

QUAD A Accreditation

Resource Guide - Effective March 2023

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Who is QUAD A?

QUAD A, formerly known as the American Association for Accreditation of Ambulatory Surgery Facilities, is an accrediting organization with programs certifying to the medical community and the lay community at large that a facility meets recognized standards. The accreditation program is operated by clinical professionals who set and evaluate the standards under the direction of a Board of Directors. QUAD A strives for the highest standards of excellence for its accredited facility by regularly updating the requirements for patient safety and quality of care.

QUAD A awards each facility a three-year term of accreditation when it has determined that the survey findings are accurate, the facility has proven a commitment to provide high quality care and services, and concludes that the facility is in compliance with all QUAD A standards, Medicare Conditions for Coverage or Conditions of Participation (as appropriate if Medicare-deemed), and state/local, and national regulations.

The QUAD A Board of Directors and all committees are comprised of anesthesia providers, nurses, podiatrists, physicians, surgeons, and dental specialist from several countries. This group of expert clinicians develops standards and makes recommendations on the status of surveyors and facilities based on their years of experience practicing in the outpatient setting. This program is peer-based, designed and administered by medical and dental professionals.

Optimal patient safety has always been QUAD A's guiding concern. We are proud that our standards may be considered the strongest of any accreditation agency that accredits outpatient settings and providers/suppliers and that many consider them to be the gold standard.

We recognize, however, that they need to be part of a living document, and we continually re-evaluate and revise these standards in the light of medical advances and changing legislative guidelines. The QUAD A accreditation programs require 100% compliance with each standard to become and remain accredited. There are no exceptions. However, when a standard refers to "appropriate or proper or adequate", reasonable flexibility and room for individual consideration by the surveyor is permitted as long as patient and staff safety remain uncompromised.



Standards Development

QUAD A always seeks to improve and has established the plan below to develop future revisions to these standards based on information gathered during surveys conducted using this manual.

- 1. QUAD A standards are updated on an approximate 3-year cycle based on:
 - a. Outcome data from the QUAD A Patient Safety Data Reporting system is evaluated and statistically analyzed to determine areas where standards can be revised or created to improve patient safety and outcomes.
 - b. Standards are updated by the Standards Committee, representing authoritative specialists in all areas of ambulatory medical care each with at least 20 years' experience in surgery, anesthesia, dentistry, or nursing.
 - c. At least every three years QUAD A standards are compared to other organizations' standards and recommendations, such as those of professional societies, including surgical, anesthesia, dental, and nursing organizations, or ministries, to identify implementation of new standards and minimize duplication.
 - d. The 3-year cycle is defined as:
 - i. Year one: QUAD A collects data from QUAD A surveys and updates from other organizations' standards and guidelines.
 - ii. Year two: The Standards Committee revises standards based upon data collected in year one.
 - iii. Year three: The updated standards are presented to the Board of Directors for consideration and approval.
- 2. During the board approval process, all standards are submitted to a medical editor for editing and clarification of wording.
- 3. Standard development includes pilot testing and evaluation upon approval of draft.
 - a. This allows for a comprehensive evaluation of each standard to make sure it is RUMBA (relevant, understandable, measurable, beneficial, and achievable).
 - b. If not RUMBA, the standard is revised by the Standards Committee.
- 4. Process of adopting standards:
 - a. Data used in the development of standards is gathered.
 - b. The Standards Committee evaluates data and drafts proposed standards.
 - c. QUAD A posts draft standards and solicits feedback from US-based and international stakeholders including societies, ministries, surveyors, and facilities.
 - d. The Standards Committee evaluates data and establishes new standards.
 - e. New standards are approved by the Standards Committee and submitted to the Board of Directors.
 - f. The Board of Directors evaluates proposed standards and approves or disapproves standards.
 - g. As new standards are introduced, they are announced in QUAD A publications and incorporated into surveyor training programs.



h. QUAD A utilizes a data review process to obtain and analyze citations and surveyor findings from previous assessments and use them to improve standards.

The planned 3-year cycle of standards analysis and revision is as follows:

1. Basis:

- a. Outcome data from the QUAD A incident reporting system and onsite survey data.
- b. Experience and expertise of committee members.
- c. Scientific literature and comparison to standards and recommendations of professional societies or government regulators.

2. Cycle:

- a. Year one: QUAD A collects survey and outcome data and updates from other organizations standards and guidelines.
- b. Year two: Committee revises standards based upon data collected in year
- c. Year three: Updates are presented for consideration and approval.
 - i. Includes editing and clarification of wording.
 - ii. Includes pilot testing and evaluation upon approval of draft.

3. Process:

- a. Data gathered by staff.
- b. Committee evaluates data and drafts proposed standards.
- c. Committee posts draft and solicits feedback.
- d. Committee evaluates data and establishes new standards.
- e. Approved by Committee and forwarded to the Board of Directors for approval.
- f. New standards are advertised and incorporated into surveyor training programs.



Approved Procedures by Program

The QUAD A Board of Directors reserves the right to review and edit these allowable procedures at any time based upon differing scopes of practice standards and changing state and federal regulations and laws.

Procedural

QUAD A procedural accreditation is intended for ambulatory facilities performing procedures under sedation in which therapeutic and diagnostic procedures are carried out. This includes gastroenterologists, urologists, gynecologists (including abortions and IVF), pain management, vascular access, radiology, and nephrology physicians. These procedures may include minimally invasive procedures and minor surgical procedures (e.g., intra-oral maxillofacial procedures, minor urological procedures to include circumcisions, vasectomies, etc.).

Pediatric Dentistry

The following list of pediatric dentistry procedures are permitted under this current version of the QUAD A Pediatric Dentistry Standards.

<u>Dentoalveolar</u>	<u>Trauma</u>
Dental Restorations	Hard and Soft Tissue Trauma
Pulpal Treatment	Lacerations
Soft Tissue Graft	Hard Tissue Dental Fractures including Alveolus
 Frenuloplasty 	Pathology
 Frenectomy 	Hard and Soft Tissue
 Extractions 	Management of Odontogenic Infection
o Simple	Soft and Hard Tissue Biopsy
o Complex	
Space Maintenance	



Oral & Maxillofacial Surgery

The following list of OMS office-based procedures are permitted under this current version of the QUAD A Oral & Maxillofacial Standards.

Dontoghanlan	Transport	
<u>Dentoalveolar</u>	Trauma	
Extractions – simple and complex	Hard & Soft Tissue Trauma	
Alveolectomy/Alveoplasty	Lacerations	
Periapical Surgery (Apicoectomy)	Fractures – Closed and Open Reduction	
Hard & Soft Tissue Grafting	Dental including Avulsion	
Harvest & Placement	Pain Management - head and neck	
Local and Distant		
Xenograft	Orthognathic & Esthetic	
Allograft	Alloplastic Implants	
Autograft	Sliding Genioplasty	
Placement of Dental Implants	Removal of Hardware	
	Aesthetic procedures as delineated by	
	State-designated Scope of Practice ¹	
<u>Pathology</u>		
Hard & Soft Tissue Biopsy and Excision		
Salivary Duct and Gland		
Odontogenic and Non-Odontogenic Lesions		
of the Jaws		
Sinus & Nose		
Grafting		
Closure of Oro-Antral and Oro-Nasal		
Communication		
Caldwell-Luc		
Management of Infections		
Hard & Soft Tissue		
Odontogenic		
TMJ Arthrocentesis and Arthroscopy		

Addendum May 2010:

Any other procedure as encompassed by the American Dental Association's definition of the specialty of Oral and Maxillofacial Surgery, subject to that which is allowed under a state's legally defined scope of practice for either dentistry or Oral and Maxillofacial Surgery.

¹ The aesthetic procedures performed by Oral & Maxillofacial surgeons that are permitted by state and federal regulations and laws, and are also performed by Board Certified Plastic Surgeons, Otolaryngologists, and Dermatologists must follow the applicable standards.



Surveyors

This section defines the expectations and requirements for all QUAD A surveyors.

Basic Surveyor Expectations

QUAD A surveyors must be organized and be prepared to conduct a QUAD A survey.

- Review the material prior to going onsite.
- Familiarize yourself with applicable QUAD A standards and applicable local, state, and federal/national regulations.
- Familiarize yourself with the location of the facility and make appropriate arrangements for a timely arrival to the facility.

QUAD A surveyors must contact the QUAD A office with questions or concerns before, during, and after the survey.

