DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop C2-21-16 Baltimore, Maryland 21244-1850



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 16-11-ALL

DATE: March 11, 2016

TO: State Survey Agency Directors

FROM: Director Survey and Certification Group

SUBJECT: Exit Conferences - Sharing Specific Regulatory References or Tags

Memorandum Summary

- Advance Guidance Procedures for Conducting the Exit Conference: The Centers for Medicare & Medicaid Services (CMS) is clarifying guidance to surveyors regarding the procedures for conducting the exit conference in the review of compliance with Medicare or Medicaid Conditions of Participation, Conditions for Coverage, and Requirements for Participation.
- **Review Exit Conference Procedures:** Please review with surveyors the exit conference procedures for conducting the federal surveys to ensure consistency of this process across States.

Background

The CMS has received questions regarding what degree of specificity surveyors should give during the Exit Conference to Medicare/Medicaid providers and suppliers regarding deficiencies found during the conduct of federal surveys. This policy memorandum is relevant to all surveyors conducting Federal surveys and for all types of Federal surveys. To address these questions and provide additional clarity and ensure uniformity in the survey procedures, CMS has revised the State Operations Manual (SOM), Chapters 2 and 5, and Appendix P. A list of all revised Sections can be found at the end of this policy memorandum. In the next few months, CMS will re-issue this memorandum to include other affected Appendices (e.g., Appendix I)

The Exit Conference during the onsite survey is both a courtesy to the provider and a way to expedite the provider's planning ahead of the formal receipt of the survey findings in the Form CMS-2567, Statement of Deficiencies. The purpose of the Exit Conference is to informally communicate preliminary survey team findings and provide an opportunity for the exchange of information with the provider's or supplier's administrator, designee or other invited staff. The findings or information conveyed at the Exit Conference are preliminary in nature and are subject to change pursuant to the State and CMS supervisory review processes. Additionally, an Exit Conference is not always guaranteed, as is noted in section 2724 of the SOM.

Long Term Care (LTC) Providers (Nursing Homes)

For LTC providers, CMS has invested considerable effort to add to the SOM more explanations and resource material under many deficiency tag codes that can be of particular use to a facility in understanding relevant deficiencies and preparing remedial action. If the provider asks for the specific regulatory basis or the specific tag code, the surveyors should generally provide this information (except as noted below), but must always caution the facility that such coding classifications are preliminary and are provided only to help the provider gain more insight into the issues through the interpretive guidance. If the facility does not specifically ask for the regulatory basis or tag, the survey team may use its own judgment in determining whether this additional information would provide additional insight for the facility.

However, if the survey team is still deliberating which tags will be most pertinent, the survey team must not speculate at the exit conference as to the specific tag coding that will be applied. For example, the team may still be deliberating whether the finding was a care planning deficiency or staff training deficiency. Similarly, the team may believe that additional consultation should occur with other State personnel (e.g., a pharmacist) before a specific tag number is assigned to the deficiency finding. In these cases, the survey team should describe the general area of non-compliance without identifying a specific tag code. This is a judgment to be made by the survey team onsite, so in preparation for the exit conference the team should deliberate as to the degree of detail that will be appropriate. This is a survey-specific decision based on the evidence gathered.

As described below, States must follow the federal process. State licensure laws do not override the procedures outlined in the federal survey process. *States are not permitted to have blanket policies that differ from the policy described in this section. For example, States may not require surveyors to always provide certain information during the Exit conference.*

Under no circumstances, however, would the surveyors provide the Scope and Severity of a given deficiency finding (unless it is an immediate jeopardy), as such finer degree of possible detail should await supervisory review. Instead, survey teams may describe the general seriousness (e.g., harm) or urgency that, in the preliminary view of the survey team, a particular deficiency may pose to the well-being of residents. If a provider asks whether the noncompliance is isolated, pattern, or widespread, the surveyor should respond with the facts (i.e., noncompliance was found affecting X number of residents).

Non-Long Term Care Providers and Suppliers

For non-LTC providers and suppliers, if the provider/supplier asks for the specific regulatory basis for the noncompliance findings, the surveyors should generally provide the regulatory grouping to the extent that the team is not still deliberating which part of the regulation is most pertinent. Consistent with existing CMS policy, the survey team should avoid identifying the specific tags, as the tag codes often identify the Condition- or Standard-level classification for most non-LTC deficiencies. Additionally such specific details should wait supervisory review. This has been CMS' long-standing policy, and we will continue this policy for non-LTC providers and suppliers.

Clinical Laboratories (CLIA)

For laboratories, given the complexity of the regulations and nature of the survey, the surveyors must indicate to the laboratory that the specific regulatory reference will be found in the Form CMS-2567 report that will be issued to them. The laboratory is informed that the information discussed in the exit interview is preliminary and the lab management will have an opportunity at the exit interview to talk in general about the issues that were found.

Life-Safety Code (LSC)

For LSC surveys, the survey team may follow the procedures for either non-LTC or LTC, depending on the degree to which, in the judgment of the team, the tag codes are important in helping the provider/supplier to understand the nature and location of the deficiency, and the corrective actions that would be necessary. Facility representatives are typically invited to accompany life safety surveyors during building tours, to improve familiarity with preliminary findings and exit conference proceedings.

Additional Considerations

We believe that the attached changes in the SOM will provide additional guidance for surveyors about what to communicate regarding the deficiency findings and create a common set of expectations for States and providers/suppliers. There are two related considerations described below that provide additional context for these changes.

