the ED may lead to an inpatient hospital admission, or a health center patient may be directly admitted to a unit of the hospital, such as labor and delivery).

- Follow-up actions by health center staff, when appropriate.

Site Visit Team Methodology

- Review health center internal operating procedures and/or documentation of arrangements with non-health center provider(s) or entity(ies) to assess continuity of care provisions.
- Interview health center staff regarding continuity of care.

Site Visit Findings

2. Did the health center's internal operating procedures and/or arrangements with non-health center provider(s) or entity(ies), if applicable, address the following:

    - How the health center will obtain or receive medical information related to patient hospital or ED visits and record such information (for example, discharge follow-up instructions and laboratory, radiology, or other results)?
      ☐ YES ☐ NO

    - Follow-up by the health center staff, when appropriate?
      ☐ YES ☐ NO

    If No was selected for any of the above, an explanation is required:

    _____

Element c: Post-Hospitalization Tracking and Follow-up

The health center follows its operating procedures and formal arrangements as documented by:

- Receipt and recording of medical information related to the hospital or ED visit, 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.

Site Visit Team Methodology

- Have a health center clinical staff member navigate the reviewer through 5–10 health center patient records.
- Interview relevant health center staff regarding access to medical information related to hospital and ED visits and associated follow-up actions by health center staff.

Site Visit Findings

3. Based on the review of sampled records and interview, was there documentation of:

    - Medical information related to the hospital or ED visit, such as discharge follow-up instructions and laboratory, radiology, or other results?
      ☐ YES ☐ NO

- Follow-up actions taken by health center staff based on the information received, when appropriate?
  ☐ YES ☐ NO

Note: *For a health center that has had no patients who have been hospitalized in the past 12 months (for example, a newly-funded health center that has just started its operations), a review of operating procedures and results of the interview with health center staff can be used to respond to these questions.*

If No was selected for any of the above, an explanation is required:

_____

SLIDING FEE DISCOUNT PROGRAM

Primary Reviewer: Fiscal Expert
Secondary Reviewer: Governance/Administrative Expert

Authority: *Section 330(k)(3)(G) of the Public Health Service (PHS) Act; 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)*

Related Considerations

Document Checklist for Health Center Staff

- ☐ Sliding fee discount program (SFDP) policy(ies).
- ☐ SFDP procedure(s).
- ☐ Sliding fee discount schedule (SFDS), including SFDSs that differ by service or service delivery method (if applicable).
- ☐ Any related policies, procedures, forms and materials that support the SFDP (for example, registration and scheduling, financial eligibility, screening, enrollment, patient notifications, billing and collections).
- ☐ Sample of 5–10 records, files or other forms of documentation of patient income and family size. Ensure the sample includes records for:
    - Uninsured and insured patients; and
    - Initial assessments for income and family size as well as re-assessments.
- ☐ For any service delivered via Column II (whether or not the service is also delivered via Column I and/or Column III), at least one but no more than three written contracts/agreements for EACH Required and EACH Additional Service. Provide any other supporting documentation demonstrating how the health center ensures sliding fee discounts for those selected services.
  Note: *The same sample of contracts/agreements is to be utilized for the review of Required and Additional Health Services, Clinical Staffing, and Sliding Fee Discount Program. The sampling methodologies for Sliding Fee Discount Program are different from Contracts and Subawards and Conflict of Interest, although they may result in some overlap in the contracts/agreements.*
- ☐ For any service delivered via Column III (whether or not the service is also delivered via Column I and/or Column II), at least one but no more than three written referral arrangements for EACH Required and EACH Additional Service. Provide any other supporting documentation demonstrating how the health center ensures sliding fee discounts for those selected services.
  Note: *The same sample of referral arrangements is to be utilized for the review of Required and Additional Health Services, Clinical Staffing, and Sliding Fee Discount Program.*
- ☐ If the board-approved SFDP policy does not state a specific amount for nominal charge(s), other documentation (for example, board minutes, reports) of board involvement in setting the amount of nominal charge(s).
- ☐ Data, reports, or any other relevant materials used to evaluate the SFDP.

- ☐ If the health center is subject to legal or contractual restrictions regarding sliding fee discounts for patients with third-party coverage, the health center will produce documentation of such restrictions.

Demonstrating Compliance

Element a: Applicability to In-Scope Services

The health center has a sliding fee discount program (SFDP)[1] that applies to all required and additional health services[2] within the HRSA-approved scope of project for which there are distinct fees.[3]

Site Visit Team Methodology

- Interview health center staff involved in implementing SFDP policies (for example, key management staff, eligibility and outreach staff, front desk staff, billing staff, office manager, case managers) including, time permitting, a walk-through of the SFDS screening and enrollment process.
- Review the health center's SFDP policy(ies), procedures, schedule(s) (single or multiple SFDSs, if applicable), and any related policies, procedures, forms, and materials.
- Review health center's Form 5A: Services Provided.
- For services provided via Column II or Column III, review the same documentation (policies, procedures, forms, and materials) in elements "i" and "j" to assess sliding fee eligibility.

Site Visit Findings

1. Are ALL services within the approved scope of project offered on a sliding fee discount schedule (SFDS) (for Columns I and II) or offered under any other type of discount (for Column III)? "Services" refers to all Required and Additional services across all applicable service delivery methods listed on the health center's Form 5A for which there are distinct fees.

   ***Notes**:*
   - *Include any findings regarding the specific STRUCTURE of the SFDS for services in Columns I, II, and III within applicable elements "c," "i," and "j."*
   - *Services (for example, transportation, translation, other non-clinical services) on Form 5A that are not billed for in the local health care market may be excluded from the health center's fee schedule(s) and, therefore, from the health center's SFDS.*

---

[1] A health center's SFDP consists of the schedule of discounts that is applied to the fee schedule and adjusts fees based on the patient's ability to pay. A health center's SFDP also includes the related policies and procedures for determining sliding fee eligibility and applying sliding fee discounts.
[2] See [Health Center Program Compliance Manual] Chapter 4: Required and Additional Health Services for more information on requirements for services within the scope of the project.
[3] A distinct fee is a fee for a specific service or set of services, which is typically billed for separately within the local health care market.

- *Do not review discounts for supplies and equipment that are related to but NOT included in the service itself as part of prevailing standards of care (for example, eyeglasses, prescription drugs, dentures). Such supplies and equipment are not considered services and are not subject to Health Center Program SFDP requirements.*

☐ YES ☐ NO

If No, an explanation is required, including specifying which in-scope services are excluded from sliding fee discounts or any other type of discount:

_____

2. Are there any patients with incomes at or below 200 percent of the Federal Poverty Guidelines (FPG) who are not considered eligible for the sliding fee discount for any Required or Additional service (Column I, II, or III) within the HRSA-approved scope of project?

☐ YES ☐ NO

If Yes, an explanation is required, including specifying why those patients are not considered eligible:

_____

Element b: Sliding Fee Discount Program Policies

The health center has board-approved policy(ies) for its SFDP that apply uniformly to all patients and address the following areas:

- Definitions of income[4] and family;
- Assessment of all patients for sliding fee discount eligibility based only on income and family size, including methods for making such assessments;
- The manner in which the health center'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 a flat nominal charge(s) at a level that would be nominal from the perspective of the patient (for example, based on input from patient board members, patient surveys, advisory committees, or a review of co-pay amount(s) associated with Medicare and Medicaid for patients with comparable incomes) and would not reflect the actual cost of the service being provided.[5]

Site Visit Team Methodology

- Interview board member(s) and key management staff.
  ***Note**: Interviews may be conducted in collaboration with the governance/administrative expert.*

---

[4] Income is defined as 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.
[5] Nominal charges are not "minimum fees," "minimum charges," or "co-pays."

- Review the health center's SFDP policy(ies).
  ***Note**: This may be combined with the policy review conducted for element "a."*
- Review any other related policies, procedures, and documents provided by the health center, if applicable.
- For health centers that choose to have a nominal charge for patients with incomes at or below 100 percent of the FPG:
  - Review documentation that the nominal charge was set at a level that would be nominal from the perspective of patients with incomes at or below 100 percent of the FPG (for example, based on input from patient board members, patient surveys, advisory committees, or a review of co-pay amount(s) associated with Medicare and Medicaid for patients with comparable incomes).
  - Review documentation that the nominal charge(s) does not reflect the actual cost of the service(s) being provided. If the SFDP policy does not state a specific amount for nominal charge(s), review other documentation (for example, board minutes, reports) of board involvement in setting the amount of nominal charge(s).

Site Visit Findings

3. Does the health center's SFDP policy include language or provisions that address all of the following:

   - Uniform applicability to all patients?
     ☐ YES ☐ NO

   - Definitions of income and family (or "household") (for example, any inclusions or exclusions in how they are defined)?
     ☐ YES ☐ NO

   - Methods for assessing patient eligibility based only on income and family size?
     ☐ YES ☐ NO

   - The manner in which SFDS(s) are structured to ensure charges are adjusted based on ability to pay (for example, flat fee amounts differ across discount pay classes, a graduated percent of charges for patients with incomes above 100 percent and at or below 200 percent of the FPG)?
     ☐ YES ☐ NO

   - The setting of a nominal charge(s) for patients with incomes at or below 100 percent of the FPG?

     ***Note:** Select "Not Applicable" if the health center does not charge patients with incomes at or below 100 percent of the FPG.*
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   If No was selected for any of the above, an explanation is required:

   _____

4. Does the health center's SFDP policy ensure that any/all charge(s) for patients with incomes at or below 100 percent of the FPG will be:

   - A flat fee?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   - Nominal from the perspective of patients with incomes at or below 100 percent of the FPG (for example, based on input from patient board members, patient surveys, advisory committees, or a review of co-pay amount(s) associated with Medicare and Medicaid for patients with comparable incomes)?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   - Not based on the actual cost of the service(s)?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   ***Note**: The health center's SFDP policy may state how the nominal charge will be determined AND/OR the amount of the nominal charge(s). If the SFDP policy does not state a specific amount for nominal charge(s), other documentation (for example, board minutes, reports) of board involvement in setting the amount of nominal charge(s) may be utilized.*

   If No was selected for any of the above, an explanation is required:

   _____

Element c: Sliding Fee for Column I Services

For services provided directly by the health center (Form 5A: Services Provided, Column I), the health center's SFDS(s) is structured consistent with its 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, which would be less than the fee paid by a patient in the first sliding fee discount pay class above 100 percent of the FPG.
- 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, and those discounts adjust based on gradations in income levels and include at least three discount pay classes.[6]
- No discounts are provided to individuals and families with annual incomes above 200 percent of the current FPG.[7]

[6] For example, a SFDS with discount pay classes of 101 percent 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.

[7] See [Health Center Program Compliance Manual] Chapter 16: Billing and Collections, if the health center has access to other grants or subsidies that support patient care.

Site Visit Team Methodology

- Review the structure of the health center's SFDS(s) for Column I services.
  ***Note**: For health centers that utilize multiple SFDSs, the structure of each SFDS must be reviewed, including, if applicable, any nominal charges.*
- Interview key management staff.

Site Visit Findings

In responding to the question(s) below, please note:
The questions relate to services provided directly by the health center (Form 5A: Services Provided, Column I).

5. For patients with incomes at or below 100 percent of the FPG, does the SFDS(s):

   - Provide a full discount (no nominal charge(s))?
     ☐ YES ☐ NO

   - Require only a nominal charge(s) ("fee")?
     ☐ YES ☐ NO

   If No was selected for BOTH of the above, an explanation is required:

   _____

6. If the health center has a nominal charge(s), is the nominal charge(s) less than the fee that would be paid by patients in the first sliding fee discount pay class above 100 percent of the FPG?
   ☐ YES ☐ NO ☐ NOT APPLICABLE

   If No, an explanation is required:

   _____

7. For patients with incomes above 100 percent and at or below 200 percent of the FPG, does the SFDS(s) provide partial discounts adjusted in accordance with gradations in income levels and consist of at least three discount pay classes (i.e., as patient income increases, the discounts decrease accordingly)?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

8. For patients with incomes above 200 percent of the FPG, is the SFDS(s) structured so that such patients are not eligible for a sliding fee discount under the Health Center Program?

   ***Note**: Health centers that provide sliding fee discounts to patients with incomes above 200 percent of the FPG may do so as long as such discounts are supported through other funding sources (for example, Ryan White Part C award).*
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

Element d: Multiple Sliding Fee Discount Schedules

For health centers that choose to have more than one SFDS, these SFDSs would be based on services (for example, having separate SFDSs for broad service types, such as medical and dental, or distinct subcategories of service types, such as preventive dental and additional dental services) and/or on service delivery methods (for example, having separate SFDSs for services provided directly by the health center and for in-scope services provided via formal written contract) and no other factors.

Site Visit Team Methodology

- Review each different SFDS in use and the basis for the separate discount schedule(s) (if applicable).
- Interview key management staff.

Site Visit Findings

9. Does the health center have more than one SFDS?
   ☐ YES ☐ NO

10. **If Yes:** Is each SFDS based either on service or service delivery method and no other factors (for example, patient insurance status, location of site, other demographic or patient characteristics)?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    If No, an explanation is required:

    _____

Element e: Incorporation of Current Federal Poverty Guidelines

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

Site Visit Team Methodology

- Review the SFDS(s) for the income ranges and family size.
- Review the current FPG and related resources.

Site Visit Findings

11. Based on the review of the health center's current SFDS(s), has the health center incorporated the current FPG in the calculations for all of the discount pay classes?
    ☐ YES ☐ NO

    If No, an explanation is required:

    _____

Element f: Procedures for Assessing Income and Family Size

The health center has operating procedures for assessing/re-assessing all patients for income and family size consistent with board-approved SFDP policies.

Site Visit Team Methodology

- Interview health center staff involved in implementing SFDP policies (for example, key management staff, eligibility and outreach staff, front desk staff, billing staff, office manager, case managers) including, time permitting, a walk-through of the SFDS screening and enrollment process.
- Review the health center's SFDP policy(ies), procedures, schedule(s) (single or multiple SFDSs, if applicable), and any related policies, procedures, forms, and materials. ***Note**: This may be combined with the policy review conducted for element "a."*

Site Visit Findings

12. Does the health center have operating procedures for assessing/re-assessing all patients (regardless of insurance status) for income and family size?
☐ YES ☐ NO

    If No, an explanation is required:

    _____

13. Are these procedures consistent with the board-approved policy for the SFDP?
☐ YES ☐ NO

    If No, an explanation is required:

    _____

Element g: Assessing and Documenting Income and Family Size

The health center has records of assessing/re-assessing patient income and family size except in situations where a patient has declined or refused to provide such information.

Site Visit Team Methodology

- Review a sample of 5–10 records, files, or other forms of documentation of patient income and family size. The health center will specifically provide a sample that includes records for:
    - Uninsured and insured patients; and
    - Initial assessments for income and family size as well as re-assessments.
- Interview key management staff.

Site Visit Findings

14. Did the review of the sample indicate that the health center is consistently assessing and re-assessing patient income and family size?
☐ YES ☐ NO

If No, an explanation is required:

_____

Element h: Informing Patients of Sliding Fee Discounts

The health center has mechanisms for informing patients of the availability of sliding fee discounts (for example, distributing materials in language(s) and literacy levels appropriate for the patient population, including information in the intake process, publishing information on the health center's website).

Site Visit Team Methodology

- Site tour(s), interviews with health center staff (for example, eligibility and outreach staff, front desk staff, billing staff, office manager, case managers), and review of mechanisms for informing patients.
- Interview key management staff.

Site Visit Findings

15. Based on site tours, interviews, and review of related materials, does the health center have mechanisms for informing patients of the availability of sliding fee discounts and how to apply for such discounts?
☐ YES ☐ NO

If No, an explanation is required:

_____

Element i: Sliding Fee for Column II Services

For in-scope services provided via contracts (Form 5A: Services Provided, Column II, Formal Written Contract/Agreement), the health center ensures that fees for such services are discounted 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, which would be less than the fee paid by a patient in the first sliding fee discount pay class above 100 percent of the FPG.
- 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, and those discounts adjust based on gradations in income levels and include at least three discount pay classes.

- No discounts are provided to individuals and families with annual incomes above 200 percent of the current FPG.

Site Visit Team Methodology

- Interview health center staff involved in administering contracts for services.
- For any service delivered via Column II (whether or not the service is also delivered via Column I and/or Column III), review at least one but no more than three written contracts/agreements for EACH Required and EACH Additional Service.
  Notes:
  - *The same sample of contracts/agreements is to be utilized for the review of Required and Additional Health Services, Clinical Staffing, and Sliding Fee Discount Program. The sampling methodologies for Sliding Fee Discount Program are different from Contracts and Subawards and Conflict of Interest, although they may result in some overlap in the contracts/agreements that are sampled for those other sections.*
  - *The fiscal expert may wish to collaborate with the clinical expert on this review because the same sample is used in Required and Additional Health Services and Clinical Staffing.*
  - *If the health center does not ensure sliding fee discounts through a provision(s) in the contract(s)/agreement(s), review any other documentation provided by the health center demonstrating how the health center ensures such discounts.*

Site Visit Findings

In responding to the question(s) below, please note:

- *The questions relate to services provided via contracts (Form 5A: Services Provided, Column II).*
- *Services (for example, transportation, translation, other non-clinical services) on Form 5A that are not billed for in the local health care market may be excluded from the health center's fee schedule(s) and, therefore, from the health center's SFDS.*

16. Does the health center provide services via contracts/agreements (Form 5A: Services Provided, Column II)?
    ☐ YES ☐ NO

17. For patients receiving service(s) through these contracts/agreements, has the health center ensured sliding fee discounts are provided in a manner that meets all Health Center Program requirements (for example, health center applies its own SFDS to amounts owed by eligible patients; contract contains specific sliding fee provisions; contracted services are provided by another health center which applies an SFDS that meets structural requirements)?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    If No, an explanation is required:

    _____

18. For patients with incomes at or below 100 percent of the FPG, has the health center ensured that such patients are:

- Provided a full discount (no nominal charge(s))?
  ☐ YES ☐ NO ☐ NOT APPLICABLE

- Assessed a nominal charge(s) ("fee")?
  ☐ YES ☐ NO ☐ NOT APPLICABLE

If No was selected for BOTH of the above, an explanation is required:

_____

19. If there is a nominal charge, is the nominal charge less than the fee that would be paid by patients in the first sliding fee discount pay class above 100 percent of the FPG?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    If No, an explanation is required:

    _____

20. For patients with incomes above 100 percent and at or below 200 percent of the FPG, does the SFDS(s) provide partial discounts adjusted in accordance with gradations in income levels and consist of at least three discount pay classes (i.e., as patient income increases, the discounts decrease accordingly)?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    If No, an explanation is required:

    _____

21. For patients with incomes above 200 percent of the FPG, is the SFDS(s) structured so that such patients are not eligible for a sliding fee discount under the Health Center Program?

    Note: *Health centers that provide sliding fee discounts to patients with incomes above 200 percent of the FPG may do so as long as such discounts are supported through other funding sources (for example, Ryan White Part C award).*
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    If No, an explanation is required:

    _____

Element j: Sliding Fee for Column III Services

For services provided via formal referral arrangements (Form 5A: Services Provided, Column III), the health center ensures that fees for such services are either discounted as described in element "c" above or discounted in a manner such that:

- Individuals and families with incomes above 100 percent of the current FPG and at or below 200 percent of the FPG receive an equal or greater discount for these services than if the health center's SFDS were applied to the referral provider's fee schedule; and
- Individuals and families at or below 100 percent of the FPG receive a full discount or a nominal charge for these services.

