
CMS Manual System

Department of Health &
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Transmittal 156

Date: June 10, 2016

SUBJECT: Revisions to the State Operations Manual (SOM) - Appendix P – Survey Protocol for Long Term Care Facilities

I. SUMMARY OF CHANGES: This instruction revises the instructions to surveyors in section IV, subsection E of Appendix P, Psychosocial Outcome Severity Guide, in order to provide additional information to surveyors about assessing for psychosocial harm.

NEW/REVISED MATERIAL - EFFECTIVE DATE: June 10, 2016

IMPLEMENTATION DATE: June 10, 2016

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix P/Survey Protocol for Long Term Care Facilities - Part I/IV Deficiency Categorization/E. Psychosocial Outcome Severity Guide

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	One-Time Notification -Confidential
	Recurring Update Notification

*Unless otherwise specified, the effective date is the date of service.

IV. Deficiency Categorization

(Rev.156, Issued: 06-10-16, Effective: 06 -10-16, Implementation: 06-10-16)

A. General Objective

After the survey team determines that a deficiency (ies) exists, assess the effect on resident outcome (severity level) and determine the number of residents potentially or actually affected (scope level). Use the results of this assessment to determine whether or not the facility is in substantial compliance or is noncompliant. When a facility is noncompliant, consider how the deficient practice is classified according to severity and scope levels in selecting an appropriate remedy. (See [§7400](#) for discussion of remedies.)

Scope and severity determinations are also applicable to deficiencies at [§483.70\(a\), Life Safety from Fire](#).

B. Guidance on Severity Levels

There are four severity levels. Level 1, no actual harm with potential for minimal harm; Level 2, no actual harm with potential for more than minimal harm that is not immediate jeopardy; Level 3, actual harm that is not immediate jeopardy; Level 4, immediate jeopardy to resident health or safety. These four levels are defined accordingly:

1. Level 1 is a deficiency that has the potential for causing no more than a minor negative impact on the resident(s).
2. Level 2 is noncompliance that results in no more than minimal physical, mental and/or psychosocial discomfort to the resident and/or has the potential (not yet realized) to compromise the resident's ability to maintain and/or reach his/her highest practicable physical, mental and/or psychosocial well-being as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services.
3. Level 3 is noncompliance that results in a negative outcome that has compromised the resident's ability to maintain and/or reach his/her highest practicable physical, mental and psychosocial well-being as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services. This does not include a deficient practice that only could or has caused limited consequence to the resident.
4. Level 4 is immediate jeopardy, a situation in which immediate corrective action is necessary because the facility's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident receiving care in a facility. (See [Appendix Q](#).)

C. Guidance on Scope Levels

Scope has three levels: isolated; pattern; and widespread. The scope levels are defined accordingly:

- I. Scope is isolated when one or a very limited number of residents are affected and/or one or a very limited number of staff are involved, and/or the situation has occurred only occasionally or in a very limited number of locations.
- II. Scope is a pattern when more than a very limited number of residents are affected, and/or more than a very limited number of staff are involved, and/or the situation has occurred in several locations, and/or the same resident(s) have been affected by repeated occurrences of the same deficient practice. The effect of the deficient practice is not found to be pervasive throughout the facility.
3. Scope is widespread when the problems causing the deficiencies are pervasive in the facility and/or represent systemic failure that affected or has the potential to affect a large portion or all of the facility's residents. Widespread scope refers to the entire facility population, not a subset of residents or one unit of a facility. In addition, widespread scope may be identified if a systemic failure in the facility (e.g., failure to maintain food at safe temperatures) would be likely to affect a large number of residents and is, therefore, pervasive in the facility.

D. General Procedures

After the team makes a decision to cite a deficiency(ies), evaluate the deficient practice's impact on the resident(s) and the prevalence of the deficient practice. Review deficiency statements, worksheets, and results of team discussions for evidence on which to base these determinations. The team may base evidence of the impact or prevalence for residents of the deficient practices on record reviews, interviews and/or observations. Whatever the source, the evidence must be credible.