First, the integrity of the State and CMS post-survey quality review process is central to having well-supported, evidenced-based deficiency findings that appropriately establish the level of harm or potential for harm to the patient/resident. CMS will evaluate this policy on an ongoing basis. If, we find that providing this level of detail undermines that process or results in providers/suppliers trying to unduly pressure surveyors, or influence the objectivity and fairness of the survey process, we will re-evaluate the policy.

This policy memorandum also clarifies that States must not leave draft CMS-2567 forms onsite before they are finalized. This type of activity undermines the survey and certification process by shortening the time for the investigation and limiting the quality assurance process for the review of the CMS-2567 forms.

States are required to follow the federal survey process as written in the SOM. States are not permitted to establish additional processes for the federal surveys (such as conducting a "pre-exit conference" which provides deficiency information that the federal exit conference prohibits). For questions related to additional processes, States must consult with their CMS Regional Office. These actions would be in violation of the 1864 Agreement (i.e., Section 1864 of the Social Security Act) which provides CMS with the authority to prescribe the survey process to be followed by the States in their review of federal Medicare/Medicaid requirements. Article II, A.1.(c) of the 1864 Agreement specifies the functions to be performed by the State. The State is "responsible for surveying for the purpose of certifying to the Secretary the compliance or non-

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compliance of providers and suppliers of services and resurveying such entities, at such times and manner as the Secretary may direct."

Contact: We would ask that States share this memorandum with all surveyors and review the Exit Conference procedures with them. Any questions on this memo can be sent to <u>DNH_TriageTeam@cms.hhs.gov</u>.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/ Thomas E. Hamilton

Attachment: SOM Revisions Chapter 2, Sections 2724 and 2727 Chapter 5, Sections 5080.2, 5300.5, and 5340 Appendix P, Task 7

cc: Survey and Certification Regional Office Management

State Operations Manual Chapter 2 - The Certification Process

(Rev. XXX, XX-XX-XX)

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2724 - Exit Conference

(Rev. X, XX-XX-XX)

Subsequent to the pre-exit conference held to allow team members to exchange and formulate survey findings, the surveyors conduct an exit conference ("an exit") with the entity's administrator, designee, and other invited staff. The purpose of the exit conference is to informally communicate preliminary survey team findings and provide an opportunity for the interchange of information, especially if there are differences of opinion. Although it is CMS' general policy to conduct an exit conference *as a courtesy to the provider and to promote timely remediation of quality of care or safety problems*, be aware of situations that would justify refusal to continue an exit conference. For example:

- If the provider is represented by counsel (all participants in the exit conference should identify themselves), surveyors may refuse to continue the conference if the entity's attorney attempts to turn it into a evidentiary hearing; or
- Any time the provider creates an environment that is hostile, overly intimidating, or inconsistent with the informal and preliminary nature of an exit conference, surveyors may refuse to conduct or continue the conference.

Additionally, as discussed in $\underline{\$2714}$, if the entity wishes to audio tape the conference, it must tape the entire meeting and provide the surveyors with a copy of the tape at the conclusion of the conference. Videotaping is also permitted if it is not disruptive to the conference, if a copy is provided at the conclusion of the conference. It is at the sole discretion of the surveyor(s) to determine if videotaping is permitted.

It is critical that the surveyors establish and maintain control throughout the exit conference. Surveyors should present their findings but refrain from arguing with the provider. Be mindful that providers are likely to react defensively to surveyor findings. The provider has a right to disagree with the findings and present arguments to refute them. Surveyors should be receptive to such disagreements. If the provider presents information to negate any of the findings, surveyors should indicate their willingness to reevaluate the findings before leaving the facility. The survey team's reasonableness demonstrates their fairness and professionalism. The degree of receptivity displayed by providers during the exit conference often depends upon the attitudes and survey style of the survey team.

If the LSC survey is conducted independently of the health survey, the fire authority conducts a separate exit conference.

The following guidelines are helpful to surveyors in performing an exit conference:

2724A - Introductory Remarks

(Rev. X, XX-XX-XX)

Introduce yourself to those present. Restate why the survey was conducted. Express the team's appreciation for anything the provider has done to facilitate the survey. Explain that the exit conference is an informal meeting *given as a courtesy to the provider* to discuss preliminary survey findings and thereby assist the provider or supplier in developing an acceptable PoC, if appropriate and required. *The tone of the exit conference should be professional and constructive. It is important to communicate that the findings are preliminary and could change following State and CMS supervisory review.* Indicate that official findings are presented in writing on Form CMS-2567 and will be forwarded to the provider within 10 working days. Indicate that the provider will, in turn, have 10 calendar days to submit a PoC. (See §2728.)

2724B - Ground Rules (*Rev. X, XX-XX-XX*)

Explain how you will conduct the exit conference and how the team's findings will be presented; for example, each surveyor may present a portion of the total findings. Inform the provider that where there are disagreements between the team and the provider about the findings that cannot be resolved during the conference or before the team leaves the facility, the provider will have the opportunity to submit additional evidence to the State, and/or the RO *through the Plan of Correction process*. (See §2728.B. concerning provider attempts to refute survey findings on the Form CMS-2567.)

2724C - Presentation of Findings

(Rev. X, XX-XX-XX)

In presenting *preliminary* findings, avoid reading your findings or *only* referring to them by their data tag number. Explain why the findings are a violation of Medicare *or Medicaid* requirements *in enough detail to assist the provider in expediting the provider's correction of any deficiencies ahead of the formal receipt of the Form CMS-2567.*

Non-Long Term Care Providers/Suppliers

For non-long term care, if the provider/supplier asks for the specific regulatory basis for a finding of noncompliance, the surveyors should generally provide the regulatory grouping to the extent that the team is not still deliberating which part of the regulation is most pertinent. However, the survey team should avoid identifying the specific tags, as the tag codes often identify the Condition- or Standard-level classification for most non-LTC deficiencies. Additionally, such specific details should wait for supervisory review.

