

EXHIBIT 7A

PRINCIPLES OF DOCUMENTATION

NOTE: Principles of Documentation are merely guidance for surveyors and do not impose obligations on either providers or surveyors for the suggestions contained in them.

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Introduction

This appendix provides guidance on how to structure a deficiency statement on the Form CMS-2567 after all the necessary information and evidence have been gathered. These guidelines include a general discussion of the legal aspects of the Statements of Deficiencies and identify and explain the principles considered in the citation of deficiencies to be documented on the Form CMS-2567. The principles are generic and apply to the documentation of survey results regardless of the particular program (Medicare, Medicaid or the Clinical Laboratory Improvement Amendments) or the particular provider or supplier type.

This guide does not replace or supersede the law, regulations, or State Operations Manual (SOM). Rather, this appendix is intended to provide guidance for documenting citations. Therefore, this appendix does not create additional substantive or procedural requirements that must be present to sustain a valid citation.

The CMS-2567 is the record of the survey where the survey team documents and justifies its determination of compliance and informs the provider or supplier of its state of compliance with the requirements for participation in the Federal programs. This information will serve as the basis for the facility to analyze its deficient practices or system failures and to develop plans of correction. The CMS-2567 may also document deficient practices identified by means other than an onsite survey, e.g., a review of compliance with the requirements to transmit comprehensive assessments to the State Agency.

Each principle is discussed in depth and includes an example of that principle. Each example is identified as being effective and is included to illustrate a particular documentation principle and may not represent a complete citation. In each case, there may be other language that may be as effective. The adequacy of any citation can be evaluated only in the context of the particular type and source of evidence, the extent and consequence of deficiency, and other relevant factors.

Definitions

Listed below are definitions that will be used throughout these materials.

COP - an abbreviation that commonly refers to a “condition of participation.” COP also is used throughout this manual to refer to a “condition for coverage” relevant to suppliers. The Conditions of Participation are requirements with which an entity must comply in order to participate in the programs.

Deficiency Citation - an entry made on the Form CMS-2567 that includes: (1) the alpha prefix and data tag number, (2) the Code of Federal Regulations (CFR), or Life Safety

Code (LSC) reference, (3) the language from that reference which pinpoints the aspect(s) of the requirement with which the entity failed to comply, (4) an explicit statement that the requirement was “NOT MET” and (5) the evidence (the deficient entity practice statement and relevant individual findings or facts) to support the decision of noncompliance (see Exhibit 0-1).

Deficient Practice - the action(s), error(s), or lack of action on the part of the entity relative to a requirement (and to the extent possible, the resulting outcome). (“practice” and “entity practice” are used interchangeably throughout this manual.)

Deficient Practice Statement - a statement at the beginning of the evidence that sets out why the entity was not in compliance with a regulation.

Entity - a generic term used to describe providers and suppliers under the Social Security Act or laboratories that participate in the CLIA program.

Evidence - an integral part of the citation that begins with a description of the deficient entity practice and identifies the relevant individual findings and facts that substantiate the failure of the entity to comply with the regulation.

Extent of deficient practice - the prevalence or frequency of a deficient entity practice.

Finding - a generic term used to describe each discrete item of information observed or discovered during the survey about practices of an entity relative to the specific requirement being cited as being not met.

Fact - an event known to have actually happened. A truth known by actual experience or observation.

Forms CMS-2567/CMS-2567L Statement of Deficiencies and Plan of Correction - the official document on which citations are recorded (see [Appendix A](#)).

Outcome - a result/consequence of entity practices (e.g., development of avoidable pressure sore/ulcer; reaction due to receipt of blood of wrong blood type.).

Recipient - one who receives services (a patient, resident or a client) from an entity regardless of whether or not that person is eligible for, or is receiving, Medicare or Medicaid.

Requirement - any structure, process or outcome that is required by the law, regulations, or the Life Safety Code (LSC).

S/S - In the LTC survey, symbol accompanied by a unique letter (A through L) that illustrates the effect of the noncompliance on the nursing home resident (severity) and the number of residents actually or potentially affected (scope) by the provider’s

noncompliance. The symbol with the letter assigned to the noncompliance appears under the tag number on the Form CMS-2567L for nursing homes. (See [Appendix P](#)).

Universe - the total number of individuals, records, observations, objects, related to the entity practice or recipients at risk as a result of a deficient practice. Used as the denominator when determining the extent of a deficient practice.

Appendix P - Guidance to Surveyors - Long-Term Care Facilities

Appendix Q - Guidelines for Determining Immediate and Serious Threat to Patient Health and Safety

Legal Aspects of the Statement of Deficiencies

The survey and certification of an entity that participates in Medicare, Medicaid or the Clinical Laboratory Improvement Amendments (CLIA) of the Public Health Service Act, is a process that must adhere to legal requirements. These programs are administered under extensive laws, regulations, operation manuals and other guidelines. Surveys and the documentation from surveys become an important part of subsequent legal proceedings arising out of the certification process.

This section is a brief overview of the legal aspects of surveying and the importance of surveyor documentation to the decision making and appeals process. It is not intended to provide complete and detailed information on the mechanics of the process. Please refer to the State Operations Manual (SOM) for more detailed information.

The survey process determines, and the documentation records, the compliance or noncompliance of providers, suppliers, and CLIA laboratories. The surveyor provides the reasons justifying any resulting enforcement action and the record on which to defend that action in the appeals process. Consistent and accurate documentation is imperative in the entire certification process as it forms the basis for the record and the certification decision. Moreover, the documentation may also be reviewed in any subsequent appeal, i.e., reconsideration, hearing before an Administrative Law Judge (ALJ) of the Departmental Appeals Board (DAB), review by the Board's Appellate Division, and judicial review.

A certification of compliance or noncompliance with the applicable requirements by the State agency or the Federal Government is an official finding and determines whether or not the provider or supplier may participate in the Medicare or Medicaid program or whether a laboratory is issued a certificate to operate under CLIA. It also determines whether any of these entities are subject to other sanctions. The decision-making process and subsequent certifications are based on the documentation of the survey in the Statement of Deficiencies (Form CMS-2567), as well as, other documentation such as surveyor worksheets or notes.

A prospective provider, supplier or clinical laboratory may request a reconsideration of a

determination that it does not qualify to participate in the Medicare/Medicaid program. A formal reconsideration is a thorough, independent review of the prior decision and the entire body of evidence. If the reconsideration determination upholds the initial decision, the entity may request an evidentiary hearing before an ALJ.

If an entity is determined to no longer meet the requirements and is subject to termination or alternate remedies/sanctions, the actual or projected termination or remedy may be appealed through an evidentiary hearing before an ALJ. If a laboratory's certificate is subject to limitation, suspension, revocation, or is actually limited, suspended, or revoked, the actual or projected limitation, suspension or revocation may be appealed through an evidentiary hearing before an ALJ. During a hearing, the government has the responsibility to show why a provider or supplier should be terminated or be subject to alternate remedies, and/or a laboratory's certificate should be limited, suspended or revoked.

The evidence must provide the underlying reason, basis or rationale for the findings of noncompliance with the regulatory requirement(s). Such a hearing is an adversarial proceeding. At the hearing, witnesses testify for both the entity and for CMS, and are subject to cross-examination. The primary evidence is the Form CMS-2567, and any other documentation used to make the determination of survey results (e.g., worksheets, narratives, etc.). The ALJ relies on the testimony of witnesses and the documentation from the survey in making a decision. All documentation used at the hearing becomes part of the public record. The ALJ issues a written decision as to whether or not the entity should be found in compliance with the requirements of the program. The ALJ is usually not a health professional, therefore, it is important that the surveyor present the findings in plain language. For this reason, the Form CMS-2567 does not contain technical jargon or abbreviations that would not be readily understood by a lay person.

If either CMS or the entity is dissatisfied with an ALJ decision or dismissal, it may file a request for review to the DAB Appellate Division. The DAB considers the evidence introduced at the ALJ hearing to determine whether the ALJ's decision had a sound factual basis. An entity dissatisfied with the DAB decision has the right to seek judicial review, CMS does not. The survey documentation again becomes an important document of the proceedings. The review by the Court is limited to the record of the proceedings before the ALJ and the DAB's Appellate Division.

Documentation on the Form CMS-2567 remains the key element in the record to support a determination to certify compliance or noncompliance with applicable requirements and, if necessary, to defend the determination before the public, during the appeals process, or in court. The documentation of each and every survey should be treated as if it will be subject to close scrutiny. The determination of compliance, as well as noncompliance must be based on objective, factual observations and not vague conclusions. A judge will usually rely on surveyor judgment if the documentation is thorough and comprehensive.

If, during the course of the survey, information/evidence involving recipient outcomes is discovered, surveyors should make every effort to relate the deficiencies to the effect on the recipient and recipient's care. Citations must relate to the statutory or regulatory requirements.

In addition, a clear and comprehensive Statement of Deficiencies is necessary to provide the entity with the information necessary to analyze its problems, define appropriate corrective action and come into compliance with the requirements.

Overview

Listed immediately below for easy reference are the principles considered in the development and completion of the Form CMS-2567. Following this listing, each principle is explained in detail in a separate section.

