

# **Health Center Program Site Visit Protocol:**

## **Introduction**

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# INTRODUCTION

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## Purpose

The purpose of Health Resources and Services Administration (HRSA) site visits<sup>1</sup> 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 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](#) (the "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 OSV also includes sections for the following:

- An analysis of one or more performance measure(s)
- Identification, as applicable, of promising practices
- A review of 340B requirements for those health centers that participate in the HRSA Office of Pharmacy Affairs 340B Drug Pricing Program.<sup>2</sup>

During the OSV, at the health center's request, consultants may choose to 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.

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<sup>1</sup> 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."

<sup>2</sup> Health centers that have questions regarding the Office of Pharmacy Affairs 340B Drug Pricing Program may contact the 340B Drug Pricing Program Call Center: [ApexusAnswers@340bpvp.com](mailto:ApexusAnswers@340bpvp.com). Apexus phone: 888-340-2787. Live chat: [www.340bpvp.com](http://www.340bpvp.com).

HRSA typically conducts OSVs during the first 10-14 months of a newly-funded/newly-designated health center's project/designation period. After the first project/designation period, HRSA conducts OSVs at least once per project/designation period, generally around 18 months. HRSA strongly encourages all health centers to review and utilize both the Compliance Manual and the SVP to prepare for site visits and to help regularly assess and assure ongoing compliance with the Health Center Program.

## Site Visit Report and Compliance Determinations

HRSA will develop and share a site visit report with the health center within 45 days after the site visit. The report will convey the site visit findings and final compliance determinations. In circumstances where HRSA has determined 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.<sup>3</sup>

The Federal Tort Claims Act (FTCA) Program will also use the site visit report to support FTCA deeming decisions, and to identify technical assistance needs for FTCA-deemed health centers.<sup>4,5</sup> 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 with the health center. The health center is expected to respond to the Corrective Action Plan 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.<sup>6</sup> Health centers may also contact the 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.

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<sup>3</sup> 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](#).

<sup>4</sup> 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.

<sup>5</sup> Health centers that have question regarding the FTCA Program or FTCA deeming requirements may contact the Health Center Program Support: 877-464-4772 or <http://www.hrsa.gov/about/contact/bphc.aspx>

<sup>6</sup> 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.

The following components are contained within each SVP section that assesses whether a health center has demonstrated compliance with Health Center Program requirements:

- **Statute and Regulations:** The supporting statute and regulations for the associated program requirements.
- **Primary and Secondary Reviewers:** The member of the site visit team who will serve 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.
- **Documents Checklist for Health Center Staff:** A list of the documents that health centers will provide to the consultant team prior to the site visit or onsite.<sup>7</sup>
  - In cases where a sample (e.g., 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 for the site visit team at the start of the site visit.
  - 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 size does not allow a consultant to assess the program requirement, the consultant may complete additional sampling in coordination with the health center.
- **Demonstrating Compliance Elements:** The elements from the Health Center Program Compliance Manual that describe how health centers would demonstrate their compliance with the applicable Health Center Program requirements. A small subset of elements are not assessed during a site visit because an assessment is conducted via other means by HRSA (e.g., competitive application review, look-alike renewal designation application review, HRSA’s Division of Grants Management Office (DGMO) review). The SVP clearly indicates where this is the case.
- **Site Visit Team Methodology:** The methods site visit teams will use to assess compliance with the corresponding demonstrating compliance elements. Methods include but are not limited to reviews of policies and procedures, samples of files and records, site tours, and interviews.
- **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.

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<sup>7</sup> 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. 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.