Health Center Program
Site Visit Protocol

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Introduction

Purpose

The purpose of Health Resources and Services Administration (HRSA) site visits[1] is to support effective monitoring of the Health Center Program. Operational Site Visits (OSVs) provide an objective assessment to verify 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 the eligibility and compliance of look-alike initial designation applicants for 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") to determine 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 based on the Compliance Manual and is the tool for assessing compliance with Health Center Program requirements during OSVs and look-alike initial designation (ID) site visits. The SVP uses standard and transparent methodologies to provide HRSA with information to monitor health center compliance.

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

HRSA conducts OSVs at least once per period of performance. For health centers with a 1-year period of performance, the OSV will take place 2–4 months into the period of performance. For health centers with a 3-year period of performance, the OSV will take place 12–16 months into the period of performance.

Health centers should use the Compliance Manual, the SVP, and other site visit resources to prepare for site visits and to regularly assess and ensure ongoing compliance with the Health Center Program.

For answers to frequently asked questions (FAQs) and resources to help health centers prepare for site visits, visit [Site Visit Resources](#).

Site Visit Report and Compliance Determinations

HRSA shares the site visit report with the health center within 45 days after the 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 one or more conditions on the health center's award or 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. 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 about the FTCA Program or FTCA deeming requirements may use the BPHC Contact Form or call 1–877–464–4772.

Health centers and look-alike initial designation applicants should review the site visit report and the Compliance Manual for guidance on resolving non-compliance findings,[3] and may contact their assigned HRSA Program Specialist or use the BPHC Contact Form for additional information or assistance.

Site Visit Protocol Structure

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

Each section of the SVP is structured as follows:

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

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

- ***Documents the Health Center Provides*:** The list of documents a health center provides to the site visit team before the site visit.[4] Documents are to be provided **at least 2 weeks before the start of the site visit.**[5] HRSA may provide additional guidance before the site visit about visit 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 HRSA site visit team is unable to assess a Health Center Program requirement using the health center's sample, the team may complete additional sampling in coordination with the health center.
    - Certain commonly used abbreviations throughout the SVP include:
        - "Form 5A: Services Provided (PDF)" abbreviated as "Form 5A."
        - "Form 5B: Service Sites (PDF)" abbreviated as "Form 5B."

- The three columns on Form 5A related to [service delivery methods](#) (PDF):
  - "Column I, Direct (Health Center Pays)" abbreviated as "Column I."
  - "Column II, Formal Written Contract/Agreement (Health Center Pays)" abbreviated as "Column II."
  - "Column III, Formal Written Referral Arrangement (Health Center Does NOT Pay)" abbreviated as "Column III."
  - **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.**

- *Compliance Assessment***:**

  - *Demonstrating Compliance Elements:* Elements from the Compliance Manual that describe how health centers would demonstrate their compliance with the applicable Health Center Program requirements.[6]

  - *Site Visit Team Methodology***:** Methods the site visit team uses to assess compliance. Methods include but are not limited to reviews of policies and procedures, samples of files and records, site tours, and interviews.[7] 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***:** Questions, based on the related methodologies, answered by the site visit team to document its compliance assessment. HRSA uses these responses, which are included in the health center's site visit report, to determine the health center's compliance with Health Center Program requirements.

Footnotes

[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."

[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] 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.

[4] 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 consultants sign additional

confidentiality statements, this should be communicated to HRSA and the site visit team before the site visit to avoid any disruption or delay in the site visit process.

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

[6] 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).

[7] 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)*

[Health Center Program Compliance Manual Related Considerations](#)

Documents the Health Center Provides

Checklist

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

Compliance Assessment

Select each element below for the corresponding text of the element, site visit team methodology, and site visit finding questions.

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 does not assess health center compliance with the portion of element "a" in brackets during the site visit. HRSA assesses compliance with the portion of element "a" in brackets during its review of the health center's competing continuation application (Service Area Competition (SAC) or Renewal of Designation (RD)).

Site Visit Team Methodology

- Interview Project Director/CEO and other key management staff about the health center's service area analysis process.
- Review the service area reports or analysis documentation.
- Review the health center's Form 5B.

Site Visit Findings

1. **Does the health center use patient origin data from its most recent UDS report when recording or updating ZIP codes on its Form 5B site entries?**

   Response is either: Yes or 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: *A health center's annual service area review may be conducted in a number of ways; for example, as part of a competitive application or as a separate activity during the year, such as review of annual UDS patient origin data or other data on where patients reside.*

   Response is either: Yes or 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
- 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 the most recent needs assessment and documentation (for example, studies, resources, reports) used to develop the needs assessment.
- If the health center is part of a larger organization (for example, a health department, mental health, or social service agency), review whether the needs assessment provides data that are relevant to the Health Center Program project and specific enough to inform the delivery of health center services.

- Interview Project Director/CEO and other key management staff about how the health center uses the needs assessment.

Site Visit Findings

3. **Does the health center complete or update a needs assessment of the current population at least once every 3 years?**

   Response is either: Yes or 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?**

   Response is either: Yes or No

   If No, an explanation is required.

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

   o **Factors associated with access to care and health care utilization (for example, geography, transportation, occupation, transience, unemployment, income level, educational attainment);**
   o **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**
   o **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).**

   Response is either: Yes or No

   If No, an explanation is required.

6. **Did the health center provide at least one example of how it used the results of its needs assessment to inform and improve the delivery of health center services?**

   Response is either: Yes or No

   If No, an explanation is required.

Footnotes

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

[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.

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)*

[Health Center Program Compliance Manual Related Considerations](#)

Documents the Health Center Provides

Checklist

- Sample of key health center documents translated for patients with limited English proficiency (for example, forms and materials used to assess eligibility for the health center's sliding fee discount program, intake forms for clinical services, instructions for accessing after-hours services).
- **FORM 5A, COLUMN I:**
  - For services delivered via **Column I** of the health center's current Form 5A:
    - A list of Form 5B service sites to be toured. Select sites where a variety of **Column I** services are provided.
    - If the health center has more than one service site, the list must include at least two health center service sites.
  - If a **Column I** service cannot be verified through a site tour: Documentation of service provision in a current patient record.[1]
    Note: *Use live navigation of the Electronic Health Record (EHR), screenshots from the EHR, or other patient record formats.*
- **FORM 5A, COLUMN II:** For services delivered via **Column II (whether or not the service is also delivered via Column I and/or Column III):**
  - For health centers with **Column II** services that occur at any locations that are not Form 5B service sites: Health center internal procedures that address how information in patient health center records is documented (for example, lab results, x-ray results).
  - *Contracts/Agreements:*
    - **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, at least one written contract. If there is more than one contract for the same service, each contract would be included in the sample, up to a maximum of three contracts. For example:
      - Primary Care Services is listed in **Column II**. The health center maintains four separate contracts for individual contracted providers. The sample would 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 would include one contract for Preventive Dental.
    - 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: *Use the same sample of contracts/agreements 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](#), even though they may result in some overlap in the contracts/agreements reviewed.*

  o *Patient Records:*
    - Based on three Required Services and two Additional Services: A total of three to five health center patient records for patients who have received required and additional health services in the past 24 months from contracted providers or contracted organizations.
        - If the same patient has received more than one of these services, the same record can be used for assessing those services.
        - If a health center delivers services through subrecipient agreements:
            - For a health center with five or fewer subrecipients, select a total of three to five patient records from each subrecipient.
            - For a health center with more than five subrecipients, select patient records from the five subrecipients that receive the largest amounts of Health Center Program subaward funds, for a total of three to five patient records from each subrecipient.

  Notes:
    - For **Column II** Services provided by individual contractors who work at a health center Form 5B site, documentation in the patient record of the services provided would occur in the health center's own patient record system.
    - Use live navigation of the EHR, screenshots from the EHR, or other patient record formats.
- **FORM 5A, COLUMN III:** For services delivered via **Column III (whether or not the service is also delivered via Column I and/or Column II):**
  o For health centers with **Column III** services: Health center operating procedures for tracking and managing referred services.
  o *Referral Arrangements:*
    - 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 III** service on Form 5A, at least one written referral arrangement. If there is more than one referral arrangement for the same service, each written arrangement would 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 its service area. The sample would 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 would include one written arrangement for Diagnostic Laboratory Services.
- 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 procedures) that contain those provisions.

  Note: *Use the same sample of referral arrangements for the review of Required and Additional Health Services, Clinical Staffing, and Sliding Fee Discount Program.*
  - *Patient Records:*
    - Based on three Required Services and two Additional Services: A total of three to five health center patient records for patients who have received required and additional services in the past 24 months from referral providers or referral organizations. 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.
      - If the same patient has received more than one of these services, the same record can be used for assessing those services.

    Note: *Use live navigation of the EHR, screenshots from the EHR, or other patient record formats.*

Note: *Refer to the Sampling Review Resource Guide to help select the samples for Required and Additional Health Services.*

Compliance Assessment

Select each element below for the corresponding text of the element, site visit team methodology, and site visit finding questions.

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 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:

- o How the service will be documented in the patient's health center record; and
- o 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:
  - o The manner by which referrals will be made and managed; and
  - o 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

- Along with the Project Director/CEO and other relevant staff, review the accuracy of the health center's Form 5A.
- Interview CMO and other clinical staff responsible for all service delivery methods (Columns I, II, and III).
- Tour sites where a variety of services are provided directly by the health center (**Column I**). If the health center has more than one service site, tour at least two service sites.
- **FORM 5A, COLUMN I:** Confirm that each service delivered via **Column I** is being directly provided by the health center through:
  - o The tours of the health center service sites;
  - o Interviews of clinical staff during the site tours; or
  - o If a **Column I** service cannot be verified through the site tour or interviews, review of at least one health center **Column I** patient record.
- **FORM 5A, COLUMN II:** For any service delivered via **Column II (whether or not the service is also delivered via Column I and/or Column III)**:
  - o For any contracted service that occurs at a location other than a health center Form 5B site (for example, lab results, x-ray results), review the health center's internal procedures that address documentation of information in the patient's health center record.
  - o *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 would be included in the sample, up to a maximum of three contracts. For example:
      - ▪ Primary Care Services is listed in **Column II**. The health center maintains four separate contracts for individual contracted providers. The sample

would 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 would include one contract for Preventive Dental.

- o *Review of Patient Records:*
  - Based on three Required Services and two Additional Services: Review a total of three to five health center patient records for patients who have received these services in the past 24 months from contracted providers or contracted organizations.
    - If the same patient has received more than one of these services, the same record can be used for assessing those services.
  - If a health center delivers services through subrecipient agreements:
    - For a health center with five or fewer subrecipients, review a total of three to five patient records from each subrecipient.
    - For a health center with more than five subrecipients, select patient records from the five subrecipients that receive the largest amounts of Health Center Program subaward funds. Review a total of three to five patient records from each subrecipient.

  Note: *For **Column II** Services provided by individual contractors who work at a health center Form 5B site, documentation in the patient record of the services provided would occur in the health center's own patient record system.*

- **FORM 5A, COLUMN III:** For any service delivered via **Column III (whether or not the service is also delivered via Column I and/or Column II)**:
  - o Review the health center's operating procedures for tracking and managing referred services.
  - o *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 III** service on Form 5A, review at least one written referral arrangement. If there is more than one referral arrangement for the same service, each written arrangement would 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 would 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 would include one written arrangement for Diagnostic Laboratory Services.
  - o *Review of Patient Records:*
    - Based on three Required Services and two Additional Services: Review a total of three to five health center patient records for patients who have received these services in the past 24 months from referral providers or referral organizations.
      - If the same patient has received more than one of these services, the same record can be used for assessing those services.

Notes:

- Use the same sample of contracts/agreements and referral arrangements 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, even though they may result in some overlap in the contracts/agreements reviewed.
- The purpose of this part of the site visit is to validate that the health center has an accurate Form 5A that reflects how the health center currently provides in-scope services.
- The sample provided by the health center would reflect the services the health center is currently providing.
- Use live navigation of the Electronic Health Record (EHR), screenshots from the EHR, or other patient record formats.
- If 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 Form 5A), the site visit team will still proceed with reviewing the sample and note the discrepancies in their site visit findings. This includes noting if any services in the sample are conducted outside the scope of project and are other lines of business.
- When reviewing the contracts or referral arrangements for enabling services (for example, transportation, translation, outreach) provided via **Column II or III**, compliance is demonstrated even if the 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).
- In the Sliding Fee Discount Program (SFDP) section, assess and document any findings on the structure or availability of a health center's SFDP as it relates to the services on Form 5A. For example, the health center is providing an additional service directly, but the service is NOT discounted through the health center's SFDP.
- Review the follow-up from hospital admissions or hospital visits in the Continuity of Care and Hospital Admitting section.

Site Visit Findings

1. **Considering all services on Form 5A across all Columns, are services recorded on Form 5A consistent with how they are offered by the health center?**

   Response is either: Yes or No

2. **IF NO: Did the health center submit Change in Scope requests to HRSA to correct all Form 5A inconsistencies?**

   Response is either: Yes or No

   If Yes OR No, specify the inconsistencies observed and whether the relevant Change in Scope requests were submitted to HRSA to correct the accuracy of Form 5A.

3. **FORM 5A, COLUMN I: Is the health center directly providing all services on its current Form 5A, Column I?**

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

   Response is: Yes, No, or Not Applicable

   If No, an explanation is required, including specifying any inconsistencies between services provided directly by the health center and those recorded on Form 5A, Column I.

4. **FORM 5A, COLUMN II:**

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

   4.1 **Does the health center maintain formal written contracts/agreements for services on its current Form 5A, Column II?**

   Response is: Yes, No, or Not Applicable

   4.2 **Do the health center's contracts/agreements document how the health center will pay for the services?**

   Response is: Yes, No, or Not Applicable

   4.3 **Do the health center's contracts/agreements or supporting internal procedures document how information about the services will be provided to the health center for inclusion in health center patient records?**

   Response is: Yes, No, or Not Applicable

   4.4 **Did the health center provide patient records from the past 24 months that document receipt of specific contracted services?**

   Response is: Yes, No, or Not Applicable

   If No OR Not Applicable was selected for any of the above, an explanation is required providing details on the specific services.

5. **FORM 5A, COLUMN III:**

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

   5.1 **Does the health center maintain formal written referral arrangements for services on its current Form 5A, Column III?**

   Response is: Yes, No, or Not Applicable

5.2 **Do the health center's formal written referral arrangements or other documentation (for example, health center procedures) include provisions that address:**

- **How 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)?**

Response is: Yes, No, or Not Applicable

5.3 **Do the health center patient records include information from these referrals (for example, lab results) and appropriate follow-up care?**

Response is: Yes, No, or Not Applicable

If No OR Not Applicable was selected for any of the above, an explanation is required providing details on the specific services.

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 the Uniform Data System (UDS) patient demographic data.
- Review the sample of translated health center documents.
- Review access to interpretation services (for example, on-site interpreters, contracts for interpretation services).
- Interview health center clinical leadership and providers about 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?**

Response is either: Yes or No

If No, an explanation is required.