Principle #1 - Entity Compliance and Noncompliance

When an entity complies with the requirements applicable to the survey conducted, the Form CMS-2567 should consist of an explicit statement that the entity is in compliance. If an entity does not comply with one or more applicable requirements, the Form CMS-2567 includes corresponding citations of noncompliance.

Principle #2 - Using Plain Language

The deficiency citation is written clearly, objectively and in a manner that is easily understood. The deficiency citation does not include consultation, advice, comments or direction aimed at the surveyed entity.

Principle #3 - Components of a Deficiency Citation

A deficiency citation consists of (A) a regulatory reference, (B) a deficient practice statement and (C) relevant findings.

A - Regulatory Reference

A Regulatory Reference includes the following components:

1. A survey data tag number,
2. The CFR or LSC reference,
3. The language from that reference which specifies the aspect(s) of the requirement with which the entity was noncompliant.
4. An explicit statement that the requirement was "NOT MET."

B - Deficient Practice Statement

The statement of deficient practice is one component of the evidence. It includes:

1. The specific action(s), error(s), or lack of action (deficient practice),
2. Outcome(s) relative to the deficient practice, when possible
3. A description of the extent of the deficient practice or the number of deficient cases relative to the total number of such cases,
4. The identifier of the individuals or situations referenced in the extent of the deficient practice, and
5. The source(s) of the information through which the evidence was obtained.

C - Relevant Facts and Findings

The facts and findings relevant to the deficient practice, answer the questions: who, what, where, when, and how. They illustrate the entity's noncompliance with the requirement or regulation.

Principle #4 - Relevance of Onsite Correction of Findings

If, during the survey, the entity corrects the situation that resulted in the deficiency, a determination of "NOT MET" must be documented on the Form CMS-2567. The entity may indicate its correction in the right-hand column of the Form CMS-2567. If, during the survey, the entity initiates corrective actions that abate a finding of immediate jeopardy, follow the guidance described in [Appendix Q](#).

Principle #5 - Interpretive Guidelines

The deficiency citation explains 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.

Principle #6 - Citation of State or Local Code Violations

The entity's failure to comply with State or local laws or regulations is not documented in the Form CMS-2567 except when the Federal regulation requires compliance with State or local laws. When the authority having jurisdiction for that State or local law has made a decision of noncompliance and has effectuated an adverse action that has been sustained through the hearing process (such as removal of the license to operate), the Form CMS-2567 should note that the entity no longer has a license.

Principle #7 - Cross-References

The cross-referencing of requirements is an acceptable form of documentation on the Form CMS-2567 only when it is applicable and provides additional strength to the linked citations. Cross-referencing is most effective when the linked citations have a direct cause and effect relationship to the deficient practices described in both citations. In all instances, the linked citation must contain sufficient evidence to demonstrate noncompliance for the referenced regulation at the linked site.

Principle #8 - Condition of Participation Deficiencies

The COP citation includes deficient practice statements and findings to support the determination of noncompliance with a condition level requirement. The findings may be incorporated either by cross references to those requirements which must be corrected to find the COP in compliance or by narrative description of the individual findings.

Principle #1 - Entity Compliance and Noncompliance

When an entity complies with the requirements applicable to the survey conducted, the Form CMS-2567 should consist of an explicit statement that the entity is in compliance for that particular survey. If an entity does not comply with one or more applicable requirements, the Form CMS-2567 includes corresponding citations of noncompliance. The statutes and implementing regulations are the legal authority for determining an entity's compliance with Federal requirements for participation or coverage in Medicare, Medicaid, and CLIA.

The Form CMS-2567 is the official document that communicates the determination of compliance or noncompliance with the Federal requirements. Also, it is the form that an entity uses to submit a plan to achieve compliance. It is an official record and is available to the public on request.

Exhibit 1-1 illustrates how to give official notice to the provider or any other interested parties of the compliance status of the entity when the surveyor has identified no deficiencies. The specific requirements with which the entity must comply, as contained in Title 42 of the Code of Federal Regulations (CFR), are included.

Exhibit 1-1 - Effective Documentation for Principle #1

Tag	Summary Statement of Deficiencies
G 000	The [Name] Home Health Agency is in compliance with 42 CFR Part 848, Requirements for Home Health Agencies.

If a nursing home has no deficiencies identified at the time of the survey, the entry on the Form CMS-2567 would read that the NH is in compliance with [42 CFR Part 483](#), "Requirements for Long Term Care Facilities."

For SNF/NF, if the provider's noncompliance is isolated and does not pose a risk of more than minimal harm (S/S=A), the deficiency is documented on the "A" Form - "Statement of Isolated Deficiencies Which Cause No Harm With Only A Potential For Minimal Harm for SNFs and NFs." (See Appendix Q?) In addition, the documentation on the Form CMS-2567L would state the SNF/NF is in substantial compliance.

Exhibit 1-2 - Effective CMS-2567L Documentation for Nursing Homes With an A level finding

Tag	Summary Statement of Deficiencies
F 000	The [Name] Nursing Home is in substantial compliance with 42 CFR Part 483 Requirements for Long Term Care Facilities

If a nursing home is in substantial compliance but has deficiencies, other than the Isolated Deficiencies which Cause No Harm with Only A Potential For Minimal Harm (S/S=B, C), the deficiencies are documented on the Form CMS-2567L and no additional language regarding substantial compliance is entered on the Form CMS-2567L.

NOTE: The remainder of the principles of documentation address how to document citations, that is, situations in which the entity has been found not to comply with one or more requirements.

Principle #2 - Using Plain Language

The deficiency citation is written clearly, objectively and in a manner that is easily understood. Each deficiency citation relates to a requirement within the CFR or the LSC. The deficiency citation should contain only the evidence to support the determination of noncompliance. Exclude the use of consultation, advice, comments or directions aimed at the surveyed entity. The deficiency citation should contain only the evidence to support the determination of noncompliance.

Inclusion of extraneous comments or consultative remarks in citations may lead to confusion. The entity surveyed and the public may not be able to distinguish between what the survey team would like to see and what is legitimate evidence of noncompliance. To decrease confusion, documentation in the Form CMS-2567 contains only the citation and evidence to support the determination on noncompliance. Extraneous information that is not relevant to demonstrating noncompliance with the specific requirement should be avoided.

An example of an extraneous remark would be: When documenting a deficient practice of failure to complete a care plan, a comment regarding the Resident's lack of knowledge regarding her Medicaid benefits is included. The Resident's knowledge regarding her Medicaid benefits has no relevance to the deficient practice regarding the care plan and only confuses the reader.

The language used to write a deficiency citation should be as clear as possible. Many styles of writing are acceptable, and style is a matter of individual preference; however, surveyors should not use slang, unfamiliar terms and phrases.

Best practice is to:

- Put all relevant facts in chronological order.
- Keep sentences short.
- Use simple sentence structure.
- Use the active voice (e.g. “The DON reprimanded the CNA” not “the CNA was reprimanded by the DON.”).
- Avoid undefined abbreviations, initials and technical jargon.
- Write in layman’s terms.
- Write to inform, not impress.
- Avoid unnecessary words.
- Avoid vague terminology (such as, seems, appears, did not always).
- Avoid words that imply or state conclusions without including the facts to support them (e.g., “only,” “just,” “unsatisfactory,” “unnecessary,” or “inadequate”).
- Ensure the accuracy of quoted material.

According to “Strunk and White,” When you become hopelessly mired in a sentence, it is best to start fresh; do not try to fight your way through against the terrible odds of syntax. Usually what is wrong is that the construction has become too involved at some point; the sentence needs to be broken apart and replaced by two or more shorter sentences.”

Principle #3 - Components of a Deficiency Citation

A deficiency citation consists of (a) a regulatory reference, (b) a statement of deficient practice, and (c) relevant findings. (For SNFs and NFs, the scope and severity decision is documented in the left column under the survey data tag number.). Since all relevant information demonstrating noncompliance have been provided in the deficiency citation, conclusion or summary remarks at the end of the deficiency citation are not necessary and should be avoided.

This principle addresses **all** of the components of a complete citation.

Regulatory Reference

When the entity's practice violates a regulation or requirement, determine the regulation that the entity may have violated. Examine the language of the regulation under which a deficiency could be cited. Determine if the requirement addresses the entity's policies and procedures, actions, or inaction.

A regulatory reference is composed of: (1) a survey data tag number, (2) the CFR or LSC reference, (3) the language from that reference which specifies the aspect(s) of the requirement with which the entity was noncompliant, and (4) an explicit statement that the requirement was "NOT MET."

Regardless of the computer software used to produce the Form CMS-2567, essential components of the citation: survey data tag, CFR or LSC reference, language of the requirement for that reference, and an explicit statement that the requirement was not met are generated automatically on the Form CMS-2567. Each handwritten citation should include all of those components. The deficient entity practice statement and the relevant findings then follow these components.

If the approved CMS software program for documenting deficiencies does not capture the language of the requirement being cited at a particular data tag or the specific regulatory/statutory requirement, incorporate the language for the specific aspect of the requirement being cited as being deficient.

