

Federally Qualified Health Center and Look-Alike Bureau of Primary Health Care Operational Site Visit Compliance Audits



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Federally qualified health centers and look-alikes (“health centers”) must comply with a number of requirements and are subject to regulation by the federal Healthcare Resources Services Administration (HRSA).¹ Project officers in HRSA’s Bureau of Primary Health Care (BPHC) are primarily responsible for overseeing health centers to ensure their compliance with health center program requirements.² HRSA has identified 19 key program requirements, which are based on requirements outlined in the Public Health Service Act and regulations.³ A summary of the program requirements is included in Figure 1.

HRSA groups the program requirements into four broad categories: patient need; the provision of services; management and finance; and governance.⁴ HRSA uses onsite visits, which it refers to as onsite technical assistance, as a method to oversee health center compliance with the program requirements.⁵

According to HRSA, there are seven types of site visits, some of which are designed specifically to assess compliance and others which are focused on providing a health center with technical assistance or training to improve its performance. Two of the seven types of site visits – new start initial and operational assessment visits – are intended to review compliance with all 19 program requirements. In addition, three other types of visits – new start follow-up, operational follow-up, and diagnostic assessment visits – may involve an assessment of compliance with some, but not all, of the program requirements. The remaining two types of visits – targeted technical assistance and routine project officer visits – are not intended to assess compliance.⁶

HRSA recently released an updated Health Center Program Site Visit Guide.⁷ The guide is HRSA’s BPHC standardized review instrument used to conduct site

Figure 1: Summary of Health Center Program Requirements*

Requirement	Description of Requirement
Patient need	
Needs assessment	Health Center demonstrates and documents the needs of its target population.
Provision of services	
Required and additional services	Health center provides (either directly or through established referral arrangements) all required primary, preventive, and enabling health services and additional health services as appropriate and necessary.
Staffing requirement	Health center maintains a core staff necessary to carry out all required and additional services, either directly or through referral arrangements; the staff must be appropriately credentialed and licensed.
Accessible hours of operation/locations	Health center provides services at times and locations that ensure accessibility, and meets the needs of population served.
After hours coverage	Health center provides professional coverage during hours when the center is closed.
Hospital admitting privileges and continuum of care	Health center physicians have admitting privileges at one or more referral hospitals, or other arrangements to ensure continuity of care.
Sliding fee discounts	Health center has a system to determine eligibility for patient discounts adjusted on the basis of a patient's ability to pay. The system must provide a full discount to individuals with incomes at or below the federal poverty level and a sliding level of discount to those with incomes up to twice the federal poverty level. No discounts may be provided to individuals with incomes over 200 percent of the federal poverty level.
Quality improvement/assurance plan	Health center has an ongoing quality improvement/assurance program that includes clinical services and management and that maintains the confidentiality of patient records.
Management and finance	
Key management staff	Health center maintains a fully staffed management team.
Contractual/affiliation agreements	Health center exercises appropriate oversight and authority over all contracted services, including ensuring that the entities it contracts with meet health center program requirements.
Collaborative relationships	Health center makes effort to establish and maintain collaborative relationships with other providers in its service area.
Financial management and control policies	Health center maintains accounting and internal controls systems. Health center ensures that an annual independent financial audit is performed in accordance with federal audit requirements.
Billing and collections	Health center has systems to maximize collections and reimbursements for its costs of providing health services.
Budget	Health center has developed a budget that reflects the costs of operations, expenses, and revenues.
Program data reporting systems	Health center has systems that accurately collect and organize data for program reporting.
Scope of project	Health center is providing the scope of services covered by its grant, including any increases in the scope based on recent grant awards.
Governance	
Board authority	Health center governing board maintains appropriate authority to oversee the operations of the center.

Board composition	The health center has a governing board of between 9 and 25 members. A majority of the governing board members are patients of the center, and they represent the individuals served by the center in terms of demographic factors such as race, ethnicity, and sex. The non-consumer members of the board must be representative of the community, and no more than half of them may derive more than 10 percent of their annual income from the health care industry.
Conflict-of-interest policy	Health center bylaws or written governing board approved policy includes provisions prohibiting conflicts of interest by board members, employees, consultants, and those who furnish goods or services to the health center. No board member shall be an employee of the health center or an immediate family member of an employee.

*Health Center Program: Improved Oversight Needed to Ensure Grantee Compliance with Requirements, GAO Report to Congress, May 12, 2012, page 9.

visits and other types of audits at health centers. It includes standardized yes or no review questions used by the site visit team to assess compliance with each program requirement, as well as to review progress on clinical and financial performance and capital grants (if applicable) and, when possible, to identify any best practices established by the health center. Health centers use the guide internally to assess compliance with program requirements and to identify clinical and financial performance improvement areas. A summary of the recent changes to the guide, and a general overview of the site visit process, is provided below.

