March 23, 2006

Thomas E. Hamilton
Director, Survey and Certification Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

By email: Thomas.hamilton@cms.hhs.gov

Re: New Psychosocial Outcome Severity Guide, S&C 06-10

Dear Mr. Hamilton:

The psychosocial outcome severity guide is an extremely important addition to the survey process, but it has significant problems that I encourage you to address before it is implemented. I have read the advanced copy of the guide, S&C 06-10, and compared it with the draft that was circulated for comment in June 2004. Although the new guidance responds to many questions that I, and presumably others, had about the 2004 draft (e.g., now explaining more clearly when and how the new guide should be used when assigning scope and severity determinations to deficiencies), I am troubled by the deletion of other points from the draft (discussed below). My chief reason for writing, however, is my concern with how the new reasonable person standard is described and used, including CMS' decision not to allow level 3 severity to be cited when a resident’s reaction to a deficiency is “markedly incongruent” to how a “reasonable person” would be expected to respond to the deficiency. I urge you to revise the guidelines to allow all three levels of severity to be applied in any of the situations where the reasonable person standard is used. In addition, the guidance raises for me the broader issue of the need to revise the scope and severity grid to create additional levels of harm.
Reasonable person standard

The psychosocial outcome severity guidance identifies three sets of circumstances when the reasonable person standard should be applied (unnumbered page 3):

- "when there is no discernable response;"
- "when circumstances obstruct the direct evaluation of the resident’s psychosocial outcome" (e.g., the resident has died or has cognitive or physical impairments. I do not understand the meaning or purposes of the factor related to the facility’s "insufficient documentation"); and
- "when the resident’s reaction to a deficient practice is markedly incongruent with the level of reaction the reasonable person would have to the deficient practice."

The guidance says that level 3 severity (actual harm) may not be used in the third situation (i.e., where the resident’s reaction is "markedly incongruent"). CMS provides no justification or explanation for this decision to exclude the possibility of a level 3 severity determination in this situation. The point of the reasonable person standard would seem to be recognizing psychosocial harm to a resident when the resident cannot articulate the harm. The guidance, however, excludes an entire group of residents who are unable to articulate psychosocial harm that would ordinarily be expected from a "reasonable person" under similar circumstances.

The examples in the training demonstrate why the decision CMS made to exclude level 3 severity is inappropriate. The second example (connected to slide 20) is copied in its entirety below:

**Example 2:** Staff do not toilet residents at night. They tell residents to wet the bed and they will clean them up and the bed in the morning. A resident interviewed about the lack of toileting at night says "it is just how things have to be" and he is "used to it."

- **Answer:** Level 2.
- **Rationale:** Selecting a level of severity for this resident, the team would use the reasonable person concept since the reaction is incongruent with the offense, and shows the resident is institutionalized to expect substandard treatment. We cannot select Level 3 using the reasonable person concept since we are unable to prove actual harm to this resident. If there are other residents who are part of this deficiency, each resident should be evaluated separately.

CMS’ explanation for choosing level 2 severity is not persuasive. The reasonable person standard attributes harm that the resident does not, or cannot, articulate. If the resident under the facts of this example had given "no discernable response" or had cognitive impairments and could not speak at all, level 3 could have been used, under CMS’ guidance.
Furthermore, the resident is described as “institutionalized to expect substandard treatment.” The resident’s response to the deficiency is not the response that would be expected from a “reasonable person” under similar circumstances. If the resident was unable to articulate any response, severity level 3 would be a possibility. I do not understand the justification for excluding level 3 when the resident is able to articulate a sentiment, although one that is inappropriate and reflective of an institutionalized personality. Becoming “institutionalized” is harm.

Example 3, which also cites a Level 2 deficiency, is equally troubling. This example states:

**Example 3:** The team is citing a deficiency for activities, since there are few activities and most residents are not included. One resident who is part of the deficiency is a cognitively impaired resident who does not verbalize. This resident was observed during all days of survey sitting in the hall or in her room with nothing to do.

- **Answer:** Level 2.
- **Rationale:** The team should select Level 2 which includes the potential not yet realized for compromise. Level 3 is too high, since the team would have to show evidence of actual harm (compromise).