After determining the severity level of a deficient practice, determine scope. When determining scope, evaluate the cause of the deficiency. If the facility lacks a system/policy (or has an inadequate system) to meet the requirements and this failure has the potential to affect a large number of residents in the facility, then the deficient practice is likely to be widespread. If an adequate system/policy is in place but is being inadequately implemented in certain instances, or if there is an inadequate system with the potential to impact only a subset of the facility's population, then the deficient practice is likely to be pattern. If the deficiency affects or has the potential to affect one or a very limited number of residents, then the scope is isolated.

If the evidence gathered during the survey for a particular requirement includes examples of various severity or scope levels, surveyors should generally classify the deficiency at the highest level of severity, even if most of the evidence corresponds to a lower severity level. For example, if there is a deficiency in which one resident suffered a severity 3 while there were widespread findings of the same deficiency at severity 2, then the deficiency would be generally classified as severity 3, isolated.

E. Psychosocial Outcome Severity Guide

Purpose

The purpose of the Psychosocial Outcome Severity Guide is to help surveyors determine the severity of psychosocial outcomes resulting from the identified noncompliance at a specific F tag. The Guide is used to determine the severity of a deficiency in any regulatory grouping (e.g., Quality of Care, Quality of Life) that resulted in a negative psychosocial outcome.

This Guide is not intended to replace the current scope and severity grid, but rather it is intended to be used in conjunction with the scope and severity grid to determine the severity of outcomes to each resident involved in a deficiency that has resulted in a psychosocial outcome. The team should select the level of severity for the deficiency based on the highest level of physical or psychosocial outcome. For example, a resident who was slapped by a staff member may experience only a minor physical outcome from the slap but suffer a greater psychosocial outcome. In this case the severity level based on the psychosocial outcome would be used as the level of severity for the deficiency.

Overview

Psychosocial outcomes (i.e., mood and behavior) may result from a facility's noncompliance with any regulatory requirement. Although a resident may experience either a negative physical outcome or a negative psychosocial outcome, some may experience or have the potential to experience both types of negative outcomes.

Psychosocial outcomes and physical outcomes are equally important in determining the severity of noncompliance, and both need to be considered before assigning a severity level. The severity level assigned should reflect the most significant negative outcome or highest level of harm/potential harm.

The presence of a given affect (i.e., behavioral manifestation of mood demonstrated by the resident) does not necessarily indicate a psychosocial outcome that is the direct result of noncompliance. A resident's reactions and responses (or lack thereof) also may be affected by pre-existing psychosocial issues, illnesses, medication side effects, and/or other factors. Because many nursing home residents have sadness, anger, loss of self-esteem, etc. in reaction to normal life experiences, the survey team must have determined that the psychosocial outcome is a result of the noncompliance *and not a pre-existing condition for the resident*.

Psychosocial outcomes of interest to surveyors are those caused by the facility's noncompliance with any regulation. This also includes psychosocial outcomes resulting from facility failure to assess and develop an adequate care plan to address a resident's pre-existing psychosocial issues, *leading* to continuation or worsening of the condition.

Instructions

This Guide is designed to be used separately for each resident included in the deficiency. Each resident's psychosocial response to the noncompliance is the basis for determining psychosocial severity of a deficiency. To determine severity, use the information gathered through the investigative process. Compare the resident's behavior (e.g., their routine, activity, and responses to staff or to everyday situations) and mood before and after the noncompliance.

If the survey team determines that a facility's noncompliance has resulted in a negative psychosocial outcome to one or more residents, the team should use this Guide to evaluate the severity of the outcome for each resident identified in the deficiency (in accordance with the instructions at Task 6). The team should determine severity based on the resident's response in the following circumstances:

- If the resident can communicate a psychosocial reaction to the deficient practice, compare this response to the Guide; or
- If the resident is unable to express her/himself verbally but shows a noticeable non-verbal response that is related to the deficient practice, compare the non-verbal response to the Guide.

