DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Quality, Safety &Oversight Group

Ref: ***QSO-25-09-ALL***

DATE: **November 21, 2024**

TO: State Survey Agency Directors

FROM: Director, Quality, Safety & Oversight Group (QSOG)

SUBJECT: **REVISED**: Revisions to Appendix Q, Guidance on Immediate Jeopardy

Memo Revision Information:
Revisions to: *QSO-19-09-ALL* ***Original release date:*** *March 5, 2019*

Memorandum Summary

- **Core Appendix Q and Subparts -** Appendix Q to the State Operations Manual (SOM), which provides guidance for identifying immediate jeopardy, has been revised. The revision creates a Core Appendix Q that will be used by surveyors for all provider and supplier types to determine when to cite immediate jeopardy.
- *All guidance for laboratories that was previously in Appendix Q will be moved to the new Subpart XI: Clinical Laboratory Improvement Amendments of 1988 (CLIA).*
- CMS has drafted subparts to Appendix Q that focus on immediate jeopardy concerns occurring in nursing homes and clinical laboratories since those provider types have specific policies related to immediate jeopardy. Appendix Q has been revised to reinsert language referring criminal acts to local law enforcement.
- *Subpart XI has been revised to reflect that laboratories can cease testing to remove the immediacy of the Immediate Jeopardy. Laboratories must determine and correct the root cause of the deficiency, issue corrected reports as applicable, and establish a mechanism to monitor the effectiveness of the actions before determination of compliance.*
- **Key Components of Immediate Jeopardy –** To cite immediate jeopardy, surveyors determine that (1) noncompliance, (2) caused or created a likelihood that serious injury, harm, impairment, or death to one or more recipients would occur or recur, and (3) immediate action is necessary to prevent the occurrence or recurrence of serious injury, harm, impairment, or death to one or more recipients.
- **Immediate Jeopardy Template –** A template has been developed to assist surveyors in documenting the information necessary to establish each of the key components of immediate jeopardy. Survey teams must use the immediate jeopardy template attached to Appendix Q to document evidence of each component of immediate jeopardy and use the template to convey information to the surveyed entity.

Background

Immediate jeopardy is a situation in which a recipient of care has suffered or is likely to suffer serious injury, harm, impairment, or death as a result of a provider's, supplier's, or laboratory's noncompliance with one or more health and safety requirements. Immediate jeopardy represents the most severe and egregious threat to the health and safety of recipients, as well as carries the most serious sanctions for providers, suppliers, and/or laboratories.

CMS provides guidance to surveyors for citing immediate jeopardy in Appendix Q of the SOM. The version of Appendix Q that is being replaced was drafted in 2004 and is being updated to clarify and increase consistency in identifying immediate jeopardy. These revisions apply to all provider and supplier types. The revisions also include subparts that focus on specific concerns with nursing homes and clinical laboratories.

Application of Core Appendix Q

This revision creates a Core Appendix Q that will be used by surveyors of all provider and supplier types and laboratories, including health, emergency preparedness, and life safety code surveys.

In order to cite immediate jeopardy, pursuant to Core Appendix Q guidelines, surveyors determine that (1) noncompliance (2) caused or created a likelihood that serious injury, harm, impairment, or death to a recipient would occur or recur; and (3) immediate action is necessary to prevent the occurrence or recurrence of serious injury, harm, impairment or death to one or more recipients.

Key Changes in the Core Appendix Q

The Core Appendix Q contains a number of key changes from the previous version of Appendix Q. Those changes include the addition of CLIA-certified entities and revised reference to Subpart XI:

- Likelihood instead of potential – The previous version of Appendix Q suggested that a potential for serious harm might constitute immediate jeopardy. Core Appendix Q makes it clear that in order to cite immediate jeopardy in situations where recipients have not already suffered serious injury, harm, impairment or death, the nature and/or extent of the identified noncompliance creates a likelihood (reasonable expectation) that such harm will occur if not corrected, not simply the potential for that level of harm to occur.