Site Visit Team Methodology

- Interview health center staff involved in administering referral arrangements for services.
- For any service delivered via Column III (whether or not the service is also delivered via Column I and/or Column II), review at least one but no more than three written referral arrangements for EACH Required and EACH Additional Service.
  Notes:
  - *The same sample of referral arrangements is to be utilized for the review of Required and Additional Health Services, Clinical Staffing, and Sliding Fee Discount Program.*
  - *The fiscal expert may wish to collaborate with the clinical expert on this review because the same sample is used in Required and Additional Health Services and Clinical Staffing.*
  - *If the health center does not ensure sliding fee discounts through a provision(s) in the referral arrangement(s), review other documentation demonstrating how the health center ensures such discounts.*

Site Visit Findings

In responding to the question(s) below, please note:

- *The questions relate to services provided via formal referral arrangements (Form 5A: Services Provided, Column III).*
- *Services (for example, transportation, translation, other non-clinical services) on Form 5A that are not billed for in the local health care market may be excluded from the health center's fee schedule(s) and, therefore, from the health center's SFDS.*

22. Does the health center provide services via formal referral arrangements (Form 5A: Services Provided, Column III)?
    ☐ YES ☐ NO

23. For patients receiving services through these referral arrangements, has the health center ensured sliding fee discounts are provided in a manner that meets the structural requirements noted in element "c"?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

24. **If No:** For patients receiving services through these referral arrangements, has the health center ensured sliding fee discounts are provided in a manner such that:

    - Individuals and families with incomes above 100 percent of the current FPG and at or below 200 percent of the current FPG receive an **equal or greater** discount ("good deal") for these services than if the health center's SFDS were applied to the referral provider's fee schedule (for example, health center has a referral arrangement with organizations that charge no fee at all for patients with incomes at or below 200 percent of the FPG); and
    - Individuals and families with incomes at or below 100 percent of the current FPG receive a full discount or a nominal charge for these services?

    ☐ YES ☐ NO ☐ NOT APPLICABLE

If No, an explanation is required, including describing the format and type of any discount(s) provided:

_____

Element k: Applicability to Patients with Third-Party Coverage

Health center patients who are eligible for sliding fee discounts and have third-party coverage are charged no more for any out-of-pocket costs than they would have paid under the applicable SFDS discount pay class.[8] Such discounts are subject to potential legal and contractual restrictions.[9]

Site Visit Team Methodology

- Interview health center staff involved in implementing SFDP policies (for example, key management staff, eligibility and outreach staff, front desk staff, billing staff, office manager, case managers) including, time permitting, a walk-through of the SFDS screening and enrollment process.
- Review the health center's SFDP policy(ies), procedures, schedule(s) (single or multiple SFDSs, if applicable), and any related policies, procedures, forms, and materials. ***Note**: This may be combined with the policy review conducted for element "a."*
- Interview relevant health center staff to determine whether the health center is subject to legal or contractual restrictions on sliding fee discounts for patients with third-party coverage. If so, the health center will produce the specific documentation of such restrictions.

Site Visit Findings

25. Based on interviews and a review of related documents, does the health center ensure that patients who are eligible for sliding fee discounts and who have third-party coverage are charged no more for any out-of-pocket costs (for example, deductibles, co-pays, and services not covered by the plan) than they would have paid under the applicable SFDS discount pay class?
    ☐ YES ☐ NO

    If No, an explanation is required, including describing any legal or contractual restrictions that the health center has documented:

    _____

[8] 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 or prohibited by the applicable insurance contract.

[9] Such limitations may be specified by applicable federal or state programs, or private payor contracts.

Element I: Evaluation of the Sliding Fee Discount Program

The health center evaluates, at least once every 3 years, its SFDP. At a minimum, the health center:

- Collects utilization data that allows it to assess the rate at which patients within each of its discount pay classes, as well as those at or below 100 percent of the FPG, are accessing health center services;
- Utilizes this and, if applicable, other data (for example, results of patient satisfaction surveys or focus groups, surveys of patients at various income levels) to evaluate the effectiveness of its SFDP in reducing financial barriers to care; and
- Identifies and implements changes as needed.

Site Visit Team Methodology

- Interview relevant health center staff involved in evaluating the SFDP.
- Interview board member(s) and key management staff.
  ***Note**: Interviews may be conducted in collaboration with the governance/administrative expert.*
- Review data, reports or any other relevant materials used to evaluate the SFDP.

Site Visit Findings

26. Does the health center evaluate the effectiveness of the SFDP in reducing financial barriers to care?
    ☐ YES ☐ NO

    If No, an explanation is required:

    _____

27. **If Yes:** Is this evaluation conducted at least once every 3 years?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    If No, an explanation is required:

    _____

28. Does the health center collect utilization data in order to assess whether patients within each of its discount pay classes are accessing health center services?
    ☐ YES ☐ NO

    If No, an explanation is required:

    _____

29. **If Yes:** Does the health center utilize these data (and, if applicable, any other data, such as collections or patient survey data) to evaluate the effectiveness of its SFDP?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    If No, an explanation is required:

    _____

30. Has the health center implemented any follow-up actions based on evaluation results (for example, changes to SFDP policy by board, implementation of improved eligibility screening processes or notification methods for sliding fee discounts)?
☐ YES ☐ NO

If No, an explanation is required:

_____

QUALITY IMPROVEMENT/ASSURANCE

Primary Reviewer: Clinical Expert
Secondary Reviewer: N/A

Authority: *Section 330(k)(3)(C) of the Public Health Service (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)*

Related Considerations

Document Checklist for Health Center Staff

- ☐ Policy(ies) that establishes the Quality Improvement/Quality Assurance (QI/QA) program.
- ☐ QI/QA-related operating procedures or processes that address:
  - Clinical guidelines, standards of care, and/or standards of practice;
  - Patient safety and adverse events, including implementation of follow-up actions;
  - Patient satisfaction;
  - Patient grievances;
  - Periodic QI/QA assessments; and
  - QI/QA report generation and oversight.
- ☐ Systems and/or procedures for maintaining and monitoring the confidentiality, privacy, and security of patient records.
- ☐ Sample of patient satisfaction results.
- ☐ Sample of two QI/QA assessments from the past 12 months and/or the related reports resulting from these assessments.
- ☐ Job or position description(s) of individual(s) who oversee the QI/QA program.
- ☐ Sample of 5–10 health center patient records[1] (for example, using live navigation of the Electronic Health Records (EHR), screenshots from the EHR, or actual records if the records are not electronic/EHR records) that include clinic visit note(s) and/or summary of care.
  Note: *The same sample of patient records utilized for reviewing other program requirement areas also may be used for this sample.*
- ☐ Documentation for related systems that support QI/QA (if applicable) (for example, event reporting system, tracking resolutions and grievances, dashboards).
- ☐ Schedule of QI/QA assessments.

[1] Health centers may choose to provide samples of patient records prior to or during the site visit. If patient records will be provided during the site visit, this should be communicated prior to the site visit to avoid any disruption or delay in the site visit process.

Demonstrating Compliance

Element a: QI/QA Program Policies

The health center has a board-approved policy(ies) that establishes a QI/QA program.[2] This QI/QA program addresses the following:

- The quality and utilization of health center services;
- Patient satisfaction and patient grievance processes; and
- Patient safety, including adverse events.

Site Visit Team Methodology

- Interview individual(s) designated to oversee the QI/QA program and related staff who support QI/QA.
- Review the health center's policy(ies) for the QI/QA program.
  Notes:
  - *The title of the QI/QA policy may vary from health center to health center (for example, this document may be called a "QI/QA plan").*
  - *If the board has not approved the QI/QA policy(ies), address this under Board Authority.*

Site Visit Findings

1. Does the health center have a QI/QA program that addresses the following areas:

   - The quality and utilization of health center services?
     ☐ YES ☐ NO

   - Patient satisfaction and patient grievance processes?
     ☐ YES ☐ NO

   - Patient safety, including adverse events?
     ☐ YES ☐ NO

   If No was selected for any of the above, an explanation is required, specifying which areas were not addressed:

   _____

Element b: Designee to Oversee QI/QA Program

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

---

[2] See [Health Center Program Compliance Manual] Chapter 19: Board Authority for more information on the health center governing board's role in approving policies.

Site Visit Team Methodology

- Review job/position description(s) or other documents for background on the responsibilities of the individual(s) overseeing the QI/QA program.
- Interview individual(s) designated to oversee the QI/QA program to further understand their role(s) and responsibilities.

Site Visit Findings

2. Does the health center have a designated individual(s) to oversee the QI/QA program?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

3. Based on the interview(s) and review of the job/position description(s) or other documentation, do the responsibilities of this individual(s) include:

   - Ensuring the implementation of QI/QA operating procedures?
     ☐ YES ☐ NO
   - Ensuring QI/QA assessments are conducted?
     ☐ YES ☐ NO
   - Monitoring QI/QA outcomes?
     ☐ YES ☐ NO
   - Updating QI/QA operating procedures, as needed?
     ☐ YES ☐ NO

   If No was selected for any of the above, an explanation is required:

   _____

Element c: QI/QA Procedures or Processes

The health center has operating procedures or processes that address all of the following:

- Adhering to current evidence-based clinical guidelines, standards of care, and standards of practice in the provision of health center services, as applicable;
- Identifying, analyzing, and addressing patient safety and adverse events and implementing follow-up actions, as necessary;
- Assessing patient satisfaction;
- Hearing and resolving patient grievances;
- Completing periodic QI/QA assessments on at least a quarterly basis to inform the modification of the provision of health center services, as appropriate; and
- Producing and sharing reports on QI/QA to support decision-making and oversight by key management staff and by the governing board regarding the provision of health center services.

Site Visit Team Methodology

- Interview individual(s) responsible for the QI/QA program.
- Review the health center's QI/QA-related operating procedures or processes that address:
    - Clinical guidelines, standards of care, and/or standards of practice;
    - Patient safety and adverse events, including implementation of follow-up actions;
    - Patient satisfaction;
    - Patient grievances;
    - Periodic QI/QA assessments; and
    - QI/QA report generation and oversight.
- Review sample of patient satisfaction results.
- Review related systems and/or documentation that support QI/QA.
- Review schedule of QI/QA assessments.
- Review sample of two QI/QA assessments from the past 12 months and/or the related reports resulting from these assessments.

Site Visit Findings

4. Does the health center have operating procedures and/or related systems that address:

    - Adherence to current, applicable evidence-based clinical guidelines, standards of care, and standards of practice (for example, provider access to EHR clinical decision-making support, job aids, protocols, and/or other sources of evidence-based care)?
      ☐ YES ☐ NO

    - A process for health center staff to follow for identifying, analyzing, and addressing overall patient safety, including adverse events?
      ☐ YES ☐ NO

    - A process for implementing follow-up actions related to patient safety and adverse events, as necessary?
      ☐ YES ☐ NO

    - A process for the health center to assess patient satisfaction (for example, fielding patient satisfaction surveys, conducting periodic patient focus groups)?
      ☐ YES ☐ NO

    - A process for hearing and resolving patient grievances?
      ☐ YES ☐ NO

    - Completion of periodic QI/QA assessments on at least a quarterly basis?
      ☐ YES ☐ NO

    If No was selected for any of the above, an explanation is required, including specifying which areas were not addressed:

    _____

5. Does the health center share reports on QI/QA, including data on patient satisfaction and patient safety with key management staff and the governing board?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

6. Was the health center able to share an example(s) of how these reports support decision-making and oversight by key management staff and the governing board regarding the provision of health center services and responses to patient satisfaction and patient safety issues?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

Element d: Quarterly Assessments of Clinician Care

The health center's physicians or other licensed health care professionals conduct QI/QA assessments on at least a quarterly basis, using data systematically collected from patient records, to ensure:

- Provider adherence to current evidence-based clinical guidelines, standards of care, and standards of practice in the provision of health center services, as applicable; and
- The identification of any patient safety and adverse events and the implementation of related follow-up actions, as necessary.

Site Visit Team Methodology

- Interview individual(s) responsible for the QI/QA program.
- Review the health center's operating procedures or processes that address periodic QI/QA assessments.
- Review related systems and/or documentation that support QI/QA.
- Review schedule of QI/QA assessments.
- Review sample of two QI/QA assessments from the past 12 months and/or the related reports resulting from these assessments.

Site Visit Findings

7. Are the health center's QI/QA assessments conducted by physicians or other licensed health care professionals (such as nurse practitioner, registered nurse, or other qualified individual) on at least a quarterly basis?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

8. Are these QI/QA assessments based on data systematically collected from patient records?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

9. Do these assessments demonstrate that the health center is tracking and, as necessary, addressing issues related to the quality and safety of the care provided to health center patients (for example, use of appropriate medications for asthma, early entry into prenatal care, HIV linkages to care, response initiated as a result of a recent adverse event)?
   ☐ YES ☐ NO

   If No, an explanation is required, including specifying which areas the health center is not tracking and/or addressing:

   _____

Element e: Retrievable Health Records

The health center maintains a retrievable health record (for example, the health center has implemented a certified Electronic Health Record (EHR))[3] for each patient, the format and content of which is consistent with both federal and state laws and requirements.

Site Visit Team Methodology

- In conjunction with a health center's clinical staff member(s), review the sample of 5–10 health center patient records.
  Note: *The same sample of patient records utilized for reviewing other program requirement areas also may be used for this sample.*

Note: *Issues related to timeliness, accuracy and completeness of data retrieval used for Uniform Data System (UDS) reporting are covered under Program Monitoring and Data Reporting Systems.*

Site Visit Findings

10. Does the health center maintain an individual health record that is easily retrievable?
    ☐ YES ☐ NO

    If No, an explanation is required:

    _____

[3] The Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) have established standards and other criteria for structured data that 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 CMS Promoting Interoperability Program Regulations and Guidance for Certified EHR Technology.

11. Does the health center have a process for ensuring that the format and content of its health records are consistent with applicable federal and state laws and requirements (for example, the health center has implemented a certified EHR)?
☐ YES ☐ NO

    If No, an explanation is required:

    _____

Element f: Confidentiality of Patient Information

The health center has implemented systems (for example, certified EHRs and corresponding standard operating procedures) for protecting the confidentiality of patient information and safeguarding this information against loss, destruction, or unauthorized use, consistent with federal and state requirements.

Site Visit Team Methodology

- Review health information technology (medical record) systems and procedures for maintaining and monitoring the confidentiality, privacy, and security of protected health information (PHI).
- Interview applicable staff (such as CMO, health information technology personnel, Compliance or Security Officer) on compliance with current federal and state requirements related to confidentiality, privacy, and security of protected health information, and actions taken by the health center to comply with these provisions across all sites (for example, staff training).

Site Visit Findings

12. Do the health center's health information technology or other record keeping procedures address current federal and state requirements related to confidentiality, privacy, and security of protected health information (PHI) including safeguards against loss, destruction, or unauthorized use?
☐ YES ☐ NO

    If No, an explanation is required:

    _____

13. Does the health center ensure its staff are trained in confidentiality, privacy, and security?
☐ YES ☐ NO

    If No, an explanation is required:

    _____

KEY MANAGEMENT STAFF

Primary Reviewer: Governance/Administrative Expert
Secondary Reviewer: Fiscal and Clinical Expert (as needed)

Authority: *Section 330(k)(3)(H)(ii), and 330(k)(3)(I)(i) of the Public Health Service (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)*

Related Considerations

Document Checklist for Health Center Staff

- ☐ Health center organization chart(s) with names and titles of key management staff (if updated since last submission to HRSA).
- ☐ Position descriptions of key management staff (if updated since last submission to HRSA).
- ☐ Bios or resumes for key management staff (if updated since last application submission to HRSA).
- ☐ Co-applicant agreement (if applicable) (if updated since last application submission to HRSA).
- ☐ Human Resources procedures relevant to recruiting and hiring of key management staff (if applicable, for health centers with key management staff vacancies).
- ☐ Project Director/CEO employment agreement.
- ☐ Project Director/CEO's Form W-2 or, if a Form W-2 has not yet been issued, documentation of receipt of salary directly from the health center (for example, pay stub).
- ☐ Notice of Award (NOA)/Notice of Look-Alike Designation (NLD) approving any Project Director/CEO position change(s) since start of the current project period or designation period OR documentation that a prior approval request(s) for such change(s) is still under review by HRSA.
- ☐ Contracts for key management staff (if applicable).
- ☐ Documentation associated with filling key management staff vacancies (if applicable) (for example, job advertisements, revised position descriptions).

Demonstrating Compliance

Element a: Composition and Functions of Key Management Staff

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

[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.

Site Visit Team Methodology

- Review Form 2: Staffing Profile and review the position descriptions or contracts for key management staff from the most recent Service Area Competition (SAC)/Renewal of Designation (RD) application, and if applicable, review any new job descriptions.
- Review the health center organization chart(s).
- Interview various members of the health center's key management staff to determine how key functions are distributed and carried out.

Site Visit Findings

1. Was the health center able to justify how the distribution of functions and allocation of time for each key management position is sufficient to carry out the approved scope of the health center project (for example, Is there a clear justification for a part-time Project Director/CEO or for the lack of a dedicated CFO position)?
   ☐ YES ☐ NO

   If No, an explanation is required, including describing why the distribution of functions and allocation of time for each key management position is insufficient to carry out the scope of project:

   _____

Element b: Documentation for Key Management Staff Positions

The health center has documented the training and experience qualifications, as well as the duties or functions, for each key management staff position (for example, in position descriptions).

Site Visit Team Methodology

N/A – *HRSA assesses whether the health center has demonstrated compliance with this element through its review of the competing continuation application (SAC or RD). No review of this element is required through the site visit.*

Site Visit Findings

N/A – *HRSA assesses whether the health center has demonstrated compliance with this element through its review of the competing continuation application (SAC or RD). No review of this element is required through the site visit.*

Element c: Process for Filling Key Management Vacancies

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

Site Visit Team Methodology

- Review health center organization chart(s) and compare to current key management staff. Note if there are any vacancies.
- If a key management staff vacancy is noted, review Human Resources procedures relevant to recruiting and hiring of key management staff and interview person(s) responsible for health center hiring/Human Resources functions and documentation associated with filling the vacancy.

Site Visit Findings

2. Does the health center have any vacant key management positions?
   ☐ YES ☐ NO

3. **If Yes:** Will or has the health center implement(ed) a process for filling this position?
   ☐ YES ☐ NO ☐ NOT APPLICABLE

   If No, an explanation is required, including specifying which position(s) are vacant:

   _____

Element d: CEO Responsibilities

The health center's Project Director/CEO[2] is directly employed by the health center,[3] reports to the health center's governing board[4] 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.

Site Visit Team Methodology

- Review health center organization chart(s).
- Review position descriptions or contracts for key management staff and, if necessary, any other documentation of key management reporting structures.

