# After the Survey

# LONG-TERM CARE SURVEY MANUAL PREPARED BY MU NHA CONSULTANT

### **SECTION 7 - AFTER THE SURVEY**

**After the Survey** - This section is designed to help you write an effective Plan of Correction and how to prepare the documentation needed to be ready for re-visit. You can find out how other licensed Missouri long-term care facilities did on their last inspection and how they wrote their plan at <a href="http://health.mo.gov/safety/showmelongtermcare/">http://health.mo.gov/safety/showmelongtermcare/</a>.

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

**Ref: QSO-19-09-ALL** 

Revised July 31, 2019

**DATE:** March 5, 2019 - *REVISED* 

**TO:** State Survey Agency Directors

**FROM:** Director

Quality, Safety & Oversight Group

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

\*\*\*Revised guidance to reinsert language referring criminal acts to law enforcement\*\*\*

#### **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 of all provider and supplier types in determining when to cite immediate jeopardy. 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.
- **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 for identifying immediate jeopardy. These revisions apply to all provider and supplier types. The revisions also include subparts that are focus on specific concerns with nursing homes and clinical laboratories.

#### **Application of Core Appendix O**

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 O**

The Core Appendix Q contains a number of key changes from the previous version of Appendix Q. Those changes include:

- <u>Likelihood instead of potential</u> 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.
- <u>Culpability has been removed</u> 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).

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• <u>No automatic immediate jeopardy citations</u> – 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 O

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.

#### **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 Integrated Surveyor Training Website at the following link: <a href="https://surveyortraining.cms.hhs.gov/">https://surveyortraining.cms.hhs.gov/</a>. This basic training is intended to provide Regional Office 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 RO and SA staff involved in immediate jeopardy determinations. All RO and SA surveyors, members of management, and training coordinators are expected to take this training as soon as practicable, but not later than March 22, 2019.

**Point of Contact:** For questions related to this information, please add in subject line "Immediate Jeopardy Inquiry" and send your email to: <a href="mailto:QSOG\_GeneralInquiries@cms.hhs.gov">QSOG\_GeneralInquiries@cms.hhs.gov</a>.

**Effective Date:** Immediately. This policy should be communicated to all survey and certification staff, their managers and the State and Regional Office training coordinators within 30 days of this memorandum.

/s/ David R. Wright Director

Attachment- Advanced Copy- Revised Appendix Q State Operations Manual

cc: Survey and Certification Regional Office Management

## **State Operations Manual**

# Appendix Q – Core Guidelines for Determining Immediate Jeopardy

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## **Transmittals for Appendix Q**

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XII - IMMEDIATE JEOPARDY TEMPLATE

#### **I** - INTRODUCTION

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

Immediate Jeopardy (IJ) represents a situation in which entity noncompliance 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 providers, suppliers, or laboratories (entities). An immediate jeopardy 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. Additional entity-specific guidance based on specific regulatory requirements is available to supplement this Core Appendix Q as necessary. Sections VI and VII of this appendix do not apply to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. Please see the CLIA-specific subpart for guidance on removing IJ and documenting 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. 187, Issued: 03-06-19, Effective: 03-06-19, Implementation: 03-06-19)

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:
  - o death;
  - o 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
  - o loss of limb, or disfigurement; or
  - o avoidable pain that is excruciating, and more than transient; or
  - o other serious harm that creates life-threatening complications/conditions.

#### • **Substantial Compliance** is:

- o One or more standard-level deficiencies with an acceptable Plan of Correction (PoC); or
- o 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.

**NOTE**: CLIA laboratories are determined to be either in compliance or not in compliance. A laboratory cited at the condition-level would be considered in compliance if a credible Allegation of Compliance (AoC) is received and verified.

## 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 <u>result</u> 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. 187, Issued: 03-06-19, Effective: 03-06-19, Implementation: 03-06-19)

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

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

A Determining Noncompliance Exists: The survey team must use applicable tasks, protocols and guidance from the State Operations Manual (SOM) and relevant Appendix Q subparts to establish that the provider is out of compliance with one or more of the federal health, safety, and/or quality regulations. The team must gather sufficient evidence through observation, interview, and record review to support the citation of noncompliance. This is done not only to verify the entity's noncompliance, but to also understand the extent, nature and scope of the noncompliance and to better understand the

impact or likely impact of the noncompliance on recipients at risk. The survey team must be able to explain what the noncompliance is, which regulation has been violated, and why the noncompliance rises to the level of IJ to their supervisor, the RO (if necessary), the entity, and finally, in their deficiency statement.

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

The survey team must identify all noncompliance that is related to the IJ situation. Noncompliance at the IJ level at one regulation or survey data tag, does not automatically trigger noncompliance at a related regulation or tag. Surveyors must analyze the facts of the noncompliance against the relevant regulations or tags. If the survey team finds that the same incident or facility practice results in multiple violations, the team must be able to articulate how the incident or practice represents a <u>distinct violation</u> of each regulation or tag. Although a comprehensive statement may contain facts illustrating deficiencies at multiple tags, surveyors may not simply copy and paste from one tag to another. Even if multiple deficiencies share common facts, surveyors may need to conduct additional investigation to evaluate additional tags thoroughly.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- When a recipient may not be able to express their feelings, there is no discernable
  response, or when circumstances may not permit the direct assessment of the
  recipient's psychosocial outcome. Such circumstances may include, but are not
  limited to, the recipient's death, cognitive impairments, physical impairments,
  emotional trauma, or insufficient documentation by the entity; or
- When a recipient's reaction to a deficient practice is markedly incongruent (or different) with the level of reaction a reasonable person would have to the deficient practice. These

situations most commonly occur when recipients suffer from cognitive impairment, brain injuries, or other disorders affecting a recipient's ability to show emotion.