- Culpability has been removed – The previous version of Appendix Q made culpability a required component to cite immediate jeopardy. Because the regulatory definitions of immediate jeopardy do not require a finding of culpability, that requirement has been removed and has been replaced with the key component of noncompliance, since the definitions of immediate jeopardy require noncompliance to be the cause of the serious injury, harm, impairment or death, or the likelihood thereof.

- Psychosocial harm – Core Appendix Q includes a section instructing surveyors to consider whether noncompliance has caused or made likely serious mental or psychosocial harm to recipients. In situations where the psychosocial outcome to the recipient may be difficult to determine or incongruent with what would be expected, the guidance instructs surveyors to use the reasonable person concept to make that determination. The reasonable person approach considers how a reasonable person in the recipient's position would be impacted by the

noncompliance (i.e. consider if a reasonable person in a similar situation could be expected to experience a serious psychosocial adverse outcome as a result of the same noncompliance).

- No automatic immediate jeopardy citations – Core Appendix Q makes it clear that each immediate jeopardy citation must be decided independently, and there are no automatic immediate jeopardy citations.

Subparts to Core Appendix Q

CMS has drafted subparts to Appendix Q that focus on immediate jeopardy concerns occurring in nursing homes and clinical laboratories since there are specific policies related to immediate jeopardy for those provider types.

CMS moved all CLIA guidance previously in Appendix Q to new Subpart XI: Clinical Laboratory Improvement Amendment of 1988 (CLIA). Subpart XI CLIA guidance has been revised to allow laboratories to cease testing to remove the immediacy of the Immediate Jeopardy. Laboratories must determine and correct the root cause of the deficiency, issue corrected reports as applicable, and establish a mechanism to monitor the effectiveness of the actions before determination of compliance. Laboratories will spend less time focusing on past actions and can use their resources to get to the root of the problem that caused the immediate jeopardy. If a laboratory chooses to cease testing, the immediate jeopardy is removed, and the laboratory will have 90 days, instead of 23 days, as prescribed in State Operations Manual (SOM), Chapter 6, to take proper corrective actions for all individuals served by the laboratory that may have been affected by the immediate jeopardy.

Immediate Jeopardy Template

CMS has established a notification process for surveyors to follow when immediate jeopardy is identified. This process ensures that providers, suppliers, or laboratories are notified as soon as possible of an immediate jeopardy finding. This process is intended to increase transparency and improve timeliness and clarity of communication to providers, suppliers, and laboratories.

Training

Online basic training for Core Appendix Q is available on the Quality, Safety, & Education Portal (QSEP) website at the following link: https://qsep.cms.gov/ProvidersAndOthers/publictraining.aspx. This basic training is intended to provide CMS and State Survey Agency surveyors, management staff, and training coordinators, as well as providers, suppliers, and laboratories, and other stakeholders, with the ability to identify immediate jeopardy.

NOTE: This is a required training for *CMS* and SA staff involved in immediate jeopardy determinations. All *CMS* and SA surveyors, members of management, and training coordinators are expected to take this training when the course becomes available.

Contact: For questions related to this information, please add in the subject line "Immediate Jeopardy Inquiry" and send your email to: QSOG_GeneralInquiries@cms.hhs.gov.

Effective Date: Immediately. Please communicate to all appropriate staff within 30 days.

/s/
David R. Wright
Director, Quality, Safety & Oversight Group

Attachment- Revised Appendix Q State Operations Manual

Resources to Improve Quality of Care:

Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid.

Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*
  See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus

Get guidance memos issued by the Quality, Safety and Oversight Group by going to CMS.gov page and entering your email to sign up. Check the box next to "CCSQ Policy, Administrative, and Safety Special Alert Memorandums" to be notified when we release a memo

State Operations Manual

Appendix Q – Core Guidelines for Determining Immediate Jeopardy

Table of Contents

(Rev. 187, Issued: 03-06-19)

I - INTRODUCTION

(*Rev.*)

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.