---

[2] While the position title of the key person who is specified in the award/designation may vary, for the purposes of the Health Center Program, [the Health Center Program Compliance Manual Chapter 11: Key Management Staff utilizes] 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] Public agency health centers utilizing a co-applicant structure would demonstrate compliance with the statutory requirement for direct employment of the Project Director/CEO by demonstrating that the public agency, as the Health Center Program awardee/designee of record, directly employs the Project Director/CEO. Refer to related requirements in [Health Center Program Compliance Manual] Chapter 19: Board Authority regarding public agencies with co-applicants.

[4] Refer to related requirements in [Health Center Program Compliance Manual] Chapter 19: Board Authority regarding the selection and dismissal of the Project Director/CEO by the health center board as part of its oversight responsibilities for the Health Center Program project.

- Review the Project Director/CEO's Form W-2 or, if a Form W-2 has not yet been issued by the health center, documentation of receipt of salary directly from the health center.
- For public agencies with a co-applicant board, review the co-applicant agreement.
- Interview Project Director/CEO.

Site Visit Findings

4. Is the Project Director/CEO directly employed by the health center as confirmed by a Form W-2 (or, if a Form W-2 has not yet been issued by the health center, documentation of receipt of salary directly from the health center such as a pay stub)?
   Note: *The Project Director/CEO is directly employed by the health center if the Project Director/CEO: (1) receives a salary directly from the health center; (2) is issued a W-2 that lists only the health center as the Project Director/CEO's employer; and (3) has an employment agreement entered into with the health center that outlines the activities required to be performed by the Project Director/CEO.*
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

5. Does the Project Director/CEO report to the health center board?

   Note: *In a public center with a co-applicant board where the public center employs the Project Director/CEO, the Project Director/CEO may report both to the co-applicant board and to another board or individual within the public agency.*
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

6. Does the Project Director/CEO oversee other key management staff in carrying out the day-to-day activities of the health center project?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

Element e: HRSA Approval for Project Director/CEO Changes

If there has been a post-award change in the Project Director/CEO position,[5] the health center requests and receives prior approval from HRSA.

[5] Such changes include situations in which the current Project Director/CEO will be disengaged from involvement in the Health Center Program 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)].

Site Visit Team Methodology

- Determine whether there has been a change in the Project Director/CEO position since the start of the current project or designation period.
    - If yes, review the associated Notice of Award (NOA)/Notice of Look-Alike Designation (NLD) approving this change.
    - If the request to change the Project Director/CEO is still under review by HRSA, review documentation that a prior approval was submitted to HRSA and consult with the federal representative on the status of the request.

Site Visit Findings

7. Has there been a change in the Project Director/CEO position since the start of the current project or designation period?

    ***Notes**:*
    - *This ONLY includes situations in which the Project Director/CEO was disengaged from involvement in the project for any continuous period for more than 3 months or reduced time devoted to the project by 25 percent or more from the level that was approved at the time of award.*
    - *Only select "Not Applicable" if this is a Look-Alike Initial Designation Site Visit.*

    ☐ YES ☐ NO ☐ NOT APPLICABLE

8. **If Yes:** Was there a Notice of Award (NOA)/Notice of Look-Alike Designation (NLD) from HRSA approving this change or did the health center provide documentation that the prior approval request is still under review by HRSA?

    ☐ YES ☐ NO ☐ NOT APPLICABLE

    If No, an explanation is required:

    _____

CONTRACTS AND SUBAWARDS

Primary Reviewer: Fiscal Expert
Secondary Reviewer: Governance/Administrative Expert

NOTE: *If the health center has a sub-recipient(s), the Governance/Administrative Expert is the Primary Reviewer of element "i" and the Fiscal Expert is the Secondary Reviewer of that element.*

Authority: *Section 330(k)(3)(I) and Section 330(q) of the Public Health Service (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*

Related Considerations

Document Checklist for Health Center Staff

- ☐ Procedures for purchasing and procurement, including, if applicable or separate, procedures for contracting and contract management.
- ☐ Policies/procedures for subrecipient monitoring.
- ☐ Most recent annual audit and management letters.
- ☐ If the health center has contracts that support the HRSA-approved scope of project (i.e., to provide health center services or to acquire other goods and services), provide a complete list of these contracts. Include all active contracts and all contracts that had a period of performance which ended less than 3 years ago. In the list, include all of the following information for each contract:
    - Whether the health center utilizes federal award funds to pay in whole or in part for the contract (not applicable to look-alikes);
    - Contractor/contract organization;
    - Value of the contract (if there is a federal share, state the federal share amount);
    - Brief description of the good(s) or service(s) provided; and
    - Period of performance/timeframe (for example, ongoing contractual relationship, specific duration).
- ☐ All subrecipient agreements (if updated since last application submission to HRSA) (not applicable to look-alikes and as applicable for awardees) that support the awardee's Health Center Program scope of project.
  Note: *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 75.351(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."*
- ☐ Based on the list of contracts provided prior to the site visit that support the HRSA-approved scope of project:

  - Five contracts AND related supporting procurement documentation for actions that **utilize federal award funds.** Choose the contracts that utilize the largest amounts of federal award funds.
    Note: *The same sample of contracts/agreements is to be utilized for the review of both Contracts and Subawards and Conflict of Interest. The sampling methodologies for Contracts and Subawards are different from Required and Additional Health Services, Clinical Staffing, and Sliding Fee Discount Program, although they may result in some overlap in the contracts/agreements.*
  - Sample of five contracts AND related supporting procurement documentation for actions that **do NOT utilize federal award funds**.

☐ Two to three reports or records (for example, monthly invoices or billing reports, data run of patients served, visits provided) drawn from the sample of contractors selected from the list provided prior to the site visit.
☐ Documentation of subrecipient monitoring methods (not applicable to look-alikes and as applicable for awardees).
☐ Sample of financial and performance reports from within the current project period from the subrecipient, including the subrecipient's annual audit (not applicable to look-alikes and as applicable for awardees).
☐ Documentation of prior approval for contracts for the performance of substantive work (i.e., contracting with a single entity for the majority of health care providers) under the federal award (if applicable).
☐ Documentation of prior approval of subrecipient arrangement(s) (not applicable to look-alikes and as applicable for awardees).
☐ Documentation of subrecipient monitoring by the health center (that occurred during the current project period).
☐ Findings from the health center's subrecipient monitoring process on subrecipient deficiencies (if applicable) and documentation that the health center has ensured the subrecipient has taken corrective action.
☐ The following documentation used by the health center to confirm subrecipient compliance:
  - Subrecipient articles of incorporation, bylaws, or other corporate documents;
  - Subrecipient sliding fee discount program (SFDP) policy;
  - Current subrecipient board roster or Form 6A (the latter, if subrecipient is a Health Center Program awardee or look-alike) indicating current board member characteristics as follows:
    - For all board members: patient status, area of expertise, and percentage income from the healthcare industry; and
    - For patient board members: gender, race, and ethnicity;
  - Subrecipient billing records from within the past 24 months to confirm the patient status of subrecipient board members;
  - Subrecipient's portion of Uniform Data System (UDS) data for an overview of subrecipient patient population demographic factors (race, ethnicity, and gender); and
  - If the subrecipient board-approved SFDP policy does not state a specific amount for nominal charge(s), other documentation (for example, subrecipient board minutes, subrecipient reports) of subrecipient board involvement in setting the amount of nominal charge(s).

Demonstrating Compliance

1. Is this a Look-Alike Site Visit?
   ☐ YES ☐ NO

   ***NOTE**: Because look-alikes do not receive federal funding under section 330 of the PHS Act, any aspects of a requirement that relate to the use of Health Center Program federal award funds are not applicable to look-alikes.*

Contracts: Procurement and Monitoring

Element a: Procurement Procedures

The health center has written procurement procedures that comply with federal procurement standards, including a process for ensuring that all procurement costs directly attributable to the federal award are allowable, consistent with federal cost principles.[1]

Site Visit Team Methodology

- Review health center's procedures for purchasing and procurement, including any related to contracting and contract management.
- Interview health center staff involved in contract procurement and monitoring.

Site Visit Findings

2. Does the health center have written procedures for procurement?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

3. Do these procedures, at a minimum, ensure that all procurements directly attributable to the federal award will be conducted in a manner providing full and open competition[2] and will only include costs allowable, consistent with federal cost principles (for example, do the procedures contain relevant references or citations to 45 CFR Part 75 Subpart E: Cost Principles)?
   ☐ YES ☐ NO ☐ NOT APPLICABLE

   If No, an explanation is required:

   _____

[1] See 45 CFR 75 Subpart E: Cost Principles.
[2] As defined by 45 CFR 75.329(f), procurement by "non-competitive proposals" is procurement through solicitation of a proposal from only one source.

Element b: Records of Procurement Actions

NOT APPLICABLE FOR LOOK-ALIKES

The health center has records for procurement actions paid for in whole or in part under the federal award 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.

Site Visit Team Methodology

- Review the five contracts AND related supporting procurement documentation for actions that **utilize federal award funds.**
  Note: *The same sample of contracts/agreements is to be utilized for the review of both Contracts and Subawards and Conflict of Interest. The sampling methodologies for Contracts and Subawards are different from Required and Additional Health Services, Clinical Staffing, and Sliding Fee Discount Program, although they may result in some overlap in the contracts/agreements.*

Site Visit Findings

4. Does the health center have any:

   - Active contracts paid for in whole or in part with federal award funds?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   - Contracts that had a period of performance which ended less than 3 years ago and that were paid for in whole or in part with federal award funds?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

5. Based on the review of the sample of contracts, was there supporting documentation of the procurement process that addressed the following:

   - Rationale for the procurement method?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   - Selection of contract type?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   - Contractor selection or rejection?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   - Basis for the contract price?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   If No was selected for any of the above, an explanation is required:

   _____

Element c: Retention of Final Contracts

NOT APPLICABLE FOR LOOK-ALIKES

The health center retains final contracts and related procurement records, consistent with federal document maintenance requirements, for procurement actions paid for in whole or in part under the federal award.[3]

Site Visit Team Methodology

- Review the five contracts AND related supporting procurement documentation for actions that **utilize federal award funds.**
  Note: *The same sample of contracts/agreements is to be utilized for the review of both Contracts and Subawards and Conflict of Interest. The sampling methodologies for Contracts and Subawards are different from Required and Additional Health Services, Clinical Staffing, and Sliding Fee Discount Program, although they may result in some overlap in the contracts/agreements.*

Site Visit Findings

6. Was the health center able to produce final executed contracts that were awarded within the past 3 years?
   ☐ YES ☐ NO ☐ NOT APPLICABLE

   If No, an explanation is required:

   _____

Element d: Contractor Reporting

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 are submitted by appropriate deadlines, funds are used for authorized purposes).

Site Visit Team Methodology

- Review two to three reports or records (for example, monthly invoices or billing reports, data run of patients served, visits provided) drawn from the sample of contractors that were selected from the list of contracts provided prior to the site visit.

Site Visit Findings

7. Based on the review of the sample, does the health center have access to records and reports as necessary to oversee contractor performance?
   ☐ YES ☐ NO

---

[3] See 45 CFR 75.361 for HHS retention requirements for records.

If No, an explanation is required:

_____

Element e: HRSA Approval for Contracting Substantive Programmatic Work

If the health center has arrangements with a contractor to perform substantive programmatic work,[4] 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).

Site Visit Team Methodology

- Review complete list of contracts (provided prior to the site visit) to identify those that support *substantive programmatic work*.
- Interview key management or other health center staff involved in procurement or contract oversight.
- Review the documentation identified by the health center that includes HRSA's approval of the contracting arrangement for *substantive programmatic work*.

Site Visit Findings

8. Based on the list of contracts reviewed and interview(s) with health center staff, does this health center currently contract with a single entity for the majority of health care providers (i.e., substantive programmatic work)?
   ☐ YES ☐ NO

9. **If Yes:** Was the health center able to produce documentation of prior approval by HRSA (i.e., the arrangement was included in a HRSA-approved application or post-award request)?

   Note: *Only select "Not Applicable" if this is a Look-Alike Initial Designation Site Visit.*
   ☐ YES ☐ NO ☐ NOT APPLICABLE

   If No, an explanation is required:

   _____

[4] For the purposes of the Health Center Program, contracting for substantive programmatic work applies to contracting with a single entity for the majority of health care providers. The acquisition of supplies, material, equipment, or general support services is not considered programmatic work. Substantive programmatic work may be further defined within HRSA Notices of Funding Opportunity (NOFOs) and applications.

Element f: Required Contract Provisions

The health center's contracts that support the HRSA-approved scope of project include provisions that address the following:

- The specific activities or services to be performed or goods to be provided;
- Mechanisms for the health center to monitor contractor performance; and
- Requirements for the contractor 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.[5]

Site Visit Team Methodology

- Review entire sample of contracts (both those that utilize and those that do not utilize federal award funds) that support the HRSA-approved Health Center Program scope of project.

Site Visit Findings

10. Does the health center have one or more contracts to provide health center services or to acquire other goods and services in support of the HRSA-approved scope of project?
☐ YES ☐ NO

11. **If Yes:** Based on the sample of contracts reviewed, do these contracts contain provisions that address the following areas:

    - Specific activities or services to be performed or goods to be provided by the contractor?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    - How the health center will monitor contract performance?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    - Data reporting expectations and intervals for such reporting?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    - Provisions for record retention and access, audit, and property management?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    If No was selected for any of the above, an explanation is required:

    _____

[5] For further guidance on these requirements, see the HHS Grants Policy Statement.

Subawards: Monitoring and Management

Element g: HRSA Approval to Subaward

NOT APPLICABLE FOR LOOK-ALIKES

If the health center has made a subaward,[6] 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 the subrecipient arrangement; or
- An approved post-award request for such subrecipient arrangements submitted within the project period (for example, change in scope).

Site Visit Team Methodology

- Review Form 8: Health Center Agreements.
- Review most recent annual audit and management letters to determine if subrecipients were identified in the audit report, including the amount of the subawards.
- Review all subrecipient agreements that support the HRSA-approved Health Center Program scope of project.
- Review the documentation identified by the health center that includes HRSA's approval of the subrecipient arrangement.

Site Visit Findings

12. Has the health center made any subawards (new or continuing) during the current project period?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

13. Was the health center able to produce documentation of prior approval by HRSA of the subrecipient arrangement (i.e., arrangement was included in the last approved Service Area Competition (SAC) application or was approved through a separate post-award request)?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    If No, an explanation is required:

    _____

Element h: Subaward Agreement

NOT APPLICABLE FOR LOOK-ALIKES

---

[6] 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.

The health center's subaward(s) that supports the HRSA-approved scope of project includes provisions that address the following:

- The specific portion of the HRSA-approved scope of project to be performed by the subrecipient;
- The applicability of all Health Center Program requirements to the subrecipient;
- The applicability to the subrecipient of any distinct statutory, regulatory, and policy requirements of other federal programs associated with their HRSA-approved scope of project;[7]
- Mechanisms for the health center to monitor subrecipient compliance and performance;
- Requirements for the subrecipient to provide data necessary to meet the health center's applicable federal financial and programmatic reporting requirements, as well as provisions addressing record retention and access, audit, and property management;[8] and
- Requirements that all costs paid for by the federal subaward are allowable consistent with federal cost principles.[9]

Site Visit Team Methodology

- Review all subrecipient agreements that support the HRSA-approved Health Center Program scope of project.

Site Visit Findings

14. Does the health center's subrecipient agreement(s) include provisions that address the following:

    - The portion of the health center project that will be carried out by the subrecipient (i.e., sites, services provided) and how?
      ☐ YES ☐ NO ☐ NOT APPLICABLE

    - All Health Center Program requirements applying to the subrecipient?
      ☐ YES ☐ NO ☐ NOT APPLICABLE

    - The applicability of any other distinct statutory, regulatory, and policy requirements of associated programs and benefits (for example, requirements that will apply if the subrecipient participates in the 340B Drug Pricing Program)?
      ☐ YES ☐ NO ☐ NOT APPLICABLE

    - Mechanisms for the health center to monitor subrecipient compliance and performance?
      ☐ YES ☐ NO ☐ NOT APPLICABLE

---

[7] Subrecipients are generally eligible to receive Federally Qualified Health Center (FQHC) payment rates under Medicaid and Medicare, 340B Drug Pricing Program, and Federal Tort Claims Act (FTCA) coverage. However, such benefits are not automatically conferred and may require additional actions and approvals (for example, submission and approval of a subrecipient FTCA deeming application).
[8] For further guidance on these requirements, see the HHS Grants Policy Statement.
[9] See 45 CFR 75 Subpart E: Cost Principles.

- The data the subrecipient must collect and report back to the awardee (for example, UDS data)?
  ☐ YES ☐ NO ☐ NOT APPLICABLE

- Record retention and access, audit, and property management (if applicable)?
  ☐ YES ☐ NO ☐ NOT APPLICABLE

- Requirements that all costs paid for under the subaward are consistent with federal cost principles?
  ☐ YES ☐ NO ☐ NOT APPLICABLE

If No was selected for any of the above, an explanation is required:

_____

Element i: Subrecipient Monitoring

NOT APPLICABLE FOR LOOK-ALIKES

The health center monitors the activities of its 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 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 are 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 subaward that may be identified through audits, on-site reviews, and other means; and
- Issuing a management decision for audit findings pertaining to the subaward.[10]

Site Visit Team Methodology

- Review all subrecipient agreements that support the HRSA-approved Health Center Program scope of project.

For the remaining methodology, review documentation from all subrecipients, not to exceed a total of five subrecipients. For a health center with more than five subrecipients, select the subrecipients that receive the largest amounts of Health Center Program subaward funds:

- Review/interview on the policies/procedures for subrecipient monitoring.
- Review documentation of subrecipient monitoring by the health center (from within the current project period).

[10] Per 45 CFR 75.521, the management decision [issued by the health center to the subrecipient] must clearly state whether or not the audit finding is sustained, the reasons for the decision, and the expected auditee action to repay disallowed costs, make financial adjustments, or take other action.

- Review findings from the health center's subrecipient monitoring process on subrecipient deficiencies (if applicable) and documentation of ensuring the subrecipient's corrective action.
- Review sample of financial and performance reports received from the subrecipient, including the subrecipient's annual audit.
- Interview health center staff who provide oversight of subrecipient activities. Review the following documentation used by the health center to confirm subrecipient compliance:
    - Subrecipient articles of incorporation, bylaws, or other corporate documents;
    - Subrecipient sliding fee discount program (SFDP) policy;
    - Current subrecipient board roster or Form 6A (the latter, if subrecipient is a Health Center Program awardee or look-alike) indicating current board member characteristics as follows:
        - For all board members: patient status, area of expertise, and percentage income from the health care industry; and
        - For patient board members: gender, race, and ethnicity.
    - Subrecipient billing records from within the past 24 months to confirm the patient status of subrecipient board members;
    - Subrecipient's portion of UDS data for an overview of subrecipient patient population demographic factors (race, ethnicity, and gender); and
    - If the subrecipient board-approved SFDP policy does not state a specific amount for nominal charge(s), other documentation (for example, subrecipient board minutes, subrecipient reports) of subrecipient board involvement in setting the amount of nominal charge(s).