Long Term Care Providers

For long term care providers (i.e., nursing homes), CMS has invested considerable effort to add to the SOM more explanations and resource material under many deficiency tag codes that can be of particular use to a facility in understanding relevant deficiencies and preparing remedial action. If the provider asks for the specific regulatory basis or the specific tag code, the surveyors should generally provide this information (except as noted below), but must always caution the facility that such coding classifications are preliminary and are provided only to help the provider gain more insight into the issues through the information provided in the interpretive guidance. If the facility does not specifically ask for the regulatory basis or tag, the survey team may use its own judgment in determining whether this additional information would provide additional insight for the facility.

However, if the survey team is still deliberating as to which tags will be most pertinent, the survey team must not speculate at the exit conference as to the specific tag coding that will be applied. For example, the team may still be deliberating as to whether the finding was a care planning deficiency or staff training deficiency. Similarly, the team may believe that additional consultation should occur with other State personnel (e.g., a pharmacist) before a specific tag number is assigned to the deficiency finding. In these cases the survey team should describe the general area of non-compliance without identifying a specific tag code. This is a judgement to be made by the survey team onsite, so in preparation for the exit conference the team should deliberate as to the degree of detail that will be appropriate to describe at the exit. This is a survey-specific decision based on the evidence gathered. As described below, states must follow the federal process. State licensure laws do not override the procedures outlined in the federal survey process. States are not permitted to have blanket policies that require surveyors to always provide certain information during the Exit conference that differs from the policy described in this section.

Under no circumstances, however, would the surveyors provide the Scope and Severity of a given deficiency finding (unless there has been a finding of Immediate Jeopardy), as such finer degree of possible detail should await supervisory review. Instead, survey teams may describe the general seriousness (e.g., harm) or urgency that, in the preliminary view of the survey team, a particular deficiency may pose to the well-being of residents. If a provider asks whether the noncompliance is isolated, pattern, or widespread, the surveyor should respond with the facts (i.e., noncompliance was found affecting X number of residents).

Clinical Laboratories (CLIA)

For laboratories, given the complexity of the regulations and nature of the survey, the surveyors must indicate to the laboratory that the specific regulatory reference will be found in the CMS-2567 report that will be issued. The laboratory is informed that the information discussed in the exit interview is preliminary and the lab management will have an opportunity at the exit interview to talk, in general, about the issues that were found.

Life Safety Code

For life safety code surveys, the survey team may follow the procedures for either non-

LTC or LTC, depending on the degree to which, in the judgement of the team, the tag codes are important in helping the provider/supplier to understand the nature and location of the deficiency, and the corrective actions that would be necessary. Facility representatives are typically invited to accompany life safety surveyors during building tours, to improve familiarity with preliminary findings and exit conference proceedings.

For all provider types, under no circumstances should you make general statements such as, "Overall the facility is very good." Stick to the facts. Do not rank requirements. Treat requirements as equally as possible. Cite problems that clearly violate regulatory requirements. The surveyors must not make statements such as, "The condition was not met," or "The standard was not met."

2724D - Closure

(Rev. XX, Issued: XX-XX-XX, Effective: XX-XX-XX, Implementation: XX-XX-XX)

When you have completed the exit conference, explain the process to the provider. Inform the provider that *the State and/or RO* will send a formal statement of deficiencies. Explain the due date for submitting a PoC and how the rest of the certification process works. If you have identified an immediate and serious threat to patient health and safety, explain the significance of that finding and the need for immediate corrective action. In this or any other instance when adverse action is anticipated, explain the implications. Make it clear that only compliance will stop the adverse action.

In an initial survey, the surveyor tells the provider or supplier to expect notification of initial approval or denial of Medicare participation from the RO, and notification by the SMA concerning Medicaid participation, if appropriate. The surveyor explains that the RO establishes the effective date of participation and notifies the provider or supplier in writing and that Medicare payment will not be made before the effective date.

Notices of Medicare recertification from the RO are not necessarily sent unless there are changes in approved services or in sizes of distinct parts certified. Notices of reapproval of NFs and ICFs/IID are made according to State policy.

2726 - Summary of SA Certification Actions Performed After Survey (Rev. 1, 05-21-04)

Following are summaries of eight SA steps of the post-survey certification process:

- 1. Prepare survey documents for eventual public disclosure.
- 2. Send Form CMS-2567 to the provider/supplier, requesting a PoC if appropriate. A PoC is required for all deficiencies except as noted in <u>§2728.B</u>.
- 3. If extensive documentation is required for adverse action, gather the necessary additional evidence. Only achievement of compliance stops termination action. A PoC may not be required when termination action is recommended because the PoC cannot substitute for Condition-level noncompliance. Review and evaluate

the PoC to:

- Ascertain whether compliance is likely to be achieved in a time acceptable to you or the RO, as appropriate; and
- Help structure the revisit after a credible allegation of compliance is received.
- 4. Consider waivers of requirements (if explicitly allowed) that may be appropriate. Prepare recommendations accordingly or, in the case of Medicaid-only waivers, prepare determinations granting or denying waivers.
- 5. Certify compliance or noncompliance.
- 6. Assemble all required documentation for transmission to the RO or, in a Medicaidonly case, to the SMA.
- 7. If necessary, schedule a revisit to verify the provider's follow-through on acceptable PoCs. Schedule future surveys for the next certification interval, taking into account the provider's accreditation status if applicable, the anticipated duration of waivers, and, as required by OBRA '87, flexible survey cycles for SNFs, NFs, and HHAs.
- 8. Be prepared to modify the revisit schedule for unexpected changes or requested changes in providers' coverage status or for subsequent changes in compliance status.