RECENT REVISIONS TO THE SITE VISIT GUIDE

The updated guide includes key changes to the site visit process and incorporates the requirements of new governance PIN 2014-01⁸ into Requirement #17 (Board Authority) and Requirement #18 (Board Composition). HRSA streamlined the 2011 site visit guide from 75 pages in length to 50 pages, with the objective of clarifying program requirements. Modifications to the guide include the following:

- Program Requirements (Sections I – IV) were modified to remove the performance improvement questions specific to each requirement. Questions for assessing and documenting compliance have been clarified and streamlined for all program requirements. In addition,

questions for the governance requirements have been updated to align with the 2014 Health Center Program Governance Policy Information Notice.⁹ Each program requirement now includes a list of the documents that the consultants will review onsite during or in advance of the site visit to assess compliance.

- Clinical and Financial Performance Measures (New Section V) were separated from the program requirements and placed into a separate section that clarifies HRSA's expectations and includes instructions for assessing and documenting the health center's progress on performance improvement in the areas of clinical and financial performance.
- Affordable Care Act Activities (New Section VI) was added to assess health center progress in completing activities funded under one-time capital grants awarded under the Affordable Care Act.
- Best Practices (New Section VII) was added to document innovative/best practices conducted by the health center that the site visit team observed during the site visit.
- Appendix B entitled Optional Program Requirement/Performance Improvement Summary Grid and Appendix C entitled Health Center Performance Measures have been removed from the site visit guide.

It is important that all health centers review the revised guide and revise their

policies, procedures, and internal operations to ensure that they are consistent with the modifications to the guide.

THE HRSA SITE VISIT PROCESS

Overview

Site visits are designed so that the site visit team performs a full organizational assessment in all operational areas (fiscal, clinical, administration, and governance). Each health center will have an operational assessment at least once every three years. The site visit follows the Health Center Program Site Visit Guide and is considered an essential component of Federal Health Center Program oversight and technical assistance.¹⁰

Purpose

The primary purpose of site visits is to assess compliance with some or all of the program requirements. The site visit team will prepare a site visit report, which is intended to provide standard and comprehensive documentation on each health center's compliance status with the program requirements. Site visits provide an opportunity for onsite technical assistance from the consultant team and/or project officer on how to improve health center performance and/or address noncompliance. Health centers should use a site visit report as a roadmap to address areas of noncompliance and performance improvement throughout the budget/project period.¹¹

Who Conducts the Site Visit?

A team of three consultants who together have expertise across all key program requirements in the areas of clinical, fiscal, and governance/administrative management conduct the site visit. The consultants are selected from a pool of individuals with expertise in health center operations and have received training from BPHC. Sometimes, BPHC project officers¹² attend the site visits. Site visits usually take two to three days.¹³

Site Visit Process — Before the Visit

The health center's project officer sends the health center a formal email confirming the site visit. The project officer and/or consultant team lead will then contact the health center to schedule a pre-site visit telephone conference call and will provide a list of documents for the health center to gather and have available for review before or during the site visit. During the pre-site visit telephone conference call, the project officer will introduce the members of site visit team, confirm the health center's location, and discuss the onsite audit process including the agenda, document list, site tour requirement, entrance and exit conferences, work areas designated for use by the site visit team, and expectations regarding the role of management staff and availability and participation of board members during the site visit.¹⁴

Health Center Pre-Site Visit Preparation

The health center chief executive officer (CEO) should make sure all staff are aware of the visit and should explain how they might be involved in the site visit. The CEO should provide or arrange for the management team to have a refresher course on the health center program requirements. The CEO should make specific staff assignments so that staff can prepare for the visit and should determine who will serve as the primary onsite contact for each operational area.

All staff members, management team members, and board members should review the Health Center Site Visit Guide, and staff members should be assigned responsibility for specific program requirements. Staff of each functional area of the health center should review and be familiar with the applicable sections of the program requirements. They should review all questions for that section and prepare answers to review questions.