Federal certification requirements are located at Title 42 of the Code of Federal Regulations (CFR) or in the Life Safety Code.¹ (LSC) The requirements are further coded into a series of alpha numeric data tags (e.g., F201, A53, G156, etc.) that allow essential survey information to be retrieved and analyzed to determine trends and patterns of noncompliance. The numerical order of survey data tags approximates the order of the requirements within the CFR or LSC¹.

Tag	Summary Statement of Deficiencies
F 174 S/S (A-L)	42 CFR 483.10 (k) The resident has the right to have reasonable access to the use of a telephone where calls can be made without being overheard. This requirement is NOT MET as evidenced by:

Requirements

Federal requirements for participation or coverage can be categorized as follows:

- **Structure - requirements** that specify the initial conditions that must be present for an entity to be certified to participate and that, in general, are expected to remain as is unless there is a need for major renovation, reorganization or expansion of services. Some examples of structure requirements include:

The agency has by-laws that **or** Each bedroom measures

- **Process - requirements** that specify the ongoing manner in which an entity must operate. They do not allow the entity discretion to vary from what is specified. Examples of process requirements include:

The plan of care must be reviewed by **or** The physical examination is conducted on an annual basis

¹ If a LSC chapter references another chapter or NFPA reference document, the referenced chapter or document should also be cited. For instance, 1985 Life Safety Code, 13-3.5.1: Sprinkler systems shall be in accordance with Chapter 7.7-7.1: Sprinkler systems shall comply with NFPA 13, Sprinkler systems... 4-4.1: Buildings shall be sprinkled throughout the premises.

- **Outcome - requirements** that specify the results that must be obtained or events that must occur or not occur following an act. Generally, these requirements are stated in terms of the recipient's response to receipt of needed services or conditions that must result from, or are prevented by, implementing one or more processes. Example of outcome requirements include:

The facility must ensure that a resident maintains acceptable parameters of....

F-314: Based on the comprehensive assessment of a resident, the facility must ensure that a resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates they are unavoidable.

The findings document the outcomes that occurred or failed to occur or failure to assist the individual(s) to achieve optimal improvement in overall functioning or to prevent avoidable regression or loss of function. The citation documents sufficient facts to illustrate the level of harm that has occurred or may occur.

Deficient Practice Statement

The statement of deficient practice must be written in terms specific enough to allow a reasonably knowledgeable person to understand the aspect(s) of the requirement that is (are) not met. They are also used to identify the levels of scope and severity of the deficiency. It includes what the entity did or did not do which caused the noncompliance.

The statement of deficient practice must not repeat the regulation, but should state what the facility did that was wrong or failed to do, to let the reader know what to look for in the findings. The statement of deficient practice presents the specific action(s), error(s), or lack of action(s) relative to the requirement.

The evidence for a citation begins with a statement of deficient practice that summarizes the issues that led to the determination that the entity was not in compliance with that requirement and contains all the objective findings. The statement of deficient entity practice includes: (1) the specific action(s), error(s), lack of action (deficient practice); (2) when possible, resultant outcome(s) relative to the deficient practice; (3) a description of the extent of the deficient practice or the number of deficient cases relative to the total number of such cases; (4) the code of the individuals or situations referenced in the extent of the practice; and (5) reference to the source(s) of the information through which the evidence was obtained.

Some certification requirements state multiple expectations at a single survey data tag. The entity must maintain compliance with each facet of the requirement in order to continue participation. The failure to comply with only one expectation may be sufficient evidence for a citation of the entire requirement. The deficient practice must be described

in concise clear terms so that the entity can determine which part of the regulation it has NOT MET. The deficient practice statement should be organized and presented in a logical manner and should relate to each part of the regulation with which the entity failed to comply.

Exhibit 3-2 - Effective Documentation of Deficient Practice Statement

Tag	Summary Statement of Deficiencies
F 455	<p>42 CFR 483.70 (c)(1)</p> <p>The facility must provide sufficient space and equipment in dining, health services, recreation, and program areas to enable staff to provide residents with needed services as required by these standards and as identified in each resident's plan of care.</p> <p>This requirement was NOT MET as evidenced by:</p> <p>Based on observation, record review and staff interviews, the facility failed to provide a space and the equipment required for physical therapy services for 4 of 10 sampled residents (4, 6, 7, and 10) who needed mat exercises, ambulation in parallel bars, and weight training to improve their physical functioning.</p> <p>Findings include:</p>

Extent

Extent is the prevalence or frequency of a deficient practice and is a numerical quantification of the deficient practice. The extent is expressed in a numerical format by identifying the number of deficient cases within the total number of relevant cases or universe. For example, 4 of 6 residents observed during lunch. The universe may be all of the recipients provided care and services by an entity, if the failed practice affects all the recipients, e.g., when a hospital does not provide adequate maintenance of the fire alarm system. When the failed practice does not affect all the recipients of care and services provided by an entity, the surveyor must attempt to determine the relevant universe or the total number of recipients who could be affected by the failed practice. For instance: The ESRD center does not provide adequate monitoring of anti-coagulant therapy. Only those patients on anti-coagulant therapy would be affected by the deficient practice. Therefore, the universe would be the total number of patients with orders for anti-coagulants.

The surveyor then determines the number of individuals within the sample or expanded sample on anti-coagulant therapy who were harmed or could be harmed by the failed practice. Did the ESRD center fail to monitor all of those patients on anti-coagulant therapy? If not, how many were not monitored? The total number of patients affected by the failed practice divided by the total number of patients that could have been affected

by the failed practice provides a numerical quantification in percent of the extent of the failed practice.

The extent of deficient practice will depend upon whether:

1. The requirement related to all cases or individuals served by the entity;
2. Surveyors had knowledge of all cases to which the requirement applied;
3. The requirement related to a subset of all the cases or individuals served by the entity or only a sample of applicable situations or cases;
4. The deficient practice was determined through only random opportunities for discovery.

Based on observation, the facility failed to maintain appropriate lighting standards for 7 of 12 emergency exits and failed to test pressure back flows on 2 of 2 water lines. In this example, there are 3 separate expressions of extent: the deficient practice created a potential hazard/impact on the entire recipient population, there were 12 exits and the lighting was insufficient at 7 of those 12, and 2 of 2 water lines were deficient.

- Knowledge of all cases or situations

When the deficiency is based on knowledge obtained about all applicable cases or situations, both this total and the number of cases/situations that evidenced deficiency should be recorded within the body of the citation. The following phrases illustrate a variety of acceptable measures:

In an interview with the pharmacist at 2:00 p.m. on 5/29/XX he stated that of 98 residents at the facility for whom Haldol had been prescribed, 74 had individual program plans that had not been developed with the participation of...

The hospital's pharmacy committee minutes dated 01/11/XX confirmed that of the 86 patients to whom medications are administered, 45 (approximately 53%) were identified as being unable to...

Nineteen of the 20 residential living units were observed to need the following repairs:

Each of the 5 seclusion rooms used by the facility

- Sample of applicable situations

When the requirement is not applicable to all of the cases or individuals served by an entity, the extent would be developed by using only the cases or individuals with a negative outcome as a result of the deficient practice divided by the total number of cases or individuals in the sample that could have been impacted by the deficient practice. The extent of deficiency should be reported in numeric, quantified terms. For example:

Review of records for 10 of the 60 patients who received transfusions between 7/10/XX and 9/30/XX revealed that the facility failed to monitor the vital signs for 6 of the 10 patients...

Records for 2 of the 4 surgical patients in the recovery room at 9 AM on 1/7/XX and 3 of the additional 9 records reviewed of patients having had surgery between 12/28/XX and 1/6/XX revealed that no history and physical had been documented or dictated.

Based on record review, and patient and staff interviews, the facility failed to complete an incident and accident report for 1 of 8 sampled patients (#6) reviewed and failed to analyze incident reports for health/safety hazards for 16 of 16 incidents reviewed.

Based on observation, interview and record review, the facility failed to respond to residents' requests for assistance in a manner that maintained or enhanced their dignity for 5 of 9 sample residents (#5, 9, 12, 18, 24).

Resident Assessments of 5 residents in the sample of 10 had not been evaluated by...

For 22 of 50 clients in the sample who have current restraint programs authorized, 19 were...

- Random opportunities for discovery

When the deficiency is based on random opportunities for discovery of the problem, all of the applicable cases or situations may not be known. Surveyors may quantify their observation but may not be able to reference a total number of cases or situations that apply. Even though this procedure does not yield as precise a measure as has been discussed above, the report of measure is valid, particularly when serious outcomes of the deficiency have been observed and reported.

For example:

In 3 of 4 random observations, the facility failed to honor the resident's requested preference for an alternate meal choice (RS #1, 2, 3).

Based on record review, interview and patient observation, the staff did not recognize and failed to assess the patient for the signs and symptoms of possible fecal impaction.

During the tour of Ward J-7 on XX/XX/XX at 10:00 am, three CNAs were observed addressing residents about their incontinent and personal hygiene in the solarium using extremely loud voices that could be heard down the hall. (RS #1, 2, 3, 4).

