DATE: March 10, 2005

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: All Provider Types - Independent but Associated Deficiency Citations

Letter Summary

- The purpose of this memorandum is to affirm our expectation that when noncompliance with a federal requirement has been identified, the facility or provider will receive a deficiency associated with the noncompliance.
- This memorandum restates existing CMS policy in Appendix P regarding independent but linked deficiency citations.
- This clarification applies to all provider types.

Attached you will find documents supporting this requirement including:

- Regulatory language that identifies facility compliance requirements; and
- Relevant areas of the State Operations Manual (SOM), Appendix P Task 5C and 6. This guidance addresses the necessity of survey teams to review all requirements in order to determine if there was noncompliance with any of the regulations.

There are instances in which a deficient practice creates noncompliance with more than one regulation. In those situations, noncompliance with each requirement should be cited. This situation may be referred to as “independent but associated” citations. This guidance applies to all provider types.

Some investigative protocols (such as those for pressure ulcers, hydration, and weight loss) include a list of regulations that may or may not be a concern depending upon investigation. The surveyor is expected to conduct further investigation, if concerns are identified, to determine whether non-compliance is present with those additional requirements.

For Example:
If a resident develops avoidable pressure ulcers after admission, the surveyor may make the determination that the facility failed to meet the requirement that a resident entering a facility without a pressure ulcer does not acquire one unless it is unavoidable. In that case, the pressure ulcer (sore) requirement (tag F314) is out of compliance. During the investigation, the surveyor might also find the facility did not conduct a comprehensive assessment of the resident’s risk for development of a pressure ulcer. If so, the facility has also failed to comply with the regulatory language at F272. This tag requires a comprehensive assessment and is not specific to just pressure ulcers.
If the facility fails to do a comprehensive assessment of residents in other care areas, these would be combined with the pressure ulcer finding into a citation that describes the facility failure at F272. This example is not simply a matter of referencing non-compliance of one requirement with a second requirement. Rather, it reflects determining two distinct requirements have not been met after conducting a thorough review.

Another facility may have failed to meet the requirement for F314 because the resident developed an avoidable pressure ulcer. During the review the surveyor noted there was not sufficient staff to implement the care plan. In that case, the staffing requirement at F353 would also be out of compliance, since that regulation requires the facility to employ sufficient staff to provide care to the residents based on their care plan. In these two cases only determining non-compliance with F314 does not account for what the facility failed to do. Equally important, it does not inform the facility of the problems they need to fix.

In General:

1. Cite to the regulatory language, summarizing or describing the deficient practice as it relates to the requirement:
   
   o If the failure led to a negative or potentially negative outcome, cite the appropriate outcome tag; and
   o Cite the specific process and/or structure requirement if specific failures in the areas of process or structure are identified through investigation.

2. While writing the survey finding on Form CMS-2567, it is important to remember that the language for related deficiencies should not merely be repeated. Language should be written at each tag that reflects noncompliance for that specific requirement.

We expect the survey process to be conducted consistent with Federal guidance and the Centers for Medicare & Medicaid Services (CMS) remains committed to monitoring adherence with our program requirements. The expectation that the certification program will be conducted consistent with our guidance is the basis on which the State performance review is conducted.

Concerns:
We have heard from some providers that citation of more than one deficiency for a single type of negative outcome simply represents “piling it on” by states or CMS. The regulations do not support this view. Nor do we agree as a matter of proper management and practice. Often one citation will focus on or manifest cause for a poor outcome, while another citation may focus on a systemic or root cause. It is vital that health care providers address all factors that contribute to negative outcomes.

If you have any further questions or concerns regarding the issues in this letter, please contact Cindy Graunke at (410) 786-6782 or Beverly Cullen at (410) 786-6784.
Effective Date: The information in this memorandum should be shared with survey staff within 30 days of the publication date.

Training: The information contained in this announcement should be shared with all survey staff, their managers and the state/RO training coordinators.

/s/
Thomas E. Hamilton

CC: Survey and Certification Regional Office Management (G-5)

Attachment
ADDENDUM

The survey process requires surveyors to determine a facility's compliance with the applicable requirements. In order to maintain certification in the Medicare/Medicaid program, nursing homes must be in compliance with all of the regulations. This is in regulation at the following:

42 CFR 483.1 (b) - Scope. The provisions of this part contain the requirements that an institution must meet in order to qualify to participate as a Skilled Nursing Facility (SNF) in the Medicare program, and as a Nursing Facility (NF) in the Medicaid program. They serve as the basis for survey activities for the purpose of determining whether a facility meets the requirements for participation in Medicare and Medicaid.

