CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal 228 **Date: December 13, 2024**

SUBJECT: Revisions to State Operations Manual (SOM) Appendix Q – Core Guidelines for Determining Immediate Jeopardy

I. SUMMARY OF CHANGES: Revisions have been made to the Guidance content of Appendix Q – Core Guidelines for Determining Immediate Jeopardy – XI Subpart: Clinical Laboratory Improvement Amendments of 1988 (CLIA).

NEW/REVISED MATERIAL - EFFECTIVE DATE*: December 13, 2024
IMPLEMENTATION DATE: December 13, 2024

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 – Core Guidelines for Determining Immediate Jeopardy/I - Introduction
R	Appendix Q – Core Guidelines for Determining Immediate Jeopardy/III – Definitions
R	Appendix Q – Core Guidelines for Determining Immediate Jeopardy/V - Analytic Process for Determining Immediate Jeopardy
R	Appendix Q – Core Guidelines for Determining Immediate Jeopardy/VI - Calling Immediate Jeopardy
R	Appendix Q – Core Guidelines for Determining Immediate Jeopardy/VII - Removing Immediate Jeopardy
R	Appendix Q – Core Guidelines for Determining Immediate Jeopardy/XI – Subpart: Clinical Laboratory Improvement Amendments of 1988 (CLIA)

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.**

State Operations Manual
Appendix Q – Core Guidelines for Determining Immediate Jeopardy

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(Rev. 228; Issued: 12-13-24)

TRANSMITTALS FOR APPENDIX Q

I - INTRODUCTION

(*Rev. 228; Issued: 12-13-24; Effective: 12-13-24; Implementation:12-13-24*)

Immediate Jeopardy (IJ) represents a situation in which noncompliance *by providers, suppliers, or laboratories (hereinafter referred to as "entities")* has placed the health and safety of recipients in its care at risk for serious injury, serious harm, serious impairment, or death. These situations must be accurately identified by surveyors, thoroughly investigated, and resolved by the entity as quickly as possible. In addition, noncompliance cited at IJ is the most serious deficiency type and carries the most serious sanctions for entities. An *IJ* situation is one that is clearly identifiable due to the severity of its harm or likelihood for serious harm and the immediate need for it to be corrected to avoid further or future serious harm.

The intent of this guidance is to standardize the key components of IJ into a "Core" document that can be applied to all certified Medicare/Medicaid entities *and Clinical Laboratory Improvement Act of 1988 (CLIA) certified entities*. Additional entity-specific guidance based on specific regulatory requirements is available to supplement this Core Appendix Q as necessary. Please see the CLIA-specific subpart *XI* for guidance on *documenting IJ and* removing IJ on the Form CMS- 2567.

III– DEFINITIONS

(*Rev. 228; Issued: 12-13-24; Effective: 12-13-24; Implementation:12-13-24*)

The following definitions apply only as they are used in this document and may not be applicable to all entities. Refer to the entity-specific subparts for further information.

- **Likely/Likelihood** means the nature and/or extent of the identified noncompliance creates a reasonable expectation that an adverse outcome resulting in serious injury, harm, impairment, or death will occur if not corrected.

- **Noncompliance** means failure to meet one or more federal health, safety, and/or quality regulations.

- **Psychosocial** refers to the combined influence of psychological factors and the surrounding social environment on physical, emotional, and/or mental wellness.

- **Recipient** is a person (patient, resident, or client) who receives care and/or services from a Medicare and/or Medicaid participating provider/supplier,

or a patient or individual served by a laboratory subject to CLIA.

- **Recipient at Risk** is a recipient who, as a result of noncompliance, and in consideration of the recipient's physical, mental, psychosocial or health needs, and/or vulnerabilities, is likely to experience a serious adverse outcome.

- **Removal Plan/Immediate Action** includes all actions the entity has taken or will take to immediately address the noncompliance that resulted in or made serious injury, serious harm, serious impairment, or death likely.

- **Serious injury, serious harm, serious impairment, or death** are adverse outcomes which result in, or are likely to result in:

    - death; *or*
    - a significant decline in physical, mental, or psychosocial functioning, (that is not solely due to the normal progression of a disease or aging process); or
    - loss of limb, or disfigurement; or
    - avoidable pain that is excruciating, and more than transient; or
    - other serious harm that creates life-threatening complications/conditions.