Based on observation, on XX/XX/XX the integrity of firewalls located between 1-East and 1-West was breached by a hole measuring 5 inches...

During tour on unit on XX/XX/XX at 2:15 p.m., RS #1 was observed to be mechanically restrained to his bed in locked leather cuffs while he was asleep...

Identifiers

An individual's name must not appear in the Form CMS-2567. The identity of the recipients of deficient practice or any persons, including surveyors, who will be referred to in the report, must remain confidential. They are included in the report by indicating their identifiers, which can be letters, numbers, or a combination or both. These identifiers also appear in the statement of deficient practice and in the findings.

When the person referred to in the report is an entity staff member, the person(s) may be addressed by their position, discipline, or job title, or be assigned an identifier.

Identification of each case found to be deficient provides the entity with information necessary to evaluate the context of the problem. When the evidence refers to individual recipients, the statement of deficient entity practice should reference by identifiers.

The coding system used to indicate the recipients should be decipherable by the entity, and retrievable by the RO or SA. Whenever possible, if a revisit or follow-up survey finds noncompliance for the same individual as in the standard survey, reassign the same identifier code. If it is not possible to use the same identifier, use a different set of numbers for revisits so that in the event of a hearing, the same identifier is not used for two different recipients. Every effort should be made to protect a recipient's privacy especially regarding information gathered during an in-depth interview. Do not identify recipients or family members without their permission. If the interviewee does not wish the entity to know the source of the information provided to you, that information may be recorded on the Form CMS-2567 without an identifier. The CMS-2567 would state, 'During a confidential interview....' However, the interviewee must be told that there is no guarantee this information will remain confidential as a court may require that confidential information be disclosed. If the interviewee's identity is not disclosed to the

entity, the Form CMS-2567 must contain sufficient information for the entity to correct the deficient practice, and to contest the deficiency, if it desires.

When the deficient entity practice references personnel files or staff training, a separate coding system should be developed to identify the staff affected by the deficient entity practice without using their names.

When random observations or recipients/cases/records beyond the original sample(s) are included in a citation, an identifier should be given to the individual so that the entity may evaluate the extent of the problem or patterns and correct the deficient entity practice.

For example:

During dining observations in an ICFs/MR, 4 non-sample random clients are observed who were not given an opportunity for incidental training during their dining experience.

After further investigation focused on the identified concern, if a citation is developed, these randomly observed clients need to be assigned an identifier so that the entity may address the deficient practice in its POC.

Examples of identifiers include:

Sample Recipient identifiers:...for 3 of the 5 clients in the sample (Clients 2340, 5496, and 0429). Staff identifiers: (Title or Position) Based on interview with the ADON responsible for infection control, the entity failed **OR** Staff Identifier Coding System: 7 of 10 CNAs did not receive the 12 hours of in service training (So, 2, 3, 4, 7, 9, 10). Confidential Interview Identifier: Based on record review, the ESRD (entity) failed to allow patient participation in the development of the long term care plan for 4 of 10 patients (#2, 4, 5, 10). In addition a confidential interview revealed...

Sources of the Evidence

The source of evidence is the manner through which the evidence was obtained. Sources of evidence may include: observation, interview, and record review. They contain specific information regarding the who, what, when, where, and how of the event(s) or situation(s) that contributed to the deficiency. It is best to utilize supporting evidence obtained from more than one source of evidence.

The sources of evidence are presented in the statement of deficient practice and are described in detail in the findings portion of the Form CMS-2567 report.

Each statement of deficient practice identifies the source(s) through which the evidence was obtained, that is, from observation, interview, or reviews of records or other documents. Sources identified in the entity practice statement must be represented in the findings. The findings describe the specifics regarding the sources.

For example:

What was learned from the source; the date, time, and location of the observations; the date and time of the interviews; titles of the interviewed persons and the types and dates of records/documents used in the identification of the deficient practices.

Do not identify the recipients or families when using information from the interview. Use a generic term to identify the person who has been interviewed, e.g., a family member, or a resident. Identify by title those staff who were interviewed. If more than one of the same type is interviewed, then the number of staff should be identified.

Observations

Observation is the process by which a surveyor gathers information in accordance with the requirements, based on input obtained from the five senses. It is what the surveyor sees, hears, touches, smells or tastes during the survey that evidences an entity's deficiency. It must answer the who, what, where, when, and how questions. A surveyor may observe if the actions or outcomes described in a clinical or administrative record actually occur in the daily operation of the entity. Actions or outcomes that are described in a clinical or administrative record and observed are also recorded as an observation.

The surveyor must note the specific date and time the observations were made and describe the observation.

Detailed documentation of observations of deficient practice assists the provider in identifying when and where the deficient practice occurred. Time includes the number of observations in which the deficient practice was observed and, as appropriate, the duration of each observation. For example, a series of observations that identify the failure to deliver service from 4:00 P.M. to 6:00 P.M., may help the entity to identify staffing or supervisory concerns, such as, inadequate supervision or sufficient staffing on a particular shift. Terms such as "throughout the survey," "during observation on the second day of the survey," etc. are vague, too general and should be avoided. Exhibit 3-3 illustrates an appropriate manner to document the evidence that was obtained through observation.

Exhibit 3-3 - Effective Documentation of Observation-Based Findings

Tag	Summary Statement of Deficiencies
K 021	<p>NFPA 101 STANDARD: LIFE SAFETY CODE STANDARD</p> <p>Doors in fire separation walls, hazardous area exposure, horizontal exits, or smoke partitions may be held open only by devices arranged to automatically close all such doors by zone or throughout the facility upon activation of:</p> <p>(a) The required manual alarm system and</p> <p>(b) Local smoke detectors designed to detect smoke passing through the opening or a required smoke detection system and</p> <p>(c) The automatic sprinkler system, if installed.</p> <p>13-2.11.5</p> <p>Based on observations, the facility used a door wedge (an unapproved Device) to hold open 1 of the 9 entry doors included in the facility's fire Safety system.</p> <p>Findings include</p> <p>On facility tour between 2:30 and 3:30PM on xx/xx/xx, a door wedge was Observed at the foot of the West entry door holding the door open. The Door was being held in an open position and could not automatically close in case of fire.</p>

Interviews

The interview process largely consists of talking to individuals (e.g., patients, clients, residents, family, visitors, staff, physicians, ombudsman) to collect information in accordance with requirements about the entity practices. Information obtained through interviews can provide evidence to support a deficiency.

For example:

Surveyors talk with recipients to determine whether the entity fulfills the commitments it has made in records; staff are interviewed to determine their knowledge of the needs of the recipient and of entity policies and procedures. To the greatest extent possible, the surveyor verifies the information obtained from interview through observation or record review. In the absence of other objective validation of information, information may also be confirmed/verified through multiple interview sources.

Exhibit 3-4 - Effective Documentation of Interview Based on Findings

Tag	Summary of Statement of Deficiencies
F 252	<p>42 CFR 483.15 (h)(1)</p> <p>The facility must provide a safe, clean, comfortable and homelike environment, allowing the resident to use his or her personal belongings to the extent possible.</p> <p>This requirement was NOT MET as evidenced by:</p> <p>Based on observation and interview, the facility failed to provide a homelike environment for 2 of 15 sampled residents (#5, #6) whose rooms lacked individual decorations and any personal belongings.</p> <p>Findings include:</p> <ol style="list-style-type: none">1. Observations made during the tour at 10 AM on xx/xx/xx, noted that Resident 5's room was barren of any individualized decorations and personal belongings. During an interview on XX/XX/XX at 3:00 p.m., Resident #5 stated, "I miss my pictures; they are all I have left. I want them with me but no one will get them for me. I want my own toiletries too!"2. At 10 AM on xx/xx/xx, Resident #6's room was observed to be barren of any individualized decorations and personal belongings. During an interview on XX/XX/XX at 11:00 a.m., a family member of Resident #6 stated, "My (Resident #6) would like to have a rocking chair. I asked the nurse if I could bring it in and she said she would check on it and let me know. This was about three weeks ago and she has not yet told me if it was acceptable or not." <p>During an interview with the director of nursing (DON) on XX/XX/XX at 1:00 p.m., the DON revealed that the facility was aware of the residents' requests for personal belongings but had tried to discourage displays of any personal items to reduce theft in the facility.</p>

Review of Records and Other Documents

Evidence discovered during review of the entity's documentation is discussed with the staff to determine if additional documentation or other information exists. Record or document review is the process through which administrative (e.g., statements of policy and procedure, committee minutes, injury/incident reports) and clinical (e.g., comprehensive assessments and evaluations, consultations, laboratory reports, plans of care, progress notes) documents are read and analyzed. Through review of recipients' clinical records, surveyors determine the needs of individuals and the extent to which the

entity has addressed those needs. Through review of administrative documents, surveyors assess the entity's compliance with requirements for the maintenance and use of those documents.

When using information obtained through record review, identify the record that contained the information. If the deficiency results from a lack of documentation, make sure the documentation is requested from the staff member who might or who should know where the documentation can be found.

Obtain copies of the records, which show the deficient practice to prove the deficiency, and to show after-the-fact changes that may be made by the entity.