Notes:

- *Self-attestation by the subrecipient is not sufficient to confirm compliance.*
- *The health center awardee is responsible for ensuring that the subrecipient meets all of the Health Center Program requirements applicable to the health center awardee's federal award. For example, when a health center awardee that receives a 330(e) award has a subrecipient that—independent of the subaward—also receives a 330(h) award directly from HRSA, the 330(e) awardee ensures that the subrecipient meets all 330(e) requirements.*

Site Visit Findings

15. Does the health center have a process for monitoring the activities of the subrecipient during the current project period? Specifically, does the process ensure that the subrecipient maintains compliance with all Health Center Program requirements and all other applicable requirements specified in the federal award, including, if necessary, implementing corrective actions?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    If Yes OR No, an explanation is required describing the health center's monitoring methods:

    _____

16. Does the health center have a specific process for receiving and reviewing financial and performance reports (including the subrecipient's annual audit) during each project period that addresses the following areas:

- Achievement of performance goals?
  ☐ YES ☐ NO ☐ NOT APPLICABLE

- Submission of UDS data by appropriate deadlines?
  ☐ YES ☐ NO ☐ NOT APPLICABLE

- Use of funds for authorized purposes?
  ☐ YES ☐ NO ☐ NOT APPLICABLE

If No was selected for any of the above, an explanation is required:

_____

17. Did the health center receive and review the following reports from the subrecipient during the current project period:

    - Financial reports, including the subrecipient's audit?
      ☐ YES ☐ NO ☐ NOT APPLICABLE

    - Performance reports, including submission of data for the health center's UDS reporting?
      ☐ YES ☐ NO ☐ NOT APPLICABLE

    If No, an explanation is required, including specifying which reports the health center did not receive or review:

    _____

18. Has the health center identified any deficiencies with the subrecipient's financial or performance reporting during the current project period, including any in the subrecipient's annual audit?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

19. **If Yes:** Is there documentation that the health center ensured the subrecipient took timely corrective action on the identified deficiencies?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    If No, an explanation is required specifying what deficiencies remain:

    _____

20. Was the health center able to document that each subrecipient is currently compliant with Board Composition requirements, as demonstrated through the following:

    Note: *Select "No" if the health center is unable to provide documentation that verifies that the subrecipient is in compliance OR if the documentation provided does not demonstrate subrecipient compliance.*

    - Is the subrecipient's board currently composed of at least 9 and no more than 25 members?
      ☐ YES ☐ NO ☐ NOT APPLICABLE

- Are at least 51 percent of subrecipient board members classified by the subrecipient as patients?

  Note: *Select "Not Applicable" only if the subrecipient has an approved waiver from the awardee (only available if the health center awardee receives an award under section 330(g), 330(h) and/or 330(i) and does not receive an award under section 330(e)).*

  ☐ YES ☐ NO ☐ NOT APPLICABLE

- Was the health center able to confirm that individuals classified by the subrecipient as patient board members have received at least one in-scope service at an in-scope service site within the past 24 months that generated a health center visit?

  Note: *Select "Not Applicable" only if the subrecipient has an approved waiver from the awardee (only available if the health center awardee receives an award under section 330(g), 330(h) and/or 330(i) and does not receive an award under section 330(e)).*

  ☐ YES ☐ NO ☐ NOT APPLICABLE

- Are patient board members as a group representative of the subrecipient's patient population in terms of race, ethnicity, and gender consistent with the demographics reported in the health center's UDS report?

  Note: *Select "Not Applicable" only if the subrecipient has an approved waiver from the awardee (only available if the health center awardee receives an award under section 330(g), 330(h) and/or 330(i) and does not receive an award under section 330(e)).*

  ☐ YES ☐ NO ☐ NOT APPLICABLE

If No OR Not Applicable is selected for any of the above, an explanation is required:

_____

21. Was the health center able to document that each subrecipient is currently compliant with Board Authority requirements by demonstrating that the subrecipient's articles of incorporation, bylaws (either for the subrecipient's board or, if applicable, the co-applicant of a public agency subrecipient), or other corporate documents (for example, co-applicant agreement) outline the following required health center authorities and responsibilities:

    - Holding monthly meetings?
      ☐ YES ☐ NO ☐ NOT APPLICABLE

    - Approving the selection (and termination or dismissal, as appropriate) of the subrecipient's Project Director/CEO?
      ☐ YES ☐ NO ☐ NOT APPLICABLE

    - Approving the subrecipient's health center project annual budget and applications?
      ☐ YES ☐ NO ☐ NOT APPLICABLE

- Approving the subrecipient's health center services and the location and hours of operation of health center sites?
  ☐ YES ☐ NO ☐ NOT APPLICABLE

- Evaluating the performance of the subrecipient's health center project?
  ☐ YES ☐ NO ☐ NOT APPLICABLE

- Establishing or adopting policy related to the operations of the subrecipient's health center project?
  ☐ YES ☐ NO ☐ NOT APPLICABLE

- Assuring the subrecipient operates in compliance with applicable federal, state, and local laws and regulations?
  ☐ YES ☐ NO ☐ NOT APPLICABLE

If No is selected for any of the above, an explanation is required:

_____

22. Was the health center able to document that each subrecipient is currently compliant with sliding fee discount program (SFDP) requirements by demonstrating that the subrecipient's SFDP policy includes language or provisions that address all of the following:

    Note: *Select "No" if the health center is unable to provide documentation that verifies that the subrecipient is in compliance OR if the documentation provided does not demonstrate subrecipient compliance.*

    - Uniform applicability to all patients?
      ☐ YES ☐ NO ☐ NOT APPLICABLE

    - Definitions of income and family (or "household") (for example, any inclusions or exclusions in how they are defined)?
      ☐ YES ☐ NO ☐ NOT APPLICABLE

    - Methods for assessing patient eligibility based only on income and family size?
      ☐ YES ☐ NO ☐ NOT APPLICABLE

    - The manner in which sliding fee discount schedule(s) are structured to ensure charges are adjusted based on ability to pay (for example, flat fee amounts differ across discount pay classes, a graduated percent of charges for patients with incomes above 100 percent and at or below 200 percent of the Federal Poverty Guidelines (FPG))?
      ☐ YES ☐ NO ☐ NOT APPLICABLE

    - The setting of a nominal charge(s) for patients with incomes at or below 100 percent of the FPG?

      Note: *Select "Not Applicable" if the subrecipient does not charge patients with incomes at or below 100 percent of the FPG.*
      ☐ YES ☐ NO ☐ NOT APPLICABLE

If No was selected for any of the above, an explanation is required:

---

23. Was the health center able to document that each subrecipient's SFDP policy ensures that any/all charge(s) for patients at or below 100 percent of the FPG will be:

***Notes**:*

- *Select "No" if the health center is unable to provide documentation that verifies that the subrecipient is in compliance OR if the documentation provided does not demonstrate subrecipient compliance.*
- *Select "Not Applicable" if the health center does not charge patients with incomes at or below 100 percent of the FPG.*
- *The subrecipient's SFDP policy may state how the nominal charge will be determined AND/OR the amount of the nominal charge(s). If the SFDP policy does not state a specific amount for nominal charge(s), other documentation (for example, board minutes, reports) of board involvement in setting the amount of nominal charge(s) may be utilized.*

- A flat fee?
  ☐ YES ☐ NO ☐ NOT APPLICABLE

- Nominal from a patient's perspective (for example, based on input from patient board members, patient surveys, advisory committees, or a review of co-pay amount(s) associated with Medicare and Medicaid for patients with comparable incomes)?
  ☐ YES ☐ NO ☐ NOT APPLICABLE

- Not based on the actual cost of the service?
  ☐ YES ☐ NO ☐ NOT APPLICABLE

If No was selected for any of the above, an explanation is required:

---

24. Was the health center able to describe how it has (if the health center identified subrecipient noncompliance) or would (if the health center has not identified subrecipient noncompliance to-date) ensure that the subrecipient resolves noncompliance with Health Center Program requirements:
☐ YES ☐ NO ☐ NOT APPLICABLE

If Yes OR No, an explanation is required. **If No:** describe the deficiencies in the health center's process. **If Yes:** describe the health center's process. **If the health center has identified subrecipient noncompliance:** specify the requirements and how the health center has confirmed or will confirm subrecipient compliance:

Element j: Retention of Subaward Agreements and Records

NOT APPLICABLE FOR LOOK-ALIKES

The health center retains final subrecipient agreements and related records, consistent with federal document maintenance requirements.[11]

Site Visit Team Methodology

- Review all subrecipient agreements that support the HRSA-approved Health Center Program scope of project.
- Review documentation of subrecipient monitoring.
- Review sample of financial and performance reports received from the subrecipient.

Site Visit Team Findings

25. Was the health center able to produce final (executed) subrecipient agreements that have been awarded within the past 3 years and related financial and other performance records?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    If No, an explanation is required:

    _____

[11] See 45 CFR 75.361 for HHS retention requirements for records.

CONFLICT OF INTEREST

Primary Reviewer: Governance/Administrative Expert
Secondary Reviewer: Fiscal Expert

Authority: *Section 330(a)(1) and 330(k)(3)(D) of the Public Health Service (PHS) Act; 42 CFR 51c.113 and 42 CFR 56.114; and 45 CFR 75.327*

Related Considerations

Document Checklist for Health Center Staff

- ☐ Procedures for purchasing and procurement, including, if applicable or separate, procedures for contracting and contract management.
- ☐ Two most recent annual audits and management letters.
- ☐ Documentation containing the health center's standards of conduct (for example, articles of incorporation, bylaws, board manual, employee manual, policies and procedures, disclosure forms). For contracts that support the HRSA-approved scope of project, five contracts AND related supporting procurement documentation for actions that **utilize federal award funds.** Choose the contracts that utilize the largest amounts of federal award funds.
  Note: *The same sample of contracts/agreements is to be utilized for the review of both Contracts and Subawards and Conflict of Interest. The sampling methodologies for Conflict of Interest are different from Required and Additional Health Services, Clinical Staffing, and Sliding Fee Discount Program, although they may result in some overlap in the contracts/agreements.*
- ☐ In cases where a real or apparent conflict of interest was identified in the procurement action, related written disclosures (for example, board minutes documenting disclosure(s), standard form(s) to report disclosure(s)) completed by employees, officers, board members, and agents of the health centers.
- ☐ Agreements with parent corporation, affiliate, subsidiary, or subrecipient organization (if applicable).

Demonstrating Compliance

1. Is this a Look-Alike Site Visit?
   ☐ YES ☐ NO

   NOTE*: Because look-alikes do not receive federal funding under section 330 of the PHS Act, any aspects of a requirement that relate to the use of Health Center Program federal award funds are not applicable to look-alikes.*

Element a: Standards of Conduct

NOT APPLICABLE FOR LOOK-ALIKES

The health center has and implements written standards of conduct that apply, at a minimum, to its procurements paid for in whole or in part by the federal award. Such standards:

- Apply to all health center employees, officers, board members, and agents[1] involved in the selection, award, or administration of such contracts;
- Require written disclosure of real or apparent conflicts of interest;[2]
- Prohibit individuals with real or apparent conflicts of interest with a given contract from participating in the selection, award, or administration of such contract;[3]
- Restrict health center employees, officers, board members, and agents involved in the selection, award, or administration of contracts from soliciting or accepting gratuities, favors, or anything of monetary value for private financial gain from such contractors or parties to sub-agreements (including subrecipients or affiliate organizations);[4] and
- Enforce disciplinary actions on health center employees, officers, board members, and agents for violating these standards.

Site Visit Team Methodology

- Interview health center Project Director/CEO, board member(s), and other relevant staff involved in procurement and/or Human Resources regarding the health center's standards of conduct.
- Review relevant documents where standards of conduct relative to procurement are contained.
- Review process for disclosing real or apparent conflicts of interest in writing by employees, officers, board members, and agents of the health center (for example, board minutes documenting disclosure(s), standard form(s) to report disclosure(s)). ***Note:*** *Signed disclosure statements or forms from all health center staff and board members are NOT required to demonstrate compliance. The purpose of the review is to assess whether the health center has a mechanism in place for health center staff and board members to disclose real or apparent conflicts of interest when they arise.*

---

[1] An agent of the health center includes, but is not limited to, a governing board member, an employee, officer, or contractor acting on behalf of the health center.
[2] A conflict of interest arises when the employee, officer, or agent (including but not limited to any member of the governing board), 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.
[3] 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.
[4] Health centers may set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value. See *Related Considerations* in [Health Center Program Compliance Manual] Chapter 13: Conflict of Interest.

Site Visit Findings

2. Was the health center able to provide document(s) that contain its written standards of conduct for the selection, award and administration of contracts that, at a minimum, apply to its procurements paid for in whole or in part by the federal award?
   ☐ YES ☐ NO ☐ NOT APPLICABLE

   If No, an explanation is required:

   _____

3. Do these written standards of conduct:

   - Apply to all health center employees, officers, board members, and agents involved in the selection, award, or administration of such contracts?
     ☐ YES ☐ NO ☐ NOT APPLICABLE
   - Require written disclosure of any real or apparent conflicts of interest?
     ☐ YES ☐ NO ☐ NOT APPLICABLE
   - Prohibit individuals with a real or apparent conflict of interest with a given contract from participating in the selection, award, or administration of such contract?
     ☐ YES ☐ NO ☐ NOT APPLICABLE
   - Prohibit accepting gratuities, favors, or anything of monetary value?
     ☐ YES ☐ NO ☐ NOT APPLICABLE
   - Provide for disciplinary actions for violating the conflict of interest requirements?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   If No was selected for any of the above, an explanation is required, including specifying which areas were not addressed:

   _____

4. Does the health center have a process for disclosing real or apparent conflicts of interest in writing by employees, officers, board members, and agents of the health center should such conflicts arise?
   ☐ YES ☐ NO ☐ NOT APPLICABLE

   If No, an explanation is required:

   _____

Element b: Standards for Organizational Conflicts of Interest

If the health center has a parent, affiliate, or subsidiary 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.

Site Visit Team Methodology

- Review agreements with parent corporation, affiliates, subsidiaries, and subrecipients (if applicable).
- Review two most recent annual audits and management letters for any references to related party transactions.
- Review the documentation containing the health center's written standards of conduct.

Site Visit Findings

5. Does the health center have a parent, affiliate or subsidiary that is not a state, local government, or Indian tribe?
   ☐ YES ☐ NO

6. **If Yes:** Was the health center able to provide document(s) that contain its written standards of conduct for the selection, award, and administration of contracts that involve the related party or organization?
   ☐ YES ☐ NO ☐ NOT APPLICABLE

   If No, an explanation is required:

   _____

7. Do the health center's organizational conflict of interest standards prevent or mitigate any identified or apparent conflicts of interest?
   ☐ YES ☐ NO ☐ NOT APPLICABLE

   If No, an explanation is required:

   _____

Element c: Dissemination of Standards of Conduct

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

---

[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).

Site Visit Team Methodology

- Review documentation containing the health center's standards of conduct, including, if applicable, those covering organizational conflict of interest.
- Review sample of written disclosures with respect to real or apparent conflicts of interest completed by employees, officers, board members, and agents of the health centers.
- Interview health center Project Director/CEO, board member(s), and other relevant staff involved in procurement and/or Human Resources regarding mechanisms or procedures for informing employees, officers, board members, and agents of the health center's standards of conduct.

Site Visit Findings

In responding to the question(s) below, please note:

- *For look-alikes, this element is applicable ONLY for those look-alikes that have a parent, affiliate, or subsidiary that is not a state, local government, or Indian tribe as identified in the assessment of element "b."*
- *For all other look-alikes, select "Not Applicable."*

8. Does the health center inform employees, officers, board members, and agents of its conflict of interest standards of conduct?
   ☐ YES ☐ NO ☐ NOT APPLICABLE

   If No, an explanation is required:

   _____

Element d: Adherence to Standards of Conduct

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).

Site Visit Team Methodology

- Review the five contracts AND related supporting procurement documentation for actions that **utilize federal award funds.**
  Note: *The same sample of contracts/agreements is to be utilized for the review of both Contracts and Subawards and Conflict of Interest. The sampling methodologies for Conflict of Interest are different from Required and Additional Health Services, Clinical Staffing, and Sliding Fee Discount Program, although they may result in some overlap in the contracts/agreements.*
- In cases where a real or apparent conflict of interest was identified in the procurement action, review related written disclosures (for example, board minutes documenting disclosure(s), standard form(s) to report disclosure(s)) completed by employees, officers, board members, and agents of the health centers.
- Review audits and management letters for any findings related to conflicts of interest.

Site Visit Findings

In responding to the question(s) below, please note:

- *For look-alikes, this element is applicable ONLY for those look-alikes that have a parent, affiliate, or subsidiary that is not a state, local government, or Indian tribe as identified in the assessment of element "b."*
- *For all other look-alikes, select "Not Applicable."*

9. Were any conflicts of interest (real or apparent), including organizational conflicts of interest, identified in the past 3 years that were associated with procurement involving federal funds?
   ☐ YES ☐ NO ☐ NOT APPLICABLE

10. **If Yes**: Was the health center able to produce documentation that it adhered to its standards of conduct related to the identified conflict(s) of interest, including the completion of written disclosures?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    If No, an explanation is required:

    _____

COLLABORATIVE RELATIONSHIPS

Primary Reviewer: Governance/Administrative Expert
Secondary Reviewer: Clinical Expert

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

Related Considerations

Document Checklist for Health Center Staff

- ☐ Documentation of established collaboration with other providers and organizations in the health center's service area, including local hospitals, specialty providers, and social service organizations, to provide access to services not available through the health center.
- ☐ Documentation of coordination efforts with other federally-funded, as well as state and local, health services delivery projects and programs serving similar patient populations in the service area. At a minimum, this includes documentation of efforts to establish coordination with one or more health centers in the service area (for example, email or other correspondence of requests and responses for coordination).
- ☐ Uniform Data System (UDS) Mapper documentation showing other health centers with sites in the service area.

Note: *Examples of collaboration or coordination documentation may include but are not limited to memoranda of agreement (MOAs) or memoranda of understanding (MOUs); letters; monthly collaboration meeting agendas with health center leaders; cross-referral of patients between health centers; or evidence of membership in a city-wide community health planning council or emergency room diversion program.*

Demonstrating Compliance

Element a: Coordination and Integration of Activities

The health center documents its efforts to collaborate with other providers or programs in the service area, including local hospitals, specialty providers, and social service organizations (including those that serve special populations), to provide access to services not available through the health center in order to support:

- Reductions in the non-urgent use of hospital emergency departments;
- Continuity of care across community providers; and
- Access to other health or community services that impact the patient population.

Site Visit Team Methodology

- Interview Project Director/CEO regarding collaboration activities, including example(s) of how the health center's collaborative relationship(s) supports each of the following:
    - Reductions in the non-urgent use of hospital emergency departments;
    - Continuity of care across community providers; and
    - Access to other health or community services that impact the patient population.
- Review Collaboration section and any relevant attachments from most recent Service Area Competition (SAC) and other awards (for example, New Access Point).
- Review sample of MOUs, MOAs or any other documentation of collaboration with other community providers or organizations, including local hospitals, specialty providers, and social service organizations (including those that serve special populations).