2727 - Limitations on Technical Assistance Afforded by Surveyors (*Rev. X, XX-XX-XX*)

SAs are encouraged to communicate with providers and their associations. Discussions of program requirements and the survey process can result in a better understanding of the process by all parties involved. Further, $\frac{\$1819(g)(1)(B)}{\$1819(g)(1)(B)}$ and $\frac{1919(g)(1)(B)}{1919(g)(1)(B)}$ of the Act mandate that the State conduct periodic educational programs for staff and residents (and their representatives) of SNFs and NFs in order to present current regulations, procedures, and policies. (See $\frac{\$1010.D}{.}$)

When deficiencies are found during the survey process, the surveyor provides an explanation to the provider concerning the deficiency in specific terms *as described in §2724C* to help the provider understand why the requirement is not met. Frequently, the explanation will embody the action needed to correct the problem. In situations where there may be several possible causes for the deficiency, it is not the surveyor's responsibility to delve into the facility's policies and procedures to determine the root cause of the deficiency or to sift through various alternatives to suggest an acceptable remedy. For example, if a provider was cited for maintaining incomplete clinical records, specify what is missing - not why it is missing or what process is best for ensuring that the records will be complete in the future.

State Operations Manual Chapter 5 - Complaint Procedures

(Rev. XXX, XX-XX-XXXX)

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5080.2 - Survey Exit Conference and Report to the Provider/Supplier (*Rev. XX, Issued: XX-XX-XX, Effective: XX-XX-XX, Implementation: XX-XX-XX*)

Generally, the SA conducts an exit conference with the provider/supplier at the completion of the on-site portion of the complaint investigation survey. The SA informs the provider/supplier of the survey findings, including a general description of any deficiencies found. The description should be detailed enough to inform the provider/supplier of the types of activities that require the provider's/supplier's corrective action. However, the SA must not comment on the scope and severity of the deficiencies identified for long term care facilities. For non-long term care providers/suppliers, the SA must not comment on manner and degree, that is, whether the deficiencies identified were condition- or standard-level. Surveyors must also not make reference to any "Tags" related to deficiencies identified *in non-long term care as this identifies condition- or standard-level. Instead identify the regulatory grouping where concerns exist. See Section 2724 for additional information about presenting findings during the Exit Conference.*

For non-long term care providers/suppliers, the SA must <u>not</u> provide a list of patients interviewed, observed, or whose medical records were reviewed, and does not identify specific patients whose cases are associated with specific deficiencies. (The provider/supplier has the right to request a copy of any documentation the surveyors copy to support deficiency findings; therefore the provider/supplier should have enough information after the exit conference to begin corrective actions.)

The SA informs the provider/supplier that survey findings will be documented on Form CMS 2567, which will be sent to the provider/supplier and subsequently will be made available to the public under the disclosure of survey information provisions. For deemed provider/suppliers, the SA informs the provider/supplier that the RO will be consulted and (depending on RO practice), either the RO or the SA will inform the facility of the results of the survey investigation via the Form CMS 2567.

The SA/RO sends to the provider/supplier a written report of the investigation findings as a summary record of the investigation. At a minimum, this would include the Form CMS 2567 and applicable notices. For surveys of deemed providers/suppliers (not including EMTALA surveys), the RO sends a copy of the written report to the applicable accrediting organization(s), following the procedures specified in Section 5110. At the RO's or SA's discretion, the materials may be sent to the accrediting organization via e-mail.

(See Section 5300.5 for guidance on the exit conference for long term care facilities, Section 5440.5 for EMTALA investigations, as well as the provider/supplier-specific appendices of the <u>SOM</u>, and Appendix V of the SOM concerning EMTALA.)

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NOTE: Sections 5300 to 5390 relate to nursing homes.

5300 - Investigation of Complaints for Nursing Homes (Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

Section 42 CFR 488.332 provides the Federal regulatory basis for the investigation of complaints about nursing homes.

The survey agency must review all complaint allegations and conduct a standard or an abbreviated standard survey to investigate complaints of violations of requirements if its review of the allegation concludes that:

- A deficiency in one or more of the requirements may have occurred; and
- Only a survey can determine whether a deficiency or deficiencies exist.

The survey agency does not conduct a survey if the complaint raises issues that are outside the purview of Federal participation requirements.

Complaint investigations follow, as appropriate, the pertinent survey tasks, and information gathered is recorded on the appropriate survey worksheets. However, if the documentation required is minimal, use Form CMS-807 to record information during the complaint investigation. Record deficiencies on Form CMS-2567 and/or, the "Statement of Isolated Deficiencies Which Cause No Harm with Only a Potential for Minimal Harm for SNFs and NFs". The completed Form CMS-2567 must be made a part of the complaint record.

If necessary, a specialized team may be used to investigate complaints. Team members may include, but are not limited to, an attorney, auditor, and appropriate health professionals. The specialized team is not necessarily composed of qualified surveyors. However, specialized team members provide unique talents and expertise that assist at least one qualified surveyor in identifying, gathering, and preserving documented evidence. Further information regarding the composition of the survey team is provided in <u>Chapter 7</u>.

The timing, scope, duration and conduct of a complaint investigation are at the discretion of the SA, except when a determination is made that immediate jeopardy may be present and ongoing or a higher level of actual harm may be present. If the complaint concerns conditions on a certain day (e.g., on weekends), or on a certain shift (e.g., 11 p.m. - 7 a.m.), the SA should make

an attempt to investigate it at the relevant time. In most cases, the following tasks, or portion of tasks, should be performed during a complaint investigation.