7. **Did the health center provide examples of key documents currently in use that are translated into different languages for its patient population and that enable patients to access health center services?**

    Response is either: Yes or 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 the UDS patient demographic data.
- Review the sample of translated health center documents.
- Review access to interpretation services (for example, on-site interpreters, contracts for interpretation services).
- Interview health center clinical leadership and relevant staff about 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. **Did the health center 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)?**

    Response is either: Yes or No

    If No, an explanation is required.

Footnotes

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

[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 for further details, including the Form 5A Service Descriptors (PDF) 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 uses 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 (PDF). 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 uses 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 (PDF) for information about eligibility for FTCA coverage for covered activities by 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 (PDF).

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)

Health Center Program Compliance Manual Related Considerations

Documents the Health Center Provides

Checklist

- Credentialing and privileging procedures for licensed independent practitioners (LIP), other licensed or certified practitioners (OLCP), or other clinical staff.
  Note: *Credentialing and privileging procedures may be included in Human Resource procedures.*
- If the health center has a website: The website URL.
- Most recent needs assessment.
- Current clinical staffing profile that lists:
  - Name,
  - Position,
  - FTE,
  - Credential (for example, RN, MD),
  - Hire date,
  - Provider type: LIP, OLCP, or other clinical staff (for example, non-certified medical/dental assistants, community health representatives, case managers),
  - Staff who are bilingual or multilingual.
- Files for current clinical staff that contain credentialing and privileging information: four to five LIP files; four to five OLCP files; and, if the health center has other clinical staff, two to three files for those other clinical staff. For the selected files, include:
  - Representation from different clinical disciplines and service sites.
  - Employees, contractors, and volunteers.
  - Providers who do procedures beyond core privileges for their clinical disciplines.
  - Providers who have been initially credentialed.
  - Providers who have been re-credentialed/re-privileged.
- Any contracts or agreements with outside entities, such as Credentialing Verification Organizations (CVOs), that perform credentialing functions (such as primary source verification).
- If clinical services are provided via **Column II or III**:
  - **No more than three** written contracts/agreements with provider organizations. Prioritize contracts for any clinical services that are only offered via **Column II**.
  - **No more than three** written referral arrangements. Prioritize referral arrangements for any clinical services that are only offered via **Column III**.
  - Any additional documentation showing the health center has ensured credentialing and privileging of the contracted and referral providers. For example, documentation showing 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.

Notes:
- Select contracts and referral arrangements 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.
- Use the same sample of contracts/agreements and referral arrangements 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, even though they may result in some overlap in the contracts/agreements reviewed.

Compliance Assessment

Select each element below for the corresponding text of the element, site visit team methodology, and site visit finding questions.

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, or equivalent health center leadership about scope of services, current clinical staffing, and recruitment and retention processes.
- Tour at least one to two health center sites where a variety of **Column** I services are provided.
- Review the current clinical staffing profile.
- Review the 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 staffing for services provided via contracts/agreements and written referral arrangements.

Site Visit Findings

1. **Does the health center's current clinical staffing makeup (such as employees, volunteers, contracted and referral providers) enable it to carry out the approved scope of project on Form 5A?**

   Response is either: Yes or No

If No, an explanation is required specifying why staffing is insufficient and for which services.

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 other clinical leadership (for example, Dental Director, Pharmacy Director) about how the number and mix of clinical staff support patient access.
- Review the health center's most recent needs assessment and Uniform Data System (UDS) Summary Report. Specifically review the 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 tours, and interviews with clinical leadership).

Site Visit Findings

2. **Did the health center provide one to two examples of how the mix (for example, pediatric and adult providers) and number (for example, full or part time staff, contracted providers) of clinical staff are responsive to the size, demographics, and needs of its patient population?**

   Response is either: Yes or No

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

3. **Based on the health center's most recent UDS, is the number and mix of current staff (considering all sites and all service delivery methods) sufficient to ensure reasonable patient access to health center services?**

   Response is either: Yes or 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 for LIPs, OLCPs, and other clinical staff.
  Note: *Credentialing and privileging procedures may be included in Human Resource procedures.*
- Review any contracts or agreements the health center has with outside entities, such as CVOs, that perform credentialing functions (such as primary source verification).
- Interview the individuals 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
    - A state licensing body that conducts primary source verification of education and training for LIPs.
  - The health center's methods for tracking timelines for re-credentialing staff, including renewal of licensure and any required DEA registration.

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 what sources to use for verification of education and training.
- In states in which the licensing agency, specialty board, or registry conducts primary source verification of education and training, the health center may use the state's primary verification of state licensure or board certification as 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*:**

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

   4.1 **Clinical staff member's identity using a government-issued picture identification?**

   Response is either: Yes or No

   4.2 **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?**

   Response is either: Yes or No

   4.3 **Verification of the education and training of OLCPs and, as applicable, other clinical staff using a primary or secondary source, as determined by the health center?**

   Response is either: Yes or No

   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*:**

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

   5.1 **Current licensure, registration, or certification using a primary source for LIPs and OLCPs?**

   Response is either: Yes or No

   5.2 **Completion of a query through the NPDB?**

   Response is either: Yes or No

   5.3 **DEA registration, as applicable?**

   Response is either: Yes or No

   5.4 **Current documentation of basic life support training or comparable training completed through licensure or certification?**

   Response is either: Yes or No

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 for LIPs, OLCPs, and other clinical staff.
  Note: *Credentialing and privileging procedures may be included in Human Resource procedures.*
- Interview the individual or committee that completes or has approval authority for privileging of clinical staff to determine:
  - o How fitness for duty, immunization, and communicable disease status are verified;
  - o How clinical competence is assessed for initial granting of privileges;
  - o How clinical competence is assessed for renewal of clinical privileges; and
  - o 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?**

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

   Response is either: Yes or No

   If No, an explanation is required.

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.*

   Response is either: Yes or 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*:**

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

   8.1 **Immunization and communicable disease status?**

   Response is either: Yes or No

   8.2 **Current clinical competence?**

   Response is either: Yes or No

   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?**

   Response is either: Yes or 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 about credentialing and privileging records.

- Review the sample of files for current clinical staff that contain credentialing and privileging information (as defined by the health center in its operating procedures).
- Conduct the review of the file sample together with the health center individuals responsible for maintaining credentialing and privileging documentation.

Note: *Please use the [Examples of Credentialing and Privileging Documentation](#) resource for common documentation methods and sources.*

Site Visit Findings

10. **Based on the review of the sample of current clinical staff files, do 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)?**

    Response is either: Yes or No

    If No, an explanation is required.

11. **Based on the review of the sample of current clinical staff files, do 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)?**

    Response is either: Yes or 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 about credentialing and privileging processes for contracted or

referral providers.
- Review **no more than three** contracts with provider organizations. Prioritize the review of any clinical services that are only offered via **Column II**.
- Review **no more than three** written referral arrangements. Prioritize the review of any clinical services that are only offered via **Column III**.

Notes:
- Use the same sample of contracts/agreements and referral arrangements 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, even though they may result in some overlap in the contracts/agreements reviewed.
- Select contracts and referral arrangements 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 contracts/agreements, referral arrangements, or related documentation together with health center staff.
- For contracted or referral providers, examples of credentialing and privileging 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. **Does the health center 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:**

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

   12.1 **Verify provider licensure, certification, or registration through a credentialing process?**

   Response is: Yes, No, or Not Applicable

12.2 **Verify providers are competent and fit to perform the contracted services through a privileging process?**

Response is: Yes, No, or Not Applicable

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

13. **Does the health center 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:**

Notes:
  o Select "Not Applicable" if the health center does not offer any clinical services via **Column III**.
  o For all **Column III** services, the credentialing and privileging process for providers is external; for example, conducted by the referral provider or referral organization.

13.1 **Verify provider licensure, certification, or registration through a credentialing process?**

Response is: Yes, No, or Not Applicable

13.2 **Verify providers are competent and fit to perform the referred services through a privileging process?**

Response is: Yes, No, or Not Applicable

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

Footnotes

[1] Clinical staff includes licensed independent practitioners (for example, physician, dentist, physician assistant, nurse practitioner, clinical psychologist), other licensed or certified practitioners (for example, registered nurse, licensed practical nurse, registered dietitian, certified medical assistant, phlebotomist, respiratory therapist, licensed or certified behavioral health support staff), and other clinical staff providing services on behalf of the health center (for example, medical assistants, peer navigators, 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 (PDF).

[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.

[5] Many states have their own recommendations or standards for provider immunization and communicable disease screening.

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[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.

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)*

Health Center Program Compliance Manual Related Considerations

Documents the Health Center Provides

Checklist

- List of health center sites with the following information for each site:
    - Address
    - Hours of operation
    - Services offered (for example, medical, oral health, behavioral health).
- Health Center Program GeoCare Navigator Map (if updated since last application submission to HRSA).
- Patient satisfaction surveys or other forms of patient input.
- Most recent needs assessment or related studies or resources.

Compliance Assessment

Select each element below for the corresponding text of the element, site visit team methodology, and site visit finding questions.

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 agricultural worker housing 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 the Service Area Map.

- Review the needs assessment or related studies or resources.
- Review the status of any special populations funding or designation.
- Interview the Project Director/CEO, other key management staff, and board members. Discuss how the health center considered patient access when selecting the location of either:
    - 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 any special populations, into consideration in determining where to locate its sites:**

   1.1 **Patient access barriers, such as those resulting from the area's physical characteristics, residential patterns, or economic and social factors?**

   Response is either: Yes or No

   1.2 **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.**

   Response is either: Yes or 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 the list of health center sites for hours of operation.
- Review the needs assessment or related studies or resources.
- Review the patient satisfaction surveys or other forms of patient input.
- Interview the Project Director/CEO, other key management staff, and board members. Ask for one to two examples of how hours of operation are responsive to patient need.

Site Visit Findings

2. **Has the health center taken patient needs into consideration in setting the hours of operation of its sites? For example, based on available health center resources, the hours of operation are aligned with the most requested appointment times or the most in-demand services.**

   Response is either: Yes or 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 the list of health center sites and compare to the health center's Form 5B.
- Interview the Project Director/CEO or other key management staff about Form 5B accuracy.

Note: *The focus of this portion of the site visit is to validate the active service sites of the health center. Note any Form 5B inaccuracies in the site visit finding question.*

Site Visit Findings

3. **Does the health center need to add or remove any sites on its Form 5B?**

   Response is either: Yes or No

4. **IF YES: Has the health center submitted any Change in Scope requests to HRSA to correct Form 5B?**

   Response is either: Yes or No

   If Yes OR No, specify any inconsistencies observed and whether the relevant Change in Scope requests have been submitted to HRSA to correct Form 5B.

Footnotes

[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 for further details, including services and column descriptors listed on Form 5A: Services Provided.

[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 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)*

[Health Center Program Compliance Manual Related Considerations](#)

Documents the Health Center Provides

Checklist

- 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 at least one individual with current certification in basic life support at each site. Include a copy of those individuals' current certifications (for example, credentialing file for licensed independent practitioner or other licensed or certified practitioner, certification of training if non-clinical staff).
- If the health center uses its providers for after-hours coverage: Health center provider on-call schedules.
- If the health center uses non-health center providers for after-hours coverage: After-hours written arrangements with non-health center providers/entities (for example, formal agreements with other community providers, nurse call lines).
- Information provided to patients for accessing after-hours coverage.
- Three samples of after-hours clinical advice documentation in patient records.[1] Include associated documentation of follow-up.
  Notes:
  - Select a sample 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, make up the difference with after-hours call documentation that did not require follow-up.
  - Use live navigation of the Electronic Health Record (EHR), screenshots from the EHR, or other patient record formats.
- Procedures for tracking, recording, and storing of after-hours coverage interactions and any follow-up (for example, log of patient calls).
  Note: *Alternatively, a health center can use live navigation of its system.*

Compliance Assessment

Select each element below for the corresponding text of the element, site visit team methodology, and site visit finding questions.

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 about:
  - Staff members trained and certified in basic life support present at each HRSA-approved service site; and
  - The health center's clinical capacity to respond to patient medical emergencies during the health center's regularly-scheduled hours of operation.
- Review the operating procedures for provisions that ensure that all service delivery sites on Form 5B have at least one individual per site present during the health center's regularly-scheduled hours of operation to respond to patient medical emergencies.
- Review the sample of staffing schedules and of basic life support certifications to confirm that the individuals listed have current certification in basic life support and are present at each site during the health center's regularly-scheduled hours of operation.

Site Visit Findings

1. **Is 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 during the health center's regularly-scheduled hours of operation?**

   Response is either: Yes or No

   If No, an explanation is required, including stating what provisions the health center has in place to respond to patient medical emergencies during regularly-scheduled hours of operation at its sites.

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.

Site Visit Team Methodology

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

Site Visit Findings

2. **Does the health center have operating procedures for responding to patient medical emergencies during the health center's regularly-scheduled hours of operation?**

    Response is either: Yes or No

    If No, an explanation is required.

3. **Did the health center describe how it either has responded to or is prepared to respond to patient medical emergencies during regularly-scheduled hours of operation (for example, staff training or drills on use of procedures)?**

    Response is either: Yes or 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 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.
- Review any provider on-call schedules for after-hours coverage.

- Review any after-hours written arrangements with non-health center providers/entities (for example, formal agreements with other community providers, nurse call lines).
- Review the 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, or equivalent health center leadership as well as outreach or front desk staff about methods of informing patients of after-hours coverage and how the health center addresses barriers, including those due to LEP or literacy levels, that patients may face in accessing 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?**

   Response is either: Yes or No

   If No, an explanation is required.

5. **Based on the interview with clinical leadership and front desk staff, is information provided to patients at all health center service sites (on Form 5B) on how to access after-hours coverage?**

   Response is either: Yes or No

   If No, an explanation is required.

6. **Has the health center addressed barriers that patients face when attempting to use the health center's after-hours coverage? This includes barriers due to LEP or literacy levels.**

   Response is either: Yes or No

   If No, an explanation is required.

7. **Based on the after-hours call you made to the health center, did you confirm the following:**

   7.1 **You were connected to an individual with the qualification and training necessary to exercise professional judgment to address an after-hours call?**

   Response is either: Yes or No

   7.2 **This individual can refer patients to a covering licensed independent practitioner for further assessment or to locations, such as emergency rooms or urgent care facilities, for immediate care?**

Response is either: Yes or No

7.3 **Provisions are in place for calls from patients with LEP?**

Response is either: Yes or 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, or equivalent health center leadership about after-hours call documentation.
- Review the health center's operating procedures or documentation of any arrangements (for example, contract with nurse call line) for responding to patient medical emergencies after hours.
- Review three samples of after-hours documentation within patient records 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.
  Notes:
  - o 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.
  - o Use live navigation of the Electronic Health Record (EHR), screenshots from the EHR, or other patient record formats.
- Review the health center's tracking, recording, and storing of after-hours coverage interactions and any follow-up either through review of health center procedures or through live navigation of the health center system.