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

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

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

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

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

## VI. Calling Immediate Jeopardv

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

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. CLIA surveyors do not request a removal plan. In the alternative, the laboratory will provide
  evidence of correction at the time their AoC is submitted. See CLIA subpart for more information.
   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. 187, Issued: 03-06-19, Effective: 03-06-19, Implementation: 03-06-19)

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.
- **CLIA**: IJs specific to laboratories may or may not be determined at the time of the onsite survey, so the surveyor/team should communicate with SA management and/or the CMS RO using current guidance. If IJ is identified at the time of the onsite survey, the surveyor/team will share its concerns with the laboratory, 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, (or AoC for CLIA) 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.

## <u>A – KEY COMPONENTS OF IMMEDIATE JEOPARDY FOR LTC SURVEYORS</u> 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.

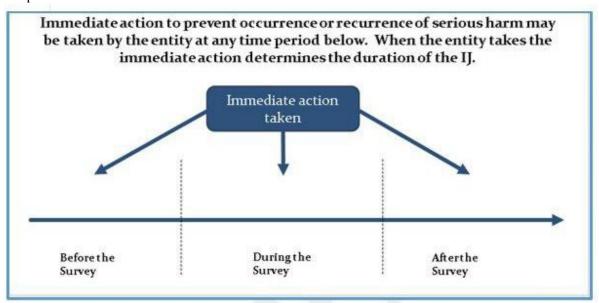
## **Need for Immediate Action**

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 immediate19

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.





#### 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.

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#### 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

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;
  - 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

3<sup>rd</sup> 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.

#### **IMPROVEMENT AMENDMENTS OF 1988 (CLIA)\***

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

## Determining Immediate Jeopardy (IJ)

The CLIA definition of IJ appears in the general section of Appendix Q.

In general, IJ is 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. The determination of IJ requires the laboratory take immediate action to remove jeopardy, and provide information or evidence that jeopardy has been removed. IJ is synonymous with imminent and serious risk to human health and significant hazard to the public health.

The three (3) components of immediate jeopardy are:

- Noncompliance: The laboratory is non-compliant with one or more Condition-level requirements.
- Serious Injury, Harm, or Death (Actual OR Likely): 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.
- Need for Immediate Action: Immediate corrective action is necessary to remove the jeopardy. The surveyor should first consider a laboratory out of compliance at the Condition-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.

The number of deficiencies does not necessarily relate to whether or not a Condition 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.

Next, determine if the Condition-level noncompliance reaches the level of immediate jeopardy. The surveyors should ask themselves:

- Do the deficient practices result in inaccurate or the high probability of inaccurate, unreliable, or untimely test results?
- Is the situation one in which immediate corrective action is necessary because the laboratory's noncompliance has already caused or is likely to cause serious injury, harm, or death to individuals served by the laboratory?
- Does the laboratory's continued activity(ies) constitute a significant hazard to individuals served by the laboratory or to the public health or safety of the general public?
- Do the deficiencies warrant immediate limitation or suspension of the laboratory's CLIA certificate?

• Is there information or data <u>not</u> available at the time of the survey, or within a reasonable time frame, that must be provided by the laboratory in order to determine if the deficient practice has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death?

In summary, the steps for regulatory considerations include:

- 1. Are CLIA regulatory deficiencies identified?
- 2. Does the deficiency(ies) constitute(s) Condition-level non-compliance?
  - Do the deficiencies prevent certification?
- 3. Does the Condition-level non-compliance pose an immediate jeopardy to patient health and safety?
  - Is there an option for other enforcement remedies?

#### Removal of IJ

Removal of IJ in CLIA laboratories requires the removal of past, present, and future jeopardy. Ceased testing by the laboratory removes the present and future IJ, but does not address past IJ. The laboratory must address how patients were affected, or likely affected, by the deficient practice which triggered IJ prior to its removal (i.e., past jeopardy).

Refer to SOM §6116.8, Figure 4-1.

Refer to SOM §6282, Noncompliance With One or More Conditions - Immediate Jeopardy Exists.

\*The following sections of the Core Document **do not apply** to CLIA:

- Section V, Section B, ¶¶ 3-6, Determining if Serious Injury, Serious Harm...
- Section V, Psychosocial/Mental Harm and using the Reasonable Person Concept
- Section VI
- Section VII

## 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 <u>reasonable expectation</u> that an adverse outcome resulting in serious injury, harm, impairment, or death <u>will occur</u> 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	•

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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	when key component exists.
		 <b>A</b>
Serious injury, serious harm,	Yes/No	
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.		
		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#	<b>Issue Date</b>	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