Application of the Reasonable Person Concept

There are circumstances in which the survey team may apply the "reasonable person concept" to determine severity of the deficiency. To apply the reasonable person concept, the survey team should determine the severity of the psychosocial outcome or potential outcome the deficiency may have had on a reasonable person in the resident's position (i.e., what degree of actual or potential harm would one expect a reasonable person in a similar situation to suffer as a result of the noncompliance).

NOTE: The reasonable person concept described in this Guide is merely a tool to assist the survey team's assessment of the severity level of negative psychosocial outcomes. Although the reasonable person concept is used in many areas of the law, the application of common law defenses to the assessment of severity pursuant to this Guide would be inappropriate and is expressly precluded.

The survey team should use the reasonable person concept when the resident's psychosocial outcome may not be readily determined through the investigative process:

- When there is no discernable response or when circumstances obstruct the direct evaluation of the resident's psychosocial outcome. Such circumstances may include, but are not limited to, the resident's death, subsequent injury, cognitive impairments, physical impairments, or insufficient documentation by the facility. In this situation, the survey team may use the reasonable person concept to evaluate the severity (Level 2, Level 3, or Level 4) of the deficient practice; or
- 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. In this situation, the survey team may use the reasonable person concept to evaluate the potential severity (Level 2 or Level 4) of the deficient practice.

Clarification of Terms

"Anger" refers to an emotion caused by the frustrated attempts to attain a goal, or in response to hostile or disturbing actions such as insults, injuries, or threats that do not come from a feared

source.¹

“Apathy” refers to a marked indifference to the environment; lack of a response to a situation; lack of interest in or concern for things that others find moving or exciting; absence or suppression of passion, emotion, or excitement.²

“Anxiety” refers to the apprehensive anticipation of future danger or misfortune accompanied by a feeling of distress, sadness, or somatic symptoms of tension. Somatic symptoms of tension may include, but are not limited to, restlessness, irritability, hyper-vigilance, an exaggerated startle response, increased muscle tone, and teeth grinding. The focus of anticipated danger may be internal or external.³

“Dehumanization” refers to the deprivation of human qualities or attributes such as individuality, compassion, or civility.⁴ Dehumanization is the outcome resulting from having been treated as an inanimate object or as having no emotions, feelings, or sensations.

“Depressed mood” (which does not necessarily constitute clinical depression) is indicated by negative statements; self-deprecation; sad facial expressions; crying and tearfulness; withdrawal from activities of interest; and/or reduced social interactions.⁵ Some residents such as those with moderate or severe cognitive impairment may be more likely to demonstrate nonverbal symptoms of depression.

“Humiliation” refers to a feeling of shame due to being embarrassed, disgraced, or depreciated. Some individuals lose so much self-esteem through humiliation that they become depressed.⁶

PSYCHOSOCIAL OUTCOME SEVERITY GUIDE

The following are levels of negative psychosocial outcomes that developed, continued, or worsened as a result of the facility’s noncompliance. This Guide is only to be used once the survey team has determined noncompliance at a regulatory requirement. The survey team must have established a connection between the noncompliance and a negative psychosocial outcome to the resident as evidenced by observations, record review, and/or interviews with residents, their representatives, and/or staff.

Areas where the survey team may more likely see psychosocial outcomes when citing a particular deficiency include, but are not limited to, F221/F222, Physical and Chemical Restraints; F223 Abuse; F224 Mistreatment, Neglect, Misappropriation; F225 Investigate and Report Allegations of Abuse; F226 Abuse and Neglect Policies; F241, Dignity; F246, Accommodation of Needs; F248, Activities; F279, Comprehensive Care Plans; F280, Right to Participate in Care Planning; F309, Quality of Care (pain, dementia care); F319, Treatment/Services for Mental/Psychosocial Functioning; F320, No Behavior Difficulties Unless Unavoidable; and F329, Drug Regimen is Free From Unnecessary Drugs. While the survey team may find negative psychosocial outcomes related to any of the regulations, these areas may be more susceptible to a negative psychosocial outcome or contain a psychosocial element that may be greater in severity than the physical outcome.