If the regulation requires a policy on specific issues, ascertain that the policy fails to address the necessary issues before determining it is deficient.

Examples of documenting information from records and some of the additional investigation necessary, include:

Patient Y's medical record contained a urinalysis report dated XX/XX/XX for urine which was sent to a laboratory on XX/XX/XX. The report indicated the sample had been contaminated and recommended that a new sample be submitted. The record did not indicate that another specimen had been sent and the staff on XX/XX/XX were unable to determine if any had been sent.

The medical record did not contain the results of the urinalysis for the sample sent to the lab on XX/XX/XX. Staff were unable to locate the report and reported upon inquiry of the lab that the results had not been sent to the facility.

The initial Minimum Data Set (MDS), dated XX/XX/XX, documented that a resident was readmitted from home on XX/XX/XX with a reddened area. The nurses notes dated XX/XX/XX, documented a "reddened area to left ankle."

Exhibit 3-5 - Effective Documentation of Record Review-Based Findings

Tag	Summary Statement of Deficiencies
V 321	<p>405.2137(b)(4)STANDARD: PATIENT CARE PLAN</p> <p>The care plan for patients whose medical conditions has not stabilized is reviewed at least monthly by the professional patient care team described in paragraph (b)(2) of this section. For patients whose condition has become stabilized, the care plan is reviewed every 6 months. The care plan is revised as necessary to insure that it provides for the patient's ongoing needs.</p> <p>This STANDARD is NOT MET as evidenced by:</p> <p>Based on record review, the provider failed to address changes in therapies on the Patient Care Plan (PCP) for 2 of 7 patients (#1, #4).</p> <ol style="list-style-type: none">1. Review of the admission progress note dated 4/10/XX showed that Patient #1 started receiving peritoneal dialysis (in the home) on 4/1/XX. Per the 10/2/XX Social Services note, Patient #1 was switched (at the request of the patient) from peritoneal to hemodialysis (in the dialysis center) on 9/11/XX. Review of the most current PCP dated 12/2/XX revealed that this change in treatment modality was not addressed in the PCP.2. Patient #4 started hemodialysis (in the dialysis center) on 2/11//xx per the admission assessment. The 9/8/XX Physicians Progress note indicated that Patient #4 received a transplanted kidney on 4/5/XX, but restarted hemodialysis again on 8/1/XX after the transplant was rejected. Review of the PCP dated 12/2/XX revealed that the patient's changes in status were not addressed in the PCP.

Exhibit 3-6 - Effective Documentation of Record Reviews

Tag	Summary Statement of Deficiencies
F 225 S/S	<p data-bbox="386 310 678 346">42 CFR 483.13 (c)(2)</p> <p data-bbox="386 346 1346 569">The facility must ensure that all alleged violations involving mistreatment, neglect or abuse, including injuries of unknown source and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with State law through established procedures (including to the State survey and certification agency).</p> <p data-bbox="386 604 1036 640">This requirement was NOT MET as evidenced by:</p> <p data-bbox="386 676 1346 821">Based upon staff interview, review of medical records, and review of the policy and procedure manual, facility staff did not report to the administrator bruising of unknown origin for 2 residents in the sample of 20 (#15, 24).</p> <p data-bbox="386 856 662 892">The findings include:</p> <ol data-bbox="386 928 1346 1738" style="list-style-type: none"> <li data-bbox="386 928 1346 1150">1. A record entry dated XX/XX/XX, for resident #24 noted that staff had observed bruises on the resident's genitals and inner thigh. During an interview at 1:00 p.m. on XX/XX/XX, the Director of Nurses stated that the Administrator had been ill for 2 months around that time and she had been acting Administrator. She said, "Staff did not report the bruises to me ...I have not investigated for the cause of the bruises." <li data-bbox="386 1186 1346 1444">2. A record entry, dated XX/XX/XX, for resident #15 noted that staff had discovered that the bridge of the resident's nose was very bruised and no indications of a possible cause were noted. An interview with the charge nurse on the south wing on XX/XX/XX at 10:00 a.m. confirmed that no one knew how the bruise occurred. The injury of unknown origin had not been reported to the administrator and had not been investigated. <li data-bbox="386 1480 1346 1738">3. Review of the policy and procedure manual on XX/XX/XX, did not provide evidence that the facility had established procedures in the manual that specify how allegations of abuse or injuries of unknown origin were to be reported. During interview on XX/XX/XX at 3:00 p.m., the administration confirmed that the facility had no current policy or procedure directing staff regarding when to report possible abuse or injuries of unknown origin.

The following are examples of complete citations that comply with the Principles of Documentation.

Exhibit 3-7 - This example reports the evidence in a way that the entity can understand that the requirement was not met and how the survey team determined that the requirement was not met. The facts are stated clearly, the deficient practice is apparent, and there is no extraneous information within the citation that might cause confusion. All of the components of a complete citation are included.

Exhibit 3-7 - Effective Documentation of Principle #3

Tag	Summary Statement of Deficiencies
L 210	<p>418.94 (a)Standard: Supervision</p> <p>A registered nurse visits the home site at least every two weeks when aide services are being provided, and the visit includes an assessment of the aide services.</p> <p>This STANDARD is NOT MET as evidenced by:</p> <p>Based on review of 4 of 12 medical records (#5, 3, 9, 12) and interviews in 2 of 4 home visits (#5, 12), it was determined that the registered nurse visit did not include an assessment of whether the aide provided grooming services (shampoo and shower) to the patients.</p> <p>The findings include:</p> <ol style="list-style-type: none">1. Review of medical records for Patient #5 revealed that: between 10/20/XX to 12/20/XX, the records did not contain documentation that any of the registered nurse visits to the home site included an assessment of the aide services. The son of Patient #5 said, during an interview on 12/28/XX, "The aide never shampoos my Mom's hair and the nurse said that she is supposed to be doing that." During an interview at 10 a.m. on 12/29 with the nurse caring for the patient, the nurse acknowledged that the family member had mentioned the shampoos, the plan of care did indicate the patient was to receive shampoos, but she had not followed up with the aide about not doing them, nor had she verified what was reflected on the aide assignment sheet or what the aide had recorded.2. Review of medical records for Patient #12 revealed that: between 10/28/XX to 12/28/XX, the records did not contain documentation that any of the registered nurse visits to the home site included an assessment of the aide services. The family member of Patient #12 said, during an interview on 12/28/XX, "The aide did not give (my family member) a shower; instead the aide gave (my family member) a very quick bath in bed. I don't know why but the aide always comes late and leaves early."

Tag	Summary Statement of Deficiencies
	3. The same lack of documentation regarding registered nurse visits to the home site to assess aide services was found in medical records for Patients #3 for review period 03/10/XX to 05/07/XX; and #9 for review period 02/11/XX to 03/29/XX.

Each of the three sources may not be necessary to confirm a deficiency. Regardless of the particular avenue(s) through which information about an entity's compliance with requirements is gathered, the Principles of Documentation statement should include how the information was obtained.

Outcomes

To the extent possible, especially where described or anticipated in the requirement(s), the deficient practice indicates outcome(s). The statement of findings describes the specific results and consequences of the entity's deficient practice for the individual cases reported. Negative outcomes include deterioration, failure to improve or maintain, etc. Although no negative outcome may be evident from the deficient practice, a failure to comply with a requirement is a deficiency. Many requirements are not outcome oriented. An example of outcome requirements includes:

A resident who enters the facility without pressure sores does not develop pressure sores.

Exhibit 3-8 - Effective Documentation of Deficient Practice Statement

Tag	Summary Statement of Deficiencies
F 314	<p>42 CFR 483.25 (c)</p> <p>Based on a comprehensive assessment of a resident, the facility must ensure that (1) a resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable: and</p> <p>This requirement was NOT MET as evidenced by:</p> <p>"Based on observation, staff interview, and record review, the facility failed to provide services to prevent the development of a pressure ulcer, to promote healing and to adhere to infection control measures (universal precautions) designed to prevent cross contamination resulting in the development of an avoidable Stage III pressure ulcer for 1 of 3 sample residents (R#2) with pressure sores. Resident #2 experienced ongoing pain, infection and was unable to continue activities of daily living."</p> <p>Findings include:</p>

This example reports the evidence in a way that the entity can understand that the requirement was not met and how the survey team determined that the requirement was not met. The statement identifies the extent of the deficient entity practice, includes identifiers for the individuals affected by the deficient entity practice, identifies the sources from which the information was obtained, and clearly states the outcomes of the deficient entity practice.

Findings

Findings support or illustrate an entity's noncompliance with a requirement. Cite only findings attributable to the entity. Each statement of deficient practice is followed by the specific findings (**who, what, where, when, how**) that illustrate the entity's noncompliance for each case/issue referenced in the deficient practice statement. The facts are presented in a concise and logical sequence. The findings include the outcomes, descriptions of actions/situations, identifiers, and sources. Any evidence that supports a finding and affects the deficiency determination must be incorporated into the deficiency citation.

When details for a number of individual examples have been described to illustrate a particular deficient practice, a final entry may describe additional similar findings and identifiers to demonstrate the magnitude of the problem.

