



2019 Site Visit Protocol: Summary of Updates

The Health Resources and Services Administration (HRSA) implemented the Health Center Program Site Visit Protocol (SVP) for all Operational Site Visits (OSVs) and look-alike initial designation site visits in January 2018. The SVP is the tool used to assess compliance with Health Center Program requirements. It is designed to provide HRSA with information necessary to perform its oversight responsibilities using a standard and transparent methodology that aligns with the Health Center Program Compliance Manual (“Compliance Manual”).

As part of continuous quality improvement efforts, HRSA collected feedback about the SVP and site visit process from stakeholders, including health centers, strategic partners, site visit team reviewers, and HRSA staff. In response to this feedback, HRSA made several updates to increase the SVP’s effectiveness, clarity, consistency, and transparency. No changes were made to the Compliance Manual.

Summary of Major Updates

The table below provides a summary of significant changes and the SVP sections impacted. In addition, methodology changes that impacted documents reviewed by the site visit team reviewer(s) resulted in associated updates to the corresponding items in the “Document Checklist for Health Center Staff.”

Note: Throughout the table, “Demonstrating Compliance Element” is abbreviated as “DCE”, and the SVP sections containing “Site Visit Findings” questions is abbreviated as “questions”.

Section	Area(s) Impacted	Summary of Update(s)
Introduction	<ul style="list-style-type: none"> ❖ Purpose ❖ Site Visit Report and Compliance Determinations 	<ul style="list-style-type: none"> • Updated language in the Purpose explaining frequency of OSVs based on project period length, consistent with current HRSA requirements. • Added language to Site Visit Report and Compliance Determinations regarding

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		<p>expectations and specific deadlines for health center submission of documentation to the site visit team prior to the OSV and onsite.</p>
Needs Assessment	<ul style="list-style-type: none"> ❖ Document Checklist for Health Center Staff ❖ DCE b methodology and question(s) 	<ul style="list-style-type: none"> • Revised the review instructions of DCE b <i>Update of Needs Assessment</i> to require it to be assessed in its entirety. Previously this DCE was only partially reviewed through the OSV. Associated documents, methodology, and questions were updated accordingly.
Required and Additional Health Services	<ul style="list-style-type: none"> ❖ DCE a methodology 	<ul style="list-style-type: none"> • Revised the methodology for DCE a <i>Providing and Documenting Services within Scope of Project</i> when assessing Form 5A: Column I services. The site visit reviewer(s) will visit at least two (previously one) sites where the majority of services are provided. • Updated sample of written contracts/agreements, referral arrangements, and health center patient records for services provided via Form 5A: Column II and Column III in the methodology for DCE a <i>Providing and Documenting Services within Scope of Project</i>.
Clinical Staffing	<ul style="list-style-type: none"> ❖ Document Checklist for Health Center Staff ❖ DCE c note(s) and methodology ❖ DCE f methodology and question(s) 	<ul style="list-style-type: none"> • Modified sample of contract and referral arrangements in the methodology for DCE f <i>Credentialing and Privileging of Contracted or Referral Providers</i> to minimize burden by utilizing the same sample pulled for Required and Additional Health Services.

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		<ul style="list-style-type: none"> • Clarified questions for DCE f <i>Credentialing and Privileging of Contracted or Referral Providers</i> to improve understanding of how to assess contracts and referral arrangements for compliance with credentialing and privileging requirements. • Added updated note to the methodology for DCE c <i>Procedures for Review of Credentials</i> about primary source verification and credentialing of other clinical staff who are neither licensed nor certified.
Accessible Locations and Hours of Operation	No major updates	No major updates
Coverage for Medical Emergencies During and After Hours	<ul style="list-style-type: none"> ❖ DCE a methodology and question(s) ❖ DCE c methodology ❖ DCE d methodology 	<ul style="list-style-type: none"> • Updated methodologies for DCE a <i>Clinical Capacity for Responding to Emergencies During Hours of Operation</i>, DCE c <i>Procedures or Arrangements for After Hours Coverage</i>, and DCE d <i>After Hours Call Documentation</i> to provide clarifying language on how to verify health center after-hours coverage. • Updated question for DCE a <i>Clinical Capacity for Responding to Emergencies During Hours of Operation</i> to improve alignment with element language regarding responding to emergencies during regularly scheduled hours of operation.
Continuity of Care and Hospital Admitting	No major updates	No major updates
Sliding Fee Discount Program	<ul style="list-style-type: none"> ❖ Document Checklist for Health Center Staff ❖ DCE a question(s) ❖ DCE i question(s) 	<ul style="list-style-type: none"> • Updated questions for DCE k <i>Applicability to Patients with Third Party Coverage</i> to include review of documentation