II– IMMEDIATE JEOPARDY REGULATIONS

(Rev. 187, Issued: 03-06-19, Effective: 03-06-19, Implementation: 03-06-19)

The following regulatory definitions of IJ have slight variations, but they contain the same key components that are essential for surveyors to use in determining if IJ is present across federally regulated entities:

- Standards for Payments to Intermediate Care Facility/Individuals with Intellectual Disabilities (ICF/IID) and Nursing Facility (NF) - §442.2
  Immediate Jeopardy means a situation in which immediate corrective action is necessary because the provider's noncompliance with one or more requirements of participation or conditions of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to an individual receiving care in a facility.
- Provider Agreements and Supplier Approval (except NFs, ICF-IIDs, & Laboratories) - §489.3 Immediate Jeopardy means a situation in which the provider's or supplier's noncompliance with one or more requirements, conditions of participation, conditions for coverage, or conditions for certification has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident or patient.
- Survey and certification of Long-Term Care Facilities (Skilled Nursing Facility (SNF), Nursing Facility (NF), and/or dually certified SNF/NF) - §488.301
  Immediate Jeopardy means a situation in which the provider'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.
- Laboratory Requirements (CLIA) - §493.2

Immediate Jeopardy means a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition 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. This term is synonymous with imminent and serious risk to human health and significant hazard to the public health.

NOTE: The standard used for Life Safety Code follows the regulatory requirements for each provider/supplier type, where LSC is applicable. Refer to the entity-specific subparts for further information.

III– DEFINITIONS

(Rev.)

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.

IV– KEY COMPONENTS OF IMMEDIATE JEOPARDY

(Rev. 187, Issued: 03-06-19, Effective: 03-06-19, Implementation: 03-06-19)

The regulatory definitions noted in section II above form the basis for identifying three key components that are essential for surveyors to use in determining the presence of IJ. These components include:

- **Noncompliance:** An entity has failed to meet one or more federal health, safety, and/or quality regulations;

  AND

- **Serious Adverse Outcome or Likely Serious Adverse Outcome:** As a **result** of the identified noncompliance, serious injury, serious harm, serious impairment or death has occurred, is occurring, or is likely to occur to one or more identified recipients at risk;

  AND

- **Need for Immediate Action:** The noncompliance creates a need for immediate corrective action by the provider/supplier to prevent serious injury, serious harm, serious impairment or death from occurring or recurring.

V- ANALYTIC PROCESS FOR DETERMINING IMMEDIATE JEOPARDY

(Rev.)

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.)

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.)

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.

VIII- Documenting Immediate Jeopardy on the Form CMS-2567

(Rev. 187, Issued: 03-06-19, Effective: 03-06-19, Implementation: 03-06-19)

When IJ has been identified and removed during the current survey or the revisit, the SA must ensure the core components of IJ and the actions taken by the entity to remove the IJ are documented on the Form CMS-2567. The documentation must identify and describe the following information:

- The date the IJ began (the date entity's noncompliance caused a serious adverse outcome, **or**
  made a serious adverse outcome likely), if known;
- The date the entity was notified;
- The specific requirement that has been violated, including a description of the noncompliance and the serious adverse outcome that occurred, or was likely to occur;
- Identification of recipients that were affected or were identified at risk of serious injury, harm, impairment, or death within the deficient practice statement;
- Date when the IJ was removed, as confirmed by an onsite verification by surveyor(s); and
- A statement of the seriousness of the remaining noncompliance, if any (i.e. Condition/ Standard/Element-level, or scope/severity).

Findings on the IJ Template which are presented by the survey team in the exit conference are always preliminary, whether the IJ is removed or not (SOM Chapter 2, Section 2724). After the survey ends, the SA (and/or RO) will review and discuss the findings of the Form CMS-2567 with the survey team.

During the review and/or enforcement process, the surveying entity (either the SA or RO) may determine that IJ exists based on survey results that have already been collected, but the IJ was not conveyed to the entity. The SA or RO must immediately notify the entity

that IJ has been determined. This is done by providing the IJ Template, which clearly and concisely communicates the noncompliance, the actual or likely serious adverse outcome to the recipient, and why the entity must take immediate corrective action to prevent the occurrence or recurrence of a serious adverse outcome or death. As necessary, the SA or RO may conduct additional onsite investigations.

The notice and/or Form CMS-2567 describing the IJ must be delivered within the timeframes specified in SOM, Chapter 3, section 3010. The SA will inform the RO of the presence of IJ for all Medicare and dually- participating entities. For Medicaid-only entities, the SA notifies the State Medicaid Agency and informs the RO per the protocol established between the SA and the RO.