42 CFR 483.75 (b) - 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 (emphasis added).

42 CFR 488.301 - Definitions. Deficiency means a SNF’s or NF’s failure to meet a participation requirement specified in the Act or in part 483, subpart B of this chapter.

Excerpts from Appendix P of the State Operations Manual (SOM) – Survey Protocol for Long Term Care Facilities

The survey process contains specific procedures, which are delineated in the SOM, Appendix P, to provide guidance for a surveyor in how to conduct the standard, extended, revisits and complaint surveys. Within the guidance, in order to promote consistency, investigative protocols have been developed that provide specific processes for the surveyor to utilize in evaluating areas of concern such as the following: Hydration; Unintended Weight Loss; Dining and Food Service; Nursing Services - Sufficient Staffing; Adverse Drug Reactions, and the Abuse Prohibition Protocol. Within each protocol, at the end, is a section titled Task 6, Determination of Compliance. This section provides guidance for the surveyor to investigate regulatory requirements related to the issue that may be out of compliance and to cite deficiencies if negative findings are identified. This section includes a list of several regulatory requirements. An example of the Investigative Protocol – Hydration, is attached for review.

TASK 6 - Information Analysis for Deficiency Determination

A component of the survey process is the decision making by the survey team to determine if the facility is in compliance with all the requirements (emphasis added). The surveyors are required to conduct a review of all the requirements as a team to ascertain whether they identified any areas of non-compliance and to delineate the areas of non-compliance that will be cited. For the purpose of this paper, only excerpts of the Task 6, which describe the review of the regulatory requirements, will be attached.

This section also defines a "deficiency as a facility’s failure to meet a participation requirement." It should be noted that the guidance states that all regulatory requirements that are deficient may be issued based upon findings. (Please refer to Task 6 in the SOM, Appendix P for the complete version.)
Investigative Protocol
Hydration

Objectives:

- To determine if the facility identified risk factors which lead to dehydration and developed an appropriate preventative care plan; and
- To determine if the facility provided the resident with sufficient fluid intake to maintain proper hydration and health.

Task 5C: Use:

Use this protocol for the following situations:

- A sampled resident who flagged for the sentinel event of dehydration on the Resident Level Summary;
- A sampled resident who has one or more QI conditions identified on the Resident Level Summary, such as:
  - #11 - Fecal impaction;
  - #12 - Urinary tract infections;
  - #13 - Weight loss;
  - #14 - Tube feeding;
  - #17 - Decline in ADLs;
  - #24 - Pressure Ulcer
- A sampled resident who was discovered to have any of the following risk factors: vomiting/diarrhea resulting in fluid loss, elevated temperatures and/or infectious processes, dependence on staff for the provision of fluid intake, use of medications including diuretics, laxatives, and cardiovascular agents, renal disease, dysphagia, a history of refusing fluids, limited fluid intake or lacking the sensation of thirst.

Procedures:

- Observations/interviews conducted as part of this procedure should be recorded on the Forms CMS-805 and/or the Form CMS-807.
- Determine if the resident was assessed to identify risk factors that can lead to dehydration, such as those listed above and also whether there were abnormal laboratory test values which may be an indicator of dehydration.
NOTE: A general guideline for determining baseline daily fluid needs is to multiply the resident’s body weight in kilograms (kg) x 30ml (2.2 lbs = 1 kg), except for residents with renal or cardiac distress, or other restrictions based on physician orders. An excess of fluids can be detrimental for these residents.

- Determine if an interdisciplinary care plan was developed utilizing the clinical conditions and risk factors identified, taking into account the amount of fluid that the resident requires. If the resident is receiving enteral nutritional support, determine if the tube feeding orders included a sufficient amount of free water, and whether the water and feeding are being administered in accordance with physician orders?

- Observe the care delivery to determine if the interventions identified in the care plan have been implemented as described.
  - What is the resident’s response to the interventions? Does staff provide the necessary fluids as described in the plan? Do the fluids provided contribute to dehydration, e.g., caffeinated beverages, alcohol? Was the correct type of fluid provided with a resident with dysphagia?
  - Is the resident able to reach, pour and drink fluids without assistance? Is the resident consuming sufficient fluids? If not, is staff providing the fluids according to the care plan?
  - Is the resident’s room temperature (heating mechanism) contributing to dehydration? If so, how is the facility addressing this issue?
  - If the resident refuses water, are alternative fluids offered that are tolerable to the resident?
  - Are the resident’s beverage preferences identified and honored at meals?
  - Does staff encourage the resident to drink? Are they aware of the resident’s fluid needs? Is staff providing fluids during and between meals?
  - Determine how the facility monitors to assure that the resident maintains fluid parameters as planned. If the facility is monitoring the intake and output of the resident, review the record to determine if the fluid goals or calculated fluid needs were met consistently.