Site Visit Findings

1. Does the health center have documentation of its efforts to collaborate with other providers or programs in the service area, specifically local hospitals, specialty providers, and social service organizations (including those that serve special populations), to provide access to services not available through the health center?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

2. Was the health center able to provide at least one documented example of how its collaborative relationship(s) supports each of the following:

   - Reductions in the non-urgent use of hospital emergency departments;
   - Continuity of care across community providers; and
   - Access to other health or community services that impact the patient population?

   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

Element b: Collaboration with Other Primary Care Providers

The health center documents its efforts to coordinate and integrate activities with other federally-funded, as well as state and local, health services delivery projects and programs 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).

Site Visit Team Methodology

- Review Uniform Data System (UDS) Mapper to identify other health centers with sites in the service area.
- Interview health center Project Director/CEO regarding coordination with other federally-funded, as well as state and local, health services delivery projects and programs

serving similar patient populations in the service area (at a minimum, other health centers in the service area).
- Review relevant documentation of efforts to coordinate or documentation of established coordination.

Site Visit Findings

In responding to the question(s) below, please note:
The health center determines how to document collaboration or coordination with providers and organizations in its service area. For example, documentation of collaborative relationship(s) that support reductions in emergency department use may be in the form of meeting minutes or evidence of membership in an emergency room diversion program.

3. Was the health center able to document established relationships with at least one health center in the service area?

   Note: *Only select "Not Applicable" if there are no other health centers in the service area.*
   ☐ YES ☐ NO ☐ NOT APPLICABLE

   If No OR Not Applicable, an explanation is required, including describing any documentation by the health center of efforts to establish a relationship in cases when another health center is not responsive to collaboration. If Not Applicable, state if the UDS Mapper documentation shows there are no other health centers in the service area:

   _____

4. Does the health center have documentation of its efforts to coordinate and integrate activities with other federally-funded, state, and local health service delivery projects and programs serving similar patient populations in the service area?
   ☐ YES ☐ NO

   If No, an explanation is required, including stating if there are no other federally-funded, state, or local health services delivery projects or programs serving similar patient populations in the service area:

   _____

Element c: Expansion of HRSA-Approved Scope of Project

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 health care providers serving similar patient populations in the service area (health centers, rural*

[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 Notices of Funding Opportunity (NOFOs), Notices of Award (NOAs), look-alike designation instructions, or other federal statutes, regulations, or policies.

health clinics, local hospitals including critical access hospitals, health departments, other providers including specialty providers, as applicable); or

- *If such letters or documents cannot be obtained from these providers, the health center documents its attempts to coordinate or collaborate with these health care providers (health centers, rural health clinics, local hospitals including critical access hospitals, health departments, other providers including specialty providers, as applicable) on the specific request or application proposal.*

Site Visit Team Methodology

N/A – *HRSA assesses whether the health center has demonstrated compliance with this element through its review of Change in Scope requests and/or competing applications. No review of this element is required through the site visit.*

Site Visit Findings

N/A – *HRSA assesses whether the health center has demonstrated compliance with this element through its review of Change in Scope requests and/or competing applications. No review of this element is required through the site visit.*

FINANCIAL MANAGEMENT AND ACCOUNTING SYSTEMS

Primary Reviewer: Fiscal Expert
Secondary Reviewer: Governance/Administrative Expert

Authority: *Sections 330(e)(5)(D), 330(k)(3)(D), 330(k)(3)(N), and 330(q) of the Public Health Service (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*

Related Considerations

Document Checklist for Health Center Staff

- ☐ Financial management and internal control procedures (may also be in the form of financial/accounting policies, manuals, or other related documents).
- ☐ Procedures for drawdown, disbursement, and expenditure of federal award funds (may be included in the financial management and internal control procedures or may be separate).
- ☐ Policies and/or procedures that govern and track the use of non-grant funds (if applicable).
- ☐ Two most recent annual audits and management letters.
- ☐ Sample of two financial reports provided to the board and key management staff (selected from the past 6 months) including the most recent interim financial statements.
- ☐ Manuals or documentation of the financial management system(s) used by the health center (for example, financial accounting software, practice management system). ***Note:*** *Some or all of the financial management system(s) may be contracted out or carried out via a Health Center Controlled Network.*
- ☐ Sample of source documentation to support expenditures made under the federal Health Center Program award for the last quarter:
    - Drawdowns under the Health Center Program award with supporting documentation (for example, financial records, receipts, invoices);
    - Last non-payroll drawdown under the Health Center Program award with supporting documentation;
    - If there was a capital-related Health Center Program award drawdown within the last 3 years, the last capital drawdown with supporting documentation; and
    - Copy of the journal entry that records these drawdowns in the general ledger under the Health Center Program award.
- ☐ Aged Accounts Receivable (as of most recent interim financial statements).
- ☐ Aged Accounts Payable (as of most recent interim financial statements).

Demonstrating Compliance

1. Is this a Look-Alike Site Visit?
   ☐YES ☐NO

   ***NOTE**: Because look-alikes do not receive federal funding under section 330 of the PHS Act, any aspects of a requirement that relate to the use of Health Center Program federal award funds are not applicable to look-alikes.*

Element a: Financial Management and Internal Control Systems

The health center has and utilizes a financial management and internal control system that reflects Generally Accepted Accounting Principles (GAAP) for private non-profit health centers or Government Accounting Standards Board (GASB) principles for public agency health centers[1] and that 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;
- The safeguarding of 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;[4] and
- The 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.

Site Visit Team Methodology

- Interview health center's CFO and/or other relevant staff and, if applicable, contractors who have responsibility for the health center's financial management systems.
- Review the two most recent audits and management letters.

---

[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 Program scope of project. For additional detail, see [Health Center Program Compliance Manual] Chapter 17: 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 are required to 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."
[4] The requirement to safeguard federal assets as described in this bullet substantially reflects the requirement to have written policies and procedures in place to ensure the appropriate use of federal funds in compliance with applicable federal statutes, regulations, and the terms and conditions of the federal award. See Section 330(k)(3)(N) of the PHS Act.

- Review financial management, accounting, and internal control procedures and systems.
- Review sample of financial reports provided to the board and key management staff including the most recent interim financial statements.
- Review Aged Accounts Receivable and Aged Accounts Payable.

Site Visit Findings

2. Does the health center's financial management and internal control system reflect GAAP or GASB principles?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

3. Is the health center able to track actual expenditures in comparison to the Health Center Program project budget?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

4. Do the health center's financial management and internal control systems have the capacity to account for the expenditure of Health Center Program project funds (for example, segregation of funds) and safeguard the use of associated assets and property (for example, procedures for inventory management, maintaining property records)?
   ☐ YES ☐ NO

   If No, an explanation is required regarding the health center's inability to account for expenditures and/or safeguard assets:

   _____

5. Was the health center able to demonstrate a capacity to track its financial performance for the purposes of monitoring financial stability?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

Element b: Documenting Use of Federal Funds

NOT APPLICABLE FOR LOOK-ALIKES

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

source[5] (receipt) and application (expenditure) of funds for federally-funded activities in whole or in part. 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).

Site Visit Team Methodology

- Have CFO or other financial staff walk through the health center's use of the last quarter of federal Health Center Program award funds, starting from drawdown through obligation and payment of such funds for authorized expenditure.
- Review sample of source documentation to support expenditures made under the federal Health Center Program award for the last quarter.

Site Visit Findings

6. Based on the sample, does the health center have a financial management system that is able to account for the Health Center Program federal award and related expenditures (for example, in chart of accounts) made under the award? Specifically, do the health center's financial records contain relevant information and related source documentation?
   ☐ YES ☐ NO ☐ NOT APPLICABLE

   If No, an explanation is required:

   _____

Element c: Drawdown, Disbursement and Expenditure Procedures

NOT APPLICABLE FOR LOOK-ALIKES

The health center has written procedures for:

- Drawing down federal award funds in a manner that minimizes the time elapsing between the transfer of the federal award funds from HRSA and the disbursement of these funds by the health center; and
- Assuring that expenditures of federal award funds are allowable in accordance with the terms and conditions of the federal award and with the federal cost principles[6] in 45 CFR Part 75 Subpart E.

Site Visit Team Methodology

- Review health center's procedures for drawdown, disbursement, and expenditure of federal award funds utilizing the federal Payment Management System (PMS).
- Interview CFO or other health center individuals authorized to draw down and expend federal award funds.

---

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

Site Visit Findings

7. Does the health center have written procedures for drawing down federal funds?
   ☐ YES ☐ NO ☐ NOT APPLICABLE
   If No was selected, an explanation is required:

   _____

8. Does the health center have written procedures with provisions or steps that:

   - Limit the drawdown to minimum amounts needed to cover allowable project costs?
     ☐ YES ☐ NO ☐ NOT APPLICABLE
   - Time drawdowns in a manner that minimizes the time elapsing between the transfer of the federal award funds from HRSA and the disbursement of these funds by the health center?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   If No was selected for any of the above, an explanation is required:

   _____

9. Does the health center have written procedures with specific provisions or steps that ensure all expenditures utilizing federal award funds are allowable in accordance with:

   - The terms and conditions of the federal award, including those that limit the use of federal award funds?[7]
     ☐ YES ☐ NO ☐ NOT APPLICABLE
   - The federal cost principles in 45 CFR Part 75 Subpart E?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   If No was selected for any of the above, an explanation is required:

   _____

Element d: Submitting Audits and Responding to Findings

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.

[7] For more information on legislative mandates related to annual appropriations that limit the use of funds from HRSA awards, visit the HRSA Grants Policies, Regulations, & Guidance website.

Site Visit Team Methodology

- Review most recent audit and management letter.
- If there are any audit findings, questioned or unallowable costs, reportable conditions, material weaknesses, or significant deficiencies noted, interview the health center's CFO and/or other relevant health center individuals regarding status of corrective actions.

Site Visit Findings

10. Did the health center expend $750,000 or more in federal award funds during its last complete fiscal year?
    ☐ YES ☐ NO

11. **If Yes**: Has (i.e., audit is complete at the time of site visit) or will (i.e., audit is in progress at the time of site visit) the health center ensure an audit is conducted in accordance with federal audit requirements?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    If No, an explanation is required:

    _____

12. Based on review of the most recent audit and management letter, were there any findings, questioned or unallowable costs, reportable conditions, material weaknesses, or significant deficiencies, including any cited in the previous audit report?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

13. **If Yes:** Has the health center either completed corrective actions to address the finding(s) or was the health center able to document steps it is currently taking to address the finding(s)?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    If No, an explanation is required:

    _____

Element e: Documenting Use of Non-Grant Funds

The health center can document that any non-grant funds generated from Health Center Program project activities, in excess of what is necessary to support the HRSA-approved total Health Center Program project budget, 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.

Site Visit Team Methodology

- Interview the health center's CFO and/or Project Director/CEO or other relevant health center individuals.
- Review policies, procedures, or systems that govern and track the use of non-grant funds (if applicable).

Site Visit Findings

14. In the last complete fiscal year, did the health center generate revenue from health center activities that was then utilized for activities outside the scope of the project?
☐ YES ☐ NO

15. **If Yes:** Was the health center able to document that these funds were used:

- To support activities that benefit the current patient population?
☐ YES ☐ NO ☐ NOT APPLICABLE

- For purposes that are not specifically prohibited by the Health Center Program?
☐ YES ☐ NO ☐ NOT APPLICABLE

If No was selected for any of the above, an explanation is required:

_____

BILLING AND COLLECTIONS

Primary Reviewer: Fiscal Expert
Secondary Reviewer: Governance/Administrative Expert (as needed)

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

Related Considerations

Document Checklist for Health Center Staff

- ☐ Registration, eligibility, outreach, and enrollment procedures.
- ☐ Current fee schedule(s) for each service area (for example, medical, dental, behavioral health).
- ☐ Billing and Collections policies or procedures and systems including:
    - Provision(s) to waive or reduce fees owed by patients;
    - Third-party payor billing procedures and/or contracts;
    - Refusal to pay policy (if applicable); and
    - Procedures for notifying patients of additional costs for supplies and equipment related to but not included in the service (if applicable).
- ☐ List of provider and program/site billing numbers for Medicaid, CHIP, Medicare, or any other documentation of participation (for example, individual provider NPIs).
- ☐ Current data on the following revenue cycle management metrics, if available: collection ratios, bad debt write off as a percentage of total billing, collections per visit, charges per visit, percentage of accounts receivable (A/R) less than 120 days, days in A/R (for context on billing and collections efforts).
- ☐ Sample of claims submissions and resubmissions. For the sample, randomly choose 7 claims submissions and resubmissions for patient visits reflective of the health center's major third-party payors from across at least 3 unique services (for example, routine primary care, preventive dental, behavioral health, obstetrics) for a total of at least 21 claims submissions and resubmissions reviewed. Within this sample of 21 claims submissions and resubmissions, include at least 7 rejected claims.
- ☐ Report showing the last 6 months of claims data, specifically including the claims numbers, dates of service, and dates claims were filed/billed.
- ☐ Sample of billing and payment records for charges requested from patients. For the sample, randomly choose 5 records for patient visits from across at least 3 unique services (for example, routine primary care, preventive dental, behavioral health, obstetrics) for a total of at least 15 records reviewed:
    - Ensure the sample includes patients that are eligible for the health center's sliding fee discount program (SFDP) (i.e., incomes at or below 200 percent of the Federal Poverty Guidelines (FPG)).
    - If applicable, include records for patients that are not eligible for the SFDP (i.e., incomes above 200 percent of the FPG).
- ☐ Sample of two to three billing records where patient fees were waived or reduced.
- ☐ Documentation of methods for notifying patients of additional costs for supplies and equipment related to but not included in the service (if applicable).

- ☐ Documentation of cases where the health center has applied its refusal to pay policy within the past 24 months (if applicable).
- ☐ Documentation used to determine fee schedule(s) based on health center costs and locally prevailing rates (for example, operating costs for service delivery, relative value units (RVUs) or other relevant data sources, Medicare/Medicaid cost reports).
- ☐ Documentation of participation in other public or private program or health insurance plans (if applicable) (for example, list or copy of third-party payor contracts including any managed care contracts).
- ☐ Contracts with outside organizations that conduct billing or collections on behalf of the health center (if applicable).

Demonstrating Compliance

Element a: Fee Schedule for In-Scope Services

The health center has a fee schedule for services that are within the HRSA-approved scope of project and are typically billed for in the local health care market.

Site Visit Team Methodology

- Review fee schedule(s).
- Compare the health center fee schedule(s) to Form 5A required and additional services.
- Interview CFO/financial or billing staff.
- Review most recent data and documentation of analysis used for determining and setting fees.

Site Visit Findings

1. Does the fee schedule(s) include fees for all in-scope services typically billed for in the local health care market?

   ***Note**: Services (for example, transportation, translation, other non-clinical services) on Form 5A that are not billed for in the local health care market may be excluded from the health center's fee schedule(s).*

   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

Element b: Basis for Fee Schedule

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

Site Visit Team Methodology

- Review fee schedule(s).
- Compare the health center fee schedule(s) to Form 5A required and additional services.
- Interview CFO/financial or billing staff.
- Review most recent data and documentation of analysis used for determining and setting fees.

Site Visit Findings

2. Did the health center use data on locally prevailing rates and actual health center costs to develop its current fee schedule(s)?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

Element c: Participation in Insurance Programs

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

Site Visit Team Methodology

- Review list of provider and program/site billing numbers or any other documentation of participation in Medicaid, CHIP, and Medicare.
- Review documentation (if applicable) of participation in other public or private program or health insurance plans.
- Interview CFO/financial or billing staff.

Site Visit Findings

3. Does the health center have documentation of its participation in Medicaid, CHIP, and Medicare?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

4. Does the health center participate in other public or private assistance programs or health insurance?
   ☐ YES ☐ NO

   If No, an explanation is required, including the justification that the health center provided as to why it is not appropriate to participate in any other programs or insurance plans:

   _____

Element d: Systems and Procedures

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] and
- Requesting applicable payments from patients, while ensuring that no patient is denied service based on inability to pay.

Site Visit Team Methodology

- Interview staff involved in the billing and collections process as well as staff involved in educating patients on insurance options (for example, front desk staff, billing office staff, outreach and enrollment staff).
- Review billing and collections systems including third-party payor billing procedures and/or contracts.
- Review contracts with outside organizations that conduct billing or collections on behalf of the health center (if applicable).
- Review eligibility, education, and, if applicable, enrollment procedures (for example, new patient registration and screening procedures).

Site Visit Findings

5. Was the health center able to explain how it educates patients on the availability of insurance coverage options?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

6. Does the health center have systems in place for billing Medicare, Medicaid, CHIP and other public and private assistance programs or insurance?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

[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, refer to the FTCA Health Center Policy Manual, Section I: E. Eligibility and Coverage, Coverage Under Alternate Billing Arrangements.

7. Does the health center have a system(s) in place for collecting balances owed by patients?
   ☐ YES ☐ NO
   If No, an explanation is required:

   _____

8. When requesting payment(s) from patients, do the health center's billing and collections systems/procedures ensure that no patient is denied service based on inability to pay?
   ☐ YES ☐ NO

   If Yes OR No, an explanation is required, including describing the systems or procedures:

   _____

Element e: Procedures for Additional Billing or Payment Options

If a health center elects to offer additional billing options or payment methods (for example, payment plans, grace periods, prompt or cash payment incentives), the health center has operating procedures for implementing these options or methods and for ensuring they are accessible to all patients regardless of income level or sliding fee discount pay class.

Site Visit Team Methodology

- Review billing and collections systems and any related procedures for additional billing options or payment methods (if applicable).

Site Visit Findings

9. Does the health center offer additional billing options or payment methods (for example, payment plans, grace periods, prompt or cash payment incentives)?
   ☐ YES ☐ NO

   If Yes, an explanation is required specifying what additional billing options or payment methods are offered by the health center:

   _____

10. **If Yes:** Does the health center have operating procedures for implementing these options or methods?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    If No, an explanation is required:

    _____

11. Does the health center ensure these options or methods are accessible to all patients regardless of income level or sliding fee discount pay class?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    If No, an explanation is required:

    _____

Element f: Timely and Accurate Third-Party Billing

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[2] consistent with the terms of such contracts and other arrangements.

Site Visit Team Methodology

- Review sample of claims submission and resubmission data.
- Review third-party payor billing procedures.
- Interview CFO and staff involved in the billing and collections process.

Site Visit Findings

12. Does the health center submit claims within 14 business days from the date of service?
☐ YES ☐ NO

    If No, an explanation is required stating the timeline for claims submissions and how the health center ensures timely submission of claims to third-party payors:

    _____

13. Was the health center able to document that it corrects and resubmits claims that have been rejected due to accuracy?
☐ YES ☐ NO

    If No, an explanation is required, including specifying any cases in which Medicaid, CHIP, Medicare, or any other third-party payor has suspended payments to the health center and why:

    _____

Element g: Accurate Patient Billing

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

---

[2] This includes services that the health center provides directly (Form 5A: Services Provided, Column I) or provides through a formal written contract/agreement (Form 5A: Services Provided, Column II).
[3] See [Health Center Program Compliance Manual] Chapter 9: Sliding Fee Discount Program for more information on the SFDS.