5300.1 - Task 1: Offsite Survey Preparation (Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

Review any information about the facility that would be helpful to know in planning the investigation. Contact the ombudsman to discuss the nature of the complaint and whether there have been any similar complaints reported to and substantiated by the ombudsman.

Review the related regulatory requirements or standards that pertain to the complaint. For example, if it is a complaint about abuse, review the requirements at 42 CFR 483.13.

Plan the investigation. Before going to the nursing home, plan what information to obtain during the complaint investigation based on the information already acquired. Consider practical methods to obtain that information.

5300.2 - Task 2: Entrance Conference/Onsite Preparatory Activities (Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

Onsite complaint investigations should always be unannounced. Upon entrance, advise the facility's Administrator of the general purpose of the visit. The SA explains the reason for the survey and avoids any impression that a predetermination has been made as to the validity of the allegation. It is important to let the facility know why you are there, but protect the confidentiality of those involved in the complaint. Do not release information that will cause opportunities to be lost for pertinent observations, interviews, and record reviews required for a thorough investigation. For example, if the complaint is that food that is intended to be served hot is always served cold, do not tell the facility the exact complaint. Rather, tell them it is a situation related to dietary requirements.

5300.3 - Task 5: Information Gathering (Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

The order and manner in which information is gathered depends on the type of complaint that is being investigated. Conduct comprehensive, focused, and/or closed record reviews as appropriate for the type of complaint. Generally, it is not necessary to review records and information from more than one year ago. However, the SA is not precluded from doing so if concerns identified during the investigation indicate it is necessary in order to determine current compliance. It is very important to remember that the determination of whether the complaint happened is not enough. The surveyor needs to determine noncompliant facility practices related to the complaint situation and which, if any, requirements are not met by the facility.

Perform information gathering in order of priorities, i.e., obtain the most critical information first. Based on this critical information about the incident, determine what other information to obtain in the investigation.

Observations, record review and interviews can be done in any order necessary. As information is obtained, use what has been learned to determine what needs to be clarified or verified as the investigation continues.

Observe the physical environment, situations, procedures, patterns of care, delivery of services to residents, and interactions related to the complaint. Also, if necessary, observe other residents with the same care need. After determining what occurred, i.e., what happened to the resident and the outcome, investigate what facility practice(s) or procedures affected the occurrence of the incident.

EXAMPLE

It was verified through the investigation that a resident developed a pressure sore/ulcer which progressed to a Stage IV, became infected and resulted in the resident requiring hospitalization for aggressive antibiotic therapy. Observe as appropriate: dressing changes, especially to any other residents with Stage III or IV pressure sores; infection control techniques such as hand washing, linen handling, and care of residents with infections; care given to prevent development of pressure sores (e.g., turning and repositioning, use of specialized bedding when appropriate, treatments done when ordered, keeping residents dry, and provision of adequate nutritional support for wound healing).

Record Review: If a specific resident is involved, focus on the condition of the resident before and after the incident. If there are care issues, determine whether the appropriate assessments, care planning, implementation of care, and evaluations of the outcome of care have been done as specified by the regulatory requirements.

EXAMPLE

For a complaint of verbal and physical abuse, review the record to determine the resident's mood and demeanor before and after the alleged abuse. Determine if there are any other reasons for the change in the resident's demeanor and behavior. Determine whether an assessment has been done to determine the reason for the change in mood and behavior. Does the record document any unexplained bruises and/or complaints of pain, and whether they occurred in relation to the alleged incident?

Interviews: Interview the person who made the complaint. If the complainant is not at the facility at the time of the survey, he/she should be interviewed by telephone, if possible. Also, interview the person the complaint is about. Then, interview any other witnesses or staff involved. In order to maintain the confidentiality of witnesses, change the order of interviews if necessary. It may not always be desirable to interview the person who made the complaint first, as that may identify the person as the complainant to the facility. Interview residents with similar care needs at their convenience.

As interviews proceed, prepare outlines needed for other identified witnesses and revise outlines as new information is obtained.

During information gathering to investigate a complaint about the care and services provided to residents in a nursing home, findings of past noncompliance may be identified. Before considering a citation of past noncompliance with a specific regulatory tag, surveyors must determine if current compliance with the specific regulatory tag exists. Similar to verifying correction of current noncompliance on a revisit, surveyors should use a variety of methods to determine whether correction of the past noncompliance occurred and continues. This may include, but is not limited to, the following:

- Interviews with facility staff, such as the administrator, nursing staff, social services staff, medical director, quality assessment and assurance committee members, and/or other facility staff, as indicated, to determine what procedures, systems, structures, and processes have been changed.
- Reviewing through observation, interview and record review, how the facility identified and implemented interventions to address the noncompliance. Examples of interventions may include, but are not limited to:
 - The facility's review, revision, or development of policies and/or procedures to address the areas of concerns;
 - The provision and use of new equipment, as necessary;
 - The provision of staff training required to assure ongoing compliance for the implementation and use of new and/or revised policies, procedures, and/or equipment, especially with new and/or temporary staff;
 - The provision of additional staffing, changes in assignments or deployment of staff, as needed; and
 - The provision of a monitoring mechanism to assure that the changes made are being supervised, evaluated, and reinforced by responsible facility staff.
- Evaluating whether the facility has a functioning quality assessment and assurance committee whose responsibilities include the identification of quality issues; providing timely response to ascertain the cause; implementing corrective action; implementing monitoring mechanisms in place to assure continued correction and revision of approaches, as necessary, to eliminate the potential risk of occurrence to other residents and to assure continued compliance.

A citation of past noncompliance must meet all of the criteria described in Task 6 below.