- **Substantial Compliance** is:

    - One or more standard-level deficiencies with an acceptable Plan of Correction (PoC); or
    - A deficiency cited at severity Level One for SNFs or NFs (i.e. Scope and Severity A, B, or C) with an acceptable PoC for B and C level deficiencies.

V- ANALYTIC PROCESS FOR DETERMINING IMMEDIATE JEOPARDY

(Rev. 228; Issued: 12-13-24; Effective: 12-13-24; Implementation:12-13-24)

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.

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 *affect* 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.

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.

VI. Calling Immediate Jeopardy

(Rev. 228; Issued: 12-13-24; Effective: 12-13-24; Implementation:12-13-24)

Survey teams must use the IJ Template attached to this Appendix to determine if IJ exists, and use the template to communicate the finding of IJ to the entity.

When the surveyor/survey team determines the entity's noncompliance has caused a serious adverse outcome, or has made a serious adverse outcome likely, and immediate action is needed to prevent serious harm from occurring or recurring, the survey team must consult with their State Agency (SA) for confirmation that IJ exists, and seek direction. In some cases, it may be necessary for the survey team to stop all other investigations due to the need for additional investigation into the IJ situation.

NOTE: Some SAs have procedures which include consulting the RO upon identification of IJ. Surveyors must know their IJ notification processes.

When there is agreement from the SA (and/or RO) that IJ exists, the survey team must immediately:

- Notify the administrator (or appropriate staff member who has full authority to act on behalf of the entity) that IJ has been identified and provide a copy of the completed IJ template to the entity; and
- Request a written IJ removal plan, which is the immediate action(s) the entity will take to address the noncompliance that resulted in or made serious injury, serious harm, serious impairment, or death likely.

  NOTE: Date and time that the IJ Template was provided to the entity must be noted on the template and on the Form CMS-2567.

In an effort to clearly and concisely communicate a finding of IJ, survey teams must use the IJ Template attached to this appendix to determine if IJ exists, and the SA must provide the completed IJ template to the entity when IJ is called – in most cases this will be before the surveyor/survey team exits.

It is expected that identification of IJ will be made while the survey team is onsite. Notification to the entity administrator should only be done after IJ has been verified by the surveyor/survey team and the SA (and/or RO). In rare cases, IJ may be identified by the SA or RO after the survey team has exited the premises of the entity. In these cases, the survey team must return to the entity to validate the finding using the IJ Template.

VII -Removing Immediate Jeopardy

(Rev. 228; Issued: 12-13-24; Effective: 12-13-24; Implementation:12-13-24)

Removal Plan: A removal plan documents the immediate action an entity will take to prevent serious harm from occurring or recurring. Following verification of IJ with the SA (and/or the RO), the survey team must notify the entity immediately that IJ has been identified. A removal plan will be required and must be provided to the SA as soon as the entity has identified the steps it will take to ensure that no

recipients are suffering **or are likely** to suffer serious injury, serious harm, serious impairment, or death as a result of the entity's noncompliance. The removal plan identifies all actions the entity will take to immediately address the noncompliance that has resulted in or made serious injury, serious harm, serious impairment, or death likely by detailing how the entity will keep recipients safe and free from serious harm or death caused by the noncompliance. Unlike a plan of correction, it is not necessary that the removal plan completely correct all noncompliance associated with the IJ, but rather it must ensure serious harm will not occur or recur. The removal plan must include a date by which the entity asserts the likelihood for serious harm to any recipient no longer exists.

NOTES:

- **Hospitals and Critical Access Hospitals (CAHs):** Since IJ situations specific to the Emergency and Medical Treatment and Labor Act (EMTALA) requirements are determined by the CMS RO, the surveyor/team will share its concerns with the hospital or CAH, but must clearly state that the findings are preliminary.

There is no requirement that IJ must be removed prior to conducting the exit conference. The SA may use its discretion to delay the team's exit until a removal plan is accepted and the IJ is determined to be removed, if the entity is capable of removing the IJ while the surveyors are onsite. Additionally, there is no Federal requirement that surveyors must remain continuously onsite until the IJ is removed.

Approval of the Removal Plan: The entity's removal plan will be evaluated and approved by the SA or by the survey team in consultation with the SA. A determination must be made as to whether, if implemented appropriately, the removal plan will remove the likelihood that serious harm will occur or recur. Approving the written removal plan does not mean the IJ is removed. To remove IJ, the entity must **implement** the removal plan, and the survey team must verify through observation, interview, and record review, that all actions the facility took were effective in removing the likelihood that serious injury, serious harm, serious impairment, or death would occur or recur.