If the RO determines that IJ exists and was not identified by the SA, the RO will immediately contact the SA for further discussion and the appropriate next steps to take. If the SA agrees with the RO that IJ exists, the SA will immediately notify the entity of the IJ by providing the IJ Template. In addition, the SA may determine that more information is necessary, and send a surveyor(s) to resume further investigation. In situations when the SA does not concur with the RO's determination of IJ, the RO will notify the entity of the IJ noncompliance. If the RO determines that further investigation is needed, the RO will make the necessary arrangements to send a surveyor team for additional investigation before IJ notice is sent. When this occurs, the RO and SA will collaborate to determine who will conduct the onsite revisit to determine if IJ is removed and/or corrected.

Even when IJ is removed prior to the exit conference, an onsite revisit will be required to determine substantial compliance. (See entity specific guidance for revisit requirements.)

IX- References

(Rev. 187, Issued: 03-06-19, Effective: 03-06-19, Implementation: 03-06-19)

Note: Please refer to the Appendix Q subparts for appropriate, provider-specific instruction.

Attachments: provider-specific subparts

- LTC Subpart
- CLIA Subpart

State Operations Manual:

- SOM 2700
  Survey Process
  - SOM §3005E
  - SOM §§3010-3012
  - SOM Chapter 6
  - SOM §§7307-7309
  - SOM Chapter 10
  - SOM Survey Appendices
  - SOM Exhibit 7A, "The Principles of Documentation for the Form CMS 2567"

X – SUBPART: LONG-TERM CARE (LTC)

(Rev. 187, Issued: 03-06-19, Effective: 03-06-19, Implementation: 03-06-19)

Long-Term Care Subpart to Appendix Q – Core Guidelines for Determining Immediate Jeopardy This document contains guidance specific to identification of Immediate Jeopardy (IJ) in Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs) (including dually-certified SNF/NFs), and is to be used in conjunction with the Appendix Q – Core Guidelines for Determining Immediate Jeopardy, which may be referred to as the Core Appendix Q.

The definition or IJ used in the survey process for SNFs and NFs is at 42 CFR 488.301 which states:

> "Immediate Jeopardy means a situation in which the provider'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."

As noted in the Core Appendix Q, to determine that IJ exists, surveyors must identify the key components: Noncompliance; Serious Injury, Harm, Impairment, or Death, or likelihood thereof; and Need for Immediate Action. Surveyors of LTC facilities must ensure that the evidence they gather supports citing the deficient practice at the severity level of Immediate Jeopardy versus a lesser severity level, and must attempt to identify, to the best of their ability, the duration of noncompliance.

Because it represents a critical situation, when IJ is suspected, the survey team, or surveyor in cases of complaint surveys, may have to temporarily stop all other survey tasks and investigations to conduct additional investigations to confirm or rule out the IJ.

A – KEY COMPONENTS OF IMMEDIATE JEOPARDY FOR LTC SURVEYORS

Noncompliance

Resources for Determining Noncompliance: There are a number of resources available to LTC surveyors to assist in establishing noncompliance. Some F-tags (survey data tags found in the Interpretive Guidelines for Long Term Care Facilities in Appendix PP) provide Key Elements of Noncompliance, which describe the elements necessary to prove noncompliance for that particular tag. In addition, surveyors should refer to the guidance in Appendix PP, the relevant Critical Element and Facility Task Pathways, and current standards of practice to assist in determining noncompliance.

If IJ is not identified but noncompliance continues, surveyors should proceed with their investigation to determine the appropriate severity level with the identified noncompliance, and incorporate it into the survey as they would other identified deficiencies.

Duration of noncompliance: While gathering evidence of noncompliance, LTC surveyors should attempt to identify at what point the entity's noncompliance made serious harm occur or likely to occur and if it has been removed or corrected. If removed, LTC surveyors should determine at what point it was removed, and whether the noncompliance continues at a lower scope and severity. This information may be used when determining the duration of enforcement remedies (See State Operations Manual [SOM], Chapter 7, Section 7510). It is not necessary for noncompliance to be present and ongoing at the time of the LTC survey in order for the LTC surveyor to cite IJ. If corrected, the surveyor should attempt to identify when the noncompliance was corrected and would be considered "past noncompliance" as discussed below.