5300.4 - Task 6: Information Analysis (Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

Review all information collected. If there are inconsistencies, do additional data collection as needed, to resolve the inconsistencies. Determine if there is any other information still needed.

Determine whether:

- The allegations are substantiated or unsubstantiated;
- The facility failed to meet any of the regulatory requirements; and
- The facility practice or procedure that contributed to the complaint has been changed to achieve and/or maintain compliance.

To cite past noncompliance with a specific survey data tag (F-tag or K-tag), all of the following three criteria must be met:

- 1) The facility was not in compliance with the specific regulatory requirement(s) (as referenced by the specific F-tag or K-tag) at the time the situation occurred;
- 2) The noncompliance occurred after the exit date of the last standard recertification survey and before the survey (standard, complaint, or revisit) currently being conducted; and
- 3) There is sufficient evidence that the facility corrected the noncompliance and is in substantial compliance at the time of the current survey for the specific regulatory requirement(s), as referenced by the specific F-tag or K-tag.

A nursing home does not provide a plan of correction for a deficiency cited as past noncompliance as the deficiency is already corrected; however, the survey team documents the facility's corrective actions on Form CMS-2567.

5300.5 - Task 7: Exit Conference

(Rev. XX, Issued: XX-XX-XX; Effective/Implementation Dates: XX-XX-XX)

Conduct an Exit Conference related to a complaint survey in accordance with the process described of Task 7 in Appendix P. Do not inform the nursing facility of confidential information unless the individual who provided the information specifically authorizes you to do so.

If a deficiency is not present now, but was present and has been corrected, notify the facility orally and in writing that the complaint was substantiated because deficiencies existed at the time that the complaint situation occurred. (See SOM <u>Chapter 7</u>, Survey and Enforcement Process for Skilled Nursing Facilities and Nursing Facilities, for specific information about citing past noncompliance.)

If the complaint is unsubstantiated, (i.e., the surveyor(s) cannot determine that it occurred and there is no indication of deficient practice), notify the facility of this decision.

5310 - Action on Complaints of Resident Neglect and Abuse, and Misappropriation of Resident Property (Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

5310.1 - Written Procedures

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

The State must have written procedures for the timely review and investigation of allegations of resident abuse and neglect, and misappropriation of resident property.

5310.2 - Review of Allegation (Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

The State Reviews all allegations of resident neglect and abuse and misappropriation of resident property regardless of the source of the complaint.

5310.3 - Investigating Allegations (Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

If there is reason to believe, either through oral or written evidence, that an individual used by a facility to provide services to residents could have abused or neglected a resident or misappropriated a resident's property, the State must investigate the allegation. During the investigation, the SA should evaluate how the facility developed policies and procedures to prevent the abuse, and after the abuse occurred, how the facility took action to report and investigate the allegations while ensuring the safety of the residents.

5310.4 - Factors Beyond the Control of the Individual (Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

The State must not make a finding that an individual neglected a resident if the individual demonstrates that such neglect was caused by factors beyond the control of the individual.

EXAMPLE: A nurse aide could not be found negligent for not providing clean bed and bath linens to a resident if the facility had no clean bed and bath linens available. However, the facility is responsible for providing clean bed and bath linens to residents.

5320 – Reporting Findings of Abuse, Neglect, or Misappropriation of Property to the Nurse Aide Registry (Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

5320.1 - Notification Procedures - Preliminary Determinations (Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

If the State makes a preliminary determination, based on oral or written evidence and its investigation, that resident neglect, abuse, or misappropriation of property has occurred, the State completes the following notification procedures:

1. Individuals Notified - The State notifies the following individuals in writing within 10 working days of the investigation:

- **a.** Individual(s) implicated in the investigation; and
- **b.** The current administrator of the facility in which the incident occurred.

2. Notice Information - The following information is included in the notice:

- **a.** Nature of the allegation (specific facts);
- **b.** Date and time of the occurrence;
- **c.** A statement that the individual implicated in the investigation has a right to a hearing and must request the hearing within 30 days from the date of the notice. Provide the individual with the specific information needed to request a hearing, such as the name and address of a contact in the State to request a hearing;
- **d.** Statement that if the individual fails to request a hearing, in writing, within 30 days from the date of the notice, the presumed substantiated findings is reported to the nurse aide registry or the appropriate licensure authority;
- **e.** The intent to report findings substantiated by a hearing in writing to the nurse aide registry and/or to the appropriate licensure authority;
- **f.** Consequences of waiving the right to a hearing;
- **g.** Consequences of a finding through the hearing process that the resident abuse or neglect, or misappropriation of property did occur; and
- **h.** Right of the accused individual to be represented by an attorney at the individual's own expense.

5320.2 - Conduct of Hearing for Nurse Aides

1- Time frame to Complete the Hearing

The State must complete the hearing and the hearing record within 120 days from the day it receives the request for a hearing.

2 - Hearing Location

The State must hold the hearing in a manner consistent with State practice at a reasonable place and time convenient for the individual.

5320.3 - Reporting Findings

1 - Reporting to Entities

If the individual waives the right to a hearing or the time to request a hearing has expired, or if the hearing finding is that the individual neglected or abused a resident or misappropriated a resident's property, the substantiated findings must be reported in writing within 10 working days to:

- a. The individual;
- b. Current administrator of the facility in which the incident occurred;
- c. The administrator of the facility that currently employs the individual, if it is not the same facility in which the incident occurred;
- d. Applicable licensing authorities; and

The nurse aide registry for nurse aides as specified in 42 CFR 483.156(c) and discussed in §4141. Section 4141 discusses the function of the registry, the information contained in the registry, and responsibility for the registry.