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

**Ref: QSO 18-18-NH** 

**DATE:** June 15, 2018

**TO:** State Survey Agency Directors

**FROM:** Director

Quality, Safety & Oversight Group

**SUBJECT:** Final Revised Policies Regarding the Immediate Imposition of Federal Remedies

### **Memorandum Summary**

- This memo replaces the following Survey & Certification (S&C) Memos: 16-31-NH released July 22, 2016 and revised on July 29, 2016, and S&C: 18-01-NH, released in draft on October 27, 2017. The October 2017 memo solicited comments on a proposed directive requiring, for certain situations, immediate imposition of federal remedies on Medicare and Medicaid participating skilled nursing facilities. After reviewing comments, CMS is issuing a final version of the directive. Substantive revisions to the prior Immediate Imposition of Federal Remedies guidance include:
  - When the current survey identifies Immediate Jeopardy (IJ) that does not result in serious injury, harm, impairment or death, the CMS Regional Offices may determine the most appropriate remedy;
  - We clarified that Past Noncompliance deficiencies (as described in §7510.1 of this chapter) are **not** included in the criteria for Immediate Imposition of Remedies; and,
  - For Special Focus Facilities (SFFs), S/S level "F" citations under tags F812, F813 or F814 are excluded from immediate imposition of remedies.
- Revisions to Chapter 7 of the State Operations Manual (SOM) (Attachment): The Centers for Medicare & Medicaid Services (CMS) has revised guidance in Chapter 7 of the SOM related to the Immediate Imposition of Federal Remedies as noted in this memo and its attachment. Other sections of Chapter 7 have been revised to ensure conformity and consistency with these revisions.

#### **Background**

Skilled Nursing Facilities (SNFs), Nursing Facilities (NFs) and dually participating facilities (SNF/NFs) are required to be in substantial compliance with Medicare and Medicaid requirements at all times and are always responsible for the health and safety of their residents.

The purpose of federal remedies, which are imposed after finding a facility is out of substantial compliance with Medicare and Medicaid requirements, is to encourage quick action on the part of facilities to promptly achieve, sustain, and maintain compliance with all federal requirements.

#### Page 2 – State Survey Agency Directors

When a facility fails to maintain compliance with federal Medicare and Medicaid participation requirements, there are specific statutorily mandated remedies under sections 1819 and 1919 of the Social Security Act that CMS is statutorily required to take that address higher scope and severity (S/S) harm level deficiencies, substandard quality of care and cases of extended noncompliance. To support the purpose of federal remedies, we are directing the immediate imposition of federal remedies in certain situations.

In addition to the required remedies that must be imposed when a facility is determined to be out of substantial compliance, CMS will select federal remedies that inspire a facility to act quickly in order to achieve compliance and maintain continued compliance with Medicare and Medicaid requirements. Noncompliance may occur for a variety of reasons; however, whenever a facility is out of substantial compliance, it is a danger to the health and safety of its residents and can result in harm or likely harm to residents.

The CMS Regional Offices (ROs) should consider the extent to which the cited noncompliance is a one-time mistake or accident, the result of larger systemic concerns, or a more intentional action or disregard for resident health and safety in order to select a remedy that protects the health, safety and well-being of patients by encouraging the facility to quickly achieve compliance with Medicare and Medicaid requirements. When facilities are out of substantial compliance for designated time periods, have deficiencies that harm residents in violation of quality of care regulations, have repeated deficiencies that harm residents or put them in immediate jeopardy, and when SFFs are cited for certain deficiencies, States must refer case information to CMS ROs for enforcement action as specified in Chapter 7 of the SOM.

## Revisions to Chapter 7 of the State Operations Manual (SOM), Chapter 7 - Survey and Enforcement Process for Skilled Nursing Facilities and Nursing Facilities (Attachment)

- CMS has revised guidance relating to the Immediate Imposition of Federal Remedies in Chapter 7 of the SOM as reflected in the advanced copy attached to this memo. Substantive revisions to the prior Immediate Imposition of Federal Remedies guidance S&C: 16-31-NH include:
  - When the current survey identifies Immediate Jeopardy (IJ) that does not result in serious injury, harm, impairment or death, the CMS RO must immediately impose a remedy. Some of the possible remedies include a civil money penalty (CMP), directed in service training, directed plan of correction. A complete list of enforcement remedies can be found at <a href="https://www.gpo.gov/fdsys/pkg/CFR-2014-title42-vol5/pdf/CFR-2014-title42-vol5-sec488-408.pdf">https://www.gpo.gov/fdsys/pkg/CFR-2014-title42-vol5/pdf/CFR-2014-title42-vol5-sec488-408.pdf</a>;
  - Clarifying that Past Noncompliance deficiencies (as described in §7510.1 of Ch. 7 of the State Operations Manual (i.e. Determining Citations of Past Noncompliance at the Time of the Current Survey) are **not** included in the criteria for Immediate Imposition of Remedies; and,
  - For SFFs, scope/severity level "F" citations under tags F812, F813 or F814 are
    excluded from immediate imposition of remedies. The complete list of all F-Tags is
    located at: <a href="https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/List-of-Revised-FTags.pdf">https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/List-of-Revised-FTags.pdf</a>

Other sections of Chapter 7 have been revised to ensure conformity and consistency with these revisions. Specifically, the following sections, which include previous language that has been

Page 3 – State Survey Agency Directors renumbered, moved and/or consolidated to provide better organized guidance:

- §7205 Survey Frequency: 15-Month Survey Interval and 12-Month Statewide Average
- §7205.1 Last Day of Survey
- §7205.1.1 Setting the Mandatory 3-Month and 6-Month Sanction Time Frames
- §7310 Immediate Jeopardy (IJ) Does Not Exist
- §7317 Acceptable Plan of Correction
- §7400.4 Other Factors That May Be Considered in Selecting Enforcement Remedy Within a Remedy Category
- §7510.1 Determining Citations of Past Noncompliance at the Time of the Current Survey

The final version of these revisions to Chapter 7, when published in the SOM may differ slightly from this attached interim advanced copy.