Corrective Action Taken Before the Current Survey and Past Noncompliance:

Past Noncompliance means a deficiency citation at a specific survey data tag (F-tag or K-tag), that meets all of the following three criteria:

1. The facility was not in compliance with the specific regulatory requirement(s) (as referenced by the specific-tag) at the time the situation occurred;

2. The noncompliance occurred after the exit date of the last standard (recertification) survey and before the survey (standard, complaint, or revisit) currently being conducted, and

3. There is sufficient evidence that the facility corrected the noncompliance and is in substantial compliance at the time of the current survey for the specific regulatory requirement(s), as referenced by the specific tag.

Past noncompliance (PNC) at the IJ level refers to situations where the facility has taken sufficient corrective actions prior to the survey to both remove the immediate jeopardy and fully correct the noncompliance before the start of the survey.

PNC must be considered when the facility has taken all necessary action to achieve substantial compliance at the time of the current survey.

However, surveyors must investigate and verify through independent observations, interviews and record review, that the actions taken by the facility removed and corrected the IJ situation such that substantial compliance exists. In cases of PNC, no plan of correction or revisit is required because the facility is in substantial compliance at the time of the current survey; however, the Regional Office (RO) will have discretion to impose enforcement remedies in accordance with the CMP tool and (relevant sections of) Chapter 7 of the SOM.

Noncompliance which frequently triggers IJ concerns: Refer to the triggers identified in section B below for examples of noncompliance which frequently result in, or make likely, serious injury, serious harm, serious impairment, or death.

Serious Injury, Harm, Impairment, or Death

Nursing Home Residents' Vulnerabilities: Nursing homes care for some of the most vulnerable people in our society, often having high acuity and multiple co-morbidities. Because a particular vulnerability may make a resident more susceptible to serious harm, surveyors must consider the particular vulnerabilities of the individual resident at risk when determining whether noncompliance has resulted in, or has created the likelihood of serious injury, serious harm, serious impairment, or death. However, the vulnerability of nursing home residents should not result in an automatic IJ; each situation must be evaluated on its own terms to determine if the components of IJ are present.

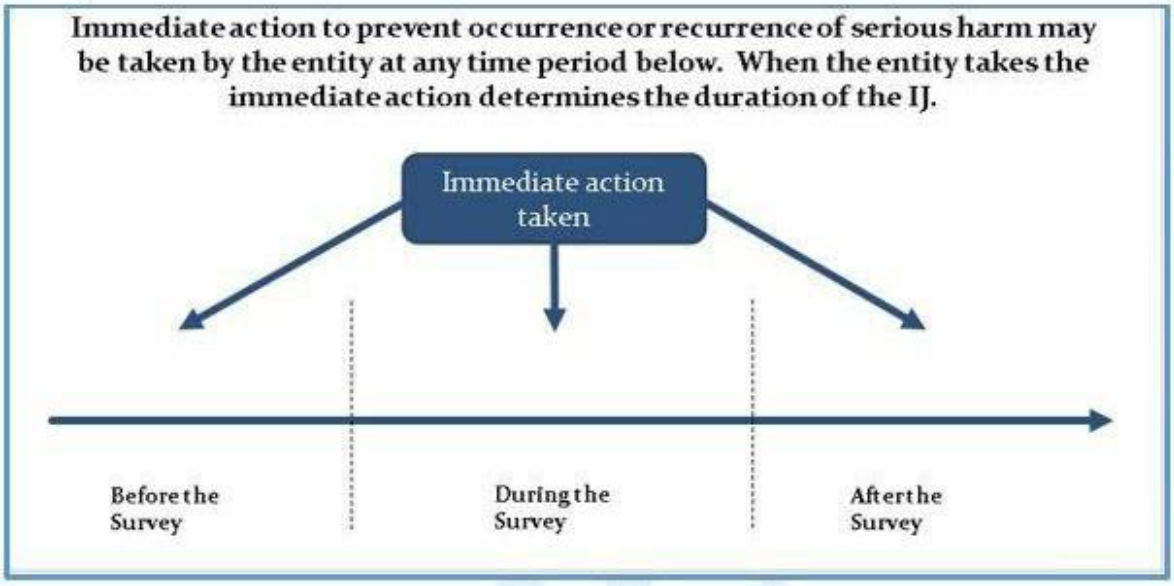
NOTE: Death always reaches the threshold for the component of serious harm.