2 - Information Submitted to the Nurse Aide Registry

The following information must be included and remain in the registry permanently, unless the finding was made in error, the individual was found not guilty in a court of law, or the State is notified of the individual's death. See $\underline{\$4141}$.B.

- **a.** Documentation of the investigation, including the nature of the allegation and the evidence that led to the conclusion that the allegation was valid;
- **b.** The date of the hearing, if the individual chose to have one, and its outcome; and
- **c.** A statement by the individual disputing the allegation if the individual chose to make one.

3 - Information Retained in the Nurse Aide Registry Permanently

The registry must remove entries for individuals who have performed no nursing or nursingrelated services for 24 consecutive months, unless the individual's registry entry includes documented findings of abuse, neglect, or misappropriation of property.

5330 - Reporting Abuse to Law Enforcement and the Medicaid Fraud Control Unit

When the SA or RO substantiates a finding of abuse, the SA or RO must report the substantiated findings to local law enforcement and, if appropriate, the Medicaid Fraud Control Unit.

5340 - Post-Survey Certification Actions for Nursing Homes (*Rev. XX, Issued: XX-XX; Effective/Implementation Dates: XX-XX-XX*)

Following the investigation, the *survey team* records any findings on Form CMS-2567, *the SA conducts a supervisory review of the CMS-2567 form and sends the provider a copy.* The SA requests a POC for any uncorrected deficiencies. See <u>§2728</u>.

When Federal deficiencies are identified, the SA initiates certification actions as follows:

- 1. Noncompliance that Constitutes Immediate Jeopardy to Resident Health and Safety The SA initiates procedures in accordance with §§7307 to 7309.
- 2. Noncompliance that Does Not Constitute Immediate Jeopardy to Resident Health and Safety The SA initiates procedures in accordance with §§7311 to 7316.
- 3. In Substantial Compliance The SA initiates procedures in accordance with §7319.

5350 – Data Entry

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

The SA enters survey information into the ASPEN system (via ASPEN Central Office or ACTS), including Forms CMS-670 and CMS-2567.

5360 - Processing of Complaints Originating with or Investigated by the CMS RO

(Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

The RO establishes procedures and clear organizational accountability to ensure that any complaint is properly evaluated, documented, acknowledged, and handled timely and appropriately. The RO uses ACTS to ensure timely and appropriated action on all allegations originating with or investigated by the RO.

The extent and nature of RO involvement with a given complaint varies depending on the nature of the allegation and the receiving organization. The following procedures address the major variants of RO involvement.

5370 - Pre-Investigation Actions on Allegations Originating Through the RO (Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

Most complaints originate through the SA and are recorded and controlled by the SA. When a complaint is filed directly with the RO, however, the RO assumes those initial SA responsibilities.

5380 - RO Processing of RO Investigated Complaints (Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

This less frequent class of complaints includes allegations retained by the RO or forwarded to the RO by the SA for investigation or special processing. The RO responsibilities vary based on the type of complaint.

1 - Direct RO Investigation

These procedures apply when a direct RO investigation is conducted. When directly investigating, the RO begins by ensuring that it or the SA has met all intake, acknowledgment, and priority assignment requirements in \$5010 to \$5020.

2 - Conducting the Investigation

The RO follows the procedures for investigation in §5300.

3 – RO Certification Actions

When Federal deficiencies are identified, the RO initiates certification actions as follows:

- a. Noncompliance that Constitutes Immediate Jeopardy to Resident Health and Safety The RO initiates procedures in accordance with §§7307 to 7309. The RO performs the SA responsibilities described in these sections.
- b. Noncompliance that Does Not Constitute Immediate Jeopardy to Resident Health and Safety The RO initiates procedures in accordance with §§7311 to 7316.
- c. In Substantial Compliance The RO initiates procedures in accordance with §7319.

4 - Reporting

The RO should report survey information into the ASPEN system (via ASPEN Central Office or ACTS), including Forms CMS-670 and CMS-2567.

5390 – RO Oversight of Complaint-Related Processes (Rev. 18, Issued: 03-17-06; Effective/Implementation Dates: 03-17-06)

- 1. The RO considers any complaint data in targeting look-behind surveys or reviews.
- 2. The RO monitors data in summary form either through a log or data system. See <u>§5060</u>.

These records should include:

- Identification of region or State-wide patterns;
- Pinpointing of problem providers or States;
- Evaluation of SA processing times, workloads, performance, etc.; and
- Identification of overall SA workloads, including unsubstantiated and Medicaid-only complaint volumes.

3. Based on needs identified from oversight activities, the RO provides SA training and technical assistance.

NOTE: Sections 5400 to 5480.2 relate to alleged EMTALA violations.

State Operations Manual Appendix P - Survey Protocol for Long Term Care Facilities - Part I

(Rev. XXX, XX-XX-XX)

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Task 7 - Exit Conference

A. General Objective and Intent

The exit conference is a courtesy to the facility to provide the preliminary findings of the surveyors so that the facility can take swift corrective action to address any deficiencies. Surveyors must indicate that all findings are preliminary and are subject to supervisory review by the State and/or RO. Deficiency citations are not final and the CMS 2567 must not be given to the facility until after the State and/or RO conduct a supervisory review.

B. Conduct of Exit Conference

Conduct the exit conference with facility personnel. Invite the ombudsman and an officer of the organized residents group, if one exists, to the exit conference. Also, invite one or two residents to attend. The team may provide an abbreviated exit conference specifically for residents after completion of the normal facility exit conference. If two exit conferences are held, notify the ombudsman and invite the ombudsman to attend either or both conferences.