The health center should prepare hard copies of documents, place them in well-organized and tabbed and labeled binders for the site visit team consultants, and arrange meeting rooms, review rooms, wireless

connectivity, and any other issues to allow the visit to go smoothly. The health center board members should be encouraged to attend both the entrance and exit conferences.¹⁵

Site Visit Entrance Conference

The consultant team will use the introductory entrance conference to generally describe the site visit process and schedule, and this conference usually will not last more than one hour. Each member of the consultant team and health center staff should introduce themselves.¹⁶

Site Visit Document Review

Health center staff should provide timely responses to requests for information and documents that occur prior to the site visit. The documents requested in advance by the consultant team may include, but are not limited to: (1) board meeting minutes and financial reports; (2) board committees and meeting schedules; (3) governance policies and procedures; (4) health center bylaws; (5) strategic plan; (6) needs assessment; (7) board recruitment plan; (8) conflict of interest policy; (9) current board roster; (10) organizational chart with names and positions; (11) list of employees, position, and FTE allocation; (12) job descriptions; (13) audits/financial reports; (14) management reports; (15) Quality of Care Review/Quality Improvement Program meeting minutes; (16) staff recruitment and retention plan; (17) contracts/collaborative agreements; (18) personnel manual and staff evaluation instrument; (19) clinical, financial, and other policy and procedure manuals; (20) corporate compliance plan, policies, and procedures; (21) fees and billing forms and policies; (22) sliding fee scale discount program; and (23) financial reports. Staff should have all information organized for easy accessible review in separate folders or binders.¹⁷

Site Visit Clinical Review

The clinical review will consist of a review of hours of operation and staffing model

(e.g., physicians, physician assistants (PAs), nurse practitioners (NPs), dentists, and behavioral health staff), interviews with health center staff (medical director/chief medical officer, clinicians and nonclinicians); review and analysis of credentialing and privileging policies and procedures (status of files and peer review process); health center's delivery of required and additional services (comprehensive primary care, oral health, behavioral health, and tracking and follow-up of contracted or referred services such as laboratory, radiology, specialty referrals, and hospitalizations); after hours coverage process; Quality of Care Review/Quality Improvement Program (committee meeting minutes, and service utilization analysis); roles of the governing board (clinical leadership and data to support board decisions); analysis of selected clinical performance measures; and the status of electronic health records meaningful use status and patient-centered medical home recognition.¹⁸

Site Visit Financial Review

The financial review will include interviews with the key personnel including the health center chief financial officer, billing manager, and other selected staff; review of audited and interim financial statements; review of financial policies and procedures, including status of internal controls and financial and cost data; review of the schedule of fees/charges and schedule of discounts (sliding fee scale); review of the budget; and an analysis of selected financial performance measures.¹⁹

Site Visit Administrative Review

The administrative review will include interviews with the health center CEO, chief operations officer (COO), and other selected managers and staff, review of personnel policies and selected personnel files, review of the most recent CEO performance evaluation, and review of the needs assessment.²⁰

Site Visit Governance Review

The governance review will include interviews with health center board members, review of board and board-committee minutes, review of the health center bylaws, analysis of the status of patient majority board members, and review of health center strategic planning activities.²¹

Site Visit Exit Conference

The site visit will end with an exit conference, which typically takes place mid-day on the third day of the visit. The exit conference should be attended by key management staff and board members, particularly board leadership. Preliminary findings will be discussed, and recommendations for resolution and/or additional areas of noncompliance will be provided.

Health center management should ask for the rationale or basis for the proposed findings. The findings that are shared during the exit conference generally will be the same as will be found on the final site visit report transmitted to the health center by BPHC but should still be considered preliminary. The exit conference provides an opportunity to obtain clarification of suggestions for noncompliance and improvement so that the health center can respond properly. If the health center disagrees with one or more findings of noncompliance discussed at the exit conference, the health center should contact its project officer immediately to discuss the matter before the findings become final.²²

The Site Visit Report

The consultant team will prepare a site visit report, which will be reviewed and transmitted in final form to the health center by BPHC. The final site visit report should be sent to the health center no more than 45 days following the completion of the site visit. The site visit report is a final report. Findings of noncompliance may result in grant conditions, including but not limited to special award conditions, “high-risk” designation, cost disallowances,

suspension/termination of funding, re-competition of the health center grant, and any other remedies legally available and appropriate in HRSA's sole discretion.

The site visit report will outline primary compliance issues, concerns, and/or performance improvement opportunities addressed during the site visit. Each program requirement will be reviewed, a finding will be stated and, where appropriate, a recommendation also will be stated. The Performance Improvement Sections will also list findings and recommendations. All program requirements need to be designated as either “Met” or “Not Met” based on the consultant team's review and judgment of the health center's operational implementation of the program requirements. If the Program Requirements are designated as “Met,” there will be information on health center operations that shows why the program requirement is “Met.” If the program requirement is designated “Not Met,” there will be a finding that specifically addresses and explains what part(s) of the program requirement is not met (some of the requirements have multiple components) and a recommendation that specifically provides guidance to the health center on what action(s) need to be taken to achieve compliance.

If a program requirement is designated as “Not Met” in the final site visit report transmitted to the health center, this finding will lead to a condition placed on the Notice of Award. A condition on the Notice of Award requires the health center to take corrective action within a specified timeframe.