**Contact**: For questions related to this memo, please contact the DNH Triage Team at <a href="mailto:dnh\_triageteam@cms.hhs.gov">dnh\_triageteam@cms.hhs.gov</a>.

**Effective Date:** This memorandum will be effective within 30 days of its publication date. Therefore, this guidance should be communicated with all survey and certification staff, their managers, and the State/RO training coordinators within 30 days of this memorandum.

/s/ David R. Wright

Attachment: Advanced Guidance Revisions to SOM Chapter 7

cc: Survey and Certification Regional Office Management State Medicaid Agencies

CMS Manual System	Department of Health & Human Services (DHHS)	
Pub. 100-07 State Operations Provider Certification	Centers for Medicare & Medicaid Services (CMS)	
Transmittal- ADVANCE COPY	Date: XXXX	

SUBJECT: Revisions to the State Operations manual (SOM 100-07) Chapter 7

**I.** SUMMARY OF CHANGES: Revisions to the State Operations manual (SOM 100-07) Chapter 7 – To provide revisions in sections 7205 through 7205.1.1, 7304 through 7304.6, 7306 through 7306.4, 7308 through 7308.3, 7309 through 7309.5, 7310 through 7310.2, 7311 through 7311.3, 7313 through 7313.2, 7317, 7400 through 7400.5.3 and 7510.1.

## NEW/REVISED MATERIAL - EFFECTIVE DATE\*: Upon Issuance IMPLEMENTATION DATE: Upon Issuance

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.)

CHADTED/CECTION/CHDCECTION/TITLE
CHAPTER/SECTION/SUBSECTION/TITLE
Chapter 7/7205/ Survey Frequency: 15-Month Survey Interval and 12-
Month State-wide Average
Chapter 7/7205.1/ Last Day of Survey
Chapter 7/7205.1.1/ Setting the Mandatory 3-Month and 6-Month Sanction
Time Frames
Chapter 7/7304/ Mandatory Immediate Imposition of Federal Remedies
Chapter 7/7304.1/ Criteria for Mandatory Immediate Imposition of Federal
Remedies Prior to the Facility's Correction of Deficiencies
Chapter 7/7304.2/ Effective Dates for Immediate Imposition of Federal
Remedies
Chapter 7/7304.2.1/ Mandatory Criteria for Having No Opportunity to
Correct
Chapter 7/7304.2.2/ Additional State Discretion
Chapter 7/7304.3/ Responsibilities of the State Survey Agency and the
CMS Regional Office (RO) when there is an Immediate Imposition of
Federal Remedies
Chapter 7/7304.4/ Acceptable Plan of Correction
Chapter 7/7304.5/ Last Day of Survey
Chapter 7/7304.6/ Setting the Mandatory 3-Month and 6-Month
Chapter 7/7306/ Timing of Civil Money Penalties
Chapter 7/7306.1/ I Imposition of a Civil Money Penalty when a Facility is
not allowed an Opportunity to Correct

D	Chapter 7/7306.2/ Per Day Civil Money Penalty Imposed Upon Failure to Correct
D	Chapter 7/7306.3 When State Recommends a Civil Money Penalty for Past Noncompliance
D	Chapter 7/7306.4/ Amount
R	Chapter 7/7308/ Enforcement Actions When Immediate Jeopardy (IJ)
	Exists
D	Chapter 7/7308.1/ Action That Must Be Taken
D	Chapter 7/7308.2/ Enforcement Action That Must Be Taken
D	Chapter 7/7308.3/ Action That Must Be Taken
R	Chapter 7/7309/ Key Dates When Immediate Jeopardy (IJ) Exists
R	Chapter 7/7309.1/ 2nd Calendar Day
R	Chapter 7/7309.2/ 5th - 21st Calendar Day
R	Chapter 7/7309.3/ No Later Than 10th Business Day
R	Chapter 7/7309.4/ By 23rd Calendar Day
D	Chapter 7/7309.5/ By 23rd Calendar Day
R	Chapter 7/7310/ Immediate Jeopardy (IJ) Does Not Exist
D	Chapter 7/7310.1/ Introduction
D	Chapter 7/7310.2/ General
D	Chapter 7/7311/ Enforcement Action When Immediate Jeopardy Does Not Exist
D	Chapter 7/7311.1/ Actions to Be Taken
D	Chapter 7/7311.2/ Validation Authority
D	Chapter 7/7311.3/ Additional Action That Must Be Taken When
	Substandard Quality of Care Is Identified
R	Chapter 7/7313/ Procedures for Recommending Enforcement Remedies
	When Immediate Jeopardy (IJ) Does Not Exist
R	Chapter 7/7313.1/ Facilities Given an Opportunity to Correct Deficiencies
	prior to the Immediate Imposition of Federal Remedies
D	Chapter 7/7313.2/ Facilities Given an Opportunity to Correct Deficiencies
	prior to the Immediate Imposition of Federal Remedies
R	Chapter 7/7317/ Acceptable Plan of Correction
R	Chapter 7/7400/ Enforcement Remedies for Skilled Nursing Facilities
	(SNFs), Nursing Facilities (NFs) and Dually Participating Facilities
	(SNFs/NFs)
R	Chapter 7/7400.1/ Available Federal Enforcement Remedies
R	Chapter 7/7400.2/ Enforcement Remedies for the State Medicaid Agency
R	Chapter 7/7400.3/ Selection of Remedies
R	Chapter 7/7400.3.1/ Matrix for Scope & Severity
D	Chapter 7/7400.3.2/ Mandatory Enforcement Remedies
D	Chapter 7/7400.3.3/ Availability of State Medicaid Agency Remedies to the
	Regional Office in Dually Participating Facilities
R	Chapter 7/7400.4/ Other Factors That May Be Considered in Selecting
	Enforcement Remedy Within a Remedy Category
D	Chapter 7/7400.5/ Selection of Remedies
D	Chapter 7/7400.5.1/ Matrix for Scope & Severity
D	Chapter 7/7400.5.2/ Other Factors That May Be Considered in Selecting
<b>D</b>	Enforcement Remedy Within a Remedy Category
D	Chapter 7/7400.5.3/ Requirement for Facility to Submit Plan of Correction