It is important to provide clear information to facilities to assist them in developing a potential plan of correction. In presenting preliminary findings, avoid reading your findings or only referring to them by their data tag number. Explain why the findings are a violation of Medicare/Medicaid requirements in enough detail to assist the provider in expediting the provider's correction of any deficiencies ahead of the formal receipt of the CMS-2567 report.

If the provider asks for the regulatory basis or the specific tag, the surveyors should generally provide it (except as noted below), but always caution that such coding classifications are preliminary and are provided only to help the provider gain more insight into the issues through the interpretive guidance.

If the survey team is still deliberating as to which tags will be most pertinent, the survey team should not speculate at the exit conference as to the specific tag coding that will be applied. For example, the team may still be deliberating as to whether the finding was a care planning deficiency or staff training deficiency. Similarly, the team may believe that additional consultation should occur with other State personnel (e.g., a pharmacist) before a specific tag number is assigned to the deficiency finding. In these cases the survey team would describe the

general area of non-compliance without identifying a specific tag code. This is a judgment to be made by the survey team onsite, so in preparation for the exit conference the team should deliberate as to the degree of detail that will be appropriate.

Surveyors must not provide the Scope and Severity of a given deficiency finding (unless it is an immediate jeopardy), as such finer degree of possible detail should await supervisory review. Instead, survey teams may describe the general seriousness (e.g., harm) or urgency that, in the preliminary view of the survey team, a particular deficiency may pose to the well-being of residents. This is a survey-specific decision based on the evidence gathered. As described below, states must follow the federal process. State licensure laws do not override the procedures outlined in the federal survey process. If a provider asks whether the noncompliance is isolated, pattern, or widespread, the survey resolute resolution with the facts (i.e., noncompliance was found affecting X number of residents).

Under no circumstances should you make general statements such as, "Overall the facility is very good." Stick to the facts. Do not rank requirements. Treat requirements as equally as possible. Cite problems that clearly violate regulatory requirements. The survey team must not discuss survey results in a manner that reveals the identity of an individual resident.

After describing the team's preliminary deficiency findings to the facility, let them know they will receive a report of the survey which will contain any deficiencies that have been cited *following supervisory review* (Form CMS-2567). If requested, provide the facility with a list of residents included in the standard survey sample. Do not give the team's Roster/Sample Matrixes to the facility, because they contain confidential information.

If an extended survey is required and the survey team cannot complete all or part of the extended survey prior to the exit conference, inform the Administrator that the deficiencies, as discussed in the conference, may be amended upon completion of the extended survey. (See $\frac{\$2724}{100}$ for additional information concerning exit conferences.)

During the exit conference, provide the facility with the opportunity to discuss and supply additional information that they believe is pertinent to the identified findings. Because of the ongoing dialogue between surveyors and facility staff during the survey, there should be few instances where the facility is not aware of surveyor concerns or has not had an opportunity to present additional information prior to the exit conference.

II.B – The Traditional Survey (Continued)

II.B.2. - The Traditional Extended and/or Partial Extended Survey

Conduct an extended survey subsequent to a standard survey and conduct a partial extended survey subsequent to an abbreviated survey when you have determined that there is a substandard quality of care in:

• 42 CFR 483.13, Resident behavior and facility practices;

- 42 CFR 483.15, Quality of life; and/or
- 42 CFR 483.25, Quality of care.

When conducting the extended/partial extended survey, at a minimum, fully review and verify compliance with each tag number within <u>42 CFR 483.30</u>, Nursing Services; <u>42 CFR 483.40</u>, Physician Services; and <u>42 CFR 483.75</u>, Administration. Focus on the facility's policies and procedures that may have produced the substandard quality of care. As appropriate, include a review of staffing, inservice training and the infection control program. An extended/partial extended survey explores the extent to which structure and process factors such as written policies and procedures, staff qualifications and functional responsibilities, and specific agreements and contracts of the facility may have contributed to the outcomes. If the extended/partial extended survey was triggered by a deficiency in quality of care, conduct a detailed review of the accuracy of resident assessment. During the partial extended survey, consider expanding the scope of the review to include a more comprehensive evaluation of the requirements at <u>42 CFR 483.13</u>, <u>42 CFR 483.15</u>, and/or <u>42 CFR 483.25</u> in which substandard quality of care was found.

Document the observations from the extended or partial extended survey on the Form CMS-805, (see Exhibit 93) or the Form CMS-807 (see Exhibit 95).

Review of the Accuracy of Resident Assessments During an Extended/Partial Extended Survey

The objective of this review is to determine if resident assessments are accurate.

If an extended/partial extended survey is conducted based on substandard quality of care in Quality of Care (<u>42 CFR 483.25</u>), review the accuracy of resident assessments by:

- Reviewing a sample of comprehensive resident assessments completed no more than 30 days prior to conducting the survey;
- Comparing observations of the resident with the facility's assessment;
- Conducting the number of assessment reviews needed to make a decision concerning the accuracy of the facility's resident assessments; and
- Determining if observations of the resident, and interviews with resident/staff/family, "match" the facility's assessment (or specific portions of the assessment) of the resident. If observations and interviews do not "match," investigate further.

Record the indepth review of the accuracy of resident assessments on page 3 of the Form CMS-805. (See Exhibit 93.)

Timing for Conducting the Extended Survey and Partial Extended Survey

Conduct the extended or partial extended survey:

- Prior to the exit conference, in which case the facility will be provided with information from the standard, abbreviated standard, partial extended or extended surveys; or,
- Not later than 2 weeks after the standard/abbreviated survey is completed, if the team is unable to conduct the extended survey or partial extended survey concurrent with the standard survey or the abbreviated survey. Advise the facility's Administrator that there will be an extended or partial extended survey conducted and that an exit conference will be held at the completion of the survey.