

Health Center Program Site Visit Protocol:

Introduction

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INTRODUCTION

Purpose

The purpose of Health Resources and Services Administration (HRSA) site visits¹ is to support the effective oversight of the Health Center Program. Operational Site Visits (OSVs) provide an objective assessment and verification of the status of each Health Center Program awardee or look-alike's compliance with the statutory and regulatory requirements of the Health Center Program. In addition, HRSA conducts site visits to assess and verify look-alike initial designation applicants for eligibility and compliance with Health Center Program requirements to inform initial designation determinations. For the purposes of this document, the term "health center" refers to entities that apply for or receive a federal award under section 330 of the Public Health Service (PHS) Act (including section 330 (e), (g), (h) and (i)), section 330 subrecipients, and organizations designated as look-alikes.

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

- An analysis of one or more performance measure(s)
- Identification, as applicable, of promising practices

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

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

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."

for site visits and to help regularly assess and assure ongoing compliance with the Health Center Program.

Site Visit Report and Compliance Determinations

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

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

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

Site Visit Protocol Structure

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

Each of these SVP sections contains the following components:

- **Statute and Regulations:** The supporting statute and regulations for the associated program requirements.

² For additional information on how HRSA pursues remedies for non-compliance, including progressive action, see Health Center Program Compliance Manual, [Chapter 2: Health Center Program Oversight](#).

³ Unresolved Health Center Program conditions related to clinical staffing and/or quality improvement/assurance, requirements that apply to both Health Center Program and FTCA deeming, may impact FTCA deeming if they are not resolved by the time that HRSA makes annual FTCA deeming decisions.

⁴ Health centers that have question regarding the FTCA Program or FTCA deeming requirements may contact Health Center Program Support at 1-877-464-4772 or <https://www.hrsa.gov/about/contact/bphc.aspx>.

⁵ Look-alike initial designation applicants must be compliant with all Health Center Program requirements at the time of application and should refer to the look-alike Initial Designation application for further guidance on how HRSA will address findings of non-compliance at a pre-designation OSV.

- **Primary and Secondary Reviewers:** The member of the site visit team who serves as the primary reviewer for that section, based on expertise (governance/administrative, fiscal, or clinical), and an optional or suggested secondary reviewer who may add expertise and assistance as needed. The site visit team confers and works together on compliance assessments.
- **Documents Checklist for Health Center Staff:** The list of documents a health center provides to the site visit team prior to the site visit or onsite.⁶
 - Documents provided *prior to the site visit* are to be sent **at least 2 weeks prior to the start of the site visit**.
 - Documents provided *by the start of the site visit* are to be ready **when the site visit team arrives onsite**.
 - 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 and have it ready when the site visit team arrives onsite**.
 - 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.
 - If the sample provided by the health center is not sufficient to allow the HRSA site visit team to assess the program requirement, the team may complete additional sampling in coordination with the health center.
 - ***Documents not provided by the close of the first day of the site visit will not be considered in the compliance assessment by the site visit team.***
- **Demonstrating Compliance Elements:** The elements from the Compliance Manual that describe how health centers would demonstrate their compliance with the applicable Health Center Program requirements.⁷
- **Site Visit Team Methodology:** The methods a site visit team uses to assess compliance with the corresponding demonstrating compliance elements. Methods

⁶ Site visit teams, including consultants, are authorized representatives of HRSA and thus may review a health center's policies and procedures, financial or clinical records, and other relevant documents, in order to assess and verify compliance with Health Center Program and FTCA deeming requirements. Site visit teams are also subject to confidentiality standards, including Health Insurance Portability and Accountability Act (HIPAA). Consultants who violate such standards are in violation of their contract, and could be subject to Title 18, United States Code, Section 641. While it is permissible for health centers to request that HRSA staff and/or consultants sign additional confidentiality statements, this should be communicated prior to or at the beginning of the site visit to avoid any disruption or delay in the site visit process.

⁷ A small subset of elements are not assessed during a site visit because HRSA assesses them by other means (for example, competitive application review, look-alike Renewal Designation application review, HRSA Division of Grants Management Office (DGMO) review).

include but are not limited to reviews of policies and procedures, samples of files and records, site tours, and interviews.⁸

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

⁸ Interviews with health center staff are intended to supplement and assist the site visit team in its review of policies, procedures, and other documentation.