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has allowed/caused/resulted in, or is likely to allow/cause /result in serious injury, harm, impairment, or death to a resident; and
- Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Examples of negative psychosocial outcomes as a result of the facility's noncompliance may include but are not limited to:

- Suicidal ideation/thoughts and preoccupation (with a plan) or suicidal attempt (active or passive) such as trying to jump from a high place, throwing oneself down a flight of stairs, refusing to eat or drink in order to kill oneself.
- Engaging in self-injurious behavior that is likely to cause serious injury, harm, impairment, or death to the resident (e.g., banging head against wall).
- Sustained and intense crying, moaning, screaming, or combative behavior.
- Expressions (verbal and/or non-verbal) of severe, unrelenting, excruciating, and unrelieved pain; pain has become all-consuming and overwhelms the resident.
- Recurrent (i.e., more than isolated or fleeting) debilitating fear/anxiety that may be manifested as panic, immobilization, screaming, and/or extremely aggressive or agitated behavior(s) (e.g., trembling, cowering) in response to an identifiable situation (e.g., approach of a specific staff member).
- Ongoing, persistent expression of dehumanization or humiliation in response to an identifiable situation, that persists regardless of whether the precipitating event(s) has ceased and has resulted in a potentially life-threatening consequence.
- Expressions of anger at an intense and sustained level that has caused or is likely to cause serious injury, harm, impairment, or death to self or others.

Severity Level 3 Considerations: Actual Harm that is not Immediate Jeopardy

Severity Level 3 indicates noncompliance that results in actual harm, and can include but may not be limited to clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being.

Examples of negative psychosocial outcomes as a result of the facility's noncompliance may include but are not limited to:

- Significant decline in former social patterns that does not rise to a level of immediate jeopardy.
- Persistent depressed mood^{7,8,9} that may be manifested by verbal and nonverbal symptoms such as:
 - Social withdrawal; irritability; anxiety; hopelessness; tearfulness; crying; moaning;
 - Loss of interest or ability to experience or feel pleasure nearly every day for much of the day;
 - Psychomotor agitation¹⁰ (e.g., inability to sit still, pacing, hand-wringing, or pulling or rubbing of the skin, clothing, or other objects), accompanied by a bothered or sad expression;
 - Psychomotor retardation (e.g., slowed speech, thinking, and body movements; increased pauses before answering);
 - Verbal agitation¹¹ (e.g., repeated requests for help, groaning, sighing, or other repeated verbalizations), accompanied by sad facial expressions;
 - Expressions of feelings of worthlessness or excessive guilt nearly every day (not merely self-reproach or guilt about being sick or needing care);
 - Markedly diminished ability to think or concentrate;
 - Recurrent thoughts of death (not just fear of dying) or statements without an intent to act (e.g., “I wish I were dead” or “my family would be better off without me”).
- Expressions (verbal and/or non-verbal) of persistent pain or physical distress (e.g., itching, thirst) that has compromised the resident’s functioning such as diminished level of participation in social interactions and/or ADLs, intermittent crying and moaning, weight loss and/or diminished appetite. Pain or physical distress has become a central focus of the resident’s attention, but it is not all-consuming or overwhelming (as in Severity Level 4).
- Chronic or recurrent fear/anxiety that has compromised the resident’s well-being and that may be manifested as avoidance of the fear-inducing situation(s) or person(s); preoccupation with fear; resistance to care and/or social interaction; moderate aggressive or agitated behavior(s) related to fear; sleeplessness due to fear; and/or verbal expressions of fear. Expressions of fear/anxiety are not to the level of panic and immobilization (as in Severity Level 4).