• If the surveyor encounters any issues while onsite, the surveyor must contact the QUAD A office prior to taking any action, especially prior to concluding the survey and leaving the facility. This includes, but is not limited to, refusal of survey, wrong address, potential Immediate Jeopardy (IJ), hostile environment, suspected fraud, not previously identified conflict of interest, etc.

If the survey is scheduled to be conducted by a team of surveyors (more than one), prior to the survey the lead surveyor must contact the rest of the team to coordinate arrival at the facility, tentative team member assignments for the survey, and to address any questions.

- It is recommended that the team meet the night before or the morning of the scheduled survey.
- If a survey is performed by a team of surveyors, all surveyors will arrive and depart together.

During the survey, surveyors are expected to look and act as professionals representing QUAD A.

- Follow QUAD A Surveyor Code of Conduct.
- Dress professionally and respectfully.
- Surveys are intended to be educational not punitive. Be courteous, kind, and respectful and listen. Pose questions and speak in a calm, professional voice.
- If the facility has an EHR/EMR, the surveyor will review records in their original, electronic format. Asking the facility to print the medical records for review is inappropriate.

Under no circumstances should a surveyor make an independent judgment to do less than the survey requirements outlined by QUAD A's survey-related policies and procedures and



as described in the relevant CMS Appendix for the program being evaluated. (See "Surveyor Resources".)

QUAD A surveyors must adhere to post-survey requirements:

- Survey documents must be completed and returned within two business days of the conclusion of the survey.
- Surveyor must be available for at least 60 days after the survey for applicable follow-up, including review of facility submitted Plan of Corrections.
- Each surveyor must meet the requirements for annual re-approval by the QUAD A Quality Assurance Committee which includes completing required continuing education modules assigned during the year.

Surveyor Code of Conduct

To serve as an QUAD A surveyor, I agree to adhere to the following code of conduct:

- 1. I agree to conduct all surveys by fair and unbiased determination of the facility in accordance with applicable standards and survey processes set forth by QUAD A.
- 2. I agree to act and dress in a professional manner as a representative of the QUAD A accreditation program.
- 3. I agree to disclose any real or perceived Conflict of Interest that would inhibit my ability to perform a fair and unbiased survey.
- 4. I agree to adhere to the Code of Ethics set forth by my professional licensing body.
- 5. I agree to disclose any professional or financial interest in a facility that I am assigned to survey.
- 6. I agree to adhere to the responsibilities and requirements set forth in the QUAD A Surveyors Guidelines.
- 7. *Medicare surveyors*: I agree that I will not disclose the date and/or time of any Medicare survey, that all Medicare surveys will be unannounced and will attest to that upon submitting each survey report.



Surveyor Qualifications

To ensure that a surveyor is adequately qualified to perform QUAD A Medicare surveys, the surveyor must meet the following criteria:

Medicare Health Safety Surveyors:

- 1. ASC surveyors
 - a. Be a qualified practitioner able to provide documentation of current, unrestricted license as one of the following:
 - i. Doctor of Medicine
 - ii. Doctor of Osteopathy
 - iii. Nurse anesthetist (CRNA)
 - iv. Physician Assistant
 - v. Registered Nurse
- 2. RHC surveyors
 - a. Be a qualified practitioner able to provide documentation of current, unrestricted license as one of the following:
 - i. Doctor of Medicine
 - ii. Doctor of Osteopathy
 - iii. Physician Assistant
 - iv. Nurse Practitioner
 - v. Nurse Midwife
 - vi. Registered Nurse
 - vii. Psychologist
 - viii. State Licensed Mental Health Processional (Social Worker, Marriage & Family Therapist, Professional Counselor).
- 3. OPT surveyors
 - a. Be a qualified practitioner able to provide documentation of current, unrestricted license as one of the following:
 - i. Physical Therapist
 - ii. Physical Therapist Assistant
 - iii. Occupational Therapist
 - iv. Certified Occupational Therapist Assistant
 - v. Speech Language Pathologist
 - vi. Speech Language Pathologist Assistant
- 4. Submit a current Curriculum Vitae that documents experience to qualify as a surveyor.
- 5. Sign and adhere to the initial QUAD A Surveyor Agreement, including Surveyor Attestation, Conflict of Interest, Code of Conduct, Surveyor Guidelines, and agreement to participate in annual surveyor appraisal and review process conducted by QUAD A Quality Assurance Program and submit the same to QUAD A office.
- 6. Attend an QUAD A Medicare surveyor training course (on-line or in-person) and pass the Medicare Surveyor training examination administered at the conclusion of each training course, a certificate of completion will be kept on file at the QUAD A office.



- 7. Complete and pass all additional continuing education modules as assigned.
- 8. Successfully complete an on-site training survey accompanied by a senior surveyor. Documentation of the successful completion of the training survey is maintained in the surveyor's file.

Non-Medicare Health Safety Surveyors:

- 1. Surgical and Procedural surveyors
 - a. Be a qualified practitioner able to provide documentation of current, unrestricted license as one of the following:
 - i. Doctor of Medicine
 - ii. Doctor of Osteopathy
 - iii. Physician Assistant
 - iv. Registered Nurse
 - b. Physician must be board certified or eligible by a certifying board accepted by QUAD A Standards.
 - c. Two years' experience working in an office-based setting.
- 2. Oral and Maxillofacial surveyors
 - a. Be a qualified practitioner able to provide documentation of current, unrestricted license as one of the following:
 - i. Doctor of Dental Medicine (DMD) or Dental Surgery (DDS) certified or eligible for certification by the American Board of Oral and Maxillofacial Surgery (ABOMS)
- 3. Pediatric Dentistry surveyors
 - a. Be a qualified practitioner able to provide documentation of current, unrestricted license as one of the following:
 - i. Pediatric Dentist (DDS or DMD)
 - ii. Dental Anesthesiologist
- 4. Submit a current Curriculum Vitae that documents experience to qualify as a surveyor.
- 5. Sign and adhere to the initial QUAD A Surveyor Agreement, including Surveyor Attestation, Conflict of Interest, Code of Conduct, Surveyor Guidelines, and agreement to participate in annual surveyor appraisal and review process conducted by QUAD A Quality Assurance Program and submit the same to QUAD A office
- 6. Attend an QUAD A surveyor training course and pass the Surveyor training examination administered at the conclusion of each training course, a certificate of completion will be kept on file at the QUAD A office.
- 7. Complete and pass all additional continuing education modules as assigned.



Life Safety Code Surveyors:

- 1. Have at minimum, a NFPA Certified Fire Inspector 1 issued by NFPA, achieved through a course based on NFPA codes and standards or, be a registered Professional Engineer able to provide documentation of current registration or, be a licensed architect able to provide documentation of current registration or be a Certified Fire Protection Specialist
- 2. Experience with hospital or surgery buildings
- 3. Have a minimum of four years education in Fire Protection.
- 4. Submit a current Curriculum Vitae or resume that documents experience to qualify as a certified surveyor.
- 5. Sign and adhere to the practices as outlined in the current contract with QUAD A.
- 6. Complete the online LSC surveyor course as provided by QUAD A, complete and pass the examination process, a certificate of completion will be maintained on file at the QUAD A office.
- 7. Complete and pass all additional continuing education modules as assigned.

Documentation of initial certification as well as additional continuing education modules will be maintained in each surveyor file. Evidence of certification will identify the educational course or module and date of course or certification.

QUAD A Quality Assurance Committee must verify the candidate has met the conditions outlined in the QUAD A Policy for Surveyor Qualification and has reviewed all documentation submitted to determine certification as an QUAD A Surveyor. Final written approval by the Quality Assurance Committee Chair will be maintained in the surveyors file with the current Surveyor Certificate.



Onsite Surveys

Each QUAD A facility is surveyed initially and at least every three years thereafter. The QUAD A assigned surveyor will review any deficiencies with the medical director (or designee) and forward the survey results and associated documentation gathered during the survey to the QUAD A office. To be accredited by QUAD A, a facility must meet every standard. For surgical/procedural facilities, compliance must be demonstrated for the facility's identified Class (A, B, C-M, or C).