Need for Immediate Action

When noncompliance causes a serious adverse outcome (i.e., serious injury, harm, impairment, or death to a resident), or creates the likelihood that a serious adverse outcome will occur, the facility 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.

It is important to understand that the need for immediate action does not exist only when a surveyor identifies it. The duration of IJ is determined when an entity takes the immediate action necessary to remove the IJ. As Graph #1 below shows, the facility can take the immediate action before, during, or after the survey. Therefore, facility action determines the duration of the IJ.

Graph#1



B – SITUATIONS WHICH TRIGGER THE NEED FOR FURTHER INVESTIGATION IN SNF/NFs.

This section lists possible resident outcomes and/or staff/facility actions which trigger the need for further investigation by the surveyor in SNFs/NFs. This list is not all-inclusive, but rather reflects examples that occur with some frequency. The triggers describe either outcomes to the resident, or actions taken by the facility or its staff, that should cause the surveyor to consider if further investigation is needed to determine the presence of IJ. The listed triggers do not automatically constitute IJ, however. Similarly, the triggers below are not the only outcomes or actions that can result in IJ. The team must investigate and use professional judgment to determine if the noncompliance has caused or is likely to cause serious harm, injury, impairment or death to a resident. The team must rely on professional judgment and utilize the resources of the State survey agency, and the RO to determine the presence of IJ.

NOTE: Serious Harm does NOT have to occur before considering IJ. Consider both likely and actual serious harm when reviewing the triggers in the table.

The table below provides a listing of examples of resident outcomes or facility staff action that would trigger further investigation into IJ. Please note, for purposes of identifying an IJ trigger, surveyors do not have to identify that both a resident outcome and a staff/facility action has occurred.

NOTE: This listing is neither an exhaustive list of possible IJs, nor does it contain all circumstances which require further investigation by surveyors.

Abuse
Resident Outcome/Experience
Non-consensual sexual contact e.g., unwanted intimate touching, sexual assault or battery
Unexplained head and/or bodily trauma, facial injuries, or fractures
Bruises around the breast or genital area; or unexplained bruising
Fear of a person or place, of being left alone, of being in the dark, disturbed sleep, or nightmares
Extreme changes in behavior, including aggressive or disruptive behavior
Withdrawal, isolating self, feelings of guilt and shame, depression, crying, talk of suicide or attempts, running away
Staff/Facility Action
Staff threatening, intimidating, humiliating, or demeaning a resident(s)
Staff to resident physical abuse
Taking, sharing or posting of sexually explicit photographs of residents
Rape, sodomy, or sexual assault of a resident
Failure to investigate allegations of abuse or neglect; or to implement policies to prevent abuse
Confinement in room or other area by blockade, device, or threat
Quality of Care/Quality of Life
Resident Outcome/Experience
Unexpected Death due to facility noncompliance
Withdrawal, isolating self, feelings of guilt and shame, depression, crying, talk of suicide or attempts, running away
Brain Damage that is avoidable and not solely due to normal progression of a disease or aging process
Significant decline in physical, mental, or psychosocial functioning, that is avoidable and not solely due to the normal progression of a disease or aging process. Examples may include, but are not limited to: • Observations of residents: o Crying out for help or in pain; o Appearing gaunt, or emaciated without a clinical rationale; o Appearing somnolent or lethargic without a clinical rationale.
Serious injury resulting from inadequate supervision, or failure to implement care plan, or follow physician orders
Loss of limb
Disfigurement
Avoidable Excruciating Pain
Sudden and/or unexpected onset of an acute significant decline given the resident's current clinical status
Sudden onset of unexpected somnolence or lethargy