NOTE: In cases where the entity alleges the IJ was removed prior to the current survey, the survey team must verify the action taken by the entity to remove IJ, and at what point the IJ was removed.

The entity's removal plan must:

- Identify those recipients who have suffered, or are likely to suffer, a serious adverse outcome as a result of the noncompliance; and
- Specify the action the entity will take to alter the process or system failure to prevent a serious adverse outcome from occurring or

recurring, and when the action will be complete.

IJ Removal: Surveyors shall confirm that IJ has been removed by onsite verification after the entity's removal plan is approved and has been implemented. Removal of IJ means that immediate action has been taken by the entity to prevent a serious adverse outcome from occurring or recurring. This is not synonymous with the Plan of Correction, which documents steps the entity will take to come into substantial compliance.

IJ is considered to be removed when surveyors verify that the approved removal plan is fully implemented, **and** no recipient is currently experiencing serious injury, serious harm, or serious impairment; and/or serious injury, serious harm, serious impairment, or death is not likely. If the plan is not fully implemented, the IJ will continue until the removal plan is fully implemented and the likelihood of serious injury, serious harm, serious impairment, or death no longer exists.

NOTE: If the harm cannot be remedied (e.g., death or serious harm has already occurred), the removal plan must address how additional serious harm will be prevented.

If the removal plan cannot be implemented prior to the exit conference of the original survey in which IJ was cited, the IJ continues until an onsite revisit verifies the date that IJ was removed. During onsite revisit surveys, surveyors should verify that all elements of the removal plan have been implemented and that the actions taken were completed in a manner that eliminates the likelihood of serious injury, serious harm, serious impairment, or death. Surveyors **must** be onsite to verify removal of IJ. Offsite desk/telephone review for removal of IJ is not permitted. Surveyors should not automatically use the revisit date or the date the entity indicated in its removal plan as the date IJ was removed. IJ is removed on the date that is determined that all elements of the removal plan have been implemented and that actions taken were completed in a manner that eliminates the likelihood of serious injury, serious harm, serious impairment, or death.

In addition to verifying that IJ was removed, when conducting the onsite revisit, surveyors should determine the date that the entity's removal plan was fully implemented resulting in no further likelihood of serious injury, serious harm, serious impairment, or death.

Removing the IJ does not ensure that substantial compliance has been achieved. Once IJ has been removed, the SA will issue a completed Form CMS-2567 and request a plan of correction that achieves substantial compliance.

XI – SUBPART: CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA)

(*Rev. 228; Issued: 12-13-24; Effective: 12-13-24; Implementation:12-13-24*)

Determining Immediate Jeopardy (IJ)

The following definition of IJ only applies for the purpose of this subpart. The definition of IJ set forth in the CLIA regulations appears in section II of Appendix Q, and other definitions and key components applicable to this subpart are set forth in sections III and IV, respectively.

CLIA laboratories are determined to be either in compliance or not in compliance with CLIA requirements found in section 353 of the Public Health Service Act (codified at 42 U.S.C. § 263a) and Title 42 of the Code of Federal Regulations, Part 493. A laboratory cited at the condition-level will be considered in compliance once compliance is verified through an onsite revisit.

In general, IJ is a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more *c*ondition-level requirements has already caused, is causing or is likely to cause, at any time, serious injury or harm, or death to individuals served by the laboratory or to the health or safety of the general public. The determination of IJ requires the laboratory *to* take immediate action to remove *IJ*, and provide information or evidence that *IJ* has been removed. IJ is synonymous with imminent and serious risk to human health and significant hazard to the public health.

The surveyor/survey teams must use the IJ Template attached to this Appendix (section XII) to determine if IJ exists. The IJ Template is also used to communicate the findings of IJ to the laboratory. The findings contained in the IJ Template are preliminary and do not represent an official finding against the laboratory. The Form CMS-2567 is the only form that contains official survey findings.

The three (3) components of IJ, as outlined in the IJ Template, are:

- Noncompliance: *Has t*he laboratory *failed to meet one or more federal health, safety, and/or quality regulations?*
- Serious Injury, Harm, or Death (Actual OR Likely): *Is there evidence that a serious adverse outcome occurred, or a serious adverse outcome is likely as a result of the identified noncompliance?*
- Need for Immediate Action: *Does the laboratory need to take immediate action to correct noncompliance that has caused or is likely to cause serious injury, serious harm, serious impairment, or death?*

    - Immediate corrective action is necessary to remove the jeopardy. The surveyor should first consider a laboratory out of compliance at the

*c*ondition-level for one or more deficiencies, that is, in the surveyor's judgment the deficiency(ies) constitute(s) a significant or a serious problem that adversely affect(s) or has the likelihood for adversely affecting patient test results/patient care.