Onsite QUAD A surveys of surgical facilities typically involve the attention of the facility's medical director (or designee), an anesthesia provider, and various facility staff working intensely with the QUAD A surveyor(s). Onsite QUAD A surveys of other facility types involve the attention of the facility's administrator (or designee), clinical staff, and various other facility staff working intensely with the QUAD A surveyor(s). The survey process must remain focused, and therefore, QUAD A has directed that equipment representatives may not be present during QUAD A announced or unannounced surveys. Accreditation consultants may be present during the surveys; however, QUAD A requires consultants to remain silent during the survey process until complete. All QUAD A surveyor(s) have the authority to request any participants to remove themselves from the survey process if interference becomes a problem. QUAD A greatly appreciates the cooperation of all concerned parties by complying with this directive.

Initial Surveys

Surgical, Procedural, CMS ASC, Pediatric Dentistry, Oral & Maxillofacial, International Surgical, and International Dental: The initial survey is performed by a surveyor or team of surveyors after the facility has performed 10 cases in order for the survey team to review a sufficient number of clinical records and other documentation, to determine compliance.

CMS RHC and CMS OPT: The initial survey is performed by a surveyor or team of surveyors after the facility has provided care for 10 patients in order for the survey team to review a sufficient number of clinical records and other documentation, to determine compliance.

QUAD A awards each facility a three-year term of accreditation when it has determined that the survey findings are accurate, the facility has proven a commitment to provide high quality care and services and concludes that the facility is in compliance with all QUAD A standards and Medicare Conditions for Coverage or Conditions of Participation (as appropriate), state/local and national regulations.



Unannounced Surveys for Medicare-Deemed Facilities

QUAD A requires that all surveyors agree to conduct Medicare surveys in accordance with Section 2700A of the State Operations Manual, which states that surveys for all providers (including all types of hospitals) and suppliers (other than laboratories) are unannounced. To that end all surveyors must acknowledge their understanding of that requirement and assume all responsibility under Sections 1819(g)(2)(A)(i), 1919(g)(2)(A)(i), and 1891(c)(1) of the Social Security Act, which establish civil monetary penalties for any individual who notifies a facility of the date and or time of a survey.

- Surveyors must agree to abide by this requirement and attest to the same in signing the Surveyor Agreement upon becoming an active surveyor.
- The surveyor must reaffirm that the specific survey was unannounced by signing the Surveyor Attestation, including a statement of compliance, that is required for each survey report submission.

Any surveyor, whose file does not include a signed initial agreement to conduct all Medicare surveys unannounced, will not be activated for deployment on QUAD A Medicare surveys. Survey results that do not bear the surveyor's attestation that the specific survey was unannounced will not be considered valid, and the surveyor may not receive the honorarium for the survey and will become inactive until all survey reports are verified as unannounced.

Life Safety Code (LSC) Surveys

CMS ASC only - Medicare requires an independent Fire Safety Specialist contracted by QUAD A to perform a Life Safety Code (LSC) survey in accordance with the NFPA 2012 Life Safety Codes and 2012 Health Care Facilities Codes, with a report submitted to QUAD A. A copy of the report will be provided to the ASC. The ASC must correct any deficiencies noted by the Fire Safety Specialist. The Fire Safety Specialist may review any corrections and make the final determination for compliance. The ASC is responsible for all costs related to the LSC survey.

The Life Safety Code (LSC) Surveyor must consider all applicable National Fire Protection Association (NFPA), Life Safety Code (LSC), Health Care Facilities Code (HCFC), and reference document requirements when conducting the survey.



Extension Site Surveys

CMS OPT only - OPT facilities are permitted to have extension locations as approved by CMS. QUAD A renewal onsite surveys include all primary and extension locations. Each extension location must independently meet all applicable standards consistent with the primary site.

<u>Extension location</u>: Refers to a location or site from which a rehabilitation agency provides services within a portion of the total geographic area served by the primary site. The extension location is part of the Outpatient Physical Therapy facility (OPT). The extension location should be located sufficiently close to share administration, supervision, and services with the primary site and any other extension locations in a manner that renders it unnecessary for the extension location to independently meet the conditions of participation (CoP) as an OPT.

All sites (primary and extension locations) combine to comprise a single unit (an OPT) for deeming purposes. A deficiency citation at any site reflects as a deficiency for that standard for the entire OPT operating under a single CMS Certification Number (CCN). Noncompliance with standards at any single location jeopardizes the certification of the entire OPT (all associated locations). If an OPT that is already deemed applies to add an extension site and the extension site fails to comply with all applicable standards, QUAD A will deny the addition of that site. One report that contains the primary and extension site survey results will be generated by QUAD A.

Per CMS policy, only an OPT with an established CMS provider agreement may apply to add extension locations. Those OPTs seeking new (initial) participation in the Medicare program are prohibited from enrolling extension locations at the time of their initial QUAD A application. For those OPTs that are currently participating in Medicare via State certification and are seeking continued participation via deemed status (An Initial Survey with a CCN) through QUAD A's CMS-approved OPT accreditation program, may apply to add extension locations with the initial accreditation application. In these cases, all extension locations will undergo an onsite survey, along with the primary site.



Performance of Onsite Surveys

This section defines the process that the QUAD A survey team must use for completing a survey. Utilization of this process is the minimum expectation of a surveyor. Some survey teams may review additional files or materials if a determination of compliance cannot be made from using the minimum set by the QUAD A Standards, or if non-compliance that requires additional investigation is noted.

QUAD A requires 100% compliance with each standard to become and remain accredited. There are no exceptions. However, when a standard refers to "appropriate" or "proper" or "adequate", reasonable flexibility and room for individual consideration by the surveyor is permitted as long as patient and staff safety remain uncompromised. Because QUAD A requires 100% compliance with all requirements prior to attaining accreditation, facilities who achieve accreditation are not required to publicly post their survey performance data. If accreditation has been conferred and a facility possess a valid QUAD A accreditation certificate, it is because the facility has demonstrated 100% compliance with applicable standards, including providing evidence of having corrected any cited deficiencies. The medical director must attest that the facility meets all local, state, and federal/national regulations, since such governmental regulations may supersede QUAD A standards. Please note, however, that the stricter regulation applies, whether it is the federal/national, state, local, or QUAD A standard. The facility is required to annually submit a signed Medical Director's Responsibilities & Attestation (CMS OPT only – Clinic Administrator's Responsibilities & Attestation) to the QUAD A office.

It is critical that all surveys are conducted according to the survey guidelines. Survey findings must comply with the instructions for writing deficiency reports (and the CMS
Principles of Documentation, as appropriate), in order for QUAD A to determine that an adequate survey has been performed and survey findings are complete.

To ensure uniformity of the QUAD A survey process and standards compliance, QUAD A has established this pre-amble to our current standards as a guide for surveyors and facilities. QUAD A surveys must be conducted in a consistent manner to ensure a fair and unbiased evaluation for each survey performed regardless of accreditation program, CMS regulations (as appropriate), or geographic location.

QUAD A is committed to conducting thorough, standardized surveys. Surveys must include review of the facility's physical plant, policies, procedures, patient records, personnel records and interview of key staff and patients. Survey findings are a collaborative effort of the entire survey team. Final determinations on citations require discussion between team members to establish and clearly indicate surveyor evidence and appropriate citation level as defined by QUAD A. Surveyor(s) should attempt to build consensus about citations and citation level among the team; however, the lead surveyor is ultimately responsible for determining appropriate citations and citation levels in the event the team cannot agree.



Onsite Survey Overview

Review the physical layout, clinical staff size, staff credentials, and requirement for clinical record review. Note any questions or concerns you have and be prepared to review any concerns with the facility staff. A thorough review of the survey documentation will help prepare the surveyor to conduct a detailed and efficient survey.

QUAD A requires surveys be conducted in a standardized and thorough manner. The surveyor is to be collaborative and respectful with their fellow surveyors and facility staff.

The following procedures must also be utilized during the survey process:

- The surveyor must plan to be at the survey site to allow for adequate surveyor hours to complete the survey. The survey team should plan to enter the facility as the facility is opening.
- Make travel arrangements flexible enough to consider that additional hours may be required to complete the onsite survey, if needed. It is not appropriate to rush through aspects of the survey process due to inappropriately scheduled travel arrangements. There must be sufficient time allowed to complete the survey as required by QUAD A policies and protocols.

Upon arrival, the survey team should inform the facility they have arrived to conduct a survey of the facility (all locations) and request that the medical director be notified. Ask the facility to provide a dedicated, private, and secure area for the survey team to review materials and complete the survey report.