Site Visit Team Methodology

- Interview CFO and staff involved in the billing and collections process.
- Review fee schedule(s) and the appropriate corresponding SFDS, including sliding fee schedule(s) that differ by service (if applicable) (for example, Dental SFDS).
- Review billing and collections systems and any related procedures and interview staff involved in collections.
- Review sample of billing and payment records for charges requested from patients. The health center will provide 5 records for patient visits from across at least 3 unique services (for example, routine primary care, preventive dental, behavioral health, obstetrics) for a total of at least 15 records. The health center will ensure that the records include patients that are eligible for the health center's sliding fee discount program (SFDP) (i.e., incomes at or below 200 percent of the Federal Poverty Guidelines (FPG)). If applicable, the health center will include records for patients that are not eligible for the SFDP (i.e., incomes above 200 percent of the FPG).

Site Visit Findings

14. Are patients billed for services in accordance with the health center's fee schedule(s) and are the correct discounts applied to these charges (if applicable)?
    ☐ YES ☐ NO

    If No, an explanation is required:

    _____

15. Does the health center attempt to collect amounts owed for charges, co-pays, nominal charges, or discounted fees (for example, health center sends statements for outstanding balances, makes phone calls)?
    ☐ YES ☐ NO

    If No, an explanation is required:

    _____

Element h: Policies or Procedures for Waiving or Reducing Fees

The health center has and utilizes board-approved policies, as well as operating procedures, that include the specific circumstances when the health center will waive or reduce fees or payments required by the center due to any patient's inability to pay.

Site Visit Team Methodology

- Review policies and procedures that contain provision(s) to waive or reduce fees owed by patients.
- Review a sample of two to three billing records where patient fees were waived or reduced.

Site Visit Findings

16. Does the health center have a provision(s) in policy and procedure that addresses circumstances or criteria related to a patient's inability to pay (regardless of patient income level) to ensure that fees or payments will be waived or reduced?
☐ YES ☐ NO

    If Yes OR No, an explanation is required, including specifying whether the health center waives or reduces fees or payments:

    _____

17. Does the health center follow the provision(s) in its policies and procedures for waiving or reducing fees or payments?
☐ YES ☐ NO ☐ NOT APPLICABLE

    If No, an explanation is required:

    _____

Element i: Billing for Supplies or Equipment

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[4] (for example, eyeglasses, prescription drugs, 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.[5]

Site Visit Team Methodology

- Interview staff involved in billing.
- Review billing procedures and methods for notifying patients of additional costs for supplies and equipment related to but not included in the service (if applicable).

Site Visit Findings

18. Does the health center provide and charge patients for supplies and equipment related to but not included in the service itself (for example, eyeglasses, dentures)?
☐ YES ☐ NO

19. **If Yes:** Does the health center have a method for notifying patients about out-of-pocket costs for such supplies and equipment, in advance of service provision?
☐ YES ☐ NO ☐ NOT APPLICABLE

    If No, an explanation is required:

    _____

[4] These items differ from supplies and equipment that are included in a service as part of prevailing standards of care and are reflected in the fee schedule (for example, casting materials, bandages).
[5] See [Health Center Program Compliance Manual] Chapter 15: Financial Management and Accounting Systems for related information on revenue generated from such charges.

Element j: Refusal to Pay Policy

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 and notifies patients of:

- Amounts owed and the time permitted to make such payments;
- Collection efforts that will be taken when these situations occur (for example, meeting with a financial counselor, establishing payment plans); and
- How services will be limited or denied when it is determined that the patient has refused to pay.

Site Visit Team Methodology

- Interview staff responsible for billing and collections.
- Review billing and collection policies and procedures.
- Review refusal to pay policy (if applicable).
- Review documentation of cases where the health center has applied its refusal to pay policy within the past 24 months (if applicable).

Site Visit Findings

20. Does the health center limit or deny services to patients who refuse to pay?
    ☐ YES ☐ NO

21. **If Yes:** Does the health center have a refusal to pay policy?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    If No, an explanation is required:

    _____

22. Does the health center:

    - Distinguish between refusal to pay and inability to pay?
      ☐ YES ☐ NO ☐ NOT APPLICABLE
    - Notify patients of amounts owed and the time permitted to make such payments?
      ☐ YES ☐ NO ☐ NOT APPLICABLE
    - Notify patients of collection efforts that will be taken when these situations occur (for example, meeting with a financial counselor, establishing payment plans)?
      ☐ YES ☐ NO ☐ NOT APPLICABLE
    - Notify patients how services will be limited or denied when it is determined that the patient has refused to pay?
      ☐ YES ☐ NO ☐ NOT APPLICABLE

If Yes OR No, an explanation is required, including specifying whether the health center has a policy or procedure that addresses these areas:

_____

23. In cases where the health center has limited or denied services to a patient(s) due to refusal to pay, was the determination consistent with health center policy or procedure?
☐ YES ☐ NO ☐ NOT APPLICABLE

If Yes OR No, an explanation is required, including how the determination was made:

_____

BUDGET

Primary Reviewer: Fiscal Expert
Secondary Reviewer: N/A

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

Related Considerations

Document Checklist for Health Center Staff

- ☐ Updated annual budget for the health center project (if updated since last application submission to HRSA).
- ☐ Financial management procedures (for context and background on budget development process).
- ☐ Most recent annual audit and management letters or audited financial statements (as reference for any other lines of business).
- ☐ Budget to actual comparison reports for the current fiscal year and the prior fiscal year.
- ☐ Separate organizational budget(s) (if applicable) (in situations where the health center has an organizational budget that is separate from the budget for the health center project).

Demonstrating Compliance

Element a: Annual Budgeting for Scope of Project

The health center develops and submits to HRSA (for new or continued funding or designation from HRSA) an annual budget, also referred to as a "total budget,"[1,2] that reflects projected costs and revenues necessary to support the health center's proposed or HRSA-approved scope of project.

Site Visit Team Methodology

- Review health center's most current annual budget for the health center project.
- Review budget to actual comparison reports for the current fiscal year and the prior fiscal year.
- Review financial management procedures.

---

[1] A health center's "total budget" includes the Health Center Program federal award funds and all other sources of revenue in support of the health center scope of project.
[2] Any aspects of the requirement that relate to the use of Health Center Program federal award funds are not applicable to look-alikes.

- Review health center's approved scope of project (Form 5A and 5B), including any special populations funding or designation. Determine if there has been any change in the scope of project since the last Health Center Program application which impacts the current budget.
- Interview health center Project Director/CEO, CFO, and/or financial staff to understand budget formulation process (for example, budget assumptions), including any variances or questions raised by the review of budget to actual comparison reports.

Site Visit Findings

1. Has the health center developed an annual operating budget that is reflective of the projected costs and revenues necessary to support the health center's HRSA-approved scope of project (i.e., reflects revenue and expenses for all sites, services, and activities within the scope of project)?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

Element b: Revenue Sources

In addition to the Health Center Program award, the health center's annual budget includes all other projected revenue sources that will support the Health Center Program 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 (for example, Ryan White, Healthy Start) or contracts;*
- *Private support or income generated from contributions; and*
- *Any other funding expected to be received for purposes of supporting the Health Center Program project.*

Site Visit Team Methodology

N/A – *HRSA assesses whether the health center has demonstrated compliance with this element through its review of the competing continuation application (Service Area Competition (SAC) or Renewal of Designation (RD)). No review of this element is required through the site visit.*

Site Visit Findings

N/A – *HRSA assesses whether the health center has demonstrated compliance with this element through its review of the competing continuation application (SAC or RD). No review of this element is required through the site visit.*

Element c: Allocation of Federal and Non-Federal Funds

The health center's annual 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[3] and the terms and conditions[4] of the award.

Site Visit Team Methodology

***N/A –** HRSA assesses whether the health center has demonstrated compliance with this element through its review of the competing continuation application (SAC or RD). No review of this element is required through the site visit.*

Site Visit Findings

***N/A –** HRSA assesses whether the health center has demonstrated compliance with this element through its review of the competing continuation application (SAC or RD). No review of this element is required through the site visit.*

Element d: Other Lines of Business

If the health center organization 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 budget for the Health Center Program project.[5]

Site Visit Team Methodology

- Interview health center Project Director/CEO, CFO, and/or financial staff to determine whether the health center operates other lines of business.
- Review any separate organizational budget(s) (if applicable).
- Review health center's approved scope of project (Form 5A and 5B).
- Review most recent audit or audited financial statements to determine if there are other lines of business.

***Note:** Net revenue from other lines of business may be included in the health center project's operating budget.*

[3] See 45 CFR Part 75 Subpart E: Cost Principles.
[4] For example, health centers may not use HHS federal award funds to support salary levels above the salary limitations on federal awards.
[5] 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, payment as a Federally Qualified Health Center (FQHC) under Medicare/Medicaid/CHIP, 340B Drug Pricing Program eligibility, Federal Tort Claims Act (FTCA) coverage).

Site Visit Findings

2. Does the health center engage in any other lines of business (i.e., the health center serves other populations or operates sites, services, or activities that are NOT within the HRSA-approved scope of project)?
   ☐ YES ☐ NO

3. **If Yes:**

   - Can the health center document that these other lines of business are fully supported by non-health center project revenues?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   - Can the health center document that all expenses from such other lines of business are excluded from the annual operating budget for the health center project?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   If No was selected for any of the above, an explanation is required:

   _____

PROGRAM MONITORING AND DATA REPORTING SYSTEMS

Primary Reviewer: Fiscal Expert
Secondary Reviewer: Governance/Administrative Expert

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

Related Considerations

Document Checklist for Health Center Staff

- ☐ Sample of one to two data-based reports generated by the health center for the governing board or key management staff from the past 12 months (for example, dashboards, board packets, reports provided to the Finance or Quality Improvement Committee, routine reports generated by the health center for key management staff) that include information on:
    - Patient service utilization;
    - Trends and patterns in the patient population; and
    - Overall health center clinical, financial, or operational performance.

Demonstrating Compliance

Element a: Collecting and Organizing Data

The health center has a system in place for overseeing the operations of the federal award-supported activities to ensure compliance with applicable federal requirements and for monitoring program performance. 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 Uniform Data System (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.]*

Note: *HRSA will assess whether the health center has demonstrated compliance in terms of submitting timely, accurate, and complete UDS reports based on internal HRSA UDS reporting information. No review of the portion of element "a" in brackets is required through the site visit.*

Site Visit Team Methodology

- Interview relevant health center staff tasked with data management, collection, or reporting.
- Review health center's Electronic Health Records (EHR), practice management system, or other data collections systems or methods, which may include participation in a Health Center Controlled Network. This may include a navigation of the systems or methods, if helpful.
- Confer with Operational Site Visit team members for input on related data systems (for example, systems used to support Quality Improvement/Quality Assurance, Financial Management and Accounting, Billing and Collections).

Site Visit Findings

In responding to the question(s) below, please note:
Findings related to financial management and accounting systems capacity or quarterly Quality Improvement/Quality Assurance assessments are to be assessed and documented within the Financial Management and Accounting Systems requirement and *Quality Improvement/Assurance requirement, respectively, and do NOT need to be repeated here.*

1. Does the health center have systems or methods in place to collect and organize data, including ensuring the integrity of such data, for the purposes of overseeing the health center project and for monitoring and reporting on program performance?
   ☐ YES ☐ NO

   If No, an explanation is required, including specifying any deficiencies in the health center's methods or safeguards for ensuring the integrity of data:

   _____

Element b: Data-Based Reports

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

Site Visit Team Methodology

- Review one to two samples of internal health center data-based reports that include information on:
  - Patient service utilization;
  - Trends and patterns in the patient population; and
  - Overall health center clinical, financial, or operational performance.
- Interview health center key management staff and board members regarding the receipt and relevance of health center data-based reports.

[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.

Site Visit Findings

2. Do the health center's program data reporting systems or methods result in the production of relevant reports that can inform and support internal decision-making and oversight by key management staff and the governing board? This would include, but is not limited to, the production of reports regarding:

   - Patient service utilization?
     ☐ YES ☐ NO

   - Trends and patterns in the patient population?
     ☐ YES ☐ NO

   - Overall health center clinical, financial, or operational performance?
     ☐ YES ☐ NO

   If No was selected for any of the above, an explanation is required:

   _____

BOARD AUTHORITY

Primary Reviewer: Governance/Administrative Expert
Secondary Reviewer: N/A

Authority: *Section 330(k)(3)(H) of the Public Health Service (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)*

Related Considerations

Document Checklist for Health Center Staff

- ☐ Health center organization chart(s) with names of key management staff.
- ☐ Corporate organization chart(s) (only applicable for public agencies or for organizations with a parent or subsidiary).
- ☐ Articles of Incorporation.
- ☐ Bylaws (if updated since last application submission to HRSA).
- ☐ Co-applicant agreement (if applicable) (if updated since last application submission to HRSA).
- ☐ Position description for the Project Director/CEO.
- ☐ Board calendar or other related scheduling documents for most recent 12 months.
- ☐ Board agendas and minutes for:
    - Most recent 12 months.
    - Any other relevant meetings from the past 3 years that demonstrate board authorities were explicitly exercised, including approving key policies on:
        - Sliding Fee Discount Program;
        - Quality Improvement/Assurance Program;
        - Billing and Collections (policy for waiving or reducing patient fees and if applicable, refusal to pay);
        - Financial Management and Accounting Systems; and
        - Personnel.
- ☐ Sample board packets from two board meetings from within the past 12 months.
- ☐ Board committee minutes OR committee documents from the past 12 months.
- ☐ Strategic plan or long term planning documents within the past 3 years.
- ☐ Most recent evaluation of Project Director/CEO.
- ☐ Project Director/CEO employment agreement (for the purposes of provisions regarding Project Director/CEO selection, evaluation, and dismissal or termination).
- ☐ Agreements with parent corporation, affiliate, subsidiary, or subrecipient organization (if applicable).
- ☐ Collaborative or contractual agreements with outside entities that may impact the health center board's authorities or functions.

Demonstrating Compliance

1. Is the health center operated by an Indian tribe, tribal group, or Indian organization under the Indian Self-Determination Act or an Urban Indian Organization under the Indian Health Care Improvement Act? [1]
   ☐ YES ☐ NO

   NOTE: IF "YES" WAS SELECTED, NONE OF THE QUESTIONS FOR ANY OF THE ELEMENTS IN THE BOARD AUTHORITY SECTION ARE APPLICABLE.

Element a: Maintenance of Board Authority Over Health Center Project

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 Program 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 approval authority or have veto power over the health center board with regard to the required authorities and functions;[2]
- 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,[3] 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 Program project.

Site Visit Team Methodology

- Review organizational chart(s) (health center project and, if applicable, corporate), articles of incorporation, bylaws, and other relevant corporate or governing documents.
- Review health center's current Forms 5A and 5B to determine current HRSA-approved scope of project.

---

[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 [Health Center Program Compliance Manual Chapter 19: Board Authority]. Section 330(k)(3)(H) of the PHS Act.
[2] This does not preclude an executive committee from taking actions on behalf of the board in emergencies, on which the full board will subsequently vote.
[3] Public agencies are permitted to utilize a co-applicant governance structure for the purposes of meeting Health Center Program governance requirements. Public centers may be structured in one of two ways to meet the program requirements: 1) the public agency independently meets all the Health Center Program governance requirements based on the existing structure and vested authorities of the public agency's governing board; or 2) together, the public agency and the co-applicant meet all Health Center Program requirements.

- Review any collaborative or contractual agreements with outside entities that may impact the health center board's authorities or functions.
- Review co-applicant agreement (if applicable).
- Review agreements with parent corporation, affiliate, subsidiary, or subrecipient organization (if applicable).

Site Visit Findings

In responding to the question(s) below, please note:
In a public agency/co-applicant health center arrangement, the public agency is not considered to be an outside entity as it is the award recipient.

2. Do health center documents and agreements confirm that:

   - No other individual, entity, or committee (including, but not limited to, an executive committee authorized by the board) reserves or has approval/veto power over the health center board with regard to the required authorities and functions?
     ☐ YES ☐ NO

   - The health center's collaborations or agreements with other entities do not restrict or infringe upon the health center board's required authorities and functions?
     ☐ YES ☐ NO

   If No was selected for any of the above, an explanation is required:

   _____

3. **For public agencies with a co-applicant board:** Does the health center have a co-applicant agreement that:

   - Delegates the required authorities and functions to the co-applicant board?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   - Delineates the required roles and responsibilities of the public agency and the co-applicant in carrying out the health center project?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   If No was selected for either of the above, an explanation is required:

   _____

Element b: Required Authorities and Responsibilities

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;[4,5]
- Approving the selection (and termination or dismissal, as appropriate) of the health center's Project Director/CEO;
- Approving the annual Health Center Program project 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[6] 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.

Site Visit Team Methodology

- Review the health center's articles of incorporation, bylaws, and other relevant corporate or governing documents.
- Review co-applicant agreement (if applicable).

Site Visit Findings

4. Do the health center's articles of incorporation, bylaws (either for the health center board or, if applicable, the co-applicant health center board), or other corporate documents (for example, co-applicant agreement) outline the following required health center authorities and responsibilities:

    - Holding monthly meetings?
      ☐ YES ☐ NO

    - Approving the selection (and termination or dismissal, as appropriate) of the health center's Project Director/CEO?
      ☐ YES ☐ NO

    - Approving the health center's annual budget and applications?
      ☐ YES ☐ NO

    - Approving health center services and the location and hours of operation of health center sites?
      ☐ YES ☐ NO

---

[4] 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.
[5] Boards of organizations receiving a Health Center Program award/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).
[6] The governing board of a health center is generally responsible for establishing and/or approving policies that govern health center operations, while the health center's staff is generally responsible for implementing and ensuring adherence to these policies (including through operating procedures).

- Evaluating the performance of the health center?
  ☐ YES ☐ NO

- Establishing or adopting policy related to the operations of the health center?
  ☐ YES ☐ NO

- Assuring the health center operates in compliance with applicable federal, state, and local laws and regulations?
  ☐ YES ☐ NO

If No was selected for any of the above, an explanation is required, including specifying which authorities/responsibilities are not addressed in such documents:

_____

Element c: Exercising Required Authorities and Responsibilities

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 where a quorum is present to ensure the board has the ability to exercise its required authorities and functions;
- Approving the selection, evaluation and, if necessary, the dismissal or termination of the Project Director/CEO from the Health Center Program project;
- Approving applications related to the Health Center Program project, including approving the annual budget, which outlines the proposed uses of both Health Center Program award and non-federal resources and revenue;
- Approving the Health Center Program project's sites, hours of operation and services, including decisions to subaward or contract 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/strategic planning at least once every 3 years, which at a minimum addresses financial management and capital expenditure needs; and
- Evaluating the performance of the health center based on quality assurance/quality improvement assessments and other information received from health center management,[7] 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.

[7] For more information related to the production of reports associated with these topics, see [Health Center Program Compliance Manual] Chapter 18: Program Monitoring and Data Reporting Systems, Chapter 15: Financial Management and Accounting Systems, and Chapter 10: Quality Improvement/Assurance.

Site Visit Team Methodology

- Interview Project Director/CEO regarding board roles and responsibilities (for example evaluating health center performance, approving applications, conducting long-range planning, process for evaluating health center policies).
- Interview board (co-applicant board in the case of a public agency-co-applicant model) regarding how it carries out board functions, specifically:
    - How Project Director/CEO reports to the board.
    - Board roles and responsibilities (for example evaluating health center performance, approving applications, conducting long-range planning, process for evaluating health center policies).