If you answer yes to all three (3) questions, then IJ exists. The number of deficiencies does not necessarily relate to whether or not a *c*ondition is found out of compliance, but rather the impact or potential impact the deficiency(ies) has (have) on the quality of laboratory services and the results reported.

Calling IJ

When the surveyor/survey team determines the laboratory's noncompliance has caused a serious adverse outcome, or has made a serious adverse outcome likely, and immediate action is needed to prevent serious harm from occurring or recurring, the surveyor/survey team consults with CMS as directed for confirmation that IJ exists and seek direction. IJ cases need to be prioritized over other workload.

IJ may be identified by the SA or CMS after the survey team has exited the laboratory premises.

When there is agreement from the SA (and/or CMS) that IJ exists, the survey team must immediately notify the laboratory director or designee, as appropriate, that IJ has been identified and provide a copy of the completed IJ Template to the laboratory. The date and time the IJ Template was provided to the laboratory must be noted on the template. IJ should also be noted on the Form CMS-2567 under the D0000 statement.

If after the survey exit date, the SA or CMS determine that IJ exists, but the IJ was not conveyed to the laboratory, the SA or CMS must immediately notify the laboratory that IJ has been determined. This is done by providing the IJ Template, which communicates the noncompliance, the actual or likely serious adverse outcome to the recipient, and why the laboratory must take immediate corrective action to prevent the occurrence or recurrence of a serious adverse outcome or death. As necessary, the SA or CMS may conduct additional onsite investigations.

Documenting IJ on the Form CMS-2567

When IJ has been identified, the SA must ensure the core components of IJ are documented on the Form CMS-2567. For example:

D 000	INITIAL COMMENTS An unannounced complaint survey was completed on January 10, 2023. It was determined that Immediate Jeopardy (IJ) existed for the following condition level deficiencies: 42 C.F.R. § 493.1100 Condition: Facility administration 42 C.F.R. § 493.1250 Condition: Analytic systems 42 C.F.R. § 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director 42 C.F.R. § 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant	D 000

The Form CMS-2567 describing the IJ should be delivered within the timeframes specified in SOM, Chapter 6.

Removal of IJ

Removal of IJ in laboratories requires the removal *of present, and future IJ, and means that immediate action has been taken by the laboratory to prevent a serious adverse outcome from occurring or recurring. A removal plan is when the laboratory takes immediate action to prevent a serious adverse outcome from occurring or recurring. This is a removal plan, which is not synonymous with the Allegation of Compliance (AoC), which documents steps the laboratory will take to come to substantial compliance. For example, ceased testing can be done quickly and removes the immediacy of the adverse outcome even though it does not correct the deficiency. An acceptable AoC is still necessary to address corrective steps the laboratory must take to correct the deficiencies.*

If the laboratory ceases testing to remove the IJ, their AoC must still also address how patients were affected *by the deficient practices*, or likely affected, by the deficient practice. *If testing is ceased, IJ is considered removed and the laboratory must still be cited for condition-level noncompliance. See SOM, Chapter 6 for timeframes on condition-level noncompliance. Form CMS-2567 must note that IJ was identified even if testing ceased. Even when IJ is removed prior to the exit conference, an onsite revisit will be required to determine substantial compliance.*

During onsite revisit surveys, surveyors should verify that all elements of the AoC have been implemented and that the actions taken were completed in a manner that eliminates the likelihood of serious injury, serious harm, serious impairment, or death. If an AoC is submitted and found to be credible during the onsite revisit, the date of compliance will be the AoC completion date indicated on the most recent AoC submitted (as verified during the onsite revisit).

Additionally, removing the IJ does not ensure that substantial compliance has been achieved. Once IJ has been removed, the SA will issue a completed Form CMS-2567 and request an acceptable AoC with evidence of correction.

During the onsite revisit, if new IJ is identified, a new IJ Template and the Form CMS-2567 must be issued to the laboratory.

Refer to SOM §*6120.1*, Figure 4-1.
Refer to SOM §628*4*, Noncompliance with One or More Conditions - Immediate Jeopardy Exists.