The surveyor(s) should immediately hold an entrance conference with the medical director (or designee) and key staff, as identified by the facility, to:

- 1. Introduce surveyor(s) and their background.
- 2. Reason for the survey (resurvey, follow-up, complaint, etc.)
- 3. Explain the survey process and approach.
 - a. Non-Medicare surveys Point out that deficiencies corrected during the course of the survey must be cited as deficiencies, although if appropriately corrected in the presence of the survey team they may be noted as "Corrected on site" (depending on nature and severity of deficiency).
 - b. Medicare surveys Point out that deficiencies corrected during the course of the survey must be cited as deficiencies even though the survey findings may illustrate they were corrected in the presence of the survey team. A comprehensive Plan of Correction will be required for all deficiencies corrected onsite.
 - c. Components of survey for Surgical, Procedural, OMS, Pediatric Dental, and CMS ASC facilities
 - i. Familiarization Tour: There will be familiarization walkthrough of the facility including, but not limited to, the reception area, to the business office, lavatories, exam and consultation rooms, prep area, procedure room(s), recovery rooms, and discharge area.



- ii. Safety of Operating Room and Recovery Room Environment: The surveyor will concentrate on the equipment, medication, and supplies in the operating room and recovery room(s).
- iii. General Safety in the Facility: The surveyor will review documentation including, but not limited to, the safety manual, emergency protocols, transfer agreement, hazardous waste protocols, IV fluids, and medication.
- iv. CMS ASC only Observation of a case: pre-op to PACU.
- v. Document Review: The surveyor(s) will review clinical charts, personnel files, manuals, policy and procedures, peer review notes, Patient Safety Data Reporting (PSDR) records, and organizational documents.
- vi. Survey Findings: The surveyor will document all survey findings.
- vii. Exit Interview: The surveyor will review the survey process in an exit interview with the medical director and key staff with discussion of areas of deficiency and suggestions for improvement.
- 4. Request an RN or facility supervisor/administrator to accompany the surveyor(s) during the survey. Request that a staff member be appointed to assist the survey team as needed. It may be necessary for that staff member to guide surveyor(s) through patient charts or electronic medical records.
- 5. If the facility has already gathered their policies and procedures, the survey team may begin the walk through of the facility location. If not, the survey team should request the documents be pulled while the survey team conducts the walkthrough.
- 6. Ask that any patients undergoing care in the facility be made aware that an QUAD A (accreditation) survey is being performed by QUAD A surveyor(s). Facility staff must obtain consent from the patient if care will be observed as part of the survey process.

Once the entrance conference has concluded, the survey team should:

- 1. Perform the walk through of the facility.
 - a. If survey is conducted by multiple surveyors, full survey team will then meet to decide how the survey will be conducted.
 - b. The lead surveyor can adjust the assignments for each member of the team.
- 2. Perform a thorough and unbiased evaluation of the facility by observation, staff and patient interview, document and file review, and utilization of the materials provided.

Important for Medicare: Each standard must be marked compliant or deficient in the survey record. If you need additional information to determine whether the facility is in compliance with the Standards, refer to our "Surveyor Resources" for web links to access the complete CMS Interpretive Guidelines.

- a. Speak to patients about their care, objectives of treatment, knowledge and understanding of treatment, post-treatment care and patient responsibilities, discharge planning, and rights.
- b. Interview the staff about their knowledge of patient care needs, their assigned patients and responsibilities, and their knowledge of facility policies and procedures.



- c. Use open-ended probing questions, not Yes or No inquiries.
- 3. Any observations of non-compliance must be verified with a staff person from the facility and included in the deficiency statement. In addition to making a clearer deficiency statement, this assures that the surgery center staff are aware of findings as they are observed so that there are no surprises at the end of the survey.
- 4. Once the survey process is complete, the surveyor should document all findings. The surveyor must complete all mandatory survey report forms and adequately and appropriately document the survey findings according to QUAD A requirements.

Upon completion of the survey, conduct an exit interview with the medical director and key staff. Review all preliminary findings and observations. Clearly indicate the survey team is does not make accreditation decisions. The final accreditation determination is made by QUAD A.

- Inform the facility that they:
 - o Will receive a Survey Report from the QUAD A office within 10 business days.
 - Will be required to submit an acceptable Plan of Correction (PoC) for any deficiencies within 10 calendar days of QUAD A issuing the Survey Report.
 - Will be required to provide proof that deficiencies have been corrected within 60 calendar days of QUAD A issuing the Survey Report.
- Complete all surveyor documentation and return all survey documentation materials electronically within two calendar days of completing the survey. Any questions regarding the survey documentation requirements may be directed to the QUAD A accreditation department at 888-545-5222.

Please note: All deficiencies must be cited even if the facility corrects a deficiency during the survey process. The surveyor(s) may document that the deficiency has been corrected upon writing the SOD. Surveyor(s) must follow the QUAD A Principles of Documentation to document every deficiency.

Upon receipt of the survey report, the QUAD A office may contact the surveyors for additional information or clarification. It is important that surveyors provide immediate responses to post-survey questions as QUAD A is required to submit the survey findings to the facility within 10 business days from the date of the survey. Please note, surveyor honorariums are held until a complete and accurate survey report is received.



How to Conduct the Review of Clinical Records

Clinical record review is conducted as part of the survey process. The surveyor(s) must ensure that a random sample of clinical records are reviewed.

The following criteria must be met when performing clinical record review during an onsite survey:

- The facility is required to produce a log or other record of closed cases for the previous six-month period and the lead (or assigned) surveyor will select a sample of clinical records to review.
 - **Please note**: In all surveys, the surveyor must make the sample selections. It is not appropriate to allow facility staff to select the sample records to be reviewed.
- Sample size
 - CMS ASC, Surgical, Procedural, OMS, Pediatric Dentistry, International Surgical, and International Dental: The minimum number of records selected for review is 20 for a facility with a monthly case volume exceeding 50 and 10 for lower volume facilities.
 - The total number of records within the six-month case period must be noted on the review form. The average monthly case volume must be noted on the electronic survey record.
 - The sample must include a representative sampling of procedures conducted, providers performing procedures, various anesthesia types (as appropriate), and adverse events including deaths, unanticipated transfers, and post-op infections.
 - All CMS ASCs must have begun treating patients and are currently treating patients in order to enroll in the program.
 - CMS RHC: The minimum number of records selected for review is 20 for a clinic with a monthly case volume exceeding 50 patients, and 10 for lower volume clinics and initial (start-up) surveys.
 - **Please note**: The number of records reviewed should be determined by case volume, not patient visits.
 - The total number of records within the six-month case period must be noted on the review form.
 - The sample must include a representative sampling of all services provided, clinicians providing the services and open and closed records.
 - All RHCs must have begun treating patients and are currently treating patients in order to enroll in the program.
 - CMS OPT: A minimum of 20 total clinical records must be reviewed for an established organization and a minimum of 10 total for a new start-up organization. The records must represent the organization's current roster of patients as well as records from discharged patients from the past six months.
 - "Case" The term "case" in this policy is used interchangeably with the term record and is defined as unique patient admissions, including all of



the treatments, visits, and diagnosis across all services between a single admission and discharge. Even if an admission includes treatments in multiple services that are stored in separate files, they are considered one case for the record review process. However, if the same patient has been treated as part of multiple admissions, each separate admission is considered a case.

- The number of records reviewed should be determined by case volume not patient visits. The total number of records within the six-month case period must be noted on the review form to establish the monthly average.
- All OPTs must have begun treating patients and are currently treating patients in order to enroll in the program.
- The selected records to be reviewed should include a sample from each therapist and discipline (PT, OT, SLP) as offered at the site.
- A sample of both open and closed cases must be reviewed.
 - Surgical Facilities An open case is defined as a patient that is being treated the day of the survey.
 - o *CMS ASC only* The case that was observed on the day of survey must be included in the clinical record review sample.
 - o *RHC & OPT only* An open case is defined as an active patient who is currently under the care of the facility.
- The sample selected must represent a cross section of the cases performed at the facility.
 - Medicare facilities The sample selected must include both Medicare beneficiaries and non-Medicare patients.

If deficient practices are noted during the records review, the survey team should request additional record samples to substantiate the finding(s) documented from the initial sample. If the team reviews additional records, the team must include those reviews and document every record that was included in the sample review.

➤ **Medicare only**: If an egregious number of deficient practices are noted, the survey team must at least document their consideration of whether the deficiencies constitute condition level non-compliance.