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	<ul style="list-style-type: none"> ❖ DCE j question(s) ❖ DCE k methodology and question(s) ❖ Element I question(s) 	<p>regarding legal or contractual restrictions on providing sliding fee discounts for patients with third-party coverage.</p> <ul style="list-style-type: none"> • Added note to the questions for DCE a <i>Applicability to In-Scope Services</i>, DCE i <i>Sliding Fee for Column II Services</i>, and DCE j <i>Sliding Fee for Column III Services</i> to clarify that services, such as transportation and translation, that are not billed for in the local health care market may be excluded from the fee schedule and, as a result, from the sliding fee discount schedule. • Updated question for DCE i <i>Sliding Fee for Column II Services</i> to clarify that discounts should decrease as patient income increases for the sliding fee discount schedule(s) adjusted gradations. • Clarified question language for DCE I <i>Evaluation of the Sliding Fee Discount Program</i> to convey that the use of data other than utilization data is optional.
Quality Improvement/Assurance	<ul style="list-style-type: none"> ❖ DCE a methodology ❖ DCE e question(s) ❖ DCE f methodology 	<ul style="list-style-type: none"> • Added clarifying note to the methodology for DCE a <i>QI/QA Program Policies</i> to focus review on the content of the QI/QA policy and not on the title of the document. • Modified question for DCE e <i>Retrievable Health Records</i> to better align with the element language by removing reference to “structured format” with regards to patient records, clarifying that the focus of the assessment is on demonstrating

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		<p>that the health center maintains and can retrieve patient health records.</p> <ul style="list-style-type: none"> • Clarified methodology for DCE f <i>Confidentiality of Patient Information</i> to focus on assessing how a health center maintains compliance with current federal and state requirements related to confidentiality, privacy, and security.
Key Management Staff	❖ DCE d question(s)	<ul style="list-style-type: none"> • Added note to question for DCE d <i>CEO Responsibilities</i> to clarify what constitutes direct employment of the Project Director/CEO by the health center, consistent with the Bipartisan Budget Act of 2018.
Contracts and Subawards	<ul style="list-style-type: none"> ❖ Document Checklist for Health Center Staff ❖ DCE b methodology ❖ DCE c methodology ❖ DCE e methodology ❖ DCE f methodology and question(s) 	<ul style="list-style-type: none"> • Clarified the methodologies for DCE b <i>Records of Procurement Actions</i>, DCE c <i>Retention of Final Contracts</i>, DCE e <i>HRSA Approval for Contracting Substantive Programmatic Work</i>, and DCE f <i>Required Contract Provisions</i> when sampling contracts, both those paid for in whole or in part with federal award funds as well as those that do not use federal award funds. • Updated question for DCE f <i>Required Contract Provisions</i> to reflect a broader review of the sample of contracts that support the HRSA-approved scope of project.
Conflict of Interest	<ul style="list-style-type: none"> ❖ DCE a methodology ❖ DCE d methodology 	<ul style="list-style-type: none"> • Added a clarifying note to the methodology for DCE a <i>Standards of Conduct</i> regarding the types of documentation that can be used for conflict of interest disclosures, including

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		<p>clarifying that a signed disclosure form is only required when a conflict of interest arises.</p> <ul style="list-style-type: none"> Modified sample of contracts and related supporting procurement documentation in DCE d <i>Adherence to Standards of Conduct</i> to minimize burden by utilizing the same sample of contracts as Contracts and Subawards section.
Collaborative Relationships	<ul style="list-style-type: none"> ❖ Document Checklist for Health Center Staff ❖ DCE b note(s) and question(s) 	<ul style="list-style-type: none"> Added note in Document Checklist for Health Center Staff to clarify examples of documentation that can be used to show health center collaboration or coordination. Added note to the questions for DCE b <i>Collaboration with Other Primary Care Providers</i> explaining the flexibility in how health centers may demonstrate collaboration. Updated questions for DCE b <i>Collaboration with Other Primary Care Providers</i> to improve alignment with element language.
Financial Management and Accounting Systems	<ul style="list-style-type: none"> ❖ DCE c question(s) 	<ul style="list-style-type: none"> Updated questions for DCE c <i>Drawdown, Disbursement and Expenditure Procedures</i> to improve alignment with drawdown and disbursement requirements.
Billing and Collections	<ul style="list-style-type: none"> ❖ DCE f methodology and question(s) 	<ul style="list-style-type: none"> Revised methodology and questions for DCE f <i>Timely and Accurate Third Party Billing</i> to align with the element's focus on claims submissions and more closely align the claims submission timeline with