Facts

A fact is an actual occurrence, something known to exist or have happened. The findings are facts that allow the entity to compare what it did or failed to do, against what is required. The findings support the deficient practice statement. For example, if residents #1, 3, 5, and 7, are discussed in the deficient practice statement, the findings are the facts to support the noncompliance for residents #1, #3, #5, and #7. Without the presence of facts, the evidence can be construed to mean that an assumption was made, rather than a known conclusion about the entity's practice.

Failure to include pertinent facts may prevent the entity from discovering what contributed to the deficient practice. For example, there may be many reasons for the failure of a patient to receive a needed treatment, such as: the patient was not scheduled for a treatment; the staff had not been trained regarding how to provide the treatment; trained staff were not available to provide the treatment; trained staff were available but forgot to provide the treatment; proper authorization for treatment was not provided; or, the patient refused the treatment.

Identification of the pertinent facts gives the entity the means to examine the failure to comply, in light of the specific circumstances or contexts, which the failure occurred.

When writing a deficiency citation, try to provide answers to basic questions - Who?, What?, When?, Where?, and How?. Based on the nature of the deficiency, it may be

impossible or inappropriate to answer each question. However, this approach facilitates inclusion of the pertinent facts. Deficiency citations identify:

How the deficiency was determined, and how the evidence relates to the requirement;

What entity practice was noncompliant;

Who were the residents or staff involved;

Where the deficient practice occurred, e.g., specific locations in the entity or documents; and

When (e.g., for how long) the problem occurred. Include the number of observations and the duration of the observations. Include the specific dates or time period for the noncompliance. The findings also include documentation of verification or request for additional information through interviews with facility staff.

Exhibit 3-9 - The statement of the findings in this example illustrates how the relevant facts answer the basic questions of who, what, when, where and how.

Exhibit 3-9 - Documentation of Facts

Tag	Summary Statement of Deficiencies
F 369	<p>F369 42 CFR 483.35(g))</p> <p>The facility must provide special eating equipment and utensils for residents who need them.</p> <p>This requirement is NOT MET as evidenced by:</p> <p>Based on record review, observation and interview the facility failed to provide adaptive fork and spoon for a resident (R#7) who was assessed to need these items.</p> <p style="text-align: right;">“HOW” “WHAT” “WHO”</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. The care plan, dated XX/XX/XX for Resident #7 indicated that R#7, who has suffered from a recent stroke, needed adaptive utensils to eat meals independently. 2. R#7 was observed in the dining room during breakfast on XX/XX/XX and XX/XX/XX, lunch on XX/XX/XX and XX/XX/XX, and dinner on XX/XX/XX <p style="text-align: right;">“HOW” “WHAT” “HOW” and “WHERE” “WHEN” “WHEN” “WHEN”</p>

Tag	Summary Statement of Deficiencies
	struggling to eat, using a regular fork and spoon, and most of the food was falling off the utensils “WHAT” The resident ate only about 25 percent of each meal “WHAT”
	3. During an interview with the nurse aide on XX/XX/XX at 12:00 p.m., the nurse aide stated, “For a few days R#7 was given special utensils, but I don’t know what happened to them “HOW” I haven’t seen them for a week or so.” “WHEN”
	4.R#7 said during an interview on XX/XX/XX at 12:25 p.m. “My right hand just doesn’t work like it used to since I had this stroke. I was never good at using my left hand, I don’t understand “HOW” why they stopped giving me the special fork and spoon, “WHAT” I guess they just want me to eat with regular silverware.”

Organization of Findings

The findings should be organized in a chronological and logical order. Grouping related findings and facts under applicable statements of the deficient practice statement assists the entity in focusing on the development of plans to correct its deficient practices rather than on correction of the findings. The organization of the findings should clearly convey to the reader the sequential order of events that resulted in a citation. For example, situations or cases are presented in a logical sequence to show individual deterioration over time or date.

When setting forth a series of facts and events, start by setting out the relevant background facts (e.g., “Resident #1 was at risk for weight loss as set forth in the MDS dated XX/XX/XX.”) Then, if possible, set out the events in chronological order. The following example, Exhibit 3-10 illustrates a citation from the home health requirements. The citation is written based on two separate requirements contained in the language of the requirement. It includes two statements of deficient practice and organizes the relevant findings/facts under those statements.

Exhibit 3-10 - Effective Documentation of Two Deficient Practice Statement and Their Findings

Tag	Summary Statement of Deficiencies
G 108	<p data-bbox="386 352 1289 422">42 CFR 484.10(c)(1)STANDARD:RIGHT TO BE INFORMED AND PARTICIPATE IN PLANNING CARE AND TREATMENT</p> <p data-bbox="386 464 1325 680">The patient has the right to be informed, in advance about the care to be furnished, and of any changes in the care to be furnished. The HHA must advise the patient in advance of the disciplines that will furnish care, and the frequency of the visits proposed to be furnished. The HHA must advise the patient in advance of any change in the plan of care before the change is made.</p> <p data-bbox="386 722 980 753">This STANDARD is not met as evidenced by:</p> <p data-bbox="386 795 1325 936">Based on observation, interview, and record review, the agency failed to inform 2 of 12 patients (#3 and #9) reviewed about changes of the frequency of care to be furnished, and the facility failed to inform 2 of 12 patients (#7 and #10) in advance of changes to the plan of care.</p> <p data-bbox="386 978 662 1010">The findings include:</p> <p data-bbox="386 1052 786 1083">Changes in Frequency of Care:</p> <p data-bbox="386 1125 1338 1341">1. Patient #3 began receiving services on 10/15/XX due to a fractured hip. These services were to include physical therapy (PT) three times a week for 8 weeks for gait and balance training to restore ambulation ability. The PT note, dated 11/1/XX, states, "Increase in case load prohibits three sessions a week of treatment. Frequency to be once a week for reminder of treatment."</p> <p data-bbox="386 1383 1338 1635">Observation during the 12/7/XX home visit revealed that the patient is not ambulating. Interview on 12/7/XX during the home visit with Patient #3 indicates that the patient was not informed of the change of frequency of the PT services. Telephone interview with the physical therapist on 12/7/XX confirms that this patient is not ambulating due to the decreased frequency of treatment and that the patient was not informed of the change of frequency.</p> <p data-bbox="386 1677 1203 1740">2. Patient #9 began receiving services on 9/10/XX due to a stiff shoulder....</p>

	<p>Changes in Plan of Care</p> <p>1. Patient #7 began receiving services on 11/20/XX. The plan of care dated 11/23/XX, indicated that services were to include skilled nursing services for wound care and home health aide assistance for activities of daily living. On 11/28/XX, the nurse's note states: "care plan revised as the home health aide can do wound care. Sufficient healing has occurred so that skilled services are not indicated. Wound needs to be cleansed during bathing."</p> <p>Observation on the 12/8/XX home visit indicated that the wound was healed. Interview with Patient #7 indicated that the patient wondered about the whereabouts of the nurse who used to come to clean the wound. She had not seen her in a long time. Interview with the nurse indicated that as the person was progressing well, there was no need to inform her about the change in the plan of care.</p> <p>2. Patient #10 was admitted for service on 11/13/XX. The plan of care, dated 11/13/XX, identified an occupational therapy (OT) consultation to determine if environmental modifications to the home were indicated. An OT note of 11/17/XX states: "Consultation not indicated." No additional information was recorded. Interview with Patient #10 on 12/8/XX indicates that he was satisfied with the services received, but, "I hope that the person who is supposed to help with the arrangement of the house gets here soon. It is difficult for me to get around here." Interview with the Director of Services on 12/8/XX confirmed that the person was not informed of the changes to the plan of care."</p>
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Principle #4 - Relevance of Onsite Correction of Findings

If, during the survey, a deficiency is found, but the entity corrects the situation as soon as they become aware, a determination of "NOT MET" must be documented on the Form CMS-2567. The entity may indicate its correction in the right-hand column of the Form CMS-2567. If, during the survey, the entity initiates corrective actions that abate a finding of immediate jeopardy, follow the guidance described in [Appendix Q](#). The entity may indicate its correction in the right-hand column of the Form CMS-2567.

If an entity demonstrates practices that cause it to be out of compliance, there may be a system failure. The findings used as part of the evidence illustrate the result of that failure; the findings are not the cause of it. Mere correction of the findings reported to the entity prior to the exit conference would not necessarily assure that the cause of the finding had been addressed. The entity, not the survey team must ascertain the cause and correct the systems failure that caused the deficient entity practice.

Exhibit 4-1 demonstrates how to document a deficient practice even though the entity may have addressed the effects of the practice during the survey.