R	Chapter 7/7510.1/ Determining Citations of Past Noncompliance at the	
	Time of the Current Survey	

## III. FUNDING: No additional funding will be provided by CMS.

## IV. ATTACHMENTS:

	<b>Business Requirements</b>
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

<sup>\*</sup>Unless otherwise specified, the effective date is the date of service.

## 7205 - Survey Frequency: 15-Month Survey Interval and 12-Month State-wide Average

(Rev.)

This section does not apply to the date of survey for remedy imposition and termination timeframes. The survey and certification provisions set forth in  $\S\S1819(g)(2)(A)(iii)$  and 1919(g)(2)(A)(iii) of the Act and in 42 CFR  $\S488.308$  require that each skilled nursing facility and nursing facility be subject to a standard survey no later than 15 months after the last day of the previous standard survey and that the statewide average interval between standard surveys of skilled nursing facilities and nursing facilities not exceed 12 months.

## 7205.1 - Last Day of Survey (Rev.)

The last day of survey is the last day of onsite observations during a survey, regardless of whether the exit conference was performed on that same day.

For purposes of computing three months or six months from a finding of noncompliance when the health and life safety code portions of the survey are on the same enforcement track, use the last day of onsite observations of the standard health survey on which the noncompliance was identified, regardless of which survey preceded the other. Even when the life safety code was the second of the two surveys to be performed on the same enforcement track, and it was the survey that found the noncompliance, the clock still starts on the last day of the standard health survey and will always be used to begin counting the number of noncompliance days. For purposes of the first notice of noncompliance, use the last day of the survey that found the cited noncompliance.

When two separate enforcement tracks are being used (one track for the health portion and one track for the life safety code portion of the standard survey), the mandatory denial of payment for new admissions and termination time frames would be three months and six months, respectively, for each separate portion.

## 7205.1.1 - Setting the Mandatory 3-Month and 6-Month Sanction Time Frames (Rev.)

These dates should be set based on full months rather than on a number of days. With few exceptions, these dates should be set by simply going to the same numerical date in the 3rd or 6th month following the survey date. For example, if a survey ended on January 15, the 3-month effective date for the mandatory denial of payment for new admissions remedy is April 15, and the 6-month mandatory termination date is July 15.

Exceptions to this rule involve those cases for which a 3-month or 6-month numerical date is not on the calendar. In these cases, move ahead a day or two to the beginning of the next month. For example, if a survey ended on January 31, the 3-month effective date for the mandatory denial of payment for new admissions remedy would be April 31. However, since there is no April 31, the 3-month effective date is May 1 and the 6-month mandatory termination date is July 31.

## 7304 - Mandatory Immediate Imposition of Federal Remedies (Rev.)

Noncompliance may occur for a variety of reasons and can result in harm to residents or put residents at risk for harm. When facilities do not maintain substantial compliance, CMS may use various enforcement remedies to address a facility's responsibility to promptly achieve, sustain and maintain compliance with all federal requirements. To support this purpose, we are directing the immediate imposition of federal remedies in certain situations outlined in §7304.1 below, and we recommend using the type of remedy that best achieves the purpose based on the circumstances of each case.

This guidance does not apply to **past noncompliance** deficiencies as described in §7510.1 of this chapter. The determination to impose a federal remedy for past noncompliance is not mandatory and is at the discretion of the CMS Regional Office (RO).

# 7304.1 - Criteria for Mandatory Immediate Imposition of Federal Remedies Prior to the Facility's Correction of Deficiencies (Rev.)

CMS will impose federal remedies and the survey will be identified as a "No Opportunity to Correct" if the situation meets any one or more of the following criteria:

- Immediate Jeopardy (IJ) (scope and severity levels J, K, and L) is identified on the current survey; **OR**
- Any deficiency from the current survey at levels "G, H or I" that falls into any of the regulatory sections that constitute Substandard Quality of Care (SQC); **OR**
- Any deficiency at "G" or above on the current survey AND if there were any deficiencies at "G" or above on the previous standard health or LSC survey or if there was any deficiency at "G" or above on any type of survey between the current survey and the last standard health or LSC survey. These surveys (standard health or LSC, complaint, revisit) must be separated by a certification of compliance, i.e., they must be from different noncompliance cycles. For instance, level G or above deficiencies from multiple surveys within the same noncompliance cycle must not be combined to make this a "double G or higher" determination; OR
- A facility classified as a Special Focus Facility (SFF) <u>AND</u> has a deficiency citation at level "F," *(excluding any level "F" citations under tags F812, F813 or F814)* or higher for the current health survey or "G" or higher for the current Life Safety Code (LSC) survey.