- Review all related information and documentation to look for evidence of identified causes of the condition or problem. This inquiry should include interviews with appropriate facility staff and health care practitioners, who by level of training and knowledge of the resident, should know of, or be able to provide information about the causes of a resident’s condition or problem.
NOTE: If a resident is at an end of life stage and has an advance directive, according to State law, (or a decision has been made by the resident’s surrogate or representative, in accordance with State law) or the resident has reached an end of life stage in which minimal amounts of fluids are being consumed or intake has ceased, and all appropriate efforts have been made to encourage and provide intake, then dehydration may be an expected outcome and does not constitute noncompliance with the requirement for hydration. Conduct observations to verify that palliative interventions, as described in the plan of care, are being implemented and revised as necessary, to meet the needs/choices of the resident in order to maintain the resident’s comfort and quality of life. If the facility has failed to provide the palliative care, cite noncompliance with 42 CFR 483.25, F309, Quality of Care.

- Determine if the care plan is evaluated and revised based on the response, outcomes, and needs of the resident.

**Task 6: Determination of Compliance:**

- Compliance with 42 CFR 483.25(j), F327, Hydration:
  - For this resident, the facility is compliant with this requirement to maintain proper hydration if they properly assessed, care planned, implemented the care plan, evaluated the resident outcome, and revised the care plan as needed. If not, cite at F327.

- Compliance with 42 CFR 483.20(b)(1) & (2), F272, Comprehensive Assessments:
  - For this resident in the area of hydration, the facility is compliant with this requirement if they assessed factors that put the resident at risk for dehydration, whether chronic or acute. If not, cite at F272.

- Compliance with 42 CFR 483.20(k)(1), F279, Comprehensive Care Plans:
  - For this resident in the area of hydration, the facility is compliant with this requirement if they developed a care plan that includes measurable objectives and timetables to meet the resident’s needs as identified in the resident’s assessment. If not, cite at F279.

- Compliance with 42 CFR 483.20(k)(3)(ii), F 282, Provision of care in accordance with the care plan:
  - For this resident in the area of hydration, the facility is compliant with this requirement if qualified persons implemented the resident’s care plan. If not, cite at F282.
A. General Objectives

The objectives of information analysis for deficiency determination are:

- To review and analyze all information collected and to determine whether or not the facility has failed to meet one or more of the regulatory requirements;

C. Decision-Making Process

Each member of the team should review his/her worksheets to identify concerns and specific evidence relating to requirements that the facility has potentially failed to meet. In order to identify the facility’s deficient practices and to enable collating and evaluating the evidence, worksheets should reflect the source of the evidence and should summarize the concerns on relevant data tags.

- In order to ensure that no requirements are missed, proceed through the requirements sequentially as they appear in the interpretive guidelines, preferably section by section. Findings/evidence within each section should be shared by each team member during this discussion. Consider all aspects of the requirements within the tag/section being discussed and evaluate how the information gathered relates to the specifics of the regulatory language and to the facility’s performance in each requirement. The team should come to consensus on each requirement for which problems have been raised by any member. If no problems are identified for a particular tag number during the information gathering process, then no deficiency exists for that tag number.

D. Deficiency Criteria

To determine if a deficiency exists, use the following definitions and guidance:

- A “deficiency” is defined as a facility’s failure to meet a participation requirement specified in the Social Security Act or in Part 483, Subpart B (i.e., 42 CFR 483.5 - 42 CFR 483.75).

- To help determine if a deficiency exists, look at the language of the requirement. Some requirements need to be met for each resident. Any violation of these requirements, even for one resident, is a deficiency.

- Other requirements focus on facility systems.

Certain facility systems requirements must be met in an absolute sense, e.g., a facility must have an RN on duty 7 days a week unless it has received a waiver. Other facility system requirements are best evaluated comprehensively, rather than in terms of a single incident. In evaluating these requirements the team will examine both the individual parts of the system, e.g., the adequacy of the infection control protocol, the adequacy of facility policy on hand washing, as well as the actual implementation of that system.