The <u>Clinical Record Review Worksheet</u> is a part of the official survey documentation provided to the survey team by QUAD A. The review form must be completed for all records that are reviewed with findings noted appropriately. This worksheet contains required elements which must be present in each clinical record. As needed, surveyors should use the blank rows at the end of the worksheet to add facility-specific requirements based on facility policies related to clinical records.

Each record review must be scored for each standard element on the worksheet:

• Choose "NO" from the drop-down if the required element is not present in the record (Deficient).



- Add up the number of "N" responses over the total number of records reviewed for the final record score, (e.g., 3(deficient)/10(reviewed).
- Mark "N/A" if the required element does not apply to the record being reviewed.
 - Each "N/A" score requires an explanation in the comment section for that standard.
 - "N/A" should only be used for requirements that are truly conditional such as
 if a male patient does not require a pregnancy test, or per facility policy a 20year-old patient with no pre-existing conditions does not require a pre-op
 EKG/other testing.
 - o "N/A" is not appropriate for instances in which the facility chooses not to collect a certain piece of information.



How to Conduct the Review of Personnel Records

The facility must produce a complete list of all employees including contractors, PRN staffers, surgeons/proceduralists who are owners, etc. The surveyor(s) must ensure that a random sample of clinical personnel records are reviewed.

The minimum number of records selected for review is 50% of the total number of clinical personnel records. (See Glossary for QUAD A's definition of "Clinical Personnel".) For ASC and RHC only: Please note, all clinical personnel required to be licensed under State or local laws or regulations must be reviewed for verification of appropriate documentation. The total number of clinical personnel and personnel records reviewed must be documented on the form to ensure that adherence to the policy.

If deficient practices are noted during the record review, the survey team should request additional record samples to substantiate the findings documented from the initial sample. If the survey team reviews additional records, the team must document every record that was included in the sample review.

➤ **Medicare only**: If an egregious number of deficient practices are noted, the survey team must at least document their consideration of whether the deficiencies constitute condition level non-compliance.

The <u>Personnel Record Review Worksheet</u> is a part of the electronic survey documentation in the survey application provided to the survey team by QUAD A. The review form must be completed for all records that are reviewed with findings noted appropriately.

- At the top of the worksheet, please indicate the clinical personnel breakdown by type and number of providers.
- This worksheet contains required elements which must be present in each personnel file.
- As needed, surveyors should use the blank rows at the end of the worksheet to add facility-specific requirements based on facility policies related to personnel files.

Each record review must be scored for each standard element on the worksheet.

- Choose "NO" from the drop-down if the required element is not present in the record (Deficient).
 - Add up the number of "N" responses over the total number of records reviewed for the final record score, (e.g., 3(deficient)/10(reviewed)).
- Mark "N/A" if the required element does not apply to the record being reviewed.
 - Each "N/A" score requires an explanation in the comment section for that standard.
 - "N/A" should only be used for requirements that are truly not applicable, such as if a State does not require a License for certain professionals.
 - o "N/A" is not appropriate for instances in which the facility chooses not to collect a certain piece of information.



How to Conduct a Case Tracer

CMS ASC only - CMS requires surveyors to observe at least one procedure during the Medicare ASC survey process referred to as the "case tracer". The following information is a guideline for QUAD A Medicare surveyors to use in completing the case tracer requirement as a part of a Medicare survey.²

At the beginning of the survey, the lead surveyor must select one or more surgical cases for observation during the survey. Surgical patients remain in the facility up to a maximum of 24 hours; therefore, following individual cases from start to recovery or discharge is an effective tool for assessing the facility's compliance with QUAD A standards. The number of cases selected will depend on the size of the survey team, the scheduled length of the survey, and the expected duration of the surgical case. Depending on the timing of the case selected, a surveyor may begin a case observation immediately. For larger facilities (i.e., those with more than 2 ORs or procedure rooms or for multi-specialty facilities) surveyors should consider observing two cases.

In following the case(s) surveyors will look for evidence of compliance related to various QUAD A requirements, including, but not limited to, infection control, physical environment, medication administration/safety, assessment of anesthesia and procedure risk as well as the required preoperative update assessment of changes from the history and physical, provision of surgical and anesthesia services, post-surgical assessment, recovery from surgery and anesthesia, and discharge orders.

Case selection:

- Obtain the day's surgery schedule from the facility.
- Guidelines for selecting the patient to follow:
 - Choose a more complex case, based on the type of procedure, patient age, or patient co-morbidities.
 - Avoid selecting a case where surveyors anticipate that patient modesty concerns may make it harder to obtain the patient's consent.
 - To make efficient use of onsite time, avoid selecting a case where the surgical time is expected to exceed 90 minutes unless there are no shorter cases scheduled on the survey day.
- Surveyor(s) are required to follow at least one patient through admission, pre-op, surgery, post-op, and discharge.
 - o If the surgery runs longer than 90 minutes, the surveyor can opt to be present at the beginning of the procedure, then may conduct other survey

For Surgical, Procedural, Oral Maxillofacial, Pediatric Dentistry, International Surgical, International Dental, and CMS ASC surveys - QUAD A requires surveyors to observe at least one surgery during the QUAD A survey process referred to as the "case tracer". The following information is a guideline for QUAD A surveyors to use in completing the case tracer requirement as a part of an QUAD A survey.



² Verbiage to switch to for all surgery-based programs once we transition to case tracers on all appropriate surgical/procedural programs:

- duties as long as the surveyor is present when the facility transfers the patient to post-op.
- It may be useful for a surveyor to remain in the OR after the patient leaves to observe how the OR is cleaned and prepped for the next case.
 - If multiple surveyors are present, they should arrange for one surveyor to remain with the patient to observe post-operative care while a different surveyor remains in the OR.
 - If the survey is performed by a solo surveyor, observation of OR cleaning/prep may not be possible until after the observed patient is discharged.

Patient's right to refuse:

- It is the responsibility of the facility staff to obtain patient consent to allow surveyor(s) to observe the surgery.
- The patient has the right to refuse, and another surgery/patient should be selected if consent cannot be obtained for the first selection by the surveyor.

Facility's right to refuse:

- If the surgeon refuses to allow the surveyor(s) to observe the surgery, the medical director should be notified.
- Failure to allow the surveyor(s) to perform the case tracer by the facility staff must be documented in writing by the survey team and signed by the medical director. If the medical director is not onsite, a designee can sign but the medical director's awareness must be documented and initialed by surveyor(s) and facility staff.
- The lead surveyor should inform the medical director that failure to allow the survey team to complete all segments of the survey including the case tracer will result in denial of accreditation. Facility will be invoiced according to the QUAD A Cancellation Policy.

Performance of the case tracer:

- *Please note*: Throughout the survey and while observing a procedure for the case tracer, maintain an open dialogue with staff, but be aware that you are there to observe, not advise or critique. It is not appropriate to delay or stop a procedure unless you become aware of immediate jeopardy to the patient's safety.
- The surveyor should follow the patient starting with pre-operative preparation and assessment and concluding with the patient's discharge (if discharge is delayed, observation may conclude in post-anesthesia recovery).
- The case tracer is meant to observe and evaluate for compliance with multiple standards.
 - Observe for compliance with standards throughout the case, particularly transition points.
 - Observe the environment, staff interactions, patient safety practices, medication security, and infection control.
- Interview patient and/or patient's family member about patient care, knowledge of their surgery/procedure, post op care, discharge planning, and privacy/rights.



• Interview clinical staff caring for the patient about their knowledge of the patient and care needs, their assigned patients and responsibilities, and their knowledge of the policies and procedures relating to the pre-, intra-, and post-operative periods.

Completing the Case Tracer Template:

- Include required information as collected during the performance of the case tracer.
- Document all findings observed during the case tracer procedure even if those findings do not conform to the template.
- Share findings with other survey team members and cross verify information as appropriate.



Submitting Survey Documentation

QUAD A only accepts survey findings and documentation on official QUAD A *forms* [in the official QUAD A survey application]. Any surveyor created materials submitted may be considered supplemental to or supportive of official documentation, but do not independently constitute submission of a surveyor report.

All survey documentation must be submitted in electronic form, no later than two business days after the survey ends.

The QUAD A staff may not revise surveyor documentation other than to make spelling or grammatical corrections.

Statements of Deficiency must be completed according to the QUAD A Principles of Documentation.