The remedies to be imposed by statute do not change, (e.g., 3-month automatic Denial of Payment for new admissions (DPNA), 23-day termination when IJ is present and 6-month termination). In addition to these statutory remedies, the CMS RO must also immediately impose one or more additional remedies for any situation that meets the criteria identified above. The State Survey and/or Medicaid Agencies shall not permit changes to this policy.

<u>Use of Federal Remedies in Immediate Jeopardy (IJ) Citations</u> - When IJ is identified on the current survey that resulted in <u>serious injury</u>, <u>harm</u>, <u>impairment or death</u>, a CMP **must** be imposed.

For IJ citations where there is **no resultant** serious injury, harm, impairment or death but the likelihood is present, the CMS RO must impose a remedy or remedies that will best achieve the

purpose of attaining and sustaining compliance. CMPs may be imposed, but they are not required.

NOTE: "Current" survey is whatever Health and/or LSC survey is currently being performed, e.g., standard, revisit, or complaint. "Standard" survey (which does not include complaint or revisit surveys) is a periodic, resident-centered inspection that gathers information about the quality of service furnished in a facility to determine compliance with the Requirements of Participation.

<u>Process for State Enforcement Recommendations</u> - While States are not required to recommend the types of remedies to be imposed, they are encouraged to do so since States may be more familiar with a facility's history and the specific circumstances in the case at hand. The CMS RO will consider these recommendations but ultimately makes the enforcement determination. To ensure effective communication and exchange of information, CMS encourages that all documentation is included in the ASPEN -Enforcement Manager (AEM) system or any subsequent system.

Regardless of a State's recommendation, the CMS RO must take the necessary actions to impose a remedy or multiple remedies, based on the seriousness of the deficiencies following the criteria set forth in 42 C.F.R. §488.404. Also refer to §§7400.5.1 and 7400.5.2 of this chapter. In addition to any statutorily imposed remedy, additional remedies should be selected that will bring about compliance quickly and encourage facilities to achieve and maintain compliance. When making remedy choices, the CMS RO should consider the extent to which the noncompliance is the result of a one-time mistake, larger systemic concerns, or an intentional action of disregard for resident health and safety.

The State Survey Agency is authorized to both recommend and impose one or more Category 1 remedies, in accordance with §7314 of this Chapter. **CATEGORY 1** remedies include:

- Directed plan of correction,
- State monitoring, and
- Directed in-service training.

<u>Types of Remedies</u> - The choice of remedy is made that best achieves the purpose of attaining and sustaining compliance based on the circumstances of each case and recommendations from the State. Federal remedies are summarized below. Refer to §§7500 - 7556 of this chapter for more detail on these remedies.

Civil Money Penalties (CMPs) - Federal CMPs may only be imposed by the CMS RO. If a CMP is imposed, it must be done in accordance with instructions in the CMP Analytic Tool and §§7510 through 7536 of this chapter.

Directed In-Service Training – Refer to §7502 of this chapter. Consider this remedy in cases where the facility has deficiencies where there are knowledge gaps in standards of practice, staff competencies or the minimum requirements of participation and where education is likely to correct the noncompliance. Depending on the topic(s) that need to be addressed and the level of training needed, facilities should consider using programs developed by well-established centers of geriatric health services such as schools of medicine or nursing, centers for the aging, and area health education centers which have established programs in geriatrics and geriatric

psychiatry. If it is willing and able, a State may provide special consultative services for obtaining this type of training. The State or regional office may also compile a list of resources that can provide directed in-service training and could make this list available to facilities and interested organizations. Facilities may also utilize the ombudsman program to provide training about residents' rights and quality of life issues.

**Directed Plan of Correction** Refer to §7500 of this chapter. This remedy provides for directed action(s) from either the State or CMS RO that the facility must take to address the noncompliance or a directed process for the facility to more fully address the root cause(s) of the noncompliance. Achieving compliance is ultimately the facility's responsibility, whether or not a directed plan of correction is followed.

Temporary Management - Refer to 42 CFR §§488.408 and 488.410. This is the temporary appointment by CMS or the State of a substitute facility manager or administrator with authority to hire, terminate or reassign staff, obligate facility funds, alter facility procedures, and manage the facility to correct deficiencies identified in the facility's operation. A temporary manager may be imposed anytime a facility is not in substantial compliance but may also be imposed when a facility's deficiencies constitute IJ or widespread actual harm and a decision is made to impose an alternative remedy in lieu of termination. It is the temporary manager's responsibility to oversee correction of the deficiencies and assure the health and safety of the facility's residents while the corrections are being made. The temporary manager's term can extend beyond the time which deficiencies are corrected by agreement of the facility and the temporary manager. A temporary manager remedy may also be imposed to oversee orderly closure of a facility. The State will select the temporary manager when the State Medicaid Agency is imposing the remedy and will recommend a temporary manager to the regional office when CMS is imposing the remedy. Each State should compile a list of individuals who are eligible to serve as temporary managers. These individuals do not have to be located in the State where the facility is located.

**Denial of Payment for all New Medicare and Medicaid Admissions (DPNA)** – See §7506 of this chapter. This remedy may be imposed alone or in combination with other remedies to encourage quick compliance. Regardless of any other remedies that may be imposed, a mandatory denial of payment for new admissions **must** be imposed when the facility is not in substantial compliance three months after the last day of the survey identifying deficiencies, or when a facility has been found to have furnished substandard quality of care on the last three consecutive standard surveys (see 42 CFR 488.414).