Avoidable stage III/IV pressure ulcer development
Off-premises Elopement
Resident(s) found in unsafe location on-premises
Choking
Repeated Falls with one or more serious injuries
Sudden, unexpected onset of delirium, or other change in mental status
Acute respiratory distress
Staff/Facility Action
Inappropriate use of mechanical lifts
Life threatening medication error or life-saving medications not provided
Failure to honor one or more residents' advance directives
Failure to identify a significant change in condition in one or more residents
Pattern of unanswered call-bells, or unanswered call bell resulting in serious harm to one or more residents
Staffing numbers insufficient to provide basic care and services, or meet residents' basic needs
Discharge to destination that is unsafe, or does not meet the resident's immediate health and/or safety needs
Staff untrained or without sufficient competencies to meet the health and/or safety needs of one or more residents
Infection Control
Resident Outcome/Experience
Uncontrolled spread of a communicable disease or infection. Examples may include, but are not limited to no evidence of: • Surveillance activities; or • Immunization program for communicable diseases such as Influenza or Pneumonia;
Needle-stick Exposure to infectious disease
Staff/Facility Action
Using the same needles, syringes and/or finger-stick devices for more than one resident
Environmental/Structural
Resident Outcome/Experience
Chemical Burn
3rd Degree Burn
Unintended exposure to unsafe chemicals, poisons, or radiological agents
Exposure to excessive heat or cold
Bed or Side-rail Entrapment
Electrical Shock
Staff/Facility Action
Vendors and/or Employees not being Paid
Lack of, or inadequate emergency preparation. Examples may include, but are not limited to: • Lack of potable water supply; or sufficient food • Allowing temperatures to significantly raise or drop outside of 71 to 81 degrees.

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

(*Rev.*)

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 the 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.

XII – IMMEDIATE JEOPARDY TEMPLATE

(Rev. 187, Issued: 03-06-19, Effective: 03-06-19, Implementation: 03-06-19)

Immediate Jeopardy Template

Survey teams must use the Immediate Jeopardy (IJ) Template to document evidence of each component of IJ; and if IJ is confirmed, the IJ Template will be used to convey information to the entity. Any information presented on this template is subject to change and does not reflect an official finding against a Medicare provider or supplier. Form CMS-2567 is the only form that contains official survey findings.

Instructions: The survey team must use evidence gathered from observations, interviews, and record reviews to carefully consider each component of IJ outlined in the left-hand column of this template. In order for IJ to exist, the survey team must answer "Yes" to all three components and provide a preliminary fact analysis in the right hand column to support their determination. If IJ is confirmed by the survey team and SA Supervisor, provide this IJ Template to the entity and note the date and time that it was provided at the top of page 2. Use one IJ template for each tag being considered at IJ level.

For the purpose of completing this template, the following definitions apply:

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.

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.

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.

*NOTE: IJ does not require serious injury, harm, impairment or death to occur. It is sufficient that non-compliance makes serious injury, harm, impairment or death likely to occur to one or more recipients.

Date/Time IJ Template provided to entity: _____

IJ Component	Yes/No	Preliminary fact analysis which demonstrates when key component exists.
Noncompliance: Has the entity failed to meet one or more federal health, safety, and/or quality regulations? If yes, in the blank space, identify the tag and briefly summarize the issues that lead to the determination that the entity is in noncompliance with the identified 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 IJ level.	Yes/No	
A		
Serious injury, serious harm, serious impairment or death: Is there 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, briefly summarize the serious adverse outcome, or likely serious adverse outcome to the recipient.	Yes/No	
A		
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, briefly explain why.	Yes/No	

Disclaimer: The findings on this IJ Template are preliminary and do not represent an official finding against a Medicare provider or supplier. Form CMS-2567 is the only form that contains official survey finding.

Transmittals Issued for this Appendix

Rev #	Issue Date	Subject	Impl Date	CR#
R187SOMA	03/06/2019	Revision to the State Operations Manual (SOM 100-07) Appendix Q	03/06/2019	N/A
R102SOM	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
R01SOM	05/21/2004	Initial Release of Pub 100-07	N/A	N/A