How to Write a Statement of Deficiency (SOD)

Each numbered standard must have a response as appropriate per facility program and class. During the onsite survey, the surveyor(s) maintains a record of the standards for compliance and marks each standard as Compliant, Deficient or Not Applicable. If a standard for the class (A, B, C-M or C) does not apply to the identified class of the facility, indicate such by marking N/A on the answer sheet³.

All "Deficient" answers should be discussed with the medical director and/or appropriate staff, and the surveyor(s) should make recommendations as to how the deficiencies should be corrected.

For each requirement marked deficient, the surveyor will document the specific findings including the following:

- 1. An explicit statement that the requirement is "not met."
- 2. The factual evidence to support the deficiency.

If a standard does not apply to the situation in the facility, the surveyor must indicate such by marking "N/A" on the answer sheet. For every "N/A", there **must** be an explanation noted by the surveyor to justify that response.

A Statement of Deficiency (SoD) must be completed for each deficient standard. This SoD must be submitted in the QUAD A-approved format. Keep in mind the facility will use the SoDs for reference in providing a Plan of Correction (PoC) for each deficiency.

³ Once QUAD A surveyor application is ready for use in 2021, only applicable standards will be available for surveyor review making N/As no longer applicable in this instance.



The SoD must clearly and legibly explain how the facility fails to comply with the requirements directly, not how it fails to comply with any guidelines for the interpretation of those requirements. A comprehensive SoD must include the facts and findings relevant to the deficient practice, must illustrate the entity's non-compliance with the requirement, and must answer the questions: Who, What, Where, When, and How.

Sufficient supporting detail must be included, such as:

- An explicit statement that the requirement was NOT MET.
- The language from the standard which specifies the aspect(s) of the requirement with which the facility was non-compliant.
- The actual deficient practice statement, which includes:
 - o The specific action(s), error(s), or lack of action (deficient practice),
 - Outcome(s) relative to the deficient practice or the number of deficient cases relative to the total number of such cases,
 - The identifier of the individuals or situations referenced in the extent of the deficient practice, and
 - The source(s) of the information through which the evidence was obtained.
- The relevant facts and findings relevant to the deficient practice, which answer the questions: who, what, where, when, and how. These facts and findings illustrate the facility's non-compliance with the requirement or regulation.

Wherever possible, supply a numerator and denominator to demonstrate how systemic or prevalent a deficiency is, for example "4/6 clinical records failed to include an informed consent". When referring to "subsets" of applicable records or files, ensure that the appropriate "universe" is included as the denominator. For example, the survey team reviewed 20 records in total, 6 of these records were discharge records. When reviewing compliance with discharge orders, the total "universe" of applicable records would be "6". Refer to the QUAD A/CMS Principles of Documentation for further detailed instruction.

If, at any time, a surveyor is unsure of compliance/non-compliance during the survey or the extent to which the non-compliance may exist, surveyors should contact the QUAD A office to discuss the findings.

Surveyors must submit the completed survey materials electronically to the QUAD A office within 48 hours of completion of the survey. Once received QUAD A sends a deficiency report to the facility. The facility has to provide its PoC for each deficiency and submit evidence of correction (EoC) to be reviewed by the QUAD A Accreditation Committee.

Deficiencies that can pose immediate threat to patient safety are to be reported immediately to: QUAD A, Director of Clinical Compliance at 224-701-6039.

Complete honorarium and expense report in Concur, upload all receipts, and submit to the QUAD A office for processing.



Medicare ASC, OPT, RHC only:

When writing each SoD, consideration needs to be made to determine whether the found deficiency's level of non-compliance should be cited at the Standard or Condition level. Unless the QUAD A standard is tied to the CMS Condition level deficiency, then the default is Standard level. If a Standard level deficiency or a collection of Standard level deficiencies rises to the severity of a Condition, then the related Condition level deficiency must be cited. All appropriate deficiencies must be cited including the Condition level deficiency and all related Standard level deficiencies. (Exception: Emergency Preparedness. If the facility does not have an EPP program, it is sufficient to cite only the Condition level deficiency and note all the Standard level deficiencies in the section.)

Condition level non-compliance is defined as substantial non-compliance that limits the facility's capacity to furnish adequate care or potentially adversely affects the health and safety of patients. If Condition level non-compliance is found, follow-up survey(s) are required to ensure compliance before the facility can be recommended or approved for accreditation. (Exception: Emergency Preparedness. If Emergency Preparedness is the only condition cited, the facility is not required to participate in an onsite follow-up survey, the follow-up survey will be virtual.)

Observations of Condition level non-compliance are made according to the scope and severity of the non-compliance noted. This could be related to multiple related standards noted to be out of compliance, or a single standard in which the non-compliance is so pervasive or content is so severe, that a Condition level citation is warranted. The Condition citation includes deficient practice statements and findings to support the determination of non-compliance with a Condition level requirement.



Example Statement of Deficiency (SOD)

Statement of Deficiency

Official Forms Only Please

Facility ID: 1234 Surveyor: I.M. Surveyor, RN Date: 12/12/2112

☐ Condition Level Deficiency

Standard #: 14-G-4

☑ Standard Level Deficiency

Instructions:

Include the facts and findings relevant to the deficient practice must answer the questions: who, what, where, when, and how. Illustrate the entity's noncompliance with the requirement. The deficiency citation must explain how the entity fails to comply with the regulatory requirements, not how it fails to comply with the guidelines for the interpretation of those requirements. Refer to the CMS Principles of Documentation for further instruction.

This standard was NOT MET as evidenced by... (Describe the deficient practice and identify relevant findings and facts that substantiate the failure of compliance.)

The clinic failed to document physical examinations and laboratory tests as required and per clinic policy.

Findings include: (Describe each item of non-compliance as observed during the survey relative to the requirement being cited as not met. Remember to quantify findings where possible, i.e. 4/20 records.)

- -Documentation of physical examinations were missing in 4/20 clinical records reviewed. Deficient records included: Patients #2, #6, #9 and #11.
- -Documentation of laboratory test results were missing in 2/6 applicable records reviewed. Deficient records included: Patients #7 and #17.

During staff interviews at 10:45am, the Clinic Manager verified that the clinic policy was to document physical examinations on every patient and that laboratory results must be documented in the clinical record upon receipt. It was further verified that the laboratory results for:

- Patient #7 were received on 12/27/2020, but as of 01/27/21, they had not yet been placed in the record.
- Patient #17 were received on 01/03/2021, but as of 01/27/2021, they had not yet been placed in the record.



Example Statement of Deficiency (SOD)

ID	Standard	CMS Ref	Score	Findings/Comments
14-G-4	For each patient receiving health care services, the clinic or center maintains a record that includes reports of physical examinations, diagnostic and laboratory test results, and consultative findings.	491.10(a)(3)(ii) Standard	□Compliant ☑Deficient	This standard was not met as evidence by the following: The clinic failed to document physical examinations and laboratory tests as required and per clinic policy. -Documentation of physical examinations were missing in 4/20 clinical records reviewed. Deficient records included: Patients #2, #6, #9 and #11. -Documentation of laboratory test results were missing in 2/6 applicable records reviewed. Deficient records included: Patients #7 and #17. During staff interviews at 10:45am, the Clinic Manager verified that the clinic policy was to document physical examinations on every patient and that laboratory results must be documented in the clinical record upon receipt. It was further verified that the laboratory results for: • Patient #7 were received on 12/27/2020, but as of 01/27/21, they had not yet been placed in the record. • Patient #17 were received on 01/03/2021, but as of 01/27/2021, they had not yet been placed in the record.



Adverse Survey Findings

Policy for Reporting Fraud, Abuse, or Suspicious Activities

QUAD A surveyors who suspect or find documental evidence of fraud, abuse, and/or suspicious activity while performing an accreditation survey, should notify the QUAD A office during the survey, then submit a report electronically within two days of the date of survey and include all documented evidence of such fraud, abuse and/or suspicious activity to info@QUADA.org, Attention: QUAD A Director of Accreditation

If this is a Medicare-deemed facility, all reports submitted will be forwarded within two business days of receipt to the CMS Center for Program Integrity (CPI) and a copy to the appropriate CMS SOG Location that presides over the location of the surveyed facility.