**Denial of all Payment for all Medicare and Medicaid Residents (DPAA) (Discretionary).** See §7508 of this chapter. Only CMS has the authority to deny all payment for Medicare and/or Medicaid residents. This is in addition to the authority to deny payment for all new admissions (discretionary) noted above. This is a severe remedy. Factors to be considered in selecting this remedy include but are not limited to:

- 1. Seriousness of current survey findings;
- 2. Noncompliance history of the facility; and
- 3. Use of other remedies that have failed to achieve or sustain compliance.

**State Monitoring** - Refer to §7504 of this chapter. A State monitor oversees the correction of cited deficiencies in the facility as a safeguard against further harm to residents when harm or a situation with a potential for harm has occurred. Consider imposing this remedy when, for example, there are concerns that the situation in the facility has the potential to worsen or the

facility seems unable or unwilling to take corrective action. A State monitor **must** be used when a facility has been cited with substandard quality of care (SQC) deficiencies on the last three consecutive **standard health** surveys.

**Termination of Provider Agreement -** See §7556 of this chapter. While this remedy may be imposed at any time the circumstances warrant regardless of whether IJ is present; regardless of any other remedies that may be imposed, termination of a facility's provider agreement **must** be imposed when the facility is not in substantial compliance six months after the last day of the survey identifying deficiencies or within no more than 23 days if IJ is identified and not removed.

#### 7304.2 - Effective Dates for Immediate Imposition of Federal Remedies (Rev.)

Once a remedy is imposed, it *becomes* effective as of the date *specified* in the notice letter *for the remedy being imposed*. All remedies remain in effect and continue until the facility *has demonstrated and is determined to be* in substantial compliance. Substantial compliance must be verified in accordance with §7317 of this chapter. Substantial compliance may be determined to occur anytime between the latest correction date on the approved Plan of Correction (PoC) up until the date of the revisit. The date of substantial compliance is determined by the date on which the evidence provided by the facility supports correction of deficiencies as determined by the Survey Agency.

For Immediate Jeopardy (IJ) Situations: A facility's removal of the conditions that caused the IJ may, at CMS's discretion, result in the rescission of the 23-day termination. A per day CMP must be lowered when the survey agency has verified that the IJ has been removed but deficiencies at a lower level continue. Refer to the CMP Analytic Tool instructions for determining the dates of a per day CMP. However, CMS shall not rescind any other remedies imposed until the facility achieves substantial compliance or is terminated. Remedies imposed must remain in effect, irrespective of when the IJ is removed, unless otherwise rescinded or revised as a result of legal proceedings. Remedies will be immediately imposed and effectuated whether the IJ was:

- removed during the survey, or,
- removed in a subsequent IJ removal revisit before the 23<sup>rd</sup> day.

# 7304.3 - Responsibilities of the State Survey Agency and the CMS Regional Office (RO) when there is an Immediate Imposition of Federal Remedies (Rev.)

When federal remedies are to be immediately imposed as outlined in §7304:

- Within five (5) business days after the last day of the current survey when any of the criteria in §7304.1 is met the survey agency **must** notify the CMS RO their review and action; and,
- The CMS RO will review these cases within five (5) business days of receipt from the survey agency and decide if an immediate imposition of remedies is appropriate.

Timeliness is important to ensure that remedies are imposed, and notices are sent to the facility before the effective dates of the remedies to be imposed and meet the timelines for notices as outlined in §7305 of this chapter.

The survey agency (State or Federal) must enter all of these cases as a NO opportunity to correct into the Automated System Processing Environment (ASPEN)/ASPEN Enforcement Manager (AEM) system within five (5) business days of sending the initial notice to the facility. The State Survey Agency and the CMS RO must have systems in place to routinely check and monitor the ASPEN-AEM database to identify cases that may require enforcement action or additional follow-up, as needed.

## 7308 - Enforcement Actions When Immediate Jeopardy (IJ) Exists (Rev.)

If at any time during the survey one or more team members identify a possible IJ, the team must meet immediately to confer. If the team agrees that deficiencies constitute IJ, the team leader must contact, while on-site, its management to discuss the findings. If it is determined that IJ exits the team must notify the facility administration, while on-site, of the IJ findings.

When the State Survey Agency identifies IJ, it must notify the CMS Regional Office (RO), or the State Medicaid Agency, or both, as appropriate, so that either agency terminates the provider agreement within 23 calendar days of the last date of the survey, and/or appoints a temporary manager who must remove the IJ within 23 calendar days of the last date of the survey which identified the IJ. When the CMS RO imposes termination of a Medicaid provider agreement, it notifies the State Medicaid Agency to terminate the agreement. However, action can be taken more quickly than 23 days as long as the required notice is given. In either case, the IJ must be removed no later than 23 days from the last day of the survey or the provider agreement will be terminated.

In addition, when IJ is identified on the current survey, (whatever Health and/or LSC survey is currently being performed, e.g., standard, revisit, or complaint), that resulted in <u>serious injury</u>, harm, impairment or death a CMP **must** be imposed.

For IJ citations where there is no resultant serious injury, harm, impairment or death but the likelihood is present, a remedy must be imposed; however, the CMS RO may select any remedy that best achieves the purpose of achieving and sustaining compliance and address various levels of noncompliance. See Section 7400 which describes available remedies.