Site Visit Findings

8. **Does the health center document after-hours calls or, if no after-hours calls have been received, does the health center have the capacity to document these calls?**

Response is either: Yes or No

If No, an explanation is required.

9. **Based on review of systems or the sample of records, does the health center provide the necessary follow-up? For example, the health center contacts the patient within a certain number of days to check in on the patient's condition or to schedule an appointment.**

    Note: *For a health center with no after-hours calls that required follow-up (for example, a newly-funded health center that recently started its operations), review operating procedures and interview health center staff to respond to this question.*

    Response is either: Yes or No

    If No, an explanation is required.

Footnotes

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

[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.

[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.

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

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)*

Health Center Program Compliance Manual Related Considerations

Documents the Health Center Provides

Checklist

- Health center's internal operating procedures and documentation of any arrangements with non-health center providers or entities for tracking of patient hospitalization and continuity of care.
- Documentation of EITHER:
  - ○ Health center 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; OR
  - ○ All formal arrangements that address health center patient hospital admissions (for example, provisions in hospitalist contract, transfer agreements, supporting procedures, or other documentation of inpatient care coordination with the health center).
- Sample of 5–10 health center patient records[1] 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.
  Note: *Use live navigation of the Electronic Health Record (EHR), screenshots from the EHR, or other patient record formats.*

Compliance Assessment

Select each element below for the corresponding text of the element, site visit team methodology, and site visit finding questions.

Element a: Documentation of Hospital Admitting Privileges or Arrangements

The health center has documentation of:

- 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) about processes for ensuring continuity of care for patients that require inpatient hospitalization.
- Review the documentation of EITHER:
  - o Health center provider hospital admitting privileges that address delivery of care in a hospital setting to health center patients; OR
  - o All formal arrangements that address hospital admissions of health center patients.

Site Visit Findings

1. **Does the health center have:**

   - o **Documentation of health center provider hospital admitting privileges (if any health center providers are responsible for admitting and following hospitalized patients); or**
   - o **Formal arrangements with other providers or entities (such as a hospital, hospitalist group, obstetrics practice, or other health center) that address health center patient hospital admissions?**

   Response is either: Yes or No

   If Yes OR No, an explanation is required specifying the health center's arrangements 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
- Follow-up actions by health center staff, when appropriate.

Site Visit Team Methodology

- Review the health center's internal operating procedures and documentation of any arrangements with non-health center providers or entities to assess tracking of patient hospitalization and continuity of care provisions.
- Interview health center staff about continuity of care.

Site Visit Findings

2. **Does the health center's internal operating procedures and any arrangements with non-health center providers or entities include provisions that address the following:**

    2.1 **How the health center obtains or receives medical information related to patient hospital or ED visits and records such information (for example, discharge follow-up instructions and laboratory, radiology, or other results)?**

    Response is either: Yes or No

    2.2 **Follow-up by the health center staff, when appropriate?**

    Response is either: Yes or 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 about 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, is there documentation of:**

Note: *For a health center with no hospitalized patients in the past 12 months (for example, a newly-funded health center that recently started its operations), review operating procedures and interview health center staff to respond to these questions.*

3.1 **Medical information related to the hospital or ED visit, such as discharge follow-up instructions and laboratory, radiology, or other results?**

Response is either: Yes or No

3.2 **Follow-up actions taken by health center staff based on the information received, when appropriate?**

Response is either: Yes or No

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

Footnotes

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

[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).

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)

[Health Center Program Compliance Manual Related Considerations](#)

Documents the Health Center Provides

Checklist

- Sliding fee discount program (SFDP) policies.
- SFDP procedures.
- Sliding fee discount schedule (SFDS), including any SFDSs that differ by service or service delivery method.
- 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).
- For health centers that choose to have a nominal charge for patients with incomes at or below 100 percent of the FPG:
  - 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 amounts associated with Medicare and Medicaid for patients with comparable incomes.
  - Documentation that shows each nominal charge does not reflect the actual cost of the service being provided.
  - If the board-approved SFDP policy does not state a specific amount for each nominal charge or how each nominal charge is determined: Other documentation of board involvement in setting the amount of each nominal charge (for example, board minutes, reports).
- 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 showing how the health center ensures sliding fee discounts for those selected services.
  Note: *Use the same sample of contracts/agreements 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](#), even though they may result in some overlap in the contracts/agreements reviewed.*

- 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 showing how the health center ensures sliding fee discounts for those selected services. **Note:** *Use the same sample of referral arrangements for the review of* [Required and Additional Health Services](), [Clinical Staffing](), *and Sliding Fee Discount Program.*
- If the health center is subject to legal or contractual restrictions applicable to sliding fee discounts for patients with third-party coverage: Documentation of such restrictions.
- Data, reports, or any other relevant materials used to evaluate the SFDP.

Compliance Assessment

Select each element below for the corresponding text of the element, site visit team methodology, and site visit finding questions.

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 a walk-through of the SFDS screening and enrollment process.
- Review the health center's SFDP policies, procedures, and all sliding fee discount schedules.
- Review any related policies, procedures, forms, and materials that support the SFDP.
- Review the health center's Form 5A.
- 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:**

   o **Offered on a sliding fee discount schedule (SFDS) (for Columns I and II); or**
   o **Offered under any other type of discount (for Column III)?**

   Notes:
   o Include any findings about the specific STRUCTURE of the SFDS for services in Columns I, II, and III within elements "c," "i," and "j."
   o "Services" refers to all Required and Additional services across all service delivery methods on the health center's Form 5A for which there are distinct fees.

    ○   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 schedules and, therefore, from any health center SFDS.

    ○   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). These supplies and equipment are not considered services and are not subject to Health Center Program SFDP requirements.

Response is either: Yes or 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. **FOR ANY REQUIRED OR ADDITIONAL SERVICE (COLUMN I, II, OR III) WITHIN THE HRSA-APPROVED SCOPE OF PROJECT: Are there any patients with incomes at or below 200 percent of the Federal Poverty Guidelines (FPG) who are not eligible for the sliding fee discount program?**

Response is either: Yes or No

If Yes, an explanation is required, including specifying why those patients are not 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 members and key management staff about the health center's SFDP policies.
  Note: *Interviews may be conducted in collaboration with the governance/administrative expert.*
- Review the health center's SFDP policies. Review any other related policies, procedures, and materials that support the SFDP.

Note: *This may be combined with the policy review conducted for element "a."*

- For health centers that choose to have a nominal charge for patients with incomes at or below 100 percent of the FPG:
  - Review the 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 amounts associated with Medicare and Medicaid for patients with comparable incomes.
  - Review the documentation that shows each nominal charge does not reflect the actual cost of the service being provided.
  - If the SFDP policy does not state the specific amount of each nominal charge or how each nominal charge is determined, review other documentation of board involvement in setting the amount of each nominal charge (for example, board minutes, reports).

Site Visit Findings

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

   3.1 **The policy applies uniformly to all patients?**

   Response is either: Yes or No

   3.2 **The definitions of income and family (or "household")? For example, what the health center includes or does not include in the definitions.**

   Response is either: Yes or No

   3.3 **The methods for assessing patient eligibility based only on income and family size?**

   Response is either: Yes or No

   3.4 **The way each SFDS is structured to ensure charges are adjusted based on ability to pay? For example, the policy addresses that flat fee amounts differ across discount pay classes or that there is a graduated percent of charges for patients with incomes above 100 percent and at or below 200 percent of the FPG.**

   Response is either: Yes or No

   3.5 **The setting of any nominal charges 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.*

   Response is: Yes, No, or 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 charges for patients with incomes at or below 100 percent of the FPG are:**

4.1 **A flat fee?**

Response is: Yes, No, or Not Applicable

4.2 **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 Medicare and Medicaid co-pay amounts for patients with comparable incomes.**

Response is: Yes, No, or Not Applicable

4.3 **Not based on the actual cost of the service?**

Response is: Yes, No, or Not Applicable

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]

Site Visit Team Methodology

- Review the structure of the health center's SFDSs for **Column I** services.
  Note: *For health centers that use multiple SFDSs, review the structure of each SFDS including any nominal charges.*
- Interview key management staff about the health center's SFDSs for **Column I** services.

Site Visit Findings

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

5. **For patients with incomes at or below 100 percent of the FPG, does the health center's SFDS:**

    Notes: For a health center with more than one SFDS:
    o   If some SFDSs provide a full discount and other SFDSs have a nominal charge, then answer "Yes" to both sub-bulleted questions.
    o   If ANY of the SFDSs fail to provide a full discount OR a nominal charge, select "No" to both sub-bulleted questions.

    5.1 **Provide a full discount (no nominal charge)?**

    Response is either: Yes or No

    5.2 **Require only a nominal charge ("fee")?**

    Response is either: Yes or No

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

6. **If the health center has nominal charges, are the nominal charges less than the fees paid by patients in the first sliding fee discount pay class above 100 percent of the FPG?**

    Response is: Yes, No, or 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, do the SFDSs:**

    o   **Provide partial discounts adjusted in accordance with gradations in income levels (i.e., as patient income increases, the discounts decrease accordingly); and**
    o   **Consist of at least three discount pay classes?**

    Response is either: Yes or No

    If No, an explanation is required.

8. **For patients with incomes above 200 percent of the FPG, are the SFDSs structured so that these patients are not eligible for a sliding fee discount under the Health Center Program?**

    Note: *Health centers that provide discounts to patients with incomes above 200 percent of the FPG may do so, as long as these discounts are supported through other funding sources (for example, Ryan White Part C award).*

Response is either: Yes or 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

- If the health center has more than one SFDS:
    - Review each SFDS and the basis for the separate discount schedules.
    - Interview key management staff about the multiple SFDSs.

Site Visit Findings

9. **Does the health center have more than one SFDS?**

   Response is either: Yes or No

10. **IF YES: Is each SFDS based either on service or service delivery method and no other factors? For example, no SFDS is based on patient insurance status, location of site, patient characteristics, or other patient demographics.**

    Response is: Yes, No, or 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 SFDSs for 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 SFDSs, does the health center incorporate the current FPG in the calculations for all of the discount pay classes?**

    Response is either: Yes or 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 a walk-through of the SFDS screening and enrollment process.
- Review the health center's SFDP policies, procedures, and all sliding fee discount schedules. Review any related policies, procedures, forms, and materials that support the SFDP.
  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 and re-assessing all patients, regardless of their insurance status, for income and family size?**

    Response is either: Yes or No

    If No, an explanation is required.

13. **Are these procedures consistent with the board-approved policy for the SFDP?**

    Response is either: Yes or 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 the sample of 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:
  - o Uninsured and insured patients; and
  - o Initial assessments for income and family size as well as re-assessments.
- Interview key management staff about the health center's assessment, re-assessment, and documentation of patient income and family size.

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?**

    Response is either: Yes or 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

- Participate in site tours.
- Interview key management staff about the health center's mechanisms for informing patients of sliding fee discounts. Interview health center staff involved in informing patients of sliding fee discounts (for example, eligibility and outreach staff, front desk staff, billing staff, office manager, case managers).
- Review the mechanisms (for example, health center signage, health center website or social media, patient brochures) for informing patients.

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 these discounts?**

    Response is either: Yes or 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:
    o Use the same sample of contracts/agreements 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, even though they may result in some overlap in the contracts/agreements reviewed.
    o 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.
    o If the health center does not ensure sliding fee discounts through provisions in the contracts/agreements, review any other documentation (for example, documentation

that patients are billed under the health center's compliant SFDP) provided by the health center showing how the health center ensures such discounts.

Site Visit Findings

When responding to the question(s) below, please note:
- The questions relate to services provided via contracts (Form 5A, **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 schedules and, therefore, from any health center SFDS.

16. **Does the health center provide services via contracts/agreements (Form 5A, Column II)?**

    Response is either: Yes or No

17. **For patients receiving services through these contracts/agreements, does the health center ensure sliding fee discounts are provided in a manner that meets all Health Center Program requirements? For example, the health center applies its own SFDS to eligible patients' fees; a contract contains specific sliding fee provisions; contracted services are provided by another health center which uses an SFDS that meets all Health Center Program requirements.**

    Response is: Yes, No, or Not Applicable

    If No, an explanation is required.

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

    Notes:
    - If some SFDSs provide a full discount and other SFDSs have a nominal charge, then answer "Yes" to both sub-bulleted questions.
    - If ANY of the SFDSs fail to provide a full discount OR a nominal charge, select "No" to both sub-bulleted questions.

    18.1 **Provided a full discount (no nominal charge)?**

    Response is: Yes, No, or Not Applicable

    18.2 **Assessed a nominal charge ("fee")?**

    Response is: Yes, No, or Not Applicable

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

19. **If there are nominal charges, are the nominal charges less than the fees paid by patients in the first sliding fee discount pay class above 100 percent of the FPG?**

Response is: Yes, No, or 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, do the SFDSs:**

    o **Provide partial discounts adjusted in accordance with gradations in income levels (i.e., as patient income increases, the discounts decrease accordingly); and**
    o **Consist of at least three discount pay classes?**

    Response is: Yes, No, or Not Applicable

    If No, an explanation is required.

21. **For patients with incomes above 200 percent of the FPG, are the SFDSs structured so that these patients are not eligible for a sliding fee discount under the Health Center Program?**

    Note: *Health centers that provide discounts to patients with incomes above 200 percent of the FPG may do so, as long as these discounts are supported through other funding sources (for example, Ryan White Part C award).*

    Response is: Yes, No, or 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:
- o Use the same sample of referral arrangements for the review of <u>Required and Additional Health Services</u>, <u>Clinical Staffing</u>, and Sliding Fee Discount Program.
- o The fiscal expert may wish to collaborate with the clinical expert on this review because the same sample is used in <u>Required and Additional Health Services</u> and <u>Clinical Staffing</u>.
- o If the health center does not ensure sliding fee discounts through provisions in the referral arrangements, review other documentation (for example, a compliant charity care policy) showing how the health center ensures such discounts.

Site Visit Findings

When responding to the question(s) below, please note:
- The questions relate to services provided via formal referral arrangements (Form 5A, **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 schedules and, therefore, from any health center SFDS.

22. **Does the health center provide services via formal referral arrangements (Form 5A, Column III)?**

    Response is either: Yes or No

23. **For patients receiving services through these referral arrangements, does the health center ensure sliding fee discounts are provided in a manner that meets the structural requirements noted in element "c"?**

    Response is: Yes, No, or Not Applicable

24. **IF NO: For patients receiving services through these referral arrangements, does the health center ensure sliding fee discounts are provided in a manner such that:**

    - o **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**
    - o **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?**

    Response is: Yes, No, or Not Applicable

    If No, an explanation is required, including describing the format and type of any discounts 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 a walk-through of the SFDS screening and enrollment process.
- Review the health center's SFDP policies, procedures, all sliding fee discount schedules.
- Review any related policies, procedures, forms, and materials that support the SFDP.
  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 applicable to sliding fee discounts for patients with third-party coverage. If so, review the specific documentation of the 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?**

    Response is either: Yes or No

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

Element l: 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 health center staff involved in evaluating the SFDP.
- Interview board members and key management staff about the health center's evaluation of its SFDP.
  Note: *Interviews may be conducted in collaboration with the governance/administrative expert.*
- Review the 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?**

    Response is either: Yes or No

    If No, an explanation is required.