How to Report Fraud and Abuse

When reporting suspected fraud and abuse (including Medicare related fraud and abuse), please include as much of the following information as possible:

- The provider's name and any identifying number you may have.
- The item or service you are questioning.
- The date on which the item or service was supposedly furnished.
- The amount approved and paid by Medicare, if applicable.
- The date of the explanation of benefits.
- The name and Medicare number of the person who supposedly received the item or service, if applicable.
- The reason you believe Medicare should not have paid, if applicable.
- Any other information you may have showing that the claim for the item or service should not have been paid by Medicare, if applicable.



Immediate Jeopardy

Immediate Jeopardy (IJ) represents a situation in which a facility's noncompliance has placed the health and safety of recipients in its care at risk for serious injury, serious harm, serious impairment, or death. These situations must be accurately identified by surveyors, thoroughly investigated, and resolved by the facility as quickly as possible. An immediate jeopardy situation is one that is clearly identifiable due to the severity of its harm or likelihood for serious harm and the immediate need for it to be corrected to avoid further or future serious harm.

There are three key components that are essential for surveyors to use in determining the presence of IJ. These components include:

- Noncompliance: An entity has failed to meet one or more federal health, safety, and/or quality regulations,
 AND
- **Serious Adverse Outcome or Likely Serious Adverse Outcome**: As a result of the identified noncompliance, serious injury, serious harm, serious impairment or death has occurred, is occurring, or is likely to occur to one or more identified recipients at risk, *AND*
- **Need for Immediate Action**: The noncompliance creates a need for immediate corrective action by the facility to prevent serious injury, serious harm, serious impairment or death from occurring or recurring.

If IJ is suspected or found during a survey, the surveyor must call the QUAD A office during the survey to alert QUAD A of the situation and to allow QUAD A to provide appropriate guidance. It is the surveyor's responsibility to identify the potential for IJ while performing the survey.

IJ points of contact at the QUAD A Office:

 Please call the QUAD A office (847-775-1970) and mention that you may have found an "Immediate Jeopardy situation" so the appropriate personnel can be pulled to take your call.

Follow the directions for immediate jeopardy located in <u>Appendix Q of the CMS State Operations</u> Manual.



Immediate Jeopardy Reporting Template Instructions

Survey teams must use the Immediate Jeopardy (IJ) Template to document evidence of each component of IJ. This template can be found with the survey materials and is to be provided to the QUAD A office with the rest of the on-site survey materials.

Instructions: The survey team must use evidence gathered from observations, interviews, and record reviews to carefully consider each component of IJ outlined in the left-hand column of this template. In order for IJ to exist, the survey team must answer "Yes" to all three components and provide a preliminary fact analysis in the right-hand column to support their determination. Use one IJ template for each issue/scenario/situation being considered at IJ level.

For the purpose of completing this template, the following definitions apply:

Likely/Likelihood means the nature and/or extent of the identified noncompliance creates a <u>reasonable expectation</u> that an adverse outcome resulting in serious injury, harm, impairment, or death will occur if not corrected.

Noncompliance means failure to meet one or more federal health, safety, and/or quality regulations.

Recipient at Risk is a recipient who, as a result of noncompliance, and in consideration of the recipient's physical, mental, psychosocial or health needs, and/or vulnerabilities, is likely to experience a serious adverse outcome.

Serious injury, serious harm, serious impairment, or death are adverse outcomes which result in, or are likely to result in:

- Death, or
- A significant decline in physical, mental, or psychosocial functioning, (that is not solely due to the normal progression of a disease or aging process), or
- Loss of limb, or disfigurement, or
- Avoidable pain that is excruciating, and more than transient, or
- Other serious harm that creates life-threatening complications/conditions.

*NOTE: IJ does not require serious injury, harm, impairment, or death to occur. It is sufficient that non-compliance makes serious injury, harm, impairment, or death likely to occur to one or more recipients.



Quality Assurance (QA) Committee

The Quality Assurance (QA) Committee's role is to perform on-going evaluations of surveyors to ensure all surveyors are conducting complete surveys each time they are sent to a facility. The surveyor evaluation process is standardized, so all surveyors are fairly evaluated using the same criteria.

The QA Committee consistently evaluates its surveyors through an ongoing quality assurance process that incorporates facility feedback, objective performance metrics, and random validation surveys.

Annual Evaluation of Surveyors

The QA Committee is charged with the annual review of individual surveyors and required to complete an analysis and recommendation for continued certification of each QUAD A surveyor.

The annual review of surveyors by the QA Committee includes the following:

- Summary report of facility evaluations
- Continuing education
- Performance review (surveys, survey requests turned down, punctuality, survey documents, etc.)
- Complaints
- Validation survey reports (if applicable)
- Adherence to all QUAD A Surveyor policies including but not limited to:
 - Basic surveyor expectations
 - o Surveyor Code of Conduct
 - Unannounced survey policies
 - Conflicts of Interest
 - Confidentiality
- Additional information provided to the committee by QUAD A staff or other sources if pertinent to the annual review process.

A copy of the QA Committee annual surveyor review and any correction action taken will be maintained in each individual surveyor file.

Surveyor Assessment by Facility

At the conclusion of a routine survey, the facility is asked to provide feedback specific to surveyor performance and the survey experience. This feedback is taken into consideration by the QA Committee when annually reviewing each surveyor or if a specific complaint arises.

1. The QA Committee assesses surveyor performance to drive individual surveyor improvement and overall program enhancement.



- a. Surveyor performance is analyzed using performance metrics to identify opportunities for improvement relative to specific surveys, and
- b. Surveyor performance is analyzed using performance metrics to identify opportunities for improvement relative to trend analysis to capture more subtle, long-term performance concerns.
- 2. The Surveyor Performance Evaluation contains three sections:
 - a. Section 1: The surveyor's depth of familiarity with standards are scored using a 1-5 scale.
 - b. Section 2: The surveyor's performance of the essential functions of a survey are scored on a "Y/N" (Yes/No) basis.
 - c. Section 3: The surveyor's time spent onsite and narrative feedback provided by the facility are noted.
- 3. Scores may initiate a more detailed examination.
- 4. Surveyor violations can include:
 - a. If the surveyor violates a single established scoring metric during a survey, the QA Committee examines the surveyor for a trend of violations over subsequent periods.
 - b. If a survey violates more than one established scoring metric during a survey, the QA Committee initiates a review of the surveyor's performance which may include document review, interviews with the surveyor or other team members and may result in remedial action or removal from the program.

Complaints Against Surveyors

All complaints against surveyor performance or conduct are taken seriously and will be reviewed by the appropriate QUAD A personnel. It is the responsibility of the facility to report any complaint against a surveyor to the QUAD A.

- 1. All complaints against surveyor performance or conduct must be made to QUAD A in writing to the surveyor relations manager's attention.
 - a. Email is preferred.
- 2. All complaints will be reviewed by the surveyor relations manager. If the nature of the complaint compromises patient safety or the quality of the facility's survey, the surveyor relations manager will forward the complaint on to the director of accreditation who will determine the need to include the QA Committee for their review and counsel for possible action.
- 3. A survey resulting in a complaint against the surveyor that was determined to be valid and of sufficient gravity to warrant invalidation of the survey results, will be scheduled for reassessment by another surveyor. Surveyors receiving complaints that invalidate surveys will be notified within three business days that a complaint was received and the nature of the complaint. All surveyors will have the opportunity to respond to any complaints before additional punitive action takes place.
- 4. The costs associated with the reassessment of any facility due to a complaint will be absorbed by QUAD A only if the written complaint report was received by the end of the third QUAD A business day (4:30 pm Central Time) following the incident.



- 5. Any surveyor whose conduct was determined to warrant invalidation of survey results may not receive honorarium.
- 6. Surveyors who are the subject of complaints based upon performance may be required to undergo retraining before being assigned to subsequent facility surveys.
- 7. All records of complaints and the results of each review process will be maintained in the associated surveyor and facilities files by the QUAD A staff member responsible for maintaining the surveyor and facilities files respectively.

Review of Complaints Against Surveyors

In reviewing a complaint against an QUAD A surveyor, a rotating three-member review team is selected from the QA Committee members to review the complaint as communicated by the surveyor relations manager. The review team will determine if the results of a complaint invalidate the survey and if any action should be taken against the surveyor.

Each QA Committee team review may result in one of the following determinations with regard to the surveyor's status:

Active: Surveyor is eligible to be sent on surveys.

Inactive-Training: Surveyor will become eligible to conduct surveys upon completion of training in an area determined to be adversely affecting performance.