- Ongoing, persistent feeling and/or expression of dehumanization or humiliation that persists regardless of whether the precipitating, dehumanizing event(s) or situation(s) has ceased. The feelings of dehumanization and humiliation have not resulted in a life-threatening consequence.
- Apathy and social disengagement such as listlessness; slowness of response and thought (psychomotor retardation); lack of interest or concern especially in matters of general importance and appeal, resulting from facility noncompliance.
- Sustained distress (e.g., agitation indicative of under stimulation as manifested by fidgeting; restlessness; repetitive verbalization of not knowing what to do, needing to go to work, and/or needing to find something).
- Anger that has caused aggression that could lead to injuring self or others. Verbal aggression can be manifested by threatening, screaming, or cursing; physical aggression can be manifested by self-directed responses or hitting, shoving, biting, and scratching others.

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

Severity Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being. The potential exists for greater harm to occur if interventions are not provided.

Examples of negative psychosocial outcomes as a result of the facility's noncompliance may include but are not limited to:

- Intermittent sadness, as reflected in facial expression and/or demeanor, tearfulness, crying, or verbal/vocal agitation (e.g., repeated requests for help, moaning, and sighing).
- Feelings and/or complaints of discomfort or moderate pain. The resident may be irritable and/or express discomfort.
- Fear/anxiety that may be manifested as expressions or signs of minimal discomfort (e.g., verbal expressions of fear/anxiety; pulling away from a feared object or situation) or has the potential, not yet realized, to compromise the resident's well-being.
- 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, accompanied by expressions of periodic distress that do not result in maladaptive behaviors (e.g., verbal or physical aggression).

- Verbal or nonverbal expressions of anger that did not lead to harm to self or others.

Severity Level 1 Considerations: No Actual Harm with Potential for Minimal Harm

Severity Level 1 is not an option because any facility practice that results in a reduction of psychosocial well-being diminishes the resident's quality of life. The deficiency is, therefore, at least a Severity Level 2 because it has the potential for more than minimal harm.

ENDNOTES

- ¹ Gall, S., Beins, B., & Feldman, J. (1996). *The Gale Encyclopedia of Psychology*. Detroit, MI: Gale Research.
- ² Random House. (1981). *The Random House Dictionary of the English Language*. New York: Author.
- ³ American Psychiatric Association (1994). *Diagnostic and statistical manual of mental disorders (Fourth Edition)*. Washington, DC: Author.
- ⁴ Random House. (1981).
- ⁵ Minimum Data Set Version 2.0, Section E.
- ⁶ Corsini, R. (1999). *The Dictionary of Psychology*. Ann Arbor, MI: Taylor and Francis.
- ⁷ Alexopolous, G., Abrams, R., Young, R., & Shamoian, C. (1988). Cornell scale for depression in dementia. *Biological Psychiatry*, 23, 271-284.
- ⁸ Brink, T.L., Yesavage, J.A., Lum, O., Heersema, P., Adey, M., & Rose, T.L. (1982). Screening tools for geriatric depression. *Clinical Gerontologist*, 1, 37-43.
- ⁹ Warren, W.L. (1994). *Revised Hamilton Rating Scale for Depression (RHRSD)*. Los Angeles, CA: Western Psychological Services.
- ¹⁰ Cohen-Mansfield, J. (2003). Agitation in the elderly: Definitional and theoretical conceptualizations. In D.P. Hay, D. Klein, L. Hay, G. Grossberg, & J.S. Kennedy (Eds.) *Agitation in Patients with Dementia: A Practical Guide to Diagnosis and Management* (pp. 1-22). Washington, DC: American Psychiatric Publishing Inc.
- ¹¹ Cohen-Mansfield, J. (2003). Agitation in the elderly: Definitional and theoretical conceptualizations.