27. **IF YES: Is this evaluation conducted at least once every 3 years?**

    Response is: Yes, No, or Not Applicable

    If No, an explanation is required.

28. **Does the health center collect utilization data to assess whether patients within each of its discount pay classes are accessing health center services?**

    Response is either: Yes or No

    If No, an explanation is required.

29. **IF YES: Does the health center use these data or other data, such as collections or patient survey data, to evaluate the effectiveness of its SFDP?**

    Response is: Yes, No, or Not Applicable

    If No, an explanation is required.

30. **Has the health center implemented any follow-up actions based on evaluation results? For example, improved sliding fee eligibility screening, enhanced notification methods for sliding fee discounts, or board changes to SFDP policy.**

    Response is either: Yes or No

If No, an explanation is required.

Footnotes

[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.

[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."

[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.

[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.

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)*

[Health Center Program Compliance Manual Related Considerations](#)

Documents the Health Center Provides

Checklist

- Policies that establish the Quality Improvement/Quality Assurance (QI/QA) program.
- QI/QA-related operating procedures or processes that address:
  - Clinical guidelines, standards of care, and 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.
- Job or position descriptions of individuals who oversee the QI/QA program.
- Sample of patient satisfaction results.
- Documentation of any related systems that support QI/QA (for example, event reporting system, tracking resolutions and grievances, dashboards).
- QI/QA assessment schedule or calendar.
- Sample of two QI/QA assessments from the past 12 months and any related reports resulting from these assessments.
- Sample of 5–10 health center patient records[1] that include clinic visit notes or summary of care.
  Notes:
  - The same sample of patient records used for reviewing other program requirement areas may also be used for this sample.
  - Use live navigation of the Electronic Health Record (EHR), screenshots from the EHR, or other patient record formats.
- Systems (for example, certified EHRs) and record-keeping procedures for maintaining and monitoring the confidentiality, privacy, and security of protected health information (PHI).

Compliance Assessment

Select each element below for the corresponding text of the element, site visit team methodology, and site visit finding questions.

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 individuals designated to oversee the QI/QA program.
- Interview related staff who support QI/QA.
- Review the health center's policies that establish the QI/QA program.
  Notes:
    o The title of these policies may vary across health centers (for example, these policies may be in a document called a "QI/QA plan").
    o If the board has not approved these policies, address this under Board Authority.

Site Visit Findings

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

   1.1 **The quality and utilization of health center services?**

   Response is either: Yes or No

   1.2 **Patient satisfaction and patient grievance processes?**

   Response is either: Yes or No

   1.3 **Patient safety, including adverse events?**

   Response is either: Yes or 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.

Site Visit Team Methodology

- Review the job/position descriptions or other documents for background on the responsibilities of the individuals overseeing the QI/QA program.
- Interview individuals designated to oversee the QI/QA program to further understand their roles and responsibilities.

Site Visit Findings

2. **Does the health center have at least one designated individual to oversee the QI/QA program?**

   Response is either: Yes or No

   If No, an explanation is required.

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

   3.1 **Ensuring the implementation of QI/QA operating procedures?**

   Response is either: Yes or No

   3.2 **Ensuring QI/QA assessments are conducted?**

   Response is either: Yes or No

   3.3 **Monitoring QI/QA outcomes?**

   Response is either: Yes or No

   3.4 **Updating QI/QA operating procedures, as needed?**

   Response is either: Yes or 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 individuals 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 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 the sample of patient satisfaction results.
- Review the related systems or documentation of any related systems that support QI/QA.
- Review the schedule or calendar of QI/QA assessments.
- Review the sample of QI/QA assessments from the past 12 months and any related reports resulting from these assessments.

Site Visit Findings

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

    4.1 **Adherence to current, applicable evidence-based clinical guidelines, standards of care, and standards of practice (for example, Electronic Health Record (EHR) clinical decision-making support, job aids, protocols)?**

    Response is either: Yes or No

    4.2 **A process for health center staff to follow for identifying, analyzing, and addressing overall patient safety, including adverse events?**

    Response is either: Yes or No

    4.3 **A process for implementing follow-up actions related to patient safety and adverse events, as necessary?**

    Response is either: Yes or No

4.4 **A process for the health center to assess patient satisfaction (for example, fielding patient satisfaction surveys, conducting periodic patient focus groups)?**

Response is either: Yes or No

4.5 **A process for hearing and resolving patient grievances?**

Response is either: Yes or No

4.6 **Completion of periodic QI/QA assessments on at least a quarterly basis?**

Response is either: Yes or 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 QI/QA reports, including data on patient satisfaction and patient safety, with key management staff and the governing board?**

Response is either: Yes or No

If No, an explanation is required.

6. **Did the health center share at least one example of how these reports support decision-making and oversight by key management staff and the governing board on the provision of health center services and responses to patient satisfaction and patient safety issues?**

Response is either: Yes or 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 individuals responsible for the QI/QA program.

- Review the health center's operating procedures or processes that address periodic QI/QA assessments.
- Review the related systems or documentation of any related systems that support QI/QA.
- Review the QI/QA assessment schedule or calendar.
- Review the sample of QI/QA assessments from the past 12 months and any 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? For example, by nurse practitioners or registered nurses.**

   Response is either: Yes or No

   If No, an explanation is required.

8. **Are the health center's QI/QA assessments conducted on at least a quarterly basis?**

   Response is either: Yes or No

   If No, an explanation is required.

9. **Are these QI/QA assessments based on data systematically collected from patient records?**

   Response is either: Yes or No

   If No, an explanation is required.

10. **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, by initiating a new safety practice as a result of an adverse event or by increasing use of appropriate medications for asthma, early entry into prenatal care, or HIV linkages to care.**

    Response is either: Yes or No

    If No, an explanation is required, including specifying which areas the health center is not tracking 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

- Along with health center clinical staff, review the sample of health center patient records.
  Notes:
  - o The same sample of patient records used for reviewing other program requirement areas may also be used for this sample.
  - o Use live navigation of the EHR, screenshots from the EHR, or other patient record formats.

Note: *If there are issues related to timeliness, accuracy, or completeness of data retrieval used for Uniform Data System (UDS) reporting, address those under [Program Monitoring and Data Reporting Systems](#).*

Site Visit Findings

11. **Does the health center maintain individual health records that are easy to retrieve?**

    Response is either: Yes or No

    If No, an explanation is required.

12. **Does the health center ensure that the format and content of its health records are consistent with applicable federal and state laws and requirements? For example, the health center implemented a certified EHR.**

    Response is either: Yes or 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 the systems (for example, certified EHRs) and record-keeping procedures for maintaining and monitoring the confidentiality, privacy, and security of protected health information (PHI).

- Interview relevant staff such as CMO, health information technology personnel, Compliance Officer, 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

13. **Do the health center's systems (for example, certified EHRs) 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?**

    Response is either: Yes or No

    If No, an explanation is required.

14. **Does the health center ensure its staff are trained in the confidentiality, privacy, and security of patient information?**

    Response is either: Yes or No

    If No, an explanation is required.

Footnotes

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

[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.

[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.

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)

[Health Center Program Compliance Manual Related Considerations](#)

Documents the Health Center Provides

Checklist

- Health center organization charts with names and titles of key management staff (if updated since last application submission to HRSA).
- Position descriptions of key management staff (if updated since last application submission to HRSA).
- Any contracts for key management staff.
- If the health center has key management staff vacancies:
    - Human Resources procedures relevant to recruiting and hiring of key management staff.
    - Documentation associated with filling key management staff vacancies (for example, job advertisements or revised position descriptions).
- Project Director/CEO employment agreement.
- Project Director/CEO's W-2 or, if a W-2 has not yet been issued, documentation of receipt of salary directly from the health center (for example, pay stub).
- Any additional documentation of key management reporting structures.
- If the health center has a co-applicant: Co-applicant agreement (if updated since last application submission to HRSA).
- If the current Project Director/CEO has changed *since the start of the current period of performance*:
    - The Notice of Award (NOA)/Notice of Look-Alike Designation (NLD) approving the current Project Director/CEO; OR
    - If the prior approval request for the current Project Director/CEO is still under review by HRSA, the documentation of the request.

Compliance Assessment

Select each element below for the corresponding text of the element, site visit team methodology, and site visit finding questions.

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.

Site Visit Team Methodology

- Review Form 2: Staffing Profile, and the position descriptions or contracts for key management staff.
- Review the health center organization charts.
- Interview the health center's key management staff to determine how key functions are distributed and carried out.

Site Visit Findings

1. **Can the health center justify how the distribution of functions and allocation of time for each key management position are 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?**

   Response is either: Yes or No

   If No, an explanation is required, including describing why the distribution of functions and allocation of time for each key management position are 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 does not review health center compliance with this element during the site visit. HRSA assesses compliance with this element during its review of the health center's competing continuation application (SAC or RD).

Site Visit Findings

N/A – HRSA does not review health center compliance with this element during the site visit. HRSA assesses compliance with this element during its review of the health center's competing continuation application (SAC or RD).

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 the health center organization charts and compare to current key management staff. Note if there are any vacancies.
- If a key management staff vacancy is noted:
  - Review Human Resources (HR) procedures relevant to recruiting and hiring of key management staff and documentation associated with filling the vacancy; and
  - Interview staff responsible for health center hiring/HR functions.

Site Visit Findings

2. **Does the health center have any vacant key management positions?**

   Response is either: Yes or No

3. **IF YES: Will the health center implement or has the health center implemented a process for filling this position?**

   Response is: Yes, No, or Not Applicable

   If No, an explanation is required, including specifying which positions 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 the health center organization charts.

- Review the position descriptions or contracts for key management staff and any additional documentation of key management reporting structures.
- Review the Project Director/CEO's W-2 or, if a W-2 has not yet been issued by the health center, documentation of receipt of salary directly from the health center.
- Review the Project Director/CEO employment agreement.
- For public agencies with a co-applicant board, review the co-applicant agreement.
- Interview Project Director/CEO about the position and responsibilities.

Site Visit Findings

4. **Is the Project Director/CEO directly employed by the health center?**

   Note: *A health center could demonstrate compliance by presenting the Project Director's/CEO's W-2, employment agreement, pay stub, or some other type of documentation of direct employment by the health center.*

   Response is either: Yes or No

   If No, an explanation is required.

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

   Note: *In a public agency with a co-applicant board where the public agency 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.*

   Response is either: Yes or 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?**

   Response is either: Yes or No

   If No, an explanation is required.

Element e: HRSA Approval for Project Director/CEO Changes

NOT APPLICABLE FOR LOOK-ALIKE INITIAL DESIGNATION APPLICANTS

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.

Site Visit Team Methodology

- If there has been a change in the Project Director/CEO position *since the start of the current period of performance*:
  - o Review the Notice of Award (NOA)/Notice of Look-Alike Designation (NLD) approving the current Project Director/CEO; OR
  - o If the Project Director/CEO prior approval request is still under review by HRSA, review the documentation of the request.

Site Visit Findings

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

   Notes:
   - o Only select "Yes" for situations in which the Project Director/CEO:
     - ▪ Was absent from the project for any continuous period of 3 months or more; or
     - ▪ Reduced time devoted to the project by 25 percent or more from the level that was approved at the time of award.
   - o Only select "Not Applicable" if this is a Look-Alike Initial Designation Site Visit.

   Response is: Yes, No, or Not Applicable

8. **IF YES: Is 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?**

   Response is: Yes, No, or Not Applicable

   If No, an explanation is required.

Footnotes

[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.
[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 uses 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.

[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)].

Contracts and Subawards

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

NOTE: *If the health center has a subrecipient, 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*

[Health Center Program Compliance Manual Related Considerations](#)

Documents the Health Center Provides

Checklist

Contracts: Procurement and Monitoring

- Policies or procedures for purchasing, procurement, and contract management.
- Provide a complete list of health center contracts that support the HRSA-approved scope of project, including contracts for health center clinical services or other goods and services (for example, tech support, janitorial, payroll). Specifically, include all active contracts and all contracts that had a period of performance that ended less than 3 years ago. In the list, include all of the following information for each contract:
    - Whether the health center uses 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 goods or services provided;
    - Period of performance/timeframe (for example, ongoing contractual relationship, specific duration); and
    - Whether the contract supports substantive programmatic work.[1]
- Based on the list of contracts that support the HRSA-approved scope of project:
    - Five contracts AND related supporting procurement documentation for actions that **use federal award funds.** Choose the contracts that use the largest amounts of federal award funds.
    Note: *Use the same sample of contracts/agreements 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](#), even though they may result in some overlap in the contracts/agreements reviewed.*
    - Sample of five contracts that **do NOT use federal award funds**.

- From the sample of selected contractors: Two to three reports or records of the contractor's health center-related activities. For example, monthly invoices or billing reports, data on patients served or visits provided.
- Documentation of HRSA prior approval for any contracts for the performance of substantive programmatic work (i.e., contracting with a single entity for the majority of health care providers) under the federal award.

Subawards: Monitoring and Management

ONLY APPLICABLE FOR AWARDEES WITH AT LEAST ONE SUBRECIPIENT

NOT APPLICABLE TO LOOK-ALIKES

- Most recent annual audit and management letter.
- Policies or procedures for subrecipient monitoring.
- All subrecipient agreements (if updated since last application submission to HRSA) that support the awardee's HRSA-approved 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](#)*."*
- Documentation of HRSA prior approval of subrecipient arrangements.

  NOTE: *For a health center with five or fewer subrecipients, provide the following documentation from all subrecipients. For a health center with more than five subrecipients, provide the documentation from the five subrecipients that receive the largest amounts of Health Center Program subaward funds.*

- Sample of financial and performance reports from within the current period of performance from the subrecipient, including the subrecipient's annual audit.
- Documentation of subrecipient monitoring by the health center through audits, on-site reviews, and other means, that occurred during the current period of performance.
- If there have been subrecipient deficiencies identified by the health center through its monitoring process: Documentation ensuring that the subrecipient took corrective action.
- The following documentation used by the health center to confirm subrecipient compliance:
  - Subrecipient articles of incorporation, bylaws (either for the subrecipient's board or the co-applicant board of a public agency subrecipient), or other corporate documents (for example, co-applicant agreement);
  - Subrecipient sliding fee discount program (SFDP) policy;
    - If the subrecipient board-approved SFDP policy does not state a specific amount for each nominal charge or how each nominal charge is determined: Other documentation (for example, subrecipient board minutes, subrecipient reports) of subrecipient board involvement in setting the amount of each nominal charge;
  - Current subrecipient board roster or completed Form 6A 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: sex, race, and ethnicity;
  - o Subrecipient billing records from within the past 24 months to confirm the patient status of subrecipient board members; and
  - o Subrecipient's portion of Uniform Data System (UDS) data for an overview of subrecipient patient population demographic factors (race, ethnicity, and sex).