I do not understand the rationale for finding no actual harm in this example. The only difference that I can see between this example and examples 4 and 5, where level 3 deficiencies are described as cited, is that example 3 involves activities and examples 4 and 5 involve care issues. The guidance recognizes that any deficiency can have a psychosocial component (unnumbered page 2). The lack of activities should also allow for a level 3 severity determination.

Example 3 fails to explain whether the reasonable person standard is being used (as it should be, since the resident is unable to verbalize), and if not, why not.

The examples do not illustrate when psychosocial harm is higher than physical harm. In the fourth example, both types of harm are at the same level, level 3.

The fifth example, citing level 3 severity, does not explain how the resident’s depression is determined. It does not illustrate how the psychosocial outcome grid should be used.

**The need to revise the severity grid**

The five examples also underscore for me the need for CMS to revise the severity grid to add new levels of harm. The one example of immediate jeopardy in this guidance is the rape of a comatose resident – an extreme example that illustrates how rare a determination of immediate jeopardy is. As a result of limiting level 4 to extreme cases (and national data confirm that few deficiencies are cited at this level), there is really only a single level of harm – level 3. Although all types of actual harm need to be placed in severity level 3, survey agencies in fact frequently cite deficiencies at level 2 that, by any
reasonable interpretation, should be level 3 actual harm. The Government Accountability Office has repeatedly confirmed the placement of serious deficiencies causing harm into level 2, most recently in Nursing Homes: Despite Increased Oversight, Challenges Remain in Ensuring High-Quality Care and Resident Safety 4, GAO-06-117 (Dec. 2005), and Congressman Waxman’s multiple reports evaluating survey deficiencies in different Congressional districts have made similar findings.

The way to resolve this concern is to add new levels of harm – at least one new level and possibly two or more. I understand that the regulations would need to be revised to amend the severity grid. But more than a decade’s experience has demonstrated that the grid does not correctly reflect various levels of harm and results in the down-coding of serious quality concerns.

Other concerns

The draft described at some length what the reasonable person is. June 2004 draft, pages 19-20 (quoting State Operations Manual, Task 6E, 1995, and Preceptor Manual (1999)). The new guidance provides a very limited discussion of reasonable person and no definition (unnumbered page 3). I suggest that you add language to the guidance explaining what the reasonable person standard is and why and when it is used.

The new guidance also does not discuss cognitively intact and cognitively impaired residents, as the June 2004 draft did. It omits the sentence at the end of the discussion of these residents “A low level of cognitive functioning as documented by an individual’s score on the MDS or a test of cognitive function such as the MiniMental Exam should not by itself invalidate the individual’s report about an incident” (page 20). I had urged CMS to retain this sentence in my August 2, 2004 comments. The language is omitted. I encourage you to restore the sentence to the guidance. Research by John Schnelle has demonstrated that many residents can give meaningful and accurate information about their care and quality of life. See, e.g., Sandra Simmons, John F. Schnelle, “The Identification of Residents Capable of Accurately Describing Daily Care: Implications for Evaluating Nursing Home Care,” The Gerontologist, 41(5):605-611 (2001).

I continue to be concerned, as I was in 2004, that the descriptions of the severity levels find no harm (i.e., no level 3 severity) unless the resident has a “persistent” depressed mood. “Intermittent sadness” is classified as level 2. In my view, as I expressed in 2004, “intermittent sadness is actual harm, even though it is ‘less harm’ than ‘persistent sadness.” All of the descriptions in the guidance for level 2 severity are, from my perspective, actual harm – “feelings and/or complaints of discomfort or moderate pain,” “fear/anxiety that may be manifested as expressions or signs of minimal discomfort,” “feeling of shame or embarrassment without a loss of interest in the environment and the self,” “complaints of boredom and/or reports that there is nothing to do,” “verbal or nonverbal expressions of anger that did not lead to harm to self or others” – even if they are less intense than the descriptions for level 3. These examples need to be revised in the guidance so that deficiencies cited at level 2 severity actually reflect situations involving “no actual harm with the potential for more than minimal harm.”
Finally, the guidance does not make clear, as the June 2004 draft did, that the reasonable person standard may be used for cognitively intact residents as well as for cognitively impaired residents. I ask that you restore that language to the guidance.

I urge you to revise the psychosocial guidance document that was issued this month (which does not become effective until June 1) and to convene a meeting to begin discussions of changing the severity grid.

Thank you.

Sincerely,

Toby S. Edelman