

Health Center Program Site Visit Protocol: Quality Improvement/Assurance

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QUALITY IMPROVEMENT/ASSURANCE

Primary Reviewer: Clinical Expert

Secondary Reviewer: N/A

Authority: Section 330(k)(3)(C) of the 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)

Document Checklist for Health Center Staff

Documents Provided Prior to Site Visit:

- Policy(ies) 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/or standards of practice
 - patient safety and adverse events, including implementation of follow-up actions
 - patient satisfaction
 - patient grievances
 - periodic QI/QA assessments
 - QI/QA report generation and oversight
- Systems and/or procedures for maintaining and monitoring the confidentiality, privacy and security of patient records

Documents Provided at the Start of the Site Visit:

- Sample of patient satisfaction results
- Sample of two QI/QA assessments from the past year and/or the related reports resulting from these assessments
- Job or position description(s) of individual(s) who oversee the QI/QA program
- Sample of 5-10 health center patient records (e.g., using live navigation of the Electronic Health Records (EHR), screenshots from the EHR, or actual records if the records are not electronic/EHR records) that include clinic visit note(s) and/or summary of care.
Note: *The same sample of patient records utilized for reviewing other program requirement areas may also be used for this sample*
- Documentation for related systems that support QI/QA (if applicable) (e.g., event reporting system, tracking resolutions & grievances, dashboards)
- Schedule of QI/QA assessments

Demonstrating Compliance

Element a: QI/QA Program Policies

The health center has a board-approved policy(ies) that establishes a QI/QA program.⁴³ 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

- Review the health center's policy(ies) that establish the QI/QA program.
- Interview individual(s) designated to oversee the QI/QA program and related staff that support QI/QA.

Site Visit Findings

1. Does the health center have a QI/QA program that addresses the following areas:
 - The quality and utilization of health center services?
 YES NO
 - Patient satisfaction and patient grievance processes?
 YES NO
 - Patient safety, including adverse events?
 YES NO

Note: If board approval of QI/QA policy(ies) is lacking, address this under Board Authority.

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.

⁴³ For more information on the health center governing board's role in approving policies, please see Health Center Program Compliance Manual, [Chapter 19: Board Authority](#).

Site Visit Team Methodology

- Review job/position description(s) or other documents for background on the responsibilities of the individual(s) overseeing the QI/QA program.
- Interview individual(s) designated to oversee the QI/QA program to further understand their role(s) and responsibilities.

Site Visit Findings

2. Does the health center have a designated individual(s) to oversee the QI/QA program?
 YES NO

If No, an explanation is required:

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

- Ensuring the implementation of QI/QA operating procedures?
 YES NO
- Ensuring QI/QA assessments are conducted?
 YES NO
- Monitoring QI/QA outcomes?
 YES NO
- Updating QI/QA operating procedures, as needed?
 YES 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 individual(s) responsible for the QI/QA program.
- Review the health center's QI/QA-related operating procedures or processes that address:
 - o clinical guidelines, standards of care, and/or standards of practice
 - o patient safety and adverse events, including implementation of follow-up actions
 - o patient satisfaction
 - o patient grievances
 - o periodic QI/QA assessments
 - o QI/QA report generation and oversight
- Review sample of patient satisfaction results.
- Review related systems and/or documentation that support QI/QA.
- Review schedule of QI/QA assessments.
- Review sample of two QI/QA assessments from the past year and/or the related reports resulting from these assessments.

Site Visit Findings

4. Does the health center have operating procedures and/or related systems that address:
- o Adherence to current, applicable evidence-based clinical guidelines, standards of care, and standards of practice (e.g., provider access to EHR clinical decision making support, job aids, protocols and/or other sources of evidence-based care)?
 YES NO
 - o A process for health center staff to follow for identifying, analyzing, and addressing overall patient safety, including adverse events?
 YES NO
 - o A process for implementing follow-up actions related to patient safety and adverse events, as necessary?
 YES NO
 - o A process for the health center to assess patient satisfaction (e.g., fielding patient satisfaction surveys, conducting periodic patient focus groups)?
 YES NO
 - o A process for hearing and resolving patient grievances?
 YES NO
 - o Completion of periodic QI/QA assessments on at least a quarterly basis?
 YES 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 reports on QI/QA, including data on patient satisfaction and patient safety with key management staff and the governing board?
 YES NO

If No, an explanation is required:

6. Was the health center able to share an example(s) of how these reports support decision-making and oversight by key management staff and the governing board regarding the provision of health center services and responses to patient satisfaction and patient safety issues?
 YES 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 adheres 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 individual(s) responsible for the QI/QA program.
- Review the health center's operating procedures or processes that address periodic QI/QA assessments.
- Review related systems and/or documentation that support QI/QA.
- Review schedule of QI/QA assessments.
- Review sample of two QI/QA assessments from the past year and/or the 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 (such as nurse practitioner, registered nurse or other qualified individual)?
 YES NO

If No, an explanation is required:

8. Are these QI/QA assessments based on data systematically collected from patient records?
 YES NO

If No, an explanation is required:

9. 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 (e.g., use of appropriate medications for asthma, early entry into prenatal care, HIV linkages to care, response initiated as a result of a recent adverse event)?
 YES NO

If No, an explanation is required, including specifying which areas the health center is not tracking and/or addressing:

Element e: Retrievable Health Records

The health center maintains a retrievable health record (for example, the health center has implemented a certified EHR)⁴⁴ for each patient, the format and content of which is consistent with both federal and state laws and requirements.

Site Visit Team Methodology

- In conjunction with a health center's clinical staff member(s), review the sample of 5-10 health center patient records.

Site Visit Findings

In responding to the questions below, please note:

Issues related to timeliness, accuracy and completeness of data retrieval used for Uniform Data System (UDS) reporting are covered under Program Monitoring and Data Reporting Systems.

10. Does the health center maintain an individual health record that is in a structured format and easily retrievable?
 YES NO

If No, an explanation is required:

⁴⁴ 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 <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html>.

11. Does the health center have a process for ensuring that the format and content of its health records are consistent with applicable federal and state laws and requirements (for example, the health center has implemented a certified EHR)?
- YES 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 health information technology (medical record) systems and procedures for maintaining and monitoring the confidentiality, privacy and security of protected health information (PHI).
- Interview applicable staff (such as CMO, health information technology personnel, Compliance or Security Officer) on how they maintain up-to-date knowledge about federal and state requirements related to confidentiality, privacy and security and actions taken by the health center to comply with these provisions across all sites (e.g., staff training).

Site Visit Findings

12. Do the health center's health information technology 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?
- YES NO

If No, an explanation is required:

13. Does the health center ensure its staff are trained in confidentiality, privacy, and security?
- YES NO

If No, an explanation is required:
