
CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 192

Date: September 6, 2019

SUBJECT: Revisions to State Operations Manual (SOM), Appendix Q

I. SUMMARY OF CHANGES: CMS has revised guidance to reinsert language referring criminal acts to law enforcement.

NEW/REVISED MATERIAL - EFFECTIVE DATE: September 6, 2019

IMPLEMENTATION DATE: September 6, 2019

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 Q/ V- ANALYTIC PROCESS FOR DETERMINING IMMEDIATE JEOPARDY/A. Determining non-compliance exists

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
	Recurring Update Notification

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

State Operations Manual

Appendix Q – Core Guidelines for Determining Immediate Jeopardy

V- ANALYTIC PROCESS FOR DETERMINING IMMEDIATE JEOPARDY

(Rev. 192, Issued: 09-06-19, Effective: 09-06-19, Implementation: 09-06-19)

The survey team leader must be immediately notified of any IJ concern as soon as it is identified so that the survey team can gather to discuss the IJ concern and, if necessary, conduct further investigation. The survey team must use its professional judgment and evidence gathered from observations, interviews, and record reviews to carefully consider each key component of IJ. Survey teams must use the IJ Template attached to this Appendix to document evidence of each component of IJ and to convey information to the entity.

In order to determine that IJ exists, the team must verify that all three components of IJ have been established. The components of IJ are described below in the order they appear in the definitions, however, there is no specific order that must be followed - the determination of IJ often begins with the identification of serious harm or the likelihood of serious harm. Regardless of which component of IJ is identified first, the survey team must verify each component.

A. **Determining Noncompliance Exists:** The survey team must use applicable tasks, protocols and guidance from the State Operations Manual (SOM) and relevant Appendix Q subparts to establish that the provider is out of compliance with one or more of the federal health, safety, and/or quality regulations. The team must gather sufficient evidence through observation, interview, and record review to support the citation of noncompliance. This is done not only to verify the entity's noncompliance, but to also understand the extent, nature and scope of the noncompliance and to better understand the impact or likely impact of the noncompliance on recipients at risk. The survey team must be able to explain what the noncompliance is, which regulation has been violated, and why the noncompliance rises to the level of IJ to their supervisor, the RO (if necessary), the entity, and finally, in their deficiency statement.

Guidance for Reporting to Local Law Enforcement: When the identified noncompliance is determined to have been caused by a suspected criminal act and the entity refuses to report, or the surveyor cannot verify that a report was made to local law enforcement, the surveyor must consult with his/her supervisor immediately. The State Agency must then report the suspected criminal act to law enforcement immediately.

The survey team must identify all noncompliance that is related to the IJ situation. Noncompliance at the IJ level at one regulation or survey data tag, does not automatically trigger noncompliance at a related regulation or tag. Surveyors must analyze the facts of the noncompliance against the relevant regulations or tags. If the survey team finds that the same incident or facility practice results in multiple violations, the team must be able to articulate how the incident or practice represents a distinct violation of each regulation or tag.

Although a comprehensive statement may contain facts illustrating deficiencies at multiple tags, surveyors may not simply copy and paste from one tag to another. Even if multiple deficiencies share common facts, surveyors may need to conduct additional investigation to evaluate additional tags thoroughly.

The survey team should also identify, to the best of their ability, when the IJ began. This means determining at what point the entity's noncompliance made serious injury, serious harm, serious impairment, or death occur or likely to occur. Duration of IJ is dependent on the nature and extent of noncompliance and the recipients at risk. Often, there is an event or incident in which a serious adverse outcome is identified. However, the survey team's investigation should seek to determine how long the IJ has existed, which may be prior to the event or incident.

The duration of IJ does not automatically end if the recipient is no longer impacted by the noncompliance (e.g., recipient is no longer in the facility or has expired). The survey team must determine if the noncompliance continues to create a likelihood for serious injury, serious harm, serious impairment, or death for any other recipients.

Please note, in determining noncompliance an entity may state that they properly trained and supervised individuals and that it was a "rogue" employee that violated a regulation. If this occurs it should be cited as noncompliance despite an entity's compliance efforts to train and monitor the employee. An entity cannot disown the acts of its employees, operators, consultants, contractors, or volunteers or disassociate itself from the consequences of their actions to avoid a finding of noncompliance.

NOTE: For information on Past Noncompliance for nursing homes, refer to the SOM, Chapter 7 at 7510.1 and the LTC IJ subpart.

Completing IJ Template - Noncompliance: Answer Yes or No to whether the entity has failed to meet one or more federal health, safety, and/or quality regulations. If Yes, in the blank space for Noncompliance, identify the survey data tag and briefly summarize the issues that led to the determination that the entity is in noncompliance with that requirement. This includes the action(s), error(s), or lack of action, and the extent of the noncompliance (for example, number of cases). Use one IJ template for each tag being considered at the IJ level.

B. Determining if Serious Injury, Serious Harm, Serious Impairment, or Death has Occurred or is Likely to Occur as a Result of Identified Noncompliance: Once noncompliance has been verified, the team must differentiate between noncompliance which rises to the level of IJ and that which does not (i.e., lower level of noncompliance). This is done by determining what outcome or impact the noncompliance had or is likely to have on the recipient(s). Noncompliance which causes serious injury, serious harm, serious impairment, or death, or makes such an outcome likely is IJ.

This serious adverse outcome may be physical, mental, and/or psychosocial in nature. The surveyor will use evidence gathered during observations, interviews and/or record reviews to support the assertion that the recipient has suffered a serious adverse outcome as a result of the identified noncompliance. Only one recipient needs to have suffered or be likely to suffer a serious adverse outcome for IJ to exist.

Serious adverse outcomes can be further described as outcomes resulting in a significant decline in physical, mental, or psychosocial functioning, which is not solely due to the normal progression of a disease or the aging process. It is important to note that serious adverse outcomes may not always effect physical functioning, but may have an effect on mental or psychosocial functioning (e.g., noncompliance which causes a recipient to suffer psychosocial harm, such as from sexual abuse).

A serious adverse outcome should be considered when the noncompliance has caused death, loss of a limb, or permanent disfigurement.

Additionally, IJ should be considered when noncompliance causes a recipient to experience avoidable pain that is excruciating, and more than transient in nature. Pain is considered avoidable when there is a failure to assess, reassess, and/or take steps to manage the recipient's pain.

Lastly, a serious adverse outcome should also be considered when the identified noncompliance has caused any other serious harm that creates a life threatening complication or condition.

Likelihood: It is important to understand that IJ exists not only when an entity's noncompliance has caused or is causing serious injury, harm, impairment or death, but also when the noncompliance has made serious harm, injury, impairment or death likely. This means the surveyor/survey team must determine whether a specific serious adverse outcome is reasonably expected to occur if immediate action is not taken.

NOTE: Surveyors do not have to prove when the serious harm will occur, or that it will occur within a specific timeframe. It is sufficient to show that serious harm either has occurred or is likely to occur.

To determine if there is a likelihood of a serious adverse outcome, the surveyor/survey team uses their professional judgment and takes into account the nature and scope of the identified noncompliance, the particular vulnerabilities of the recipients at risk, and any other relevant factors to determine whether serious harm will likely occur if no corrective action or inadequate action is taken.

For example, a temporary power outage may have relatively minor consequences to the general population of recipients in a hospital or nursing home. However, if the hospital or nursing home provides care for ventilator-dependent recipients, a temporary power outage would have life-threatening consequences if adequate contingencies have not been implemented.

Other relevant factors to be considered include the magnitude of the actual or likely serious adverse outcome. In extraordinary circumstances, the provider/supplier creates conditions that are incredibly dangerous to the health and safety of recipients at risk such that immediate action is imperative, despite a relatively low mathematical probability of the adverse outcome occurring. For example, a hospital has no system to prevent infant abduction. Although the mathematical probability may be relatively low, the risk that an infant could be abducted is intolerable, and demands immediate attention.

If immediate action is needed to remove the risk of serious harm, then the survey team can sufficiently determine that a serious adverse outcome is likely to occur.

NOTE: Surveyors do not have to show that the identified noncompliance is the sole factor contributing to the serious adverse outcome, or the sole factor making a serious adverse outcome likely, but that the noncompliance must be a factor in causing or making such an outcome likely.

Psychosocial/Mental Harm and using the Reasonable Person Concept: It is important to understand that noncompliance rising to the level of IJ does not always result in serious physical adverse outcomes, but may also affect the recipient's mental or psychosocial well-being. For example, a recipient who was sexually abused by a staff member may not have significant physical outcomes, but may suffer a greater psychosocial outcome. In this case, the seriousness of the noncompliance would be based on the psychosocial outcome to the recipient. Psychosocial outcomes (e.g., changes in mood and/or behavior) may result from an entity's noncompliance with any requirement. The surveyor's investigation should attempt to determine if a recipient's change in mood and/or behavior is a significant factor of the noncompliance, or part of the recipient's baseline, or disease process.

When unable to discern the recipient's response to an entity's noncompliance, the surveyor should attempt to interview the recipient's family, legal representative, or other individuals involved in the recipient's life to understand how the recipient reacted or would have reacted to the noncompliance. If the surveyor is unable to conduct interviews with the family or representative, the surveyor should apply a reasonable person approach.

There may be some situations in which the psychosocial outcome to the recipient may be difficult to determine or incongruent with what would be expected. In these situations it is appropriate to consider the reasonable person approach which considers how a reasonable person in the recipient's position would be impacted by the noncompliance. In other words, consider if a reasonable person in a similar situation could be expected to experience a serious adverse outcome as a result of the same noncompliance. This approach may be used when identifying where psychosocial harm at an IJ level has occurred or is likely to occur. The following examples demonstrate when the reasonable person concept could be used:

- When a recipient may not be able to express their feelings, there is no discernable response, or when circumstances may not permit the direct assessment of the recipient's psychosocial outcome. Such circumstances may include, but are not limited to, the recipient's death, cognitive impairments, physical impairments, emotional trauma, or insufficient documentation by the entity; or
- When a recipient's reaction to a deficient practice is markedly incongruent (or different) with the level of reaction a reasonable person would have to the deficient practice. These situations most commonly occur when recipients suffer from cognitive impairment, brain injuries, or other disorders affecting a recipient's ability to show emotion.

NOTE: The reasonable person approach does not apply to CLIA determinations.

Completing IJ Template – Serious injury, serious harm, serious impairment or death:

Answer Yes or No whether there is evidence that a serious adverse outcome occurred, or a serious adverse outcome is likely as a result of the identified noncompliance. If Yes, in the blank space for Serious Injury, Serious Harm, Serious Impairment, Death, briefly **summarize** the serious adverse outcome, or likely serious adverse outcome to the recipient. Surveyors must not restate all the findings that will be included in the CMS-2567 form.

C. Determining Need for Immediate Action: When noncompliance causes a serious adverse outcome (i.e., serious injury, harm, impairment, or death to a recipient), or creates the likelihood that a serious adverse outcome will occur, the entity must take immediate corrective action to prevent the serious injury, serious harm, serious impairment or death from occurring or recurring. Even when the recipient has been removed from the situation, e.g., transferred to acute care, discharged, or has died, immediate action must be taken to remove the systemic problems which contributed to, caused, or were a factor in causing the serious adverse outcome, or making such an outcome likely. The key point is that when IJ exists, the entity's noncompliance has either caused serious injury, serious harm, serious impairment, or death, or created the likelihood for serious injury, serious harm, serious impairment, or death, and creates the need for immediate action so that the serious adverse outcome will not occur, or recur.

Completing IJ Template – Need for Immediate Action: Does the entity need to take immediate action to correct noncompliance that has caused or is likely to cause serious injury, serious harm, serious impairment or death?

If yes, in the blank space for Need for Immediate Action, briefly explain why.

Transmittals Issued for this Appendix

Rev #	Issue Date	Subject	Impl Date	CR#
<u>R187SOMA</u>	03/06/2019	Revision to the State Operations Manual (SOM 100-07) Appendix Q	03/06/2019	N/A
<u>R102SOM</u>	02/14/2014	State Operations Manual (SOM) Appendix Q revisions for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)	02/14/2014	N/A
<u>R01SOM</u>	05/21/2004	Initial Release of Pub 100-07	N/A	N/A