Compliance Assessment

1. **Is this a Look-Alike Site Visit?**

   Response is either: Yes or No

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

Contracts: Procurement and Monitoring

Select each element below for the corresponding text of the element, site visit team methodology, and site visit finding questions.

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.[2]

Site Visit Team Methodology

- Review the health center's policies or procedures for purchasing, procurement, and contract management.
- Interview health center staff involved in contract procurement and monitoring.

Site Visit Findings

2. **Does the health center have written policies or procedures for procurement?**

   Response is either: Yes or No

   If No, an explanation is required.

3. **Do these policies or procedures, at a minimum, ensure that all procurements directly attributable to the federal award will:**

    o **Be conducted using full and open competition;[3] and**
    o **Only include allowable costs, consistent with federal cost principles? For example, do the procedures contain relevant references or citations to [45 CFR Part 75 Subpart E: Cost Principles](#).**

    Response is: Yes, No, or Not Applicable

    If No, an explanation is required.

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 complete list of contracts.
- Review the five contracts that use **the largest amounts of federal award funds** AND the related supporting procurement documentation**.**
  Note: *Use the same sample of contracts/agreements 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](#), even though they may result in some overlap in the contracts/agreements reviewed.*

Site Visit Findings

4. **Does the health center have any:**

    4.1 **Active contracts paid for in whole or in part with federal award funds?**

    Response is: Yes, No, or Not Applicable

    4.2 **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?**

    Response is: Yes, No, or Not Applicable

5. **Based on the review of the sample of contracts, is there supporting documentation of the procurement process that addresses the following:**

   5.1 **Rationale for the procurement method?**

      Response is: Yes, No, or Not Applicable

   5.2 **Selection of contract type?**

      Response is: Yes, No, or Not Applicable

   5.3 **Contractor selection or rejection?**

      Response is: Yes, No, or Not Applicable

   5.4 **Basis for the contract price?**

      Response is: Yes, No, or 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.[4]

Site Visit Team Methodology

- Review the five contracts AND related supporting procurement documentation for actions that **use federal award funds.**
  Note: *Use the same sample of contracts/agreements 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], even though they may result in some overlap in the contracts/agreements reviewed.*

Site Visit Findings

6. **Did the health center provide final executed contracts that were awarded within the past 3 years?**

Response is: Yes, No, or 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) from the sample of selected contractors.

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?**

   Response is either: Yes or No

   If No, an explanation is required.

Element e: HRSA Approval for Contracting Substantive Programmatic Work

NOT APPLICABLE FOR LOOK-ALIKE INITIAL DESIGNATION APPLICANTS

If the health center has arrangements with a contractor to perform substantive programmatic work,[5] 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 the complete list of contracts, including those that support substantive programmatic work.
- Interview key management or other health center staff involved in procurement or contract oversight.
- Review the health center's documentation of HRSA's approval of each contracting arrangement for substantive programmatic work.

Site Visit Findings

8. **Based on the list of contracts reviewed and interviews 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)?**

    Response is either: Yes or No

9. **IF YES: Did the health center provide documentation of prior approval by HRSA (i.e., the arrangement was included in a HRSA-approved application or was approved by HRSA through a post-award request)?**

    Note: *Only select "Not Applicable" if this is a Look-Alike Initial Designation Site Visit.*

    Response is: Yes, No, or Not Applicable

    If No, an explanation is required.

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.[6]

Site Visit Team Methodology

- Review the entire sample of contracts (both those that use and those that do not use 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 for other goods and services that support the HRSA-approved scope of project?**

    Response is either: Yes or No

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

    11.1 **Specific activities or services performed or goods provided by the contractor?**

    Response is: Yes, No, or Not Applicable

    11.2 **How the health center will monitor contractor performance?**

    Response is: Yes, No, or Not Applicable

    11.3 **Requirements for contractor data reporting, including reporting frequency?**

    Response is: Yes, No, or Not Applicable

    11.4 **Provisions for record retention and access, audit, and property management?**

    Response is: Yes, No, or Not Applicable

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

Subawards: Monitoring and Management

ELEMENT "G" THROUGH ELEMENT "J" ARE ONLY APPLICABLE FOR AWARDEES WITH AT LEAST ONE SUBRECIPIENT AND ARE NOT APPLICABLE TO LOOK-ALIKES.

Select each element below for the corresponding text of the element, site visit team methodology, and site visit finding questions.

Element g: HRSA Approval to Subaward

If the health center has made a subaward,[7] 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 the most recent annual audit and management letter to determine if subrecipients were identified in the audit report, including the amount of the subawards.
- Review all subrecipient agreements that support the awardee's HRSA-approved Health Center Program scope of project.
- Review the health center's documentation of HRSA's prior approval of each subrecipient arrangement.

Site Visit Findings

12. **Did the health center make any subawards (new or continuing) during the current period of performance?**

    Response is: Yes, No, or Not Applicable

13. **Did the health center provide documentation of prior approval by HRSA of the subrecipient arrangement (i.e., arrangement was included in the last HRSA-approved Service Area Competition (SAC) application or was approved by HRSA through a post-award request)?**

    Response is: Yes, No, or Not Applicable

    If No, an explanation is required.

Element h: Subaward Agreement

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;[8]
- 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;[9] and
- Requirements that all costs paid for by the federal subaward are allowable consistent with federal cost principles.[10]

Site Visit Team Methodology

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

Site Visit Findings

14. **Do all of the health center's subrecipient agreements include provisions that address the following:**

    14.1   **The portion of the health center project (i.e., sites and services) carried out by the subrecipient and how?**

    Response is: Yes, No, or Not Applicable

    14.2   **The applicability of all Health Center Program requirements to the subrecipient?**

    Response is: Yes, No, or Not Applicable

    14.3   **The applicability of other distinct statutory, regulatory, and policy requirements of associated programs and benefits to the subrecipient? For example, requirements that apply if the subrecipient participates in the 340B Drug Pricing Program.**

    Response is: Yes, No, or Not Applicable

    14.4   **Mechanisms for the health center to monitor subrecipient compliance and performance?**

    Response is: Yes, No, or Not Applicable

    14.5   **Data the subrecipient must collect and report back to the awardee (for example, UDS data)?**

    Response is: Yes, No, or Not Applicable

    14.6   **Record retention and access, audit, and property management?**

    Response is: Yes, No, or Not Applicable

    14.7   **Requirements that all costs paid for under the subaward are consistent with federal cost principles?**

    Response is: Yes, No, or Not Applicable

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

Element i: Subrecipient Monitoring

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.[11]

Site Visit Team Methodology

- Review all subrecipient agreements that support the awardee's HRSA-approved Health Center Program scope of project.
- Review the policies or procedures for subrecipient monitoring.
- Interview health center staff who provide oversight of subrecipient activities.

For the remaining methodology: For a health center with five or fewer subrecipients, review the documentation from all subrecipients. For a health center with more than five subrecipients, review the documentation from the five subrecipients that receive the largest amounts of Health Center Program subaward funds.

- Review the documentation from within the current period of performance of subrecipient monitoring by the health center. If there have been subrecipient deficiencies, review the documentation ensuring that the subrecipient took corrective action.
- Review the sample of financial and performance reports received from the subrecipient, including the subrecipient's annual audit.
- Review the following documentation used by the health center to confirm subrecipient compliance:
  - Subrecipient articles of incorporation, bylaws (either for the subrecipient's board or the co-applicant board of a public agency subrecipient), or other corporate documents (for example, co-applicant agreement);
  - Subrecipient sliding fee discount program (SFDP) policy;
    - If the subrecipient board-approved SFDP policy does not state a specific amount of each nominal charge or how each nominal charge is determined, review other documentation (for example, subrecipient board minutes, subrecipient reports) of subrecipient board involvement in setting the amount of each nominal charge;

- o Current subrecipient board roster or completed Form 6A 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: sex, race, and ethnicity.
- o Subrecipient billing records from within the past 24 months to confirm the patient status of subrecipient board members; and
- o Subrecipient's portion of UDS data for an overview of subrecipient patient population demographic factors (race, ethnicity, and sex).

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 the Health Center Program requirements applicable to the health center awardee's federal award. *For example: A health center awardee receives a 330(e) award and has a subrecipient that receives a 330(h) award directly from HRSA. The health center awardee would ensure 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 period of performance? 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 implementing any corrective actions?**

    Response is: Yes, No, or 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 period of performance that addresses the following areas:**

    16.1   **Achievement of performance goals?**

    Response is: Yes, No, or Not Applicable

    16.2   **Submission of UDS data by appropriate deadlines?**

    Response is: Yes, No, or Not Applicable

    16.3   **Use of funds for authorized purposes?**

    Response is: Yes, No, or 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 period of performance:**

   17.1   **Financial reports, including the subrecipient's audit?**

   Response is: Yes, No, or Not Applicable

   17.2   **Performance reports, including submission of data for the health center's UDS reporting?**

   Response is: Yes, No, or Not Applicable

   If No was selected for either of the above, an explanation is required, including specifying which reports the health center did not receive or review.

18. **Did the health center identify any deficiencies with the subrecipient's financial or performance reporting during the current period of performance, including any deficiencies in the subrecipient's annual audit?**

   Response is: Yes, No, or Not Applicable

19. **IF YES: Is there documentation that the health center ensured the subrecipient took timely corrective action on the identified deficiencies?**

   Response is: Yes, No, or Not Applicable

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

20. **Did the health center provide documentation demonstrating that each subrecipient is currently compliant with the following Board Composition requirements:**

   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.*

   20.1   **The subrecipient's board is currently composed of at least 9 and no more than 25 members?**

   Response is: Yes, No, or Not Applicable

   20.2   **At least 51 percent of subrecipient board members are classified by the subrecipient as patients?**

   Note: *Select "Not Applicable" only if the awardee has approved the subrecipient's request for a waiver of patient majority board composition requirements. A waiver is 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).

Response is: Yes, No, or Not Applicable

20.3   **Each subrecipient patient board member has 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 awardee has approved the subrecipient's request for a waiver of patient majority board composition requirements. A waiver is 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).*

Response is: Yes, No, or Not Applicable

20.4   **Patient board members as a group are representative of the subrecipient's patient population in terms of race, ethnicity, and sex consistent with the demographics reported in the health center's UDS report?**

Note: *Select "Not Applicable" only if the awardee has approved the subrecipient's request for a waiver of patient majority board composition requirements. A waiver is 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).*

Response is: Yes, No, or Not Applicable

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

21.   **Did the health center provide documentation demonstrating that each subrecipient is currently compliant with the following Board Authority requirements:**

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.*

21.1   **Holding monthly meetings?**

Response is: Yes, No, or Not Applicable

21.2   **Approving the selection and termination or dismissal of the subrecipient's Project Director/CEO?**

Response is: Yes, No, or Not Applicable

21.3   **Approving the subrecipient's health center project annual budget and applications?**

Response is: Yes, No, or Not Applicable

21.4   **Approving the subrecipient's health center services?**

Response is: Yes, No, or Not Applicable

21.5 **Approving the location and hours of operation of the subrecipient's health center sites?**

Response is: Yes, No, or Not Applicable

21.6 **Evaluating the performance of the subrecipient's health center project?**

Response is: Yes, No, or Not Applicable

21.7 **Establishing or adopting policy related to the operations of the subrecipient's health center project?**

Response is: Yes, No, or Not Applicable

21.8 **Assuring the subrecipient operates in compliance with applicable federal, state, and local laws and regulations?**

Response is: Yes, No, or Not Applicable

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

22. **Did the health center provide documentation showing that each subrecipient's Sliding Fee Discount Program (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.*

22.1 **The policy applies uniformly to all patients?**

Response is: Yes, No, or Not Applicable

22.2 **The definitions of income and family (or "household")? For example, what the subrecipient includes or does not include in the definitions.**

Response is: Yes, No, or Not Applicable

22.3 **The methods for assessing patient eligibility based only on income and family size?**

Response is: Yes, No, or Not Applicable

22.4 **The way each sliding fee discount schedule is structured to ensure charges are adjusted based on ability to pay? For example, the policy addresses that flat fee amounts differ across discount pay classes or that there is a graduated percent of charges for**

patients with incomes above 100 percent and at or below 200 percent of the Federal Poverty Guidelines (FPG).

Response is: Yes, No, or Not Applicable

22.5 **The setting of any nominal charges 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.*

Response is: Yes, No, or Not Applicable

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

23. **Did the health center provide documentation showing that each subrecipient's SFDP policy ensures that any charges for patients with incomes at or below 100 percent of the FPG are:**

Notes:
   o 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.
   o Select "Not Applicable" if the health center does not charge patients with incomes at or below 100 percent of the FPG.

23.1 **A flat fee?**

Response is: Yes, No, or Not Applicable

23.2 **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 Medicare and Medicaid co-pay amounts for patients with comparable incomes.**

Response is: Yes, No, or Not Applicable

23.3 **Not based on the actual cost of the service?**

Response is: Yes, No, or Not Applicable

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

24. **Does the health center have a process that ensures the subrecipient resolves noncompliance with Health Center Program requirements?**

Response is: Yes, No, or Not Applicable

If Yes OR No, an explanation is required.

o   IF NO: Describe the deficiencies in the health center's process.
o   IF YES: Describe the health center's process.
o   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

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

Site Visit Team Methodology

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

Site Visit Team Findings

25. **Does the health center have final executed subrecipient agreements that were awarded within the past 3 years as well as related financial and other performance records?**

    Response is: Yes, No, or Not Applicable

    If No, an explanation is required.

Footnotes

[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.

[2] See 45 CFR 75 Subpart E: Cost Principles.

[3] As defined by 45 CFR 75.329(f), procurement by "non-competitive proposals" is procurement through solicitation of a proposal from only one source.

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

[5] 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.

[6] For further guidance on these requirements, see the HHS Grants Policy Statement (PDF).

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[7] 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.

[8] 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).

[9] For further guidance on these requirements, see the [HHS Grants Policy Statement](#) (PDF).

[10] See 45 CFR 75 Subpart E: Cost Principles.

[11] 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.

[12] 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*

Health Center Program Compliance Manual Related Considerations

Documents the Health Center Provides

Checklist

- Two most recent annual audits and management letters.
- Documents 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 **use federal award funds.** Choose the contracts that use the largest amounts of federal award funds.

    Note: *Use the same sample of contracts/agreements 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, even though they may result in some overlap in the contracts/agreements reviewed.*
- Agreements with any parent corporation, affiliate, subsidiary, or subrecipient organizations.
- For look-alikes that have parent, affiliate, or subsidiary organizations that are not a state, local government, or Indian tribe:
    - Five contracts AND related supporting procurement documentation for procurements involving the related parent, affiliate, or subsidiary organizations.

    Note: *Contracts in the sample are either active or have a period of performance which ended less than 3 years ago.*
- If a real or apparent conflict of interest was identified in a procurement action that occurred within the last 3 years: All related written disclosures that were completed by employees, officers, board members, and agents of the health center (for example, board minutes documenting disclosures, standard forms to report disclosures).