Exhibit 4-1 - Effective Documentation for Principle #4

Tag	Summary Statement of Deficiencies
G 145	<p>483.14(g)Standard</p> <p>Coordination of patient services</p> <p>A written summary report for each patient is sent to the attending physician at least every 62 days.</p> <p>This standard is NOT MET as evidenced by;</p> <p>Based on record review and staff interview, it was determined the home health agency failed to ensure a written summary report which included a compilation of pertinent factors of patient's clinical progress had been sent to the physicians' office for 2 of 2 sampled patients (#4, and 5) who required a 62 day summary.</p> <p>Findings include:</p> <ol style="list-style-type: none">1. Patient #4 was admitted for home health services on XX/XX/XX. The plans of care for the certification periods XX/XX/XX to XX/XX/XX and XX/XX/XX to XX/XX/XX included goals which stated "Patient will experience stable cardiopulmonary status as evidenced by clear lung sounds, no chest pain, SaO2 (saturation of arterial blood) greater than or equal to 92%." Summary reports addressing the patients progress or lack of progress were not available as part of the Patient's clinical record.2. Patient #5 was admitted for home health services on XX/XX/XX with the diagnosis of pressure ulcer and congestive heart failure. The plan of care for them certification period XX/XX/XX to XX/XX/XX included goals that stated " Patient will have pressure ulcer healed with no sign or symptoms in 10 weeks." The summary report addressing the status of the patient's wound was not available as part of the clinical record. <p>Staff interview on XX/XX/XX confirmed the HHA had not sent written summary reports to the physicians, until after the surveyor inquiry when summary reports were then completed and faxed to the physician during the survey.</p>

Correction of Immediate Jeopardy (IJ) During Survey

Exhibit 4-2 documents noncompliance with a participation requirement that resulted in a situation of immediate jeopardy. The CMS-2567 includes the facility's actions to remove the immediate jeopardy while the survey team was onsite; however, as stated above, mere correction of the findings does not assure that necessary corrections, at the systems level, have taken place. Follow the directions for immediate jeopardy located in [Appendix Q](#) of the State Operations Manual.

Exhibit 4-2 - Effective Documentation for Correction of IJ during Survey-Principle #4

Tag	Summary Statement of Deficiencies
F 223 S/S = J	<p>42 CFR 483.13(b)Requirement Abuse...The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.</p> <p>The requirement is NOT MET as evidenced by:</p> <p>Based on staff interviews and record review, the facility failed to prevent 1 of 21 sample residents (#5) from being assaulted by staff and failed to report the assault to the appropriate authorities in a timely manner and failed to take actions to prevent further such incidents to residents resulting in immediate jeopardy.</p> <p>Findings include:</p> <p>Interviews with 3 CNAs A, B, C, on duty on 7/10/XX, indicated that they observed a certified nursing assistant (CNA)(E-1) "throw" a resident (R#5)to the ground during a picnic at the facility on 5/26/XX. The CNA, who observed R#5 becoming agitated, went to the resident to bring him back into the facility. When the resident became "uncooperative and irritated" and refused to go into the building, the CNA gave the resident a "bear hug." The resident fell to the ground at which time the CNA dragged the resident by the back of his shirt into the facility, a distance of approximately 30 - 40 feet. Nurses notes on 6/1/XX state that the resident had abrasions on the lower lumbar and upper left thoracic regions, but was not able to say how he got them. During an interview with the facility administrator on 7/11/XX, the administrator said, "I was not aware of the incident until 6/1/XX when a staff member asked for medication to put on [resident #5's] cuts. I notified the health department on 6/1/XX." The administrator acknowledged he did not remove the CNA from providing resident care until questioned by the surveyor on 7/11/XX.</p>

	The administrator was notified of the immediate jeopardy at 2:00 p.m. on 7/11/XX. At 3:00 p.m. the administrator notified the survey team that the involved CNA had been removed from duty and that the CNA would be fired.
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Principle #5 - Interpretive Guidelines

The deficiency citation demonstrates 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. Various appendices to the SOM contain “Interpretive Guidelines” or “Guidance to Surveyors.” These Guidelines were designed to assist surveyors to develop a better understanding of the requirements, to apply these requirements in a consistent manner across entities, and to suggest pathways for inquiry.

Although surveyors must use the information contained in Guidelines, they must be cautious in their use. Guidelines do not replace or supersede the law or regulation, and therefore, may not be used as the basis for a citation. However, they do contain authoritative interpretations and clarifications of statutory and regulatory requirements. Interpretive guidelines can include professionally recognized standards and assist surveyors in making determinations about an entity’s compliance with requirements. When an entity is found to violate a requirement because of its connection to a professionally recognized standard, the surveyor must indicate such on the Form CMS-2567.

Surveyors should carefully consider how the practices of the entity relate to the illustrations within the Interpretive Guidelines, and then compare the entity’s practice to the specific language and requirement of the regulation before determining that a deficiency exists.

Exhibit 5-1 - Interpretive Guidelines

Regulation	Guidance To Surveyors
42 CFR 483.35 (h)(2) “Sanitary Conditions.” The facility must (2) store, prepare, distribute, and serve food under sanitary conditions; and	Hot foods which are potentially hazardous should leave the kitchen (or steam table) above 140 degrees Fahrenheit, and cold foods at or below 41 degrees Fahrenheit, etc... Referenced guidance 1999 FDA Food Code.

Exhibit 5-2 illustrates how material in Interpretive Guidelines can be used to support the citation. The critical factor is whether or not the evidence relates directly to the language and requirement within the regulation.

Exhibit 5-2 - Effective Documentation for Principle #5

Tag	Summary Statement of Deficiencies
W 214	<p>42 CFR 483.440 (c)(3)(iii)</p> <p>The comprehensive functional assessment must identify the client’s specific developmental and behavioral management needs.</p> <p>This Standard is NOT MET as evidenced by:</p> <p>Based on observations, staff interview, and record review, the facility failed to include in the comprehensive functional assessment, the client’s cognitive ability for 2 of the 4 clients in the home (#2, #3).</p> <p>The findings include:</p> <p>Review of Client #3’s medical records, dated between XX/XX/XX and XX/XX/XX, revealed 11 evaluations conducted by the professional staff. None of the evaluations specified any deficits that may have contributed to his diagnosis or his reported developmental level of functioning. Observations on XX/XX/XX and XX/XX/XX confirmed that...In an interview on XX/XX/XX, LPN1 said, “I am unclear about the client’s identified strengths.”</p>

Principle #6 - Citation of State or Local Code Violations

The entity’s failure to comply with State or local laws or regulations is not documented in the Form CMS-2567 except when the Federal regulation requires compliance with State or local laws. When the authority having jurisdiction for that State or local law has made a decision of noncompliance and has effectuated an adverse action that has been sustained through the hearing process (such as removal of the license to operate), the Form CMS-2567 should note that the entity no longer has a license.

Federal certification requirements are uniform throughout the United States. However, States and localities may have additional requirements that the entity must meet in order to continue to operate within those jurisdictions. Some licensing requirements may be more stringent or prescriptive than Federal requirements. Licensure surveys are conducted to determine an entity’s compliance with specific State or local laws and regulations. Entities that do not meet the State or local requirements for licensure may not be certified for participation in the Medicare/Medicaid programs.

In the event of a difference in the stringency of a Federal certification requirement and a corresponding State or local (e.g., licensing) requirement, the entity is to comply with the

more stringent of the two. However, when enforcement of the more stringent requirement comes from an authority other than the Federal requirement, the evidence may be recorded on the Form CMS-2567 only in the manner prescribed by CMS.

Failure of the entity to meet State or local requirements is recorded on the Form CMS-2567 at a Federal data tag for one of two reasons:

1. The language of the Federal regulation explicitly requires compliance with State or local laws and codes. Deficiency citations made under these requirements should include a reference to the particular State or local code with which the entity is noncompliant. This insures that there is legal authority to describe any conditions or practices described as deficient. Surveyors always should review their findings relative to the specific Federal requirement to determine if and when an entity's failure to achieve compliance with a licensure requirement is sufficient evidence to cite noncompliance with a Federal certification requirement.

Exhibit 6-1 is consistent with Principle #6. The entity's practice of using LPNs to conduct the health status review was deficient specifically relative to the requirement; or

Exhibit 6-1 - Effective Documentation for Principle #6

Tag	Summary Statement of Deficiencies
W 345	<p>42 CFR 483460(d)</p> <p>The facility must utilize registered nurses as appropriate and required by State law to perform the health services specified in this section.</p> <p>This STANDARD was NOT MET as evidenced by:</p> <p>Based on record review, the facility for the period between 7/1/XX and 9/30/XX, utilized Licensed Practical Nurses (LPNs) to review the health status of residents for 4 of 10 sampled records (2, 6, 12, 19).Section 76543 of the Code of Professional Health Practices (State Requirement) requires that this function be performed only by Registered Nurse (RNs).</p>

2. The authority having jurisdiction has made a determination of noncompliance with State or local law, has taken and sustained an adverse action (See Exhibit 6-2.). An adverse action is any procedure taken by a State Agency that goes beyond the approval of a plan of correction, such as, fines, ban on admissions, loss of license, etc. The authority having jurisdiction is the person or persons who have the authority to make a final determination of noncompliance and are responsible for signing the correspondence notifying the facility of the adverse action. A final determination means the determination has not been appealed or is no longer being appealed by the entity.