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		generally accepted industry standards.
Budget	No major updates	No major updates
Program Monitoring and Data Reporting Systems	No major updates	No major updates
Board Authority	<ul style="list-style-type: none"> ❖ DCE c question(s) ❖ DCE d question(s) 	<ul style="list-style-type: none"> • Updated question for DCE c <i>Exercising Required Authorities and Responsibilities</i> to clarify that the health center board documents the decision to contract or subaward. • Updated questions for DCE d <i>Adopting, Evaluating, and Updating Health Center Policies</i> to clarify the health center board's role in the evaluation and updating of health center policy(ies).
Board Composition	<ul style="list-style-type: none"> ❖ DCE b element language and question(s) ❖ DCE c element language, note(s), and question(s) 	<ul style="list-style-type: none"> • Removed word “reasonably” from phrase “reasonably represent” in element language for DCE b <i>Required Board Composition</i> and DCE c <i>Current Board Composition</i> to align with the Compliance Manual. • Updated questions for DCE c <i>Current Board Composition</i> to require a detailed explanation if current board representation is not reflective of the health center patient population. • Updated note associated with a question for DCE c <i>Current Board Composition</i> to increase flexibility regarding how the health center documents its definition of health care industry.
FTCA Deeming Requirements	<ul style="list-style-type: none"> ❖ Opening note ❖ Document Checklist for Health Center Staff 	<ul style="list-style-type: none"> • Updated opening note to clarify FTCA Corrective Action process for managing risk and claims management findings.

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	❖ Risk management methodology and question(s)	<ul style="list-style-type: none"> • Updated Document Checklist for Health Center Staff to include documentation of completed trainings. • Shifted “Risk management training plan and documentation of completed training” and “Example(s) of methods used to inform patients of the health center’s deemed status” from documentation provided at the start of the site visit to documentation provided prior to the start of the site visit. • Updated risk management methodology to include review of both board minutes and most recent reports to the board on the status of risk management activities. • Updated risk management questions to reference a copy of the risk management report. • Clarified questions on risk management training for obstetrical services and for infection prevention and control. • Updated risk management question to more clearly ask about documentation regarding completed trainings.
Performance Analysis	<ul style="list-style-type: none"> ❖ Instructions ❖ Question(s) 	<ul style="list-style-type: none"> • Added instructions to help health center and site visit reviewer(s) prepare for the root cause analysis. • Added structured chart with checkboxes for site visit reviewer(s) to identify contributing and restricting factors from a standard list.
Promising Practices	❖ Question(s)	<ul style="list-style-type: none"> • Replaced question about replicability of promising

Section	Area(s) Impacted	Summary of Update(s)
		practice(s) with question on implementation of promising practice(s).
Eligibility Requirements for Look-alike Initial Designation Applicants	No major updates	No major updates
340B Drug Pricing Program	Entire section	<ul style="list-style-type: none"> Removed the review of 340B Drug Pricing Program requirements from OSV.

Additional Updates

HRSA made the following general updates across sections of the SVP that do not constitute significant changes:

- Minor revisions to documents requested, methodologies, notes, and questions to improve alignment with Compliance Manual elements while increasing the clarity of the OSV assessment and efficiency of time onsite.
- Inclusion of interview components within methodologies to support the review of documentation/samples and to increase transparency for health center staff who may be interviewed.
- Addition of footnotes from the Compliance Manual “Requirements” sections not previously captured in the SVP to help ensure consistent implementation and assessment of DCEs.
- Corrections related to grammar, formatting, and updated links.

In addition, the SVP Tools and Resources will be updated to align with the revised SVP.