Compliance Assessment

1. **Is this a Look-Alike Site Visit?**

   Response is either: Yes or No

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

Select each element below for the corresponding text of the element, site visit team methodology, and site visit finding questions.

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 members, and other relevant staff involved in procurement and/or Human Resources (HR) about the health center's standards of conduct and the process for disclosing any real or apparent conflicts of interest.
- Review the documents that contain standards of conduct related to procurement.
  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.*

Site Visit Findings

2. **Did the health center provide documents containing its standards of conduct for the selection, award, and administration of contracts that apply to its procurements paid for in whole or in part by the federal award?**

   Response is: Yes, No, or Not Applicable

If No, an explanation is required.

3. **Do these written standards of conduct:**

   3.1 **Apply to all health center employees, officers, board members, and agents involved in the selection, award, or administration of contracts paid for in whole or in part by the federal award?**

   Response is: Yes, No, or Not Applicable

   3.2 **Require written disclosure of any real or apparent conflicts of interest?**

   Response is: Yes, No, or Not Applicable

   3.3 **Prohibit individuals with a real or apparent conflict of interest with a given contract from participating in the selection, award, or administration of any contract paid for in whole or in part by the federal award?**

   Response is: Yes, No, or Not Applicable

   3.4 **Prohibit accepting gratuities, favors, or anything of monetary value?**

   Response is: Yes, No, or Not Applicable

   3.5 **Provide for disciplinary actions for violating the conflict of interest requirements?**

   Response is: Yes, No, or 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 employees, officers, board members, and agents of the health center to disclose in writing any real or apparent conflicts of interest when a conflict occurs?**

   Response is: Yes, No, or 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 the agreements with any parent corporation, affiliate, subsidiary, or subrecipient organizations.
- Review the two most recent annual audits and management letters for any references to related party transactions.
- Review the documents that contain 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?**

   Response is either: Yes or No

6. **IF YES: Did the health center provide documents containing its written standards of conduct for the selection, award, and administration of contracts that involve the related party or organization?**

   Response is: Yes, No, or 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?**

   Response is: Yes, No, or 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.

Site Visit Team Methodology

- Review the documents containing the health center's standards of conduct, including those covering any organizational conflict of interest.
- If a real or apparent conflict of interest was identified in a procurement action that occurred within the last 3 years: Review all related written disclosures that were completed by employees, officers, board members, and agents of the health center (for example, board minutes documenting disclosures, standard forms to report disclosures).
- Interview health center Project Director/CEO, board members, and other relevant staff involved in HR and procurement. Discuss mechanisms or procedures for informing employees, officers, board members, and agents of the health center's standards of conduct.

Site Visit Findings

When 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, this element is "Not Applicable."

8. **Does the health center inform employees, officers, board members, and agents of its conflict of interest standards of conduct?**

   Response is: Yes, No, or 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 that use **the largest amounts of federal award funds** AND the related supporting procurement documentation**.**
  Note: *Use the same sample of contracts/agreements 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, *even though they may result in some overlap in the contracts/agreements reviewed.*

- For look-alikes that have parent, affiliate, or subsidiary organizations that are not a state, local government, or Indian tribe: Review the five contracts AND related supporting procurement documentation for procurements involving the related parent, affiliate, or subsidiary organizations.
  Note: *Contracts in the sample are either active or have a period of performance which ended less than 3 years ago.*
- In cases where a real or apparent conflict of interest was identified in the procurement action, review the related written disclosures that are completed by employees, officers, board members, and agents of the health center (for example, board minutes documenting disclosures, standard forms to report disclosures).
- Review the audits and management letters for any findings related to conflicts of interest.

Site Visit Findings

When 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, this element is "Not Applicable."

9. **Did the health center identify any real or apparent conflicts of interest, including organizational conflicts of interest, for procurements involving federal funds? For look-alikes, did the health center identify any real or apparent organizational conflicts of interest for procurements involving any related parent, affiliate, or subsidiary organization?**

   Response is: Yes, No, or Not Applicable

10. **IF YES: Did the health center provide documentation showing that it adhered to its standards of conduct for all identified conflicts of interest, including the completion of written disclosures?**

    Response is: Yes, No, or Not Applicable

    If No, an explanation is required.

Footnotes

[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.

[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).

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)*

Health Center Program Compliance Manual Related Considerations

Documents the Health Center Provides

Checklist

- Documentation of established collaboration with other providers and organizations in the health center service area to provide access to services not available through the health center, including:
  - o Local hospitals;
  - o Specialty providers;
  - o Social service organizations; and
  - o Organizations that serve special populations.

  Examples of documentation may include memoranda of agreement (MOAs), memoranda of understanding (MOUs), letters, evidence of membership in a city-wide community health planning council, or evidence of participation in an emergency room diversion program.
- Documentation of 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.
  - o If coordination is not established, documentation of efforts to establish coordination.
  - o Documentation must include one or more health centers in the service area.
  - o Examples of documentation may include minutes or agendas from meetings, emails, or other correspondence.
- Health Center Program GeoCare Navigator Map documentation showing other health centers with sites in the service area.

Compliance Assessment

Select each element below for the corresponding text of the element, site visit team methodology, and site visit finding questions.

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 about collaboration activities, including examples of how the health center's collaborative relationships support 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 the Collaboration section and any relevant attachments in all recent competitive (any Service Area Competition and New Access Point) or designation (Initial Designation or Renewal of Designation) applications.
- Review the sample of MOUs, MOAs, or any other documentation of collaboration with other providers or programs, including:
    - Local hospitals;
    - Specialty providers;
    - Social service organizations; and
    - Organizations that serve special populations.

    Note: *The health center determines how to document collaboration or coordination with providers and organizations in its service area.*

Site Visit Findings

1. **Does the health center have documentation of its efforts to collaborate with other providers or programs in the service area to provide access to services not available through the health center? Other providers or programs include local hospitals, specialty providers, social service organizations, and organizations that serve special populations.**

    Response is either: Yes or No

    If No, an explanation is required.

2. **Did the health center provide at least one documented example of how its collaborative relationships support 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?**

    Response is either: Yes or 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 the Health Center Program GeoCare Navigator Map to identify other health centers with sites in the service area.
- Interview health center Project Director/CEO about coordination with other federally-funded, as well as state and local, health service delivery projects and programs serving similar patient populations in the service area (at a minimum, other health centers in the service area).
- Review the relevant documentation of 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.
    - If coordination is not established, review documentation of efforts to establish coordination.
    - Documentation must include one or more health centers in the service area.
    - Examples of documentation may include minutes or agendas from meetings, emails, or other correspondence.

Note: *The health center determines how to document collaboration or coordination with providers and organizations in its service area.*

Site Visit Findings

3. **Does the health center have documentation of its efforts to establish 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.*

    Response is: Yes, No, or Not Applicable

    If No OR Not Applicable, an explanation is required. If Not Applicable, state if the Health Center Program GeoCare Navigator 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?

Response is either: Yes or 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 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 does not review health center compliance with this element during the site visit. HRSA assesses compliance with this element during its review of the health center's Change in Scope requests and competing continuation application (SAC or RD).

Site Visit Findings

N/A – HRSA does not review health center compliance with this element during the site visit. HRSA assesses compliance with this element during its review of the health center's Change in Scope requests and competing continuation application (SAC or RD).

Footnotes

[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.

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*

[Health Center Program Compliance Manual Related Considerations](#)

Documents the Health Center Provides

Checklist

- Two most recent annual audits and management letters.
- Financial management, accounting, and internal control procedures. These procedures may be in the form of financial/accounting policies, manuals, or other related documents.
- Procedures for drawdown, disbursement, and expenditure of federal award funds. These procedures may be separate or part of the financial management and internal control procedures.
- Policies or procedures that govern and track the use of non-grant funds.
- Any manuals or documentation that support the financial management system used by the health center (for example, financial accounting software, practice management system).
  Note: *Some or all of the financial management system may be contracted out or carried out via a Health Center Controlled Network.*
- Two financial reports selected from the past 6 months that were provided to the board and key management staff.
- The most recent interim financial statement.
- Aged Accounts Receivable, as of most recent interim financial statement.
- Aged Accounts Payable, as of most recent interim financial statement.
- Sample of source documentation for 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.

Compliance Assessment

1. **Is this a Look-Alike Site Visit?**

Response is either: Yes or No

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

Select each element below for the corresponding text of the element, site visit team methodology, and site visit finding questions.

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, other relevant staff, and any contractors who have responsibility for the health center's financial management system.
- Review the two most recent audits and management letters.
- Review the financial management, accounting, and internal control procedures.
- Review the financial management system used by the health center, including any supporting manuals or documentation (for example, financial accounting software, practice management system).
  Note: *Some or all of the financial management system may be contracted out or carried out via a Health Center Controlled Network.*
- Review the financial reports provided to the board and key management staff.
- Review the most recent interim financial statement.
- Review the 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?**

    Response is either: Yes or 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?**

    Response is either: Yes or No

    If No, an explanation is required.

4. **Do the health center's financial management and internal control systems have the capacity to:**

    4.1 **Account for the expenditure of Health Center Program project funds (for example, segregation of funds)?**

    Response is either: Yes or No

    4.2 **Safeguard the use of associated assets and property (for example, procedures for inventory management, maintaining property records)?**

    Response is either: Yes or No

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

5. **Does the health center have the capacity to track its financial performance for the purposes of monitoring financial stability?**

    Response is either: Yes or 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 health center 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 the sample of source documentation for 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 made under the award (for example, in chart of accounts)? Specifically, do the health center's financial records contain relevant information and related source documentation?**

   Response is: Yes, No, or 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 the health center's procedures for drawdown, disbursement, and expenditure of federal award funds from the federal Payment Management System (PMS).
- Interview CFO or other health center staff authorized to draw down and expend federal award funds.

Site Visit Findings

7. **Does the health center have written procedures for drawing down federal funds?**

   Response is: Yes, No, or Not Applicable

   If No was selected, an explanation is required.

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

   8.1 **Limit the drawdown to minimum amounts needed to cover allowable project costs?**

   Response is: Yes, No, or Not Applicable

   8.2 **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?**

   Response is: Yes, No, or 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 using federal award funds are allowable in accordance with:**

   9.1 **The terms and conditions of the federal award, including those that limit the use of federal award funds?[7]**

   Response is: Yes, No, or Not Applicable

   9.2 **The federal cost principles in 45 CFR Part 75 Subpart E?**

   Response is: Yes, No, or 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.

Site Visit Team Methodology

- Review the most recent audit and management letter.
- If there are audit findings, questioned or unallowable costs, reportable conditions, material weaknesses, or significant deficiencies noted, interview the health center's CFO and other relevant health center staff about the 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?**

    Response is either: Yes or No

11. **IF YES: Has or will the health center ensure an audit is conducted in accordance with federal audit requirements? Specifically, is the audit either complete or in progress at the time of the site visit?**

    Response is: Yes, No, or Not Applicable

    If No, an explanation is required.

12. **Based on review of the most recent audit and management letter, are there any findings, questioned or unallowable costs, reportable conditions, material weaknesses, or significant deficiencies, including any cited in the previous audit report?**

    Response is: Yes, No, or Not Applicable

13. **IF YES: Has the health center either completed corrective actions to address all findings or did the health center document steps it is currently taking to address all findings?**

    Response is: Yes, No, or 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 other relevant health center staff about the use of non-grant funds.
- Review the policies or procedures that govern and track the use of non-grant funds.
- Review the financial management system used by the health center, including any supporting manuals or documentation (for example, financial accounting software, practice management system).
  Note: *Some or all of the financial management system may be contracted out or carried out via a Health Center Controlled Network.*

Site Visit Findings

14. **In the last complete fiscal year, did the health center generate revenue from health center activities that was then used for activities outside the scope of the project?**

    Response is either: Yes or No

15. **IF YES: Does the health center have documentation that these funds were used:**

    15.1   **To support activities that benefit the current patient population?**

    Response is: Yes, No, or Not Applicable

    15.2   **For purposes that are not specifically prohibited by the Health Center Program?**

    Response is: Yes, No, or Not Applicable

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

Footnotes

[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.

[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.

[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.

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)*

Health Center Program Compliance Manual Related Considerations

Documents the Health Center Provides

Checklist

- Current fee schedule for each service (for example, medical, dental, behavioral health).
- Data used to develop and update fee schedules 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 and Medicaid cost reports.
- Sliding fee discount schedule (SFDS), including any SFDSs that differ by service or service delivery method.
- List of provider, program, or site billing numbers for Medicaid, CHIP, Medicare, or any other documentation of participation (for example, individual provider NPIs).
- Documentation of participation in any other public or private program or health insurance plans (for example, list or copy of third-party payor contracts including any managed care contracts).
- Billing and Collections policies or procedures and systems, including:
  - Provisions to waive or reduce fees owed by patients;
  - Third-party payor billing procedures and contracts;
  - Any policies on patients' refusal to pay; and
  - Procedures for notifying patients of any additional costs for supplies and equipment related to but not included in the service.
- Contracts with any outside organizations that conduct billing or collections on behalf of the health center.
- Eligibility, outreach, and enrollment procedures (for example, new patient registration and screening procedures).
- 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; and
  - Days in A/R (for context on billing and collections efforts).
- Sample of at least 21 claims submissions and resubmissions to the health center's major third-party payors:
  - Randomly choose 7 claims submissions and resubmissions for patient visits from across at least 3 unique services (for example, routine primary care, preventive dental, behavioral health, obstetrics); and

- - Within this sample, include at least 7 rejected claims.
- Report showing the last 6 months of claims data, specifically: the average filing time for the last 6 months of claims as well as the individual claims numbers, dates of service, dates claims were first billed, and filing times.
- Sample of at least 15 billing and payment records related to the health center's charges to patients:
  - Randomly choose 5 records for patient visits from across at least 3 unique services (for example, routine primary care, preventive dental, behavioral health, obstetrics);
  - Ensure the sample includes patients with incomes at or below 200 percent of the Federal Poverty Guidelines (FPG); and
  - If the health center has patients with incomes above 200 percent of the FPG include records for those patients.
- Sample of two to three billing records where patient fees or payments were waived or reduced.
- Documentation of methods for notifying patients of any additional costs for supplies and equipment related to but not included in the service.
- If the health center has a refusal to pay policy: Documentation of any cases in the past 24 months when the health center applied this policy.

Compliance Assessment

Select each element below for the corresponding text of the element, site visit team methodology, and site visit finding questions.

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 the fee schedules.
- Compare the fee schedules to Form 5A.
- Interview CFO and financial or billing staff about the fee schedules.
- Review the data used to develop and update fee schedules.

Site Visit Findings

1. **Do all fee schedules 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 schedules.

Response is either: Yes or 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 the fee schedules.
- Compare the fee schedules to Form 5A.
- Interview CFO and financial or billing staff about how the health center develops and updates its fee schedule.
- Review the data used to develop and update fee schedules.