Inactive: Surveyor will become eligible to conduct surveys upon completion of some activity determined by the QA program review team necessary to resolve the deficiency in conduct or performance.

Deactivated: Surveyor is permanently ineligible to conduct surveys.



Conflict of Interest

QUAD A is committed to maintaining the integrity of its accreditation process and to maintaining public confidence in its accrediting decisions. Therefore, it has always been and continues to be important to identify and address actual or potential conflicts of interest that might improperly affect the decisions of individuals involved in the accrediting process, specifically including surveyors who conduct surveys of facilities seeking QUAD A accreditation. It is also critical to maintain the confidentiality of the accreditation process and to assure information obtained during the conduct of a survey is not disclosed to third parties not involved in the accreditation process.

Definition of a Conflict of Interest

A conflict of interest is defined as an interest or relationship, including financial and consulting relationships, held or maintained by a surveyor that could influence the surveyor or be perceived as influencing the surveyor to act for the surveyor's personal benefit or contrary to the goal of QUAD A to conduct fair, impartial and unbiased surveys of facilities seeking accreditation.

Conflicts of interest are not confined to financial or economic interests but include relationships or affiliations with organizations with competing or conflicting goals and personal and professional relationships.

All decisions as to whether a surveyor's interest or relationship constitutes a conflict of interest or the appearance of a conflict of interest shall be made by QUAD A.

Surveyor's Duty to Disclose Conflicting Interests

Each surveyor shall disclose all actual or potential conflicts of interest that could influence or be perceived to influence the surveyor's decision-making process. Sources of possible conflicting interests include, but are not limited to, a consulting, investment or other commercial relationship with a company providing goods and services to QUAD A accredited facilities; consulting relationships with QUAD A accredited facilities; or a financial interest or practice position in an accredited facility that may compete with the surveyed facility. The foregoing examples are illustrative and should not be considered the only interests which might give rise to a conflict.

Each surveyor will be required to sign and submit to QUAD A's surveyor relations manager not less than annually the Surveyor Conflict of Interest Disclosure and Confidentiality Statement (the "Statement"). Failure or refusal to sign and submit the Statement will automatically disqualify an individual from serving as a surveyor. The Board of Directors of QUAD A may from time to time amend the content and form of the Statement. The Statement will be kept confidential except for review by the President and Executive Director of QUAD A who shall in turn maintain the confidentiality of the information contained in the Statement.



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How to Report an Identified Conflict of Interest

QUAD A Surveyors must sign and submit a *Conflict of Interest Agreement and Attestation* in order to become an active surveyor. In order for a submitted report to be considered valid by QUAD A, the surveyor must also sign the report/submission form including clauses certifying that the specific survey was conducted in accordance with the QUAD A Conflict of Interest Policy.

In the event that a surveyor becomes aware of a conflict of interest as defined in the QUAD A Conflict of Interest Policy before conducting the survey, the surveyor must report the conflict of interest in writing to QUAD A prior to traveling to the survey site but no later than the close of the second QUAD A business day (4:30pm CT) following discovery; if a conflict of interest is discovered while carrying out, or after completing the survey, the surveyor must stop any in-progress surveys and notify QUAD A immediately by telephone so the facility can be assigned a new surveyor.

- Email submissions are preferred.
- Notification of a conflict of interest must contain the classification of the conflict, either professional, financial, or personal.
- Surveyors must submit the nature of the conflict as being either with personnel of the facility or with the organization.

Resolving Conflicts of Interest

Any report of a conflict of interest will be reviewed by QUAD A's director of accreditation and the survey will be reassigned as appropriate. Any completed or partially completed surveys will be invalidated and a new survey scheduled at the expense of QUAD A. By the close of business on the day in which QUAD A receives of a conflict of interest report, the QUAD A staff member responsible for surveyor and facilities records will enter the report in the surveyor and facility files. In the event that reassignment is necessary, the staff member will begin the process of reassigning the facility to a new surveyor immediately. If a Medicare survey, the staff member will notify CMS upon confirmation of the assignment of the facility to a new surveyor and any changes to the date and time at which the survey will be carried out.

The maintenance of conflicts of interest records in the surveyor and facility files is not to be interpreted as a punitive measure. This will allow for more efficient assignment of facilities over time and should reduce the instances of surveyor conflicts of interest.

Logging the classification and nature of a conflict of interest will also help the staff to identify when a conflict no longer exists, and a surveyor becomes eligible to conduct a survey on a particular facility.



Post-Survey Processes

Disputes

In case of a disputed finding/citation, the facility as part of its Plan of Correction response must include a brief description of why it complies, the evidence of that compliance, and why it was not provided to the surveyor(s) during the onsite survey. The Accreditation Committee will review the response and may determine the facility is still deficient with the Standard(s); or the facility has demonstrated it was in compliance with the Standard(s) at the time of the survey; or may order a re-survey of the facility.

Policy for Plan of Correction Review by Surveyors

When extensive deficiencies are cited in the survey report, QUAD A may request that the surveyor(s) review the plan(s) of correction prior to approval to ensure the corrections are adequate, address every deficiency cited and appropriate.



Self-Surveys

Each facility is evaluated by their medical Director each year between surveys (years two and three of QUAD A's three-year cycle) and the completed self-survey is sent to the QUAD A Office. A facility's QUAD A accreditation remains valid if it continues to meet every standard for its program and class. Deficiencies should be noted by the facility as appropriate during this self-survey process, and a subsequent Plan of Correction must be provided with evidence of deficiency corrections. Otherwise, the accreditation may be revoked.

Instructions for Completing Self-Surveys

Please fill out the Medical Director's Responsibilities & Attestation (*CMS OPT only* – Clinic Administrator's Responsibilities & Attestation) and complete a self-survey of the facility utilizing the applicable program and class standards. Both documents must be submitted for your 2nd Year or 3rd Year QUAD A Self-Survey to be complete.



Adverse Accreditation Actions

Emergency Suspension

QUAD A may place a facility on an emergency suspension status upon receiving information that a state medical or other specialty board has taken action or begun formal proceedings which may result in it taking action against a license held by any clinician operating at the facility, or the QUAD A Board of Directors determines that the facility no longer meets the QUAD A standards for accreditation. The emergency suspension status will remain in such status pending an expedited onsite investigation and possible hearing conducted in accordance with QUAD A procedures as outlined in the QUAD A Terms & Conditions.

Denial or Loss of Accreditation

QUAD A may deny or revoke accreditation of a facility if the facility fails to satisfy every standard as applicable to the QUAD A Program and/or Class (as applicable). Additionally, QUAD A may deny or revoke the facility's accreditation if the facility fails to report the scenarios below to the QUAD A office.

If any medical professional providing services at the facility:

- a) Has had their privileges restricted or limited due to lack of clinical competence, ethical issues, refusal to take emergency call, or professional problems other than perceived or real economic competition.
- b) Has been found to be in violation of the Code of Ethics of any professional society or association for which they are a member.
- c) Has had their right to practice limited, suspended, terminated, or otherwise affected by any state, providence, or country or if they have been disciplined by any professional licensing authority.
- d) Non-reporting of any of the above to QUAD A.



Investigations

QUAD A has the authority to investigate allegations that, if substantiated, would result in non-compliance with QUAD A standards, including Medicare Conditions where appropriate.

Allegations or findings that fall outside of the QUAD A scope of authority are referred to the appropriate federal, state, and/or local agency. When QUAD A is aware that an agency or other body is also conducting an investigation, QUAD A will coordinate with that office to reduce duplicative work and avoid compromising either or both investigations.



Surveyor Resources

Various resources can be found on the QUAD A website under **Surveyor Education**.

Additional training/learning modules can be found on the <u>QUAD A Learning Management System (LMS)</u>.

CMS Appendices to be used for standards interpretation and survey process guides:

- CMS State Operations Manual, Appendix E Guidance to Surveyors: Outpatient Physical Therapy or Speech Pathology Services
- CMS State Operations Manual, Appendix G Guidance for Surveyors: Rural Health Clinics (RHCs)
- CMS State Operations Manual, Appendix L Guidance for Surveyors: Ambulatory Surgical Centers
- CMS State Operations Manual, Appendix Q Core Guidelines for Determining *Immediate Jeopardy*
- CMS State Operations Manual, Appendix Z- Emergency Preparedness for All Provider and Certified Supplier Types

CMS Principles of Documentation