  Note: *The goal is to interview a majority of board members as a group. If this is not possible, interview officers and at least one patient member. If group interview is not possible, interview individually*.
- If conducting a review for a public agency health center, interview relevant public agency staff (for example, leadership, staff within the unit of the public agency related to the health center project) about their various roles and responsibilities.
- Review board calendar or other related scheduling documents for most recent 12 months.
- Review board agendas and minutes for most recent 12 months and any other relevant meeting minutes from the past 3 years that demonstrate board authorities were explicitly exercised.
- Review any relevant board committee minutes OR committee documents for most recent 12 months that support board functions and activities.
- Review sample of board packets from two board meetings from within the past 12 months.
- Review strategic planning or related documents from within the past 3 years.
- Review most recent Project Director/CEO evaluation documentation.
- Review the position description and employment agreement for the Project Director/CEO.

Site Visit Findings

5. Do board minutes document that the board met monthly for the past 12 months and had a quorum (quorum is determined by the health center) present that enabled the board to carry out its required authorities and functions?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

6. Based on your review of board minutes, board agendas, other relevant documents, and interviews conducted with the Project Director/CEO and board members, were there examples of how the board exercises the following authorities and functions:

   - Approving the selection of, evaluating, and, if necessary, approving the dismissal or termination of the Project Director/CEO from the health center project?
     ☐ YES ☐ NO

   - 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?
     ☐ YES ☐ NO

- Approving the health center project's sites, hours of operation, and services, including (if applicable) decisions to subaward or contract for a substantial portion of the health center's services?
  ☐ YES ☐ NO

- Monitoring the financial status of the health center, including reviewing the results of the annual audit and ensuring appropriate follow-up actions are taken?
  ☐ YES ☐ NO

- Conducting long-range/strategic planning at least once every 3 years, which at a minimum addresses financial management and capital expenditure needs?
  ☐ YES ☐ NO

If No was selected for any of the above, an explanation is required, including specifying any restrictions on the board in carrying out these authorities and functions:

_____

7. Based on your review of board minutes, board agendas, other relevant documents, and interviews conducted with the Project Director/CEO and board members, were there examples of how the board evaluates the performance of the health center based on quality assurance/quality improvement assessments and other information received from health center management?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

8. **If Yes:** Based on these performance evaluations, were there also examples of follow-up actions reported back to the board regarding:

   Note: *Only select "Not Applicable" for an item below if follow-up action was not necessary*.

   - Achievement of project objectives?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   - Service utilization patterns?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   - Quality of care?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   - Efficiency and effectiveness of the center?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   - Patient satisfaction, including addressing any patient grievances?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   If No OR Not Applicable was selected for any of the above, an explanation is required:

   _____

Element d: Adopting, Evaluating, and Updating Health Center Policies

The health center board has adopted, evaluated at least once every 3 years, and, as needed, approved updates to policies in the following areas: Sliding Fee Discount Program (SFDP), Quality Improvement/Assurance, and Billing and Collections.[8]

Site Visit Team Methodology

- Review board minutes from the past 3 years to confirm that the board has reviewed and, if needed, approved updates to the following policies:
  - SFDP;
  - Quality Improvement/Assurance Program; and
  - Billing and Collections (policy for waiving or reducing patient fees and, if applicable, refusal to pay).
- Interview same board members as previously identified regarding the board's evaluation of the health center's SFDP, quality improvement/assurance program, and billing and collections policies and any related updates.

Site Visit Findings

9. Within the last 3 years, has the board adopted or evaluated health center policies in the following areas:

   - SFDP?
     ☐ YES ☐ NO

   - Quality Improvement/Assurance Program?
     ☐ YES ☐ NO

   - Billing and Collections (policy for waiving or reducing patient fees and, if applicable, refusal to pay)?
     ☐ YES ☐ NO

   If No was selected for any of the above, an explanation is required:

   _____

10. Was the health center able to provide one to two examples, if applicable, of how it has modified or updated its policies as a result of these evaluations?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    If No OR Not Applicable, an explanation is required:

    _____

[8] Policies related to billing and collections that require board approval include those that address the waiving or reducing of amounts owed by patients due to inability to pay, and, if applicable, those that limit or deny services due to refusal to pay.

Element e: Adopting, Evaluating, and Updating Financial and Personnel Policies

The health center board has adopted, evaluated at least once every 3 years, and, as needed, approved updates to policies that support financial management and accounting systems and personnel policies. However, in cases where a public agency is the recipient of the Health Center Program federal award or designation and has established a co-applicant structure, the public agency may establish and retain the authority to adopt and approve policies that support financial management and accounting systems and personnel policies.

Site Visit Team Methodology

- Review board minutes from the past 3 years to confirm that the board has reviewed and, if needed, approved updates to the following policies:
  - Financial Management and Accounting Systems; and
  - Personnel.
- Interview same board members as previously identified regarding their process for evaluating financial management and accounting systems and personnel policies.
- Review the co-applicant agreement to determine if the public agency retains authority for adopting and approving personnel and financial management policies (if applicable; ONLY if conducting a site visit for a public agency health center with a co-applicant board).

Site Visit Findings

In responding to the question(s) below, please note:
The content and extent of a health center's financial management and personnel policies may vary. For example, some financial management policies may address procurement, but the lack thereof does not indicate non-compliance. Assessing compliance with respect to procurement procedures is addressed in Contracts and Subawards.

11. Within the last 3 years, has the board evaluated health center policies that support the following areas:

    - Financial management and accounting systems?
      ☐ YES ☐ NO ☐ NOT APPLICABLE

    - Personnel?
      ☐ YES ☐ NO ☐ NOT APPLICABLE

    Note: *For health centers where the public agency retains the authority to adopt and approve the policies listed, select "Not Applicable" for the above questions.*

    If No was selected for any of the above, an explanation is required:

    _____

BOARD COMPOSITION

Primary Reviewer: Governance/Administrative Expert
Secondary Reviewer: N/A

Authority: *Section 330(k)(3)(H) of the Public Health Service (PHS) Act; and 42 CFR 51c.304 and 42 CFR 56.304*

Related Considerations

Document Checklist for Health Center Staff

- ☐ Health center organization chart(s) with names of key management staff.
- ☐ Corporate organization chart(s) (only applicable for public agencies or for organizations with a parent or subsidiary).
- ☐ Updated Form 6A or Board Roster (if board composition has changed since last application submission to HRSA).
- ☐ Articles of Incorporation.
- ☐ Bylaws (if updated since last application submission to HRSA).
- ☐ Co-applicant agreement (if applicable) (if updated since last application submission to HRSA).
- ☐ Documentation regarding board member representation (for example, applications, bios, disclosure forms).
- ☐ Billing records from within the past 24 months to verify board member patient status.
- ☐ For health centers with approved waivers, examples of the use of special populations input (for example, board minutes, board meeting handouts, board packets).

Demonstrating Compliance

1. Is the health center operated by an Indian tribe, tribal group, or Indian organization under the Indian Self-Determination Act or an Urban Indian Organization under the Indian Health Care Improvement Act?[1]
   ☐ YES ☐ NO

   NOTE: IF "YES" WAS SELECTED, NONE OF THE QUESTIONS FOR ANY OF THE ELEMENTS IN THE BOARD COMPOSITION SECTION ARE APPLICABLE.

[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 [the Health Center Program Compliance Manual]. Section 330(k)(3)(H) of the PHS Act.

Element a: Board Member Selection and Removal Process

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,[2] including a majority of the non-patient board members.[3]

Site Visit Team Methodology

- Review organizational chart(s) (health center project and, if applicable, corporate), articles of incorporation, bylaws, or other relevant corporate or governing documents and co-applicant agreement (if applicable).

Note: *Bylaw provisions regarding composition are to be assessed for compliance with Health Center Program requirements as noted in the Health Center Program Compliance Manual and are not to be assessed beyond those requirements.*

Site Visit Findings

2. Do the bylaws or other documentation specify an ongoing selection and removal process for board members?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

3. Do the bylaws or other documentation confirm that the health center board selects or removes its own members without any limitations? Specifically, the health center board has no limitations in selecting or removing any of the following:

   - The board chair?
     ☐ YES ☐ NO
   - The majority of health center board members?
     ☐ YES ☐ NO
   - The majority of the non-patient board members?
     ☐ YES ☐ NO

   If No was selected for any of the above, an explanation is required describing how the health center board is limited in its board member selection or removal process:

   _____

[2] An outside entity may only remove a board member who has been selected by that entity as an organizational representative to the governing board.
[3] 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.

Element b: Required Board Composition

The health center has bylaws or other relevant documents that require the board to be composed[4] as follows:

- Board size is at least 9 and no more than 25 members,[5] with either a specific number or a range of board members prescribed;
- 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, 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;[6] and
- Health center employees[7,8,9] 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.

---

[4] For public agencies that elect to have a co-applicant, these board composition requirements apply to the co-applicant board.
[5] For the purposes of the Health Center Program, the term "board member" refers only to voting members of the board.
[6] Per the regulations in 42 CFR 56.304, for health centers awarded/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.
[7] For the purposes of health center board composition, an employee of the health center would include an individual who would be considered a "common-law employee" or "statutory employee" according to the Internal Revenue Service (IRS) criteria, as well as an individual who would be considered an employee for state or local law purposes.
[8] In the case of public agencies with co-applicant boards, this includes employees or immediate family members of either the co-applicant organization or the public agency component in which the Health Center Program project is located (for example, department, division, or sub-agency within the public agency).
[9] 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 (for example, transportation to board meetings, childcare during board meetings); or 2) wages lost by reason of participation in the

Site Visit Team Methodology

- Review the health center articles of incorporation, bylaws, or other relevant corporate or governing documents and co-applicant agreement (if applicable).

Site Visit Findings

4. Do the bylaws or other corporate or governing documentation include provisions that ensure:

   - Board size is at least 9 and no more than 25 members, with either a specific number or a range of board members prescribed?
     ☐ YES ☐ NO

   - At least 51 percent of board members are patients served by the health center?

     Note: *Select "Not Applicable" only if the health center has an approved waiver*.
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   - Patient members of the board, as a group, represent the individuals who are served by the health center in terms of demographic factors, such as race, ethnicity, and gender?
     ☐ YES ☐ NO

   - Non-patient members are representative of the community served by the health center or the health center's service area?
     ☐ YES ☐ NO

   - 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?
     ☐ YES ☐ NO

   - No more than one-half of non-patient board members derive more than 10 percent of their annual income from the health care industry?[10]
     ☐ YES ☐ NO

---

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 awarded/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 (for example, transportation to board meetings, childcare during board meetings); 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.

[10] Per the regulations in 42 CFR 56.304, for health centers awarded/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.

- Health center employees 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?
  ☐ YES ☐ NO

If No was selected for any of the above, an explanation is required:

_____

Element c: Current Board Composition

The health center has documentation that the board is composed of:

- At least 9 and no more than 25 members;
- A patient[11] majority (at least 51 percent);
- Patient board members, as a group, represent the individuals who are served by the health center in terms of demographic factors, such as race, ethnicity, and gender, consistent with the demographics reported in the health center's Uniform Data System (UDS) report;[12]
- Representative(s) from or for each of the special population(s)[13] for those health centers that receive any award/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.[14]

---

[11] 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.
[12] For health centers that have not yet made a UDS report, this would be assessed based on demographic data included in the health center's application.
[13] Representation could include advocates for the health center's section 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 set forth in the [Health Center Program Compliance Manual] Chapter 20: Board Composition.
[14] 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 percent of their income from the health care industry.

Site Visit Team Methodology

- Review UDS data for an overview of patient population demographic factors (race, ethnicity, and gender).
- Interview board members (concurrent with interviews for Board Authority requirements), including obtaining information as to how the board evaluates board membership in terms of representing patient population demographic factors consistent with the demographics reported in the health center's UDS report.
- Review current board roster or Form 6A.
- Review documentation regarding board member representation.
- Billing records to confirm the patient status of board members.
- Review background information on health center to confirm special populations funding or designation (if applicable).

Site Visit Findings

5. Is the health center board currently composed of at least 9 and no more than 25 members?
☐ YES ☐ NO

   If No, an explanation is required, including specifying the number of total board members:

   _____

6. Are at least 51 percent of health center board members classified by the health center as patients?

   Note: *Select "Not Applicable" only if the health center has an approved waiver.*
☐ YES ☐ NO ☐ NOT APPLICABLE

   If No, an explanation is required, including specifying the number of total board members and how many (if any) are current patients of the health center:

   _____

7. Were you able to confirm that individuals classified by the health center as patient board members have actually received at least one in-scope service at an in-scope site within the past 24 months that generated a health center visit?
☐ YES ☐ NO

   If No, an explanation is required:

   _____

8. **For health centers with special populations funding/designation**: Was the health center able to identify one or more board member(s) who serves as a representative from or for each of the health center's funded/designated special population(s) (individuals experiencing homelessness, migratory and seasonal agricultural workers, residents of public housing)?
☐ YES ☐ NO ☐ NOT APPLICABLE

   If No, an explanation is required:

   _____

9. Are patient board members as a group representative of the health center's patient population in terms of race, ethnicity, and gender consistent with the demographics reported in the health center's UDS report?

   Note: *Select "Not Applicable" only if the health center has an approved waiver.*
   ☐ YES ☐ NO ☐ NOT APPLICABLE

   If No, an explanation is required regarding why patient board members as a group are not representative of the health center's patient population and what efforts the health center has made to evaluate board composition and recruit representative patient board members based on the health center's UDS data:

   _____

10. For the health center's non-patient board members, do all such board members either live or work in the community where the health center is located?
    ☐ YES ☐ NO

    If No, an explanation is required describing whether board members who do not live or work in the community have a demonstrable connection(s) to the community and, if so, describing the connection(s) to the community:

    _____

11. Do the non-patient board members have relevant skills and expertise in a variety of areas that support the board's governance and oversight role (for example, community affairs, local government, finance, banking, legal affairs, trade unions, major local employers or businesses, social services)?
    ☐ YES ☐ NO

    If No, an explanation is required:

    _____

12. Do any non-patient board members earn more than 10 percent of their annual income from the health care industry?[15]

    Note: *The health center determines how to define "health care industry" and how to determine the percentage of annual income of each non-patient board member derived from the health care industry.*
    ☐ YES ☐ NO

    If Yes, an explanation is required that includes the number of non-patient board members who earn more than 10 percent of their annual income from the health care industry and the total number of non-patient board members:

    _____

[15] Per the regulations in 42 CFR 56.304, for health centers awarded/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.

Element d: Prohibited Board Members

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, or immediate family members of current health center employees (i.e., spouses, children, parents, or siblings through blood, adoption, or marriage).

Site Visit Team Methodology

- Interview board members (concurrent with interviews for Board Authority requirements).
- Review current board roster or Form 6A.
- Review documentation regarding board member representation.

Site Visit Findings

13. Has the health center verified that the current board does not include any members who are:

    - Employees of the health center?[16,17]
      ☐ YES ☐ NO

    - Immediate family members of current health center employees (i.e., spouses, children, parents, or siblings through blood, adoption, or marriage)?
      ☐ YES ☐ NO

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

    If No was selected for any of the above, an explanation is required:

    _____

Element e: Waiver Requests

In cases where a health center receives an award/designation under section 330(g), 330(h) and/or 330(i), does not receive an award/designation under section 330(e), and requests a waiver of the patient majority board composition requirements, the health center presents to HRSA for review and approval:

[16] For the purposes of health center board composition, an employee of the health center would include an individual who would be considered a "common-law employee" or "statutory employee" according to the IRS criteria, as well as an individual who would be considered an employee for state or local law purposes.
[17] In the case of public agencies with co-applicant boards, this includes employees or immediate family members of both the co-applicant organization and the public agency component (for example, department, division, or sub-agency) in which the Health Center Program project is located.

- *"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*
  - *Its attempt(s) to recruit a majority of special population board members within the past 3 years; 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;[18] setting hours of operation of health center sites;[19] defining budget priorities;[20] evaluating the organization's progress in meeting goals, including patient satisfaction;[21] and assessing the effectiveness of the sliding fee discount program (SFDP).[22]*

Site Visit Team Methodology

N/A – *HRSA assesses whether the health center has demonstrated compliance with this element through its review of the competing continuation application (Service Area Competition (SAC) or Renewal of Designation (RD)). No review of this element is required through the site visit.*

Site Visit Findings

N/A – *HRSA assesses whether the health center has demonstrated compliance with this element through its review of the competing continuation application (SAC or RD). No review of this element is required through the site visit.*

Element f: Utilization of Special Population Input

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, including but not limited to: selecting health center services; setting hours of operation of health center sites; defining budget priorities; evaluating the organization's progress in meeting goals, including patient satisfaction; and assessing the effectiveness of the SFDP.

---

[18] See [Health Center Program Compliance Manual] Chapter 4: Required and Additional Health Services for more information on providing services within the HRSA-approved scope of project.
[19] See [Health Center Program Compliance Manual] Chapter 6: Accessible Locations and Hours of Operation for more information on health center service sites and hours of operation.
[20] See [Health Center Program Compliance Manual] Chapter 17: Budget for more information on the Health Center Program project budget.
[21] See [Health Center Program Compliance Manual] Chapter 19: Board Authority for more information on the health center board's required authorities.
[22] See [Health Center Program Compliance Manual] Chapter 9: Sliding Fee Discount Program for more information on requirements for health center SFDPs.

Site Visit Team Methodology

- **For health centers with an approved waiver:** Review the health center's HRSA-approved waiver Form 6B.
- Review documented examples from the health center on the use of special populations input.
- Interview board members (concurrent with interviews for Board Authority requirements).

Site Visit Findings

14. **For health centers with approved waivers only:** Does the health center collect and document input from the special population(s)?

    Note: *Select "Not Applicable" only if the health center does not have an approved waiver.*
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    If No, an explanation is required:

    _____

15. Was the health center able to provide at least one example of how special population input has impacted board decision-making (for example, selecting health center services; setting hours of operation of health center sites; defining budget priorities; evaluating the organization's progress in meeting goals, including patient satisfaction; or assessing the effectiveness of the SFDP)?
    ☐ YES ☐ NO ☐ NOT APPLICABLE

    If No, an explanation is required:

    _____

FEDERAL TORT CLAIMS ACT (FTCA) DEEMING REQUIREMENTS

ONLY TO BE COMPLETED FOR HEALTH CENTERS THAT ARE CURRENTLY FTCA DEEMED

Primary Reviewer: Clinical Expert
Secondary Reviewer: N/A

NOTES:

- *Please find below observations regarding the review of FTCA requirements regarding Risk and Claims Management.*
- *The FTCA Program uses the site visit report to support programmatic decisions, including but not limited to FTCA deeming decisions, and to identify technical assistance needs for FTCA deemed health centers. In circumstances where the site visit report contains FTCA risk and claims management findings that require follow-up, the FTCA Program may develop and share a Corrective Action Plan (CAP) with the health center. HRSA expects the health center to respond to the CAP and address findings.*
- *Unresolved Health Center Program conditions related to Clinical Staffing and/or Quality Improvement/Assurance requirements that apply to both Health Center Program and FTCA deeming may impact FTCA deeming if they are not resolved by the time that HRSA makes annual FTCA deeming decisions.*
- *Health centers that have questions regarding the FTCA Program or FTCA deeming requirements may contact Health Center Program Support or call 1–877–464–4772.*

Authority: *Section 224(g)-(n), 224(q) of the Public Health Service (PHS) Act (42 U.S.C. 233(g)-(n) and (q)); and 42 CFR Part 6*

Document Checklist for Health Center Staff

- ☐ Risk management policy(ies) and related operating procedures or protocols (including but not limited to procedures for tracking referrals, diagnostics, and hospital admissions ordered by health center providers, incident reporting for clinically-related complaints, and "near misses").
  Note: *Health centers may have distinct "risk management" operating procedures OR these may be included or integrated within other health center operating procedures or protocols (for example, Human Resources, Quality Improvement/Quality Assurance, Admin, Clinical, Infection Control).*
- ☐ Claims management process policy(ies)/procedures.
- ☐ Most recent HRSA-approved FTCA deeming application.
- ☐ Risk management training plan and documentation of completed training.
- ☐ Example(s) of methods used to inform patients of the health center's deemed status (for example, website, promotional materials, statements posted within an area(s) of the health center visible to patients).
- ☐ Documentation (for example, board/committee minutes, supporting data, reports) of the last two quarterly risk management assessments of health center activities designed to

reduce the risk of adverse outcomes (for example, environment of care, incident tracking, infection control, patient safety) that could result in medical malpractice or other health or health-related litigation.