Site Visit Findings

2. **Did the health center use data on locally prevailing rates and actual health center costs to develop its current fee schedules?**

   Response is either: Yes or 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 the list of provider, program, or site billing numbers for Medicaid, CHIP, Medicare, or any other documentation of participation (for example, individual provider NPIs).
- Review the documentation of participation in any other public or private program or health insurance plans.
- Interview CFO and financial or billing staff about the health center's participation in insurance programs.

Site Visit Findings

3. **Does the health center have documentation of its participation in Medicaid, CHIP, and Medicare?**

   Response is either: Yes or No

   If No, an explanation is required.

4. **Does the health center participate in other public or private assistance programs or health insurance?**

   Response is either: Yes or No

   If No, an explanation is required, including the health center's justification for 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.
- Interview staff involved in educating patients about insurance options (for example, front desk staff, billing office staff, outreach and enrollment staff).
- Review the billing and collections systems, including third-party payor billing procedures and contracts.
- Review the contracts with any outside organizations that conduct billing or collections on behalf of the health center.
- Review the eligibility, outreach, and enrollment procedures (for example, new patient registration and screening procedures).

Site Visit Findings

5. **Did the health center explain how it educates patients about available insurance coverage options?**

    Response is either: Yes or 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?**

    Response is either: Yes or No

    If No, an explanation is required.

7. **Does the health center have systems in place for collecting balances owed by patients?**

    Response is either: Yes or No

    If No, an explanation is required.

8. **When requesting payments from patients, do the health center's billing and collections systems and procedures ensure that no patient is denied service based on inability to pay?**

    Response is either: Yes or No

    If Yes OR No, an explanation is required, including describing the systems and 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 the billing and collections systems and related procedures for any additional billing options or payment methods.

Site Visit Findings

9. **Does the health center offer additional billing options or payment methods? For example, payment plans, grace periods, or prompt or cash payment incentives.**

    Response is either: Yes or 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?**

    Response is: Yes, No, or 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?**

    Response is: Yes, No, or 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 the sample of claims submission and resubmission data.
- Review the third-party payor billing procedures.
- Review the current data on the revenue cycle management metrics.
- Interview CFO and staff involved in the billing and collections process.

Site Visit Findings

12. **Does the health center submit claims within an average of 14 business days from the date of service?**

Response is either: Yes or 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. **Does the health center correct and resubmit claims that have been rejected or denied due to accuracy?**

Response is either: Yes or 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.

Site Visit Team Methodology

- Interview CFO and staff involved in the billing and collections process.
- Review the fee schedules and the corresponding SFDSs.
- Review the billing and collections systems and any related procedures.
- Review the current data on the revenue cycle management metrics.
- Review the sample of billing and payment records related to the health center's charges to patients.

Site Visit Findings

14. **Are patients billed for services using the health center's fee schedules and are the correct discounts applied to these charges?**

Response is either: Yes or 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, the health center sends statements for outstanding balances or makes phone calls.**

    Response is either: Yes or 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 the policies and procedures that contain provisions to waive or reduce fees owed by patients.
- Review the sample of billing records where patient fees or payments were waived or reduced.

Site Visit Findings

16. **Do the health center's policies and procedures include a provision stating the circumstances or criteria for when fees or payments will be waived or reduced based on a patient's inability to pay (regardless of patient income level)?**

    Response is either: Yes or No

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

17. **Based on the sample of records, does the health center follow the provision in its policies and procedures for waiving or reducing fees or payments?**

    Response is: Yes, No, or Not Applicable

    If No, an explanation is required. If the health center has no billing records where patient fees or payments were waived or reduced, an explanation is also 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 the billing procedures and methods for notifying patients of any additional costs for supplies and equipment related to but not included in the service.

Site Visit Findings

18. **Does the health center charge patients for supplies or equipment (for example, eyeglasses, dentures, insulin pump) related to but not included in the service?**

    Response is either: Yes or No

19. **IF YES: Does the health center have a method for notifying patients about out-of-pocket costs for those supplies or equipment, before providing the service?**

    Response is: Yes, No, or Not Applicable

    If No, an explanation is required.

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 the billing and collection policies and procedures.
- Review any policies on patients' refusal to pay.

- Review the documentation of any cases in the past 24 months when the health center applied its refusal to pay policy.

Site Visit Findings

20. Does the health center limit or deny services to patients who refuse to pay?

Response is either: Yes or No

21. IF YES: Does the health center have a refusal to pay policy?

Response is: Yes, No, or Not Applicable

If No, an explanation is required.

22. Does the health center:

22.1 **Distinguish between refusal to pay and inability to pay?**

Response is: Yes, No, or Not Applicable

22.2 **Notify patients of amounts owed and the time permitted to make payments?**

Response is: Yes, No, or Not Applicable

22.3 **Notify patients of collection efforts that may be taken (for example, meeting with a financial counselor, establishing payment plans)?**

Response is: Yes, No, or Not Applicable

22.4 **Notify patients how services may be limited or denied when the patient has refused to pay?**

Response is: Yes, No, or Not Applicable

If Yes OR No was selected for any of the above, an explanation is required, including specifying whether the health center has a policy or procedure that addresses each area.

23. In cases where the health center has limited or denied services to one or more patients due to refusal to pay, were the determinations consistent with health center policies or procedures?

Response is: Yes, No, or Not Applicable

If Yes OR No, an explanation is required, including how the determinations were made.

Footnotes

[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 (PDF), Section I: E. Eligibility and Coverage, Coverage Under Alternate Billing Arrangements.

[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.

[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.

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*

[Health Center Program Compliance Manual Related Considerations](#)

Documents the Health Center Provides

Checklist

- Updated annual budget for the health center project (if updated since last application submission to HRSA).
- Budget to actual comparison report for the current fiscal year.
- Budget to actual comparison report for the prior fiscal year.
- For context and background on budget development process: Financial management procedures.
- As a reference for any other lines of business: Most recent annual audit and management letter or audited financial statements.
- If the health center has an organizational budget that is separate from the health center project budget: All separate organizational budgets for the current fiscal year.

Compliance Assessment

Select each element below for the corresponding text of the element, site visit team methodology, and site visit finding questions.

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 the health center's current annual budget for the health center project.
- Review the budget to actual comparison report for the current fiscal year.
- Review the budget to actual comparison report for the prior fiscal year.
- Review the financial management procedures.
- Review the health center's approved scope of project (Form 5A and Form 5B), including any special populations funding or designation.

- Determine if there has been any change in the scope of project that impacts the current budget since the last Health Center Program application.
- Interview health center Project Director/CEO, CFO, and financial staff to understand:
  - The budget formulation process (for example, budget assumptions such as clinician productivity, payer mix); and
  - Any variances or questions raised by the review of budget to actual comparison reports.

Site Visit Findings

1. **Does the health center have an annual operating budget that reflects the projected costs and revenues necessary to support the health center's HRSA-approved scope of project; specifically, does the budget reflect revenue and expenses for all sites, services, and activities within the scope of project?**

   Response is either: Yes or 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 does not review health center compliance with this element during the site visit. HRSA assesses compliance with this element during its review of the health center's competing continuation application (SAC or RD).

Site Visit Findings

N/A – HRSA does not review health center compliance with this element during the site visit. HRSA assesses compliance with this element during its review of the health center's competing continuation application (SAC or RD).

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 does not review health center compliance with this element during the site visit. HRSA assesses compliance with this element during its review of the health center's competing continuation application (SAC or RD).

Site Visit Findings

N/A – HRSA does not review health center compliance with this element during the site visit. HRSA assesses compliance with this element during its review of the health center's competing continuation application (SAC or RD).

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

- Review the health center's approved scope of project (Form 5A and Form 5B).
- To determine whether the health center operates other lines of business:
  - Review the most recent audit or audited financial statements; and
  - Interview health center Project Director/CEO, CFO, and financial staff.
- If the health center has an organizational budget that is separate from the health center project budget, review all separate organizational budgets for the current fiscal year.

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

Site Visit Findings

2. **Does the health center engage in any other lines of business; specifically, does the health center serve other populations or operate sites, services, or activities that are NOT within the HRSA-approved scope of project?**

   Response is either: Yes or No

3. **IF YES:**

   3.1 **Can the health center document that these other lines of business are fully supported by non-health center project revenues?**

   Response is: Yes, No, or Not Applicable

   3.2 **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?**

   Response is: Yes, No, or Not Applicable

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

Footnotes

[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.

[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).

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)*

[Health Center Program Compliance Manual Related Considerations](#)

Documents the Health Center Provides

Checklist

- 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. The reports must include information on:
  - o Patient service utilization;
  - o Trends and patterns in the patient population; and
  - o Overall health center clinical, financial, or operational performance.

Compliance Assessment

Select each element below for the corresponding text of the element, site visit team methodology, and site visit finding questions.

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 does not review health center compliance with the portion of element "a" in brackets during the site visit. HRSA assesses compliance with the portion of element "a" in brackets during its review of the health center's UDS report submission.

Site Visit Team Methodology

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

Notes:
- Assess and document findings related to financial management and accounting systems capacity in the Financial Management and Accounting Systems section.
- Assess and document findings related to quarterly Quality Improvement/Quality Assurance assessments in the Quality Improvement/Assurance section.
- Do NOT repeat those findings here.

Site Visit Findings

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?**

   Response is either: Yes or 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 the one to two 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 about the receipt and relevance of health center data-based reports.

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 includes the production of reports on:**

   2.1 **Patient service utilization?**

   Response is either: Yes or No

   2.2 **Trends and patterns in the patient population?**

   Response is either: Yes or No

   2.3 **Overall health center clinical, financial, and operational performance?**

   Response is either: Yes or No

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

Footnotes

[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.

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)*

Health Center Program Compliance Manual Related Considerations

Documents the Health Center Provides

Checklist

- Health center organization charts with names of key management staff.
- For public agencies or for organizations with a parent or subsidiary: Corporate organization charts.
- Articles of Incorporation.
- Bylaws (if updated since last application submission to HRSA).
- Any additional corporate or governing documents.
- For public agencies with a co-applicant: Co-applicant agreement (if updated since last application submission to HRSA).
- Any agreements with a parent corporation, affiliate, subsidiary, or subrecipient organizations.
- Any collaborative or contractual agreements with outside entities that impact the health center board's authorities or functions.
- Board calendar or other related scheduling documents for the most recent 12 months.
- Board agendas and minutes for:
  - The most recent 12 months.
  - Any other relevant meetings from the past 3 years that demonstrate board authorities were clearly exercised, including approving key policies on:
    - Sliding Fee Discount Program;
    - Quality Improvement/Quality Assurance Program;
    - Billing and Collections, specifically policies for waiving or reducing patient fees and any policies on patients' refusal to pay;
    - Financial Management and Accounting Systems; and
    - Personnel.
  Note: *For look-alike initial designation applicants and newly-funded health centers that do not have 12 months of board agendas and minutes, all of the available board agendas and minutes from within the past 12 months.*
- Sample of board packets from two board meetings that occurred during the most recent 12 months.
- Board committee minutes OR committee documents from the most recent 12 months that support board functions and activities.
- Strategic plan or long-term planning documents from within the past 3 years.
- Position description for the Project Director/CEO.

- Project Director/CEO employment agreement, highlighting the provisions that address Project Director/CEO selection, evaluation, and dismissal or termination.
- Most recent evaluation of Project Director/CEO.

Compliance Assessment

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]**

   Response is either: Yes or No

   NOTE: *If "Yes" was selected, NONE of the questions for ANY of the elements in the Board Authority section are applicable.*

Select each element below for the corresponding text of the element, site visit team methodology, and site visit finding questions.

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 the health center organization charts, articles of incorporation, bylaws, and any additional corporate or governing documents.
- Review any corporate organization charts.
- Review the health center's Form 5A and Form 5B to determine current HRSA-approved scope of project.

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

Site Visit Findings

When responding to the question(s) below, please note:
For a public agency with a co-applicant board, the public agency is not considered to be an outside entity because it is the award recipient.

2. **Do health center documents and agreements confirm that:**

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

   Response is either: Yes or No

   2.2 **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?**

   Response is either: Yes or 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:**

   3.1 **Delegates the required authorities and functions to the co-applicant board?**

   Response is: Yes, No, or Not Applicable

   3.2 **Delineates the required roles and responsibilities of the public agency and the co-applicant board in carrying out the health center project?**

   Response is: Yes, No, or 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 any additional corporate or governing documents.
- Review any co-applicant agreement.

Site Visit Findings

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

    4.1 **Holding monthly meetings?**

    Response is either: Yes or No

    4.2 **Approving the selection and the termination or dismissal of the health center's Project Director/CEO?**

    Response is either: Yes or No

    4.3 **Approving the health center's annual budget and applications?**

    Response is either: Yes or No

    4.4 **Approving health center services?**

    Response is either: Yes or No

    4.5 **Approving the location and hours of operation of health center sites?**

    Response is either: Yes or No

4.6 **Evaluating the performance of the health center?**

Response is either: Yes or No

4.7 **Establishing or adopting policy related to the operations of the health center?**

Response is either: Yes or No

4.8 **Assuring the health center operates in compliance with applicable federal, state, and local laws and regulations?**

Response is either: Yes or No

If No was selected for any of the above, an explanation is required, including specifying which authorities or 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:
  - o Achievement of project objectives;
  - o Service utilization patterns;
  - o Quality of care;
  - o Efficiency and effectiveness of the center; and
  - o Patient satisfaction, including addressing any patient grievances.

Site Visit Team Methodology

- Interview Project Director/CEO about board roles and responsibilities (for example, evaluating health center performance, approving applications, conducting long-range planning, evaluating health center policies).
- Interview board (co-applicant board in the case of a public agency-co-applicant structure) about 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, 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 board member. If a group board interview is not possible, interview board members individually.*
- If conducting a review for a public agency health center, interview relevant public agency staff (for example, leadership and staff who work with the health center project) about their various roles and responsibilities.
- Review the board calendar or other related scheduling documents for the most recent 12 months.
- Review the board agendas and minutes for the most recent 12 months and any other relevant meeting minutes from the past 3 years that demonstrate board authorities were clearly exercised.

  Note: *For look-alike initial designation applicants and newly-funded health centers that do not have 12 months of board agendas and minutes, review all of the available board agendas and minutes from within the past 12 months.*
- Review any relevant board committee minutes OR committee documents for the most recent 12 months that support board functions and activities.
- Review the sample of board packets from two board meetings that occurred during the most recent 12 months.
- Review the strategic planning or related documents from within the past 3 years.
- Review the 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 present that enabled the board to carry out its required authorities and functions?**

   Notes:
   - The health center determines how to set quorum for board meetings consistent with state, territorial or other applicable law.
   - For look-alike initial designation applicants and newly-funded health centers that did not have 12 months of board agendas and minutes, determine whether the board met monthly based on the board minutes provided.

   Response is either: Yes or No

If No, an explanation is required.