The site visit report should be used by the health center's board, key management team, staff, and project officer as a roadmap to address areas of noncompliance and performance improvement throughout the remainder of the budget/project period. In the event that the consultant team makes findings of noncompliance with program requirements, FQHCs will have conditions added to their Notice of Award. Upon

receipt of the new Notice of Award from HRSA, the health center should review grant conditions and ensure that all conditions are consistent with the site visit report on findings of noncompliance.

The health center should prepare an official written response to any grant conditions which the consultant team found to be noncompliant and should forward that response to its project officer with a detailed corrective action plan to address those issues as well as any basis for disagreement with the findings. BPHC will offer guidance and technical assistance, as appropriate, to support the health center's success in addressing areas of noncompliance.²³

CONCLUSION

In April 2010, HRSA implemented a uniform process intended to standardize how the agency works with health centers to address noncompliance with health center program requirements identified by site visits or identified by any other manner. This “progressive action process” begins when HRSA documents an area of noncompliance by placing what it refers to as a “condition” on the health center's grant. Through this process a health center is provided with a “progressive” series of timeframes within which it must address the noncompliance. When HRSA places a condition of noncompliance on a grant, it alerts the health center by sending a notice specifying for which of the 19 program requirement(s) the health center is non-compliant, the nature of corrective action required, timeframes for achieving compliance, and the consequences if the health center fails to achieve and document compliance.²⁴

Phase 1 provides the health center with 90 days to submit documentation demonstrating that it has complied with, or developed a corrective action plan to comply with, the specified program requirements. Phase 2 provides an additional 60 days, and phase 3 another 30 days, for health centers to submit the appropriate documentation.

If the nature of the condition of noncompliance requires the health center to develop and implement a plan for achieving compliance, then the health center is provided additional implementation phases — the first of which is 120 days in length — to implement its plan and document compliance with the specified program requirements. In between each phase, HRSA provides itself with 30 days to review the health center's response and determine whether or not the response is acceptable. If a health center is unable to correct the compliance issue by the end of the progressive action process, HRSA's policies require it to terminate the health center's grant.²⁵

In light of the potentially significant consequences of noncompliance with program requirements, health centers should seek the assistance of competent health care law counsel and/or consultants to assist in the development and implementation of site visit corrective action plans and the submission of relevant documentation to HRSA. Legal counsel also may assist in the development of compliance programs that document compliance with program requirements.

Endnotes:

1. Health Center Program: Improved Oversight Needed to Ensure Grantee Compliance with Requirements, GAO Report to Congress, May 12, 2012, page 9.
2. *Id.* Federally qualified health centers (FQHCs) include all organizations receiving grants under Section 330 of the Public Health Service Act (PHS). FQHC look-alikes are organizations that meet PHS Section 330 eligibility requirements but do not receive grant funding.
3. Note 1 *supra*, page 6; Section 330 of the Public Health Service Act (42 U.S.C. Section 254(b), and Program Regulations at 42 C.F.R. Part 51c and 42 C.F.R. Parts 56.201-56.604.
4. *Id.*
5. Note 1 *supra*, page 14.
6. *Id.*
7. Health Center Program Site Visit Guide For HRSA Health Center Program Grantees and Look-Alikes, January 2014/Fiscal Year 2014, bphc.hrsa.gov/administration/visitguidepdf.pdf.
8. Policy Health Care Information Notice (PIN) 2014-1 Health Center Program Governance, released on January 27, 2014 by the Health Resources Administration, Bureau of Primary. See e.g., Michael Dowell, Carol Scott, “Executive Summary: New Health

- Center Governance Requirements," American Health Lawyers Association Practice Group Executive Summary, April 2014.
9. *Id.*
10. "Demystifying the Bureau of Primary Health Care Operational Site Visit," Bureau of Primary Health Care Grantee Enrichment Webcast, May 14, 2013, bphc.hrsa.gov/technicalassistance/trainings/05142013/enrichmentcall.pdf.
11. *Id.*
12. Project officers provide guidance and support on program requirements and serve as the first line of contact between health centers and HRSA. Health center-project officer communication is encouraged and essential.
13. *Id.*
14. *Id.*
15. *Id.*
16. *Id.*
17. *Id.*
18. *Id.*
19. *Id.*
20. *Id.*
21. *Id.*
22. *Id.*
23. *Id.* The action plan should indicate not only what has been done and what will be done but who is responsible for taking and for supervising the action to be taken.
24. "Impressing the Judges: Performance and Compliance in an Era of Presumed Non-Compliance," Roger L. Bates of Hand Arendall LLC, September 27, 2012.
25. *Id.*



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