Exhibit 6-2 - Effective Documentation for Principle #6

Tag	Summary Statement of Deficiencies
F 492	<p>42CFR483.75(b)</p> <p>Compliance with Federal, State, and local laws and professional standards. The facility must operate and provide services in compliance with all applicable Federal, State and local laws, regulations, and codes, and with accepted professional standards and principles that apply to professionals providing services in such a facility.</p> <p>This requirement is NOT MET as evidenced by:</p> <p>Based on evidence in the attached notice of determination of noncompliance, the entity did not meet (state or local) Law #XXX. An adverse action was taken against the entity by (the authority having jurisdiction.) See attached.</p>

Principle #7 - Cross-References

The cross-referencing of requirements is an acceptable form of documentation on the Form CMS-2567 only when it is applicable and provides additional strength to the linked citations. Descriptive evidence (facts and findings) from one citation may be linked into the evidence for a citation at another requirement. The evidence being linked into that requirement must support the determination of noncompliance with that requirement. Each citation must contain all components described in this document independent of the additional information being linked into that citation. Cross-referencing is most effective when the linked citations have a direct cause and effect relationship to the deficient practices described in both citations. In all instances, each citation must contain sufficient evidence to demonstrate noncompliance for the referenced regulation. Additional guidance for cross-referencing for COP level citations is provided in POD #8.

Tag	Summary Statement of Deficiencies
G 170	<p>G170 42 CFR 484.30 Skilled Nursing Services</p> <p>The HHA furnishes skilled nursing services in accordance with the plan of care.</p> <p>This requirement is NOT MET as evidenced by:</p> <p>Staff interview and review of seven clinical records requiring RN skilled services revealed that the RN did not comprehensively assess the patients or furnish the frequency of visits required by the Plan of Care for 4 of the 7 patients (H3 H5, H6, H7). See G174 for additional information regarding patients H3, H5, and H7.</p>

	<p>1. Review of H3's clinical record indicated physician orders for twice daily RN visits from 10/01 to 10/08/XX to administer IV antibiotics, assess the status of and perform a dressing change to the Stage 3 ulcer of the left heel. The aide sheet for 10/04 reflected that the aide had changed the heel dressing that a.m. The record shows two LPN visits and an evening dressing change by the LPN on 10/04 but does not contain information of an RN visit, assessment or dressing change on 10/04/XX.</p> <p>Interview at 10:30 a.m. on 11/10/XX with supervising nurse confirmed that on 10/04/XX an aide had performed the a.m. dressing change on H3's Stage 3 pressure ulcer of the heel. The supervising nurse reported that although the RN was ill and had not made the planned a.m. or p.m. visits that day, the agency's LPN had performed the visits and supervised the aide.</p> <p>2. Review of H5's clinical record indicated that the Plan of Care for H5 required RN visits from 4 to 5 times the week of 10/07/XX and 3 times a week for 3 weeks beginning 10/4/XX to assess the patient's response to changes in the medication to control her angina and blood pressure. The RN visited only 3 times (10/07, 10/08 and 10/10) during the week of 10/07 and limited her assessment to checking breath sounds and blood pressure. The RN did not evaluate for signs and symptoms or complications of either hypo or hypertension or for compliance with dietary restrictions or known side effects which accompany the use of calcium channel blockers.</p> <p>3. Review of H6's clinical record indicated the RN did not visit H6 twice daily as required by the Plan of Care to monitor the institution of sliding scale insulin for the newly diagnosed brittle diabetic. The Plan of Care required twice daily visits from --- to ---. The actual visit frequency was ---.</p>
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Tag	Summary Statement of Deficiencies
G 170	<p>G170 42 CFR 484.30 (Cont.)</p> <p>4. Review of H7's clinical record indicated the RN did not assess, record, and report to the physician the change in the status of the suture line of the hip wound on 10/21/XX. The Plan of Care required RN visits 5 times a week for 1 week then 3-5 times a week for 2 weeks or until the wound healed to change the dressing and assess the character of the post operative wound. The therapist's progress notes from the therapy visit on 10/21 at 10 a.m. (3 hours prior to the RN visit) reflect that the patient complained to the therapist of burning and dampness at the suture line.</p>

Principle #8 - COP Deficiencies

The evidence for the citation of noncompliance with a Condition of Participation explains how the extent or severity of deficient practices justifies a conclusion of noncompliance at the COP level. The COP citation includes a statement(s) of deficient entity practice(s) and findings to support the determination of noncompliance with a condition level requirement. The findings may be incorporated either by cross references to those requirements which must be corrected to find the COP in compliance or by narrative description of the individual findings. The COP citation includes ONLY those requirements that must be corrected to achieve compliance with the COP.

The determination that an entity is not in compliance with an applicable COP is one of the most serious decisions the RO or SA can make. The decision as to whether there is compliance with a particular COP depends upon the manner and degree to which the entity satisfies the various requirements and standards within each COP. If a COP is determined to be deficient, the Form CMS-2567 should identify the specific practices that must be corrected before the entity can be found to be in compliance. If these practices refer to requirements specified at Standards or other subsidiary requirements, the deficient practices and individual findings would be cited at the relevant requirements. The findings under these subsidiary requirements may be referenced under the COP citation.

For certain provider and supplier types, a COP may stand alone at a single survey data tag without accompanying standards or other requirements. The text of the particular COP may have multiple components. Based on the evaluation of the evidence, an entity can be cited at a COP level even if it violates only one component of multi-component regulations.

For example, in the Ambulatory Surgery Center program, 42 CFR 416.43 Condition for Coverage Evaluation of Quality (tag Q 9) has multiple requirements:

- (1) conduct an ongoing , comprehensive self-assessment of the quality of care provided,
- (2) include active participation of the medical staff,
- (3) include review of the medical necessity of the procedures performed and appropriateness of care,
- (4)

use the findings, when appropriate, in the revision of the center policies and (5) use the findings, when appropriate, in the consideration of clinical privileges.

There may be entity practices relevant to standards that are deficient, yet not essential for a determination of compliance with the COP. Most likely it is because the nature of these practices, individually or collectively, does not justify a conclusion of noncompliance and warrant an adverse action. Such requirements are not referenced at the COP citation. They are included at the appropriate tag number and corresponding CFR reference in the Form CMS-2567.

Exhibit 8-1 - Effective Documentation for Principle #8

Tag	Summary Statement of Deficiencies
Q 003	<p>416.41 Condition</p> <p>Governing Body and Management</p> <p>The ambulatory surgical center must have a governing body, that assumes full responsibility for determining, implementing and monitoring policies governing the centers total operation and for ensuring that these policies are administered so as to provide quality health care in a safe environment. When services are provided through a contract with an outside resource, the center must assure that these services are provided in a safe and effective manner.</p> <p>This Condition is NOT MET as evidenced by:</p> <p>Based on staff interview and review of administrative records, policies and procedures, and infection control and quality assurance documentation, it was determined that the ambulatory surgery center's governing body failed to assume full responsibility for determining, implementing and monitoring policies governing the center's total operation. The governing body failed to ensure that practitioners had been appointed to the medical staff and had been granted privileges to practice at the ASC (refer to Q19, Q20, Q21, and Q22), failed to ensure that a comprehensive quality assurance program was in place (refer to Q9); failed to ensure that an effective infection control program had been established (refer to Q14). The cumulative effect of these systemic problems resulted in the surgery center's inability to ensure the provision of quality health care in a safe environment.</p>

Conclusion

All requirements are binding. The structures, processes and outcomes required by the regulations are necessary for the entity to provide quality care, prevent negative outcomes, and facilitate positive outcomes. Failure of the entity to provide any of the

required services or to meet required conditions constitutes evidence of noncompliance regardless of the presence of outcomes. The purpose of these Principles of Documentation is to provide structure and consistency to the construction of a citation.

Correctly documenting the “Statement of Deficiencies and Plan of Correction” (Form CMS-2567) is the key to the success of the survey and certification process. Effective documentation of the survey signals the provision or denial of financial participation in the Medicare/Medicaid program, as well as the provision of or lack of quality care in health care settings.

Keep in mind that one of the roles of the surveyor is to ensure that quality health care is provided by those entities participating in the Medicare/Medicaid program. It is the surveyor’s knowledge of the regulations and how to interpret and apply these regulations in a consistent manner during the survey that will produce a clear description of the entity’s deficient practice. When the deficient practices are resolved by the entity, quality of care and quality of life can be a reality in health care settings.

Appendix A - Components to be Documented in A Deficiency Citation

COMPONENTS TO BE DOCUMENTED IN A DEFICIENCY CITATION

Data Tag					
In CFR/LSC/CLIA order					
CFR/LSC/CLIA Reference					
CFR/LSC/CLIA Requirement					
Statement that requirement is "Not Met"					
Evidence: Each Statement of deficient practice with corresponding findings (repeat each practice)	YES(Y)	NO (N)	N/A		
Extent of deficient practice					
Identifiers (confidential)					
Description of violation of regulation					
Source of evidence					
State/local code reference, if applicable					
Findings/Facts:					
Who					
What					
When					
Where					
How					
Outcome					
Observations: date, time, location					
Record/document reviews: date(s), record type					
Sequential organization of facts					
Is the Deficiency Citation...	Yes	No	N/A		
Applicable to requirement cited?					
Written in plain language?					
Free of extraneous remarks and advice					