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

   6.1 **Approving the selection, evaluation, and, if necessary, dismissal or termination of the Project Director/CEO from the health center project?**

   Response is either: Yes or No

   6.2 **Approving applications related to the health center project? For example, Service Area Competition (SAC), look-alike Renewal of Designation (RD), New Access Point (NAP), and supplemental funding applications.**

   Response is either: Yes or No

   6.3 **Approving the health center project's annual budget, which outlines the proposed uses of both federal Health Center Program award and non-federal resources and revenue?**

   Response is either: Yes or No

   6.4 **Approving the health center project's sites and hours of operation?**

   Response is either: Yes or No

   6.5 **Approving the health center project's services and any decisions to subaward or contract for a substantial portion of the health center's services?**

   Response is either: Yes or No

   6.6 **Monitoring the financial status of the health center, including reviewing the results of the annual audit and ensuring appropriate follow-up actions are taken?**

   Response is either: Yes or No

   6.7 **Conducting long-term strategic planning at least once every 3 years, which at a minimum addresses financial management and capital expenditure needs?**

   Response is either: Yes or 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 the review of board minutes, board agendas, other relevant documents, and interviews conducted with the Project Director/CEO and board members, are there examples of how the board evaluates the performance of the health center using quality**

assurance/quality improvement assessments and other information received from health center management?

Response is either: Yes or No

If No, an explanation is required.

8. **IF YES: Based on these performance evaluations, are there examples of follow-up actions that are reported back to the board about:**

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

   8.1 **Achievement of Health Center Program project objectives?**

   Response is: Yes, No, or Not Applicable

   8.2 **Service utilization patterns?**

   Response is: Yes, No, or Not Applicable

   8.3 **Quality of care?**

   Response is: Yes, No, or Not Applicable

   8.4 **Efficiency and effectiveness of the health center?**

   Response is: Yes, No, or Not Applicable

   8.5 **Patient satisfaction, including addressing any patient grievances?**

   Response is: Yes, No, or 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 the 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/Quality Assurance Program; and
  - Billing and Collections, specifically policies for waiving or reducing patient fees and any policies on patients' refusal to pay.
- Interview the same board members identified in element "c" about the board's evaluation of the health center's SFDP, quality improvement/quality assurance program, and billing and collections policies. Also, discuss any related updates to these policies.

Site Visit Findings

9. **Within the last 3 years, did the board adopt or evaluate health center policies in the following areas:**

   9.1 **SFDP?**

   Response is either: Yes or No

   9.2 **Quality Improvement/Quality Assurance Program?**

   Response is either: Yes or No

   9.3 **Billing and Collections policy for waiving or reducing patient fees, and, if applicable, refusal to pay?**

   Response is either: Yes or No

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

10. **Did the health center provide one to two examples of how it has modified or updated its policies, if needed, because of these evaluations?**

    Note: *Select "Not Applicable" if updates were not needed because of these evaluations.*

    Response is: Yes, No, or Not Applicable

    If No OR Not Applicable, an explanation is required.

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

Site Visit Findings

When responding to the question(s) below, please note:
The content of a health center's financial management and personnel policies may vary. For example, a health center may still demonstrate compliance even if its procurement procedures are not part of its board-approved financial management policy. Assess compliance with procurement procedures in Contracts and Subawards.

11. **Within the last 3 years, did the board evaluate health center policies that support the following areas:**

   Note: *For health centers where the public agency retains the authority to adopt and approve personnel policies or policies that support financial management and accounting systems, select "Not Applicable."*

   11.1 **Financial management and accounting systems?**

   Response is: Yes, No, or Not Applicable

   11.2 **Personnel?**

   Response is: Yes, No, or Not Applicable

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

Footnotes

[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 use 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.

[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).

[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.

[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.

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*

[Health Center Program Compliance Manual Related Considerations](#)

Documents the Health Center Provides

Checklist

- Health center organization charts with names of key management staff.
- For public agencies or for organizations with a parent or subsidiary: Corporate organization charts.
- Articles of Incorporation.
- Bylaws (if updated since last application submission to HRSA).
- Any additional corporate or governing documents.
- For public agencies with a co-applicant: Co-applicant agreement (if updated since last application submission to HRSA).
- Updated Form 6A (PDF) or board roster (if board composition has changed since last application submission to HRSA) 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: sex, race, and ethnicity.
- Additional documentation about current board member characteristics (for example, applications, bios, disclosure forms).
- Billing records from within the past 24 months that 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).

Compliance Assessment

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]**

   Response is either: Yes or No

   NOTE: *If "Yes" was selected, NONE of the questions for ANY of the elements in the Board Composition section are applicable.*

Select each element below for the corresponding text of the element, site visit team methodology, and site visit finding questions.

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 the organization charts, articles of incorporation, bylaws, and any additional corporate or governing documents.
- Review any corporate organization charts.
- Review any co-applicant agreement.

Note: *Assess bylaw provisions about board composition for compliance with Health Center Program requirements as noted in the Health Center Program Compliance Manual. Do not assess compliance beyond those requirements.*

Site Visit Findings

2. **Do the bylaws or other documentation specify an ongoing selection and removal process for board members?**

   Response is either: Yes or 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:**

   3.1 **The board chair?**

   Response is either: Yes or No

   3.2 **The majority of health center board members?**

   Response is either: Yes or No

   3.3 **The majority of the non-patient board members?**

   Response is either: Yes or 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.

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 sex;
- 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.

Site Visit Team Methodology

- Review the health center articles of incorporation, bylaws, and other relevant corporate or governing documents.
- Review any co-applicant agreement.

Site Visit Findings

4. **Do the bylaws or other corporate or governing documentation include provisions that ensure:**

   4.1 **Board size is at least 9 and no more than 25 members, with either a specific number or a range of board members prescribed?**

Response is either: Yes or No

4.2 **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 waive*r.

Response is: Yes, No, or Not Applicable

4.3 **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 sex?**

Response is either: Yes or No

4.4 **Non-patient members are representative of the community served by the health center or the health center's service area?**

Response is either: Yes or No

4.5 **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?**

Response is either: Yes or No

4.6 **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]**

Response is either: Yes or No

4.7 **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?**

Response is either: Yes or 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 sex, 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]

Site Visit Team Methodology

- Review the UDS data for an overview of patient population demographic factors (race, ethnicity, and sex).
- Interview board members on how the board evaluates board membership in terms of representing patient population demographic factors as reported in the health center's UDS report.
- Review the current board roster or Form 6A.
- Review the additional documentation about current board member characteristics.
- Review the billing records to confirm the patient status of board members.
- Review the health center background information to confirm any special populations funding or designation.

Site Visit Findings

5. **Is the health center board currently composed of at least 9 and no more than 25 members?**

   Response is either: Yes or 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.*

Response is: Yes, No, or Not Applicable

If No, an explanation is required, including specifying the number of total board members and how many are current patients of the health center.

7. **Based on the previous response, did each patient board member receive at least one in-scope service at an in-scope site within the past 24 months that generated a health center visit?**

   Response is either: Yes or No

   If No, an explanation is required.

8. **FOR HEALTH CENTERS WITH SPECIAL POPULATIONS FUNDING/DESIGNATION: Did the health center identify board members who serve as representatives *from or for* each of the health center's funded/designated special populations (individuals experiencing homelessness, migratory and seasonal agricultural workers, residents of public housing)?**

   Note: *At least one unique individual needs to represent each special population.*

   Response is: Yes, No, or 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 sex 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 AND no patient board members.*

   Response is: Yes, No, or 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 made to evaluate board composition and recruit representative patient board members based on the health center's UDS data.

10. **Do the health center's non-patient board members either live or work in the community where the health center is located?**

    Response is either: Yes or No

    If No, for each non-patient board member who does not live or work in the community, an explanation is required describing that board member's connections 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)?

Response is either: Yes or 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.*

    Response is either: Yes or 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.

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 to confirm there are no prohibited members.
- Review the current board roster or Form 6A.

Site Visit Findings

13. **Has the health center verified that the current board does not include any members who are:**

    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.*

    13.1   **Employees of the health center?**[16,17]

             Response is either: Yes or No

13.2   **Immediate family members of current health center employees (i.e., spouses, children, parents, or siblings through blood, adoption, or marriage)?**

Response is either: Yes or No

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:

- "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 does not review health center compliance with this element during the site visit. HRSA assesses compliance with this element during its review of the health center's competing continuation application (SAC or RD).

Site Visit Findings

N/A – HRSA does not review health center compliance with this element during the site visit. HRSA assesses compliance with this element during its review of the health center's competing continuation application (SAC or RD).

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.

Site Visit Team Methodology

For health centers with an approved waiver:
- Review the health center's HRSA-approved Form 6B waiver request.
- Review the documented examples from the health center on the use of special population input.
- Interview board members on the use of special population input.

Site Visit Findings

14. **FOR HEALTH CENTERS WITH APPROVED WAIVERS ONLY: Does the health center collect and document input from the special populations?**

    Note: *Select "Not Applicable" only if the health center does not have an approved waiver.*

    Response is: Yes, No, or Not Applicable

    If No, an explanation is required.

15. **Did the health center 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.**

    Response is: Yes, No, or Not Applicable

    If No, an explanation is required.

Footnotes

[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 (PDF)]. Section 330(k)(3)(H) of the PHS Act.

[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.

[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 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.

[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 individual under 8 U.S.C. 1138a 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.

[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.

[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.

[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.

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 Initial Designation Application Instructions & Resources](#)

Documents the Health Center Provides

Checklist

- 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**).
- Five health center patient records[1] that document the provision of various required and additional health services.
  Notes:
    - The same sample of patient records used for reviewing other program requirement areas may also be used for this sample.
    - Use live navigation of the EHR, screenshots from the EHR, or other patient record formats.
- Applicant's current organization charts with names of key management staff.
- For public agencies or for organizations with a parent or subsidiary: Corporate organization charts.
- Project Director/CEO position description.
- Project Director/CEO employment agreement.
- Most recent annual audit and management letter. If audits are not available: Audited financial statements.
- Sample of up to three Medicare or Medicaid claims or other billing documents. The sample should show the organizational entity or unit that conducts the billing.
- Bylaws (if updated since last application submission to HRSA).
- For public agencies with a co-applicant: Co-applicant agreement (if updated since last application submission to HRSA).
- If the applicant has contracts or memoranda of understanding (MOUs) 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 and MOUs that includes:
    - All active contracts and MOUs;
    - All contracts and MOUs that had a period of performance that ended less than 3 years ago; and
    - The following information for each contract and MOU:

- Contractor or contract/MOU organization;
- Brief description of all goods and services provided;
- Period of performance/timeframe (for example, specific duration, ongoing contractual/MOU relationship); and
- Whether the contract or MOU indicates a third party plays a substantive role in the Health Center Program project (for example, a contract or MOU with a single entity for the majority of: health care providers and services, key management staff, or administrative functions).
- Any and all contracts or MOUs that indicate a third party plays a substantive role in the Health Center Program project (for example, a contract for the majority of health care providers and services, a contract for the majority of key management staff, an administrative services agreement for the majority of administrative functions).
- If the applicant has a parent corporation, affiliate, subsidiary, or other controlling organization: All related agreements or other documentation.
- Documentation (for example, employment contracts) that shows the organization is not owned, operated, or controlled by another entity.

Eligibility Requirements

1. **Is this a Look-Alike Initial Designation Site Visit?**

   Response is either: Yes or No

   NOTE: *If "No" was selected, NONE of the questions in this Look-Alike Initial Designation section are applicable.*

Select each section below for the corresponding text of the eligibility requirement, site visit team methodology, and site visit finding questions.

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

- Tour service delivery sites (one or more sites on Form 5B).
- Review the patient services utilization report.
- Review the five health center patient records that document the provision of various required and additional health services.
  Notes:

- The same sample of patient records used for reviewing other program requirement areas may also be used for this sample.
- Use live navigation of the Electronic Health Record (EHR), screenshots from the EHR, or other patient record formats.

Site Visit Findings

2. **Is the applicant CURRENTLY delivering primary health care services to patients within the proposed service area?**

   Response is either: Yes or No

   If No, an explanation is required.

3. **Does the health center have at least one permanent service delivery site that:**

   Note: *A permanent site is a fixed location that operates year-round.*

   3.1 **Provides comprehensive primary medical care as the site's main purpose?**

   Response is either: Yes or No

   3.2 **Operates for a minimum of 40 hours per week?**

   Note: *Only select "Not Applicable" if the health center is applying for designation to serve only migratory and seasonal agricultural workers, in which case the health center may have a full-time seasonal rather than permanent site.*

   Response is: Yes, No, or Not Applicable

   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?**

   Response is either: Yes or 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 the applicant's current organization charts.
- Review the Project Director/CEO position description and employment agreement.
- Interview Project Director/CEO about the day-to-day oversight of health center activities.
- Interview the applicant organization's Project Director/CEO, CFO, financial staff, and board members (for example, board chair, board treasurer) about ownership and operation of the applicant organization.
- Review the most recent annual audit and management letter of the applicant organization. If audits are not available, review audited financial statements of the applicant organization.
- Review the Medicare or Medicaid claims or other billing documents that show the organizational entity or unit that conducts the billing.
- Review the bylaws of applicant organization and any co-applicant agreement for a public agency applicant with a co-applicant governing board.
- Review the complete list of contracts and MOUs to identify those that indicate a substantive role in the Health Center Program project.
- Review any and all contracts and MOUs that indicate a third party plays a substantive role in the Health Center Program project to determine if these contracts and MOUs impede or prohibit the applicant from performing a substantive role in the Health Center Program project.
- If the applicant has a parent company, affiliate, subsidiary or other controlling organization, review all related agreements or other documentation to identify if the parent company, affiliate, subsidiary or other controlling organization:
  - Plays a substantive role in the Health Center Program project; or
  - Impedes or prohibits the applicant from performing a substantive role in the Health Center Program project.
- Review any additional documentation (for example, employment contracts) that shows 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. **Does the organization applying for look-alike designation currently OWN AND CONTROL the organization's assets and liabilities? For example, the applicant organization does not have a sole corporate member or is not a subsidiary of another organization.**

    Response is either: Yes or 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 organization applying for look-alike designation 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?**

    Response is either: Yes or No

    If No, an explanation is required.

7. **Does the organization applying for look-alike designation operate the Health Center Program project? Specifically, the applicant organization operates the services and activities included in the look-alike application.**

    Response is either: Yes or No

    If No, an explanation is required.

8. **Does the organization applying for look-alike designation have a Project Director/CEO in place who carries out independent, day-to-day oversight of the health center services and activities included in the look-alike application, solely on behalf of the governing board of the applicant organization?**

    Response is either: Yes or No

    If No, an explanation is required.

9. **Did the organization applying for look-alike designation demonstrate that it will perform a substantive role in the Health Center Program project?**

    Response is either: Yes or No

    If No, an explanation is required describing the contractual or organizational arrangements that impede or prohibit the applicant from performing a substantive role in the Health Center Program project (for example, a contract for the majority of health care providers and services, a contract for the majority of key management staff, an administrative services agreement for the majority of administrative functions).

Footnotes

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