- ☐ Board meeting minutes and/or most recent report(s) (within past 12 months) to the board that include the status of risk management activities.
- ☐ For health centers with **closed** claims from within the past 5 years under the FTCA: For each **closed** claim, documentation of steps implemented to mitigate the risk of such claims in the future (for example, targeted staff training, improved records management, implementation of new clinical protocols).

Demonstrating Compliance

1. Is the health center currently deemed under the Health Center Federal Tort Claims Act (FTCA) Program?
   ☐ YES ☐ NO

   NOTE: IF "NO" WAS SELECTED, NONE OF THE QUESTIONS FOR ANY OF THE ELEMENTS IN THIS FTCA SECTION ARE APPLICABLE.

Risk Management

Element a: Risk Management Program

The health center has and currently implements an ongoing health care risk management program to reduce the risk of adverse outcomes that could result in medical malpractice or other health or health-related litigation and that requires the following:

- Risk management across the full range of health center health care 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 health center board which includes: 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.

Element b: Risk Management Procedures

The health center has risk management procedures that address the following areas for health center services and operations:

- Identifying and mitigating the health care areas/activities of highest risk within the health center's HRSA-approved scope of project, including but not limited to tracking referrals, diagnostics, and hospital admissions ordered by health center providers;
- 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 and infection control) and any non-clinical trainings appropriate for health center staff (including Health Insurance Portability and Accountability Act (HIPAA) medical record confidentiality requirements); and
- Completing an annual risk management report for the board and key management staff.

Element c: Reports on Risk Management Activities

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

Element d: Risk Management Training Plan

The health center has 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.

Element e: Individual who Oversees Risk Management

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

Site Visit Team Methodology

- Review risk management policy(ies), procedure(s), and/or protocol(s).
  Note: *Some health centers combine their Quality Improvement/Quality Assurance (QI/QA) policy(ies), procedure(s), protocol(s), or assessments with those used for risk management.*
- Review health care risk management training plan.
- Review training records to verify that appropriate staff, including all clinical staff, completed risk management training at least annually.
- Review documentation of last two quarterly risk management assessments that address one or more areas of risk.
- Review relevant board meeting minutes and most recent report(s) (within past 12 months) to the board on the status of risk management activities.
- Interview the health center individual(s) (for example, health center risk manager) who oversees and coordinates the health center's risk management activities on implementation of related policies, procedures, training, assessment, reporting, and follow-up actions.
- Interview other health center clinical leadership and individuals as necessary.

Site Visit Findings

2. Does the health center currently have an individual(s) (for example, a "risk manager") who oversees and coordinates the health center's risk management activities?
☐ YES ☐ NO

   If No, an explanation is required:

   _____

3. **If Yes:** Does this individual complete risk management training annually (for example, the risk manager takes and completes ECRI's risk management training modules 1, 2, and 3)?
☐ YES ☐ NO

   If No, an explanation is required, including stating what follow-up actions, if any, the health center has or will implement to assure that the individual(s) completes training:

   _____

4. Do the health center's risk management policies or procedures apply to all services and sites within the health center's scope of project?
☐ YES ☐ NO

   If No, an explanation is required:

   _____

5. How does the health center identify and mitigate areas/activities of highest patient safety risk? Describe if and how this informs or aligns with the health center's overall risk management program (for example, staff training, establishment of risk management goals, changes in clinical safety practices).
   An explanation is required, including one to two examples:

   _____

6. Was the health center able to provide examples of how it documents, analyzes, and addresses clinically-related complaints and "near misses" reported by health center employees, patients, and other individuals?
☐ YES ☐ NO

   If Yes OR No, an explanation is required, including describing the examples:

   _____

7. Was the health center able to produce documentation of its last two quarterly risk management assessments?
☐ YES ☐ NO

   If No, an explanation is required:

   _____

8. Was the health center able to provide a copy of a report on the status of risk management activities and progress in meeting risk management goals that was presented within the past 12 months to the board and key management staff?
☐ YES ☐ NO

   If No, an explanation is required:

   _____

9. What follow-up actions has the health center implemented based on its risk management assessments and its reporting to the board and key management staff?

   An explanation is required, including explaining the health center's reasoning if no related follow-up actions have been implemented:

   _____

10. Does the health center's training plan require risk management training for relevant clinical staff on obstetrical services?

   Notes:
   - *Health centers that do not directly provide obstetrical services such as labor and delivery (based on the health center's scope of project) but provide prenatal and postpartum care must provide relevant training to clinical staff.*
   - *Select "Not Applicable" if the health center provides all obstetrical services including prenatal and postpartum care to patients through direct referral to another provider.*

☐ YES ☐ NO ☐ NOT APPLICABLE

   If No, an explanation is required as to why such trainings are not included in the training plan:

   _____

11. Does the health center's training plan require risk management training for clinical staff on infection prevention and control for all departments?
☐ YES ☐ NO

   If No, an explanation is required:

   _____

12. Does the health center's training plan also require training for all relevant staff on HIPAA medical record confidentiality requirements?
☐ YES ☐ NO

   If No, an explanation is required:

   _____

13. Does the health center have documentation that all relevant staff completed training in accordance with the health center's annual risk management training plan?
☐ YES ☐ NO

If No, an explanation is required, including stating what follow-up actions, if any, the health center has or will implement to assure all relevant staff complete training:

_____

Claims Management

Element a: Claims Management Process

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
- 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.

Element b: Claims Activities Point-of-Contact

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.

Element c: Informing Patients of FTCA Deemed Status

The health center informs patients using plain language that it is a deemed federal PHS employee[1] via its website, promotional materials, and/or within an area(s) of the health center that is visible to patients.

Element d: History of Claims: Cooperation and Mitigation

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.

[1] For example: "This health center receives HHS funding and has federal PHS deemed status with respect to certain health or health-related claims, including medical malpractice claims, for itself and its covered individuals." For more information, visit the Federal Tort Claims Act (FTCA) website.

Site Visit Team Methodology

- Interview designated individual(s) responsible for claims management.
- Review claims management process policy(ies)/procedures.
- Review claims management and claims history section of the FTCA application.
- Review example(s) of language used to inform patients that the health center is a deemed federal PHS employee.
- For health centers with **closed** claims from within the past 5 years under the FTCA: Review for each **closed** claim documentation of steps implemented to mitigate the risk of such claims in the future.

Site Visit Findings

14. Does the health center currently have an individual(s) who is responsible for the management and processing of claims-related activities and who serves as the claims point of contact?
☐ YES ☐ NO

    If No, an explanation is required:

    _____

15. Was the health center able to describe how it has (if health center has a history of claims under FTCA) or would (if no claims history) manage health or health-related claims? Specifically, was the health center able to demonstrate how it has or would:

    - Preserve claims-related documentation (for example, medical records and associated laboratory and x-ray results, billing records, employment and scheduling records of all involved clinical providers, clinic operating procedures); and
    - Promptly communicate with HHS Office of the General Counsel, General Law Division regarding any actual or potential claim or complaint?

    ☐ YES ☐ NO

    If No, an explanation is required:

    _____

16. Does the health center inform patients (using plain language) that it is a deemed federal PHS employee via its website, promotional materials, and/or within an area(s) of the health center that is visible to patients?
☐ YES ☐ NO

    If No, an explanation is required:

    _____

17. **For health centers with a history of closed claims under the FTCA within the past 5 years:** For each **closed** claim, what steps has the health center implemented to mitigate the risk of such claim in the future?
☐ NOT APPLICABLE

    An explanation is required:

    _____

PROMISING PRACTICES

Primary Reviewer: Based on Promising Practice identified
Secondary Reviewer: Optional

Authority: *45 CFR 75.301*

Overview

A promising practice refers to an activity, procedure, approach, or policy that leads to, or is likely to lead to, improved outcomes or increased efficiency for health centers. The site visit team will use this section of the report to document any promising practices observed during the course of the site visit. **No more than two promising practices can be listed for each visit and the site visit team should closely follow the guidance below in determining whether anything rises to the level of a promising practice.**

Promising Practices may be identified in one or more of the following:

- Health Center Program requirement areas;
- Health center clinical performance;
- Medical, oral, and behavioral health care and/or enabling service or the integration of these services to meet the needs of the health center's target population; or
- Health center administration and operations (for example, staff recruitment/education).

HRSA collects these promising practices to share externally with others (for example, via BPHC website, other health centers, and technical assistance partners).

Site Visit Team Methodology

- If a promising practice is identified, assign it to one of three major categories: 1) Clinical Services, 2) Governance, or 3) Management and Finance.
    - If applicable, select a subcategory to classify the Promising Practice type further.
    - More than one subcategory and item may be linked to the Promising Practice. Examples of subcategories include:
        - Behavioral Health - Mental Health
        - Preventive Health - Cancer Screening
        - Business Operations - Patient Cycle Time
- Description of a promising practice should include the following four components:
    - **Context section**: Clearly describe the health center's innovation, challenge, or issue.
    - **Description section**: Describe the practice that the health center implemented in seeking a solution to the challenge or issue.
    - **Outcome section**: Describe the result, including the quantitative and/or qualitative data that the health center used in determining the effectiveness of their practice.
    - **Implementation section**: State how this practice can be implemented in other health centers. Please list any special needs or costs associated with this activity.

What were the required elements for the health center's successful implementation (for example, board approval, policy, funding, collaborative partners and resources, facility, transportation, community acceptance)?

- Complete the **Permission to Share** and **Point of Contact** sections. Complete the Relevant Documentation section.

Site Visit Findings

1. Were any promising practices identified as part of this site visit?
   ☐ YES ☐ NO

2. If yes, select the most appropriate category for this promising practice: Clinical Services, Governance, or Management and Finance. Then select all subcategory elements that apply.

   _____

3. **Context:** Clearly describe the health center's innovation, challenge, or issue.

   _____

4. **Description:** In detail, describe the practice implemented.

   _____

5. **Outcome:** Use quantitative and/or qualitative data to show how the practice was effective.

   _____

6. **Implementation section**: State how this practice can be implemented in other health centers. Please list any special needs or costs associated with this activity. What were the required elements for the health center's successful implementation (for example, board approval, policy, funding, collaborative partners and resources, facility, transportation, community acceptance)?

   _____

7. Did the health center consent to share this practice with others (for example, via BPHC website, other health centers, and technical assistance partners)?
   ☐ YES ☐ NO

8. Please provide the name, phone number, and email address for the staff person who should be reached for further information.

   _____

9. List any relevant documentation related to the promising practice (for example, policy, forms, patient education handout).

   _____

ELIGIBILITY REQUIREMENTS FOR LOOK-ALIKE INITIAL DESIGNATION APPLICANTS

Primary Reviewer: Governance/Administrative Expert
Secondary Reviewer: N/A

Authority: *Sections 1861(aa)(4)(b) and 1905(l)(2)(B) of the Social Security Act.*

Health Center Program Look-Alike (LAL) Initial Designation (ID) Application Instructions & Resources

Document Checklist for Health Center Staff

- ☐ Most recent annual audit and management letters or audited financial statements (if audits are not available).
- ☐ Health center organization chart(s) with names of key management staff.
- ☐ Corporate organization chart(s) (only applicable for public agencies or for organizations with a parent or subsidiary).
- ☐ Agreements with parent corporation, affiliate, subsidiary or other controlling organization (if applicable).
- ☐ Documentation (for example, employment contracts) that demonstrates the organization is not owned, operated, or controlled by another entity.
- ☐ Most recent co-applicant agreement (if applicable).
- ☐ If the applicant has contracts that support the proposed Health Center Program scope of project (i.e., to provide health center services or to acquire other goods and services), provide a complete list of these contracts. Include all active contracts and all contracts that had a period of performance which ended less than 3 years ago. In the list, include all of the following information for each contract:
    - Contractor/contract organization;
    - Brief description of the good(s) or service(s) provided;
    - Period of performance/timeframe (for example, ongoing contractual relationship, specific duration); and
    - Whether the contract constitutes substantive programmatic work[1] (i.e., contracting with a single entity for the majority of health care providers).
- ☐ Contracts for substantive programmatic work.
- ☐ Position description for the Project Director/CEO.

[1] For the purposes of the Health Center Program, contracting for substantive programmatic work applies to contracting with a single entity for the majority of health care providers. The acquisition of supplies, material, equipment, or general support services is not considered programmatic work. Substantive programmatic work may be further defined within HRSA Notices of Funding Opportunity (NOFOs) and applications.

- ☐ Patient Services Utilization Report (for example, from the Electronic Health Records (EHR)) from within the past 6 months. Data should include patient demographics, type of services, and how the service was provided (Column I, II, or III).
- ☐ Health center selection of three to five health center patient records[2] (for example, using live navigation of the EHR, screenshots from the EHR, or actual records if the records are not electronic/EHR records) that document the provision of various required and additional health services.
- ☐ Sample of up to three Medicare or Medicaid claims or other billing documents that demonstrate under what organizational entity or unit billing is conducted.
- ☐ Project Director/CEO employment agreement.

Eligibility Requirements

1. Is this a Look-Alike Initial Designation Site Visit?
   ☐ YES ☐ NO

   NOTE: IF "NO" WAS SELECTED, NONE OF THE QUESTIONS IN THIS LOOK-ALIKE INITIAL DESIGNATION SECTION ARE APPLICABLE.

Primary Care Operational Status of Look-Alike Applicant Organization

An organization applying for look-alike designation must demonstrate to HRSA that it is currently delivering primary health care services to patients within the proposed service area.

Site Visit Team Methodology

- Confirm that applicant is currently delivering primary care services through the tour of service delivery sites (one or more sites as listed on Form 5B) and the review of patient services utilization report; and
- Review selection of three to five health center patient records (either using live navigation of the Electronic Health Records (EHR), screenshots from EHR, or actual records if the records are not electronic/EHR records) that document the provision of various required and additional health services.

Site Visit Findings

2. Is the applicant **currently delivering primary health care services** to patients within the proposed service area?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

[2] Health centers may choose to provide samples of patient records prior to or during the site visit. If patient records will be provided during the site visit, this should be communicated prior to the site visit to avoid any disruption or delay in the site visit process.

3. Does the health center have at least one permanent service delivery site that:

   - Provides comprehensive primary medical care as the site's main purpose?
     ☐ YES ☐ NO

   - Operates for a minimum of 40 hours per week (with the exception of a health center serving only migratory and seasonal agricultural workers, for which the health center may have a full-time seasonal rather than permanent site)?
     ☐ YES ☐ NO ☐ NOT APPLICABLE

   Notes:
   - *A permanent site is a fixed location that operates year-round.*
   - *Only select "Not Applicable" if the health center is applying for designation to serve only migratory and seasonal agricultural workers.*

   If No was selected for any of the above, an explanation is required:

   _____

4. **If Not Applicable**: Does the health center serving only migratory and seasonal agricultural workers have at least one full-time seasonal service delivery site?
   ☐ YES ☐ NO

   If No was selected, an explanation is required:

   _____

Ownership and Control of Look-Alike Applicant Organization

An organization applying for look-alike designation must demonstrate to HRSA that it is not owned, controlled, or operated by another entity. Specifically, the organization applying for look-alike designation:

- **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 as a Federally Qualified Health Center (FQHC) are distributed to the Health Center Program project (for example, FQHC payment rates, 340B Drug Pricing); and
- **Operates** the Health Center Program project. At a minimum, the look-alike applicant organization demonstrates that it maintains a Project Director/CEO who will carry out independent, day-to-day oversight of health center activities solely on behalf of the applicant organization's governing board.

Site Visit Team Methodology

- Review applicant's current organization chart(s).
- Review Project Director/CEO position description and employment agreement.
- Interview Project Director/CEO.

- Interview CFO/financial staff of the applicant organization and board members (for example, board chair, board treasurer) regarding ownership and operation of the applicant organization.
- Review most recent annual audit and management letters or audited financial statements of the applicant organization.
- Review Medicare or Medicaid claims or other billing documents that demonstrate under what organizational entity or unit billing is conducted.
- Review bylaws of applicant organization, and if applicable, the co-applicant agreement for public agency applicants with a co-applicant governing board.
- Review complete list of contracts to identify those that support substantive programmatic work.
- Review contracts for substantive programmatic work (if applicable).
- Review any documents related to the applicant's parent company, affiliate, subsidiary or other controlling organization that has a substantial role in the operations of the applicant organization (if applicable).
- Review any additional documentation (for example, employment contracts) that demonstrates the organization is not owned, operated, or controlled by another entity.
- Interview key management or other health center staff involved in procurement or contract oversight.

Site Visit Findings

5. Was the applicant (i.e., the organization applying for look-alike designation) able to document that the applicant currently **owns and controls the organization's assets and liabilities** (for example, the applicant organization does not have a sole corporate member, is not a subsidiary of another organization)?
   ☐ YES ☐ NO

   If Yes OR No, an explanation is required specifying how the assets and liabilities of the applicant organization are owned and controlled:

   _____

6. Does the applicant have safeguards in place to ensure the benefits that accrue through look-alike designation as a FQHC (for example, FQHC payment rates, 340B Drug Pricing Program eligibility) will only be distributed to the Health Center Program project?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

7. Was the applicant (i.e., the organization applying for look-alike designation) able to document that it operates the Health Center Program project (i.e., the services and activities included in the look-alike application)?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

8. Does the look-alike applicant organization have a Project Director/CEO in place who carries out independent, day-to-day oversight of health center activities (i.e., the services and activities included in the look-alike application), solely on behalf of the governing board of the applicant organization?
   ☐ YES ☐ NO

   If No, an explanation is required:

   _____

9. Does the health center contract for substantive programmatic work?
   ☐ YES ☐ NO

   If Yes OR No, an explanation is required. **If Yes**: Specifically describe how the applicant will still perform a substantive role in the Health Center Program project. **If No**: Describe whether there are any other contractual or organizational arrangements that prohibit or impede the applicant from performing a substantive role in the Health Center Program project:

   _____