When IJ is identified, the facility must submit an allegation that the IJ has been removed. This allegation must include a plan of sufficient detail to demonstrate how and when the IJ has been removed.

A plan of correction for the deficiencies should be deferred until a revisit is conducted to verify the removal of the IJ. Documentation resulting from the revisit must be completed indicating whether the IJ was removed and deficiencies corrected (Form CMS-2567B), or that the IJ was removed but compliance had not been achieved (Form CMS-2567). When a new Form CMS-2567 is necessary, it should be written with evidence that supports the remaining noncompliance.

**NOTE:** In order for a 23-day termination to be stopped, the IJ **must be removed, even if the underlying deficiencies have not been fully corrected.** Waiting for acceptable plans of correction can result in undue delay in determining removal of IJ. Therefore, plan of corrections should be deferred until the IJ is removed.

If the facility alleges that the IJ is removed and a revisit verifies that it has been removed but the facility is still not in substantial compliance, use the non-IJ process, which requires a plan of correction for all citations. Waiting for the complete statement of deficiencies (Form CMS-2567) and the facility's plan of correction for the non-IJ deficiencies can result in undue delay in determining removal of IJ. Therefore, a Statement of Deficiencies (Form CMS-2567) and a facility's plan of correction for the non-IJ deficiencies may be deferred until the survey agency verifies the IJ is removed.

In addition, whenever a facility has deficiencies that constitute both IJ **and** substandard quality of care (SQC) (as defined in 42 CFR §488.301), the survey agency must notify the attending physician of each resident found to have received SQC as well as the State board responsible for licensing the facility's administrator. Notify physicians and the administrator licensing board in accordance with §7320.

## 7309 - Key Dates When Immediate Jeopardy (IJ) Exists (Rev.)

NOTE: These timelines apply whether the survey was conducted by a State Survey Agency, CMS Regional Office (RO) or a CMS contractor.

## **7309.1 - 2nd Calendar Day** *(Rev.)*

No later than two (2) calendar days (one of which must be a working day) following the last date of the survey which identified *the IJ* the *survey entity must notify* in writing;

- The CMS RO and the State Medicaid Agency of its findings by e-mail or facsimile (FAX): and,
- The facility of the IJ findings and that the survey entity is recommending to the CMS RO and the State Medicaid Agency that the provider agreement be terminated and that a Civil Money Penalty (CMP) or other remedies may be imposed. A temporary manager may be imposed in lieu of or in addition to termination (see §488.410)

This *notice may also* serve as *the* formal notice *from the State Survey Agency* for imposition of any category 1 remedy or denial of payment for new admissions remedy when authorized by *the* CMS *RO* and/or the State Medicaid Agency. *This notice must also* include the facility's right to informal dispute resolution *(IDR)* or an independent informal dispute resolution *(IIDR)* and to a formal appeal of the noncompliance.

**Note:** this written notice is separate from the survey entity's responsibility to inform the facility onsite during the survey of the IJ findings and their responsibility to provide a written allegation of removal of the IJ with sufficient detailed information to demonstrate how and when the IJ was removed.

7309.2 - *5th - 21st Calendar Day* (*Rev.*)

Except when formal notice of remedies is provided by the State *Survey Agency*, as authorized by CMS and/or the State Medicaid Agency, the *CMS RO* and/or the State Medicaid Agency issues a formal notification of remedies to the facility. In addition, the notice should include the facility's right to a formal appeal of the noncompliance which led to the temporary management remedy, termination, or any other enforcement actions (except State monitoring). For the temporary management remedy, the notice will advise the facility of the conditions of temporary management and that failure to relinquish control to the temporary manager will result in termination. The general public is also given notice of the impending termination.

#### 7309.3 - No Later Than 10th Business Day (Rev.)

If the survey entity verifies that the IJ has been removed, then it must send the Statement of Deficiencies (Form CMS-2567) to the facility.

**NOTE:** The facility must submit *a written* allegation of removal of the *IJ* with sufficient *detailed* information to *demonstrate* how *and when* the *IJ w*as removed. If a *PoC* is to be submitted, it must be received no later than 10 calendar days after the facility receives their *Statement of Deficiencies (Form CMS-2567)*.

## 7309.4 - *By 23rd Calendar Day* (*Rev.*)

Termination takes effect unless the *IJ* has been removed.

## 7310 - Immediate Jeopardy (IJ) Does Not Exist (Rev.)

These procedures incorporate  $\S\S1819(h)(2)(A)(ii)$ , 1919(h)(1)(B), and 1919(h)(3)(B)(ii) of the Act, as well as implementing regulations in 42 CFR 488.412.

The broad array of remedies varies in form and severity in recognition of the fact that there can be variations in impact posed by each violation of participation requirements. Therefore, while provider agreement terminations are authorized in non-immediate jeopardy cases, it is not generally necessary or desirable to choose that remedy when substantial compliance may be achieved rapidly through imposition of one or more alternative remedies.

When the surveying entity finds that a facility's deficiencies do not pose IJ to resident health or safety, but the facility is not in substantial compliance, the surveying entity may recommend that the enforcing entity either terminate the facility's provider agreement, or impose alternative remedies, or do both. The State may also provide formal notice of imposition and rescission of category I remedies and/or denial of payment for new admissions, as authorized by CMS and/or the State Medicaid Agency. The action may be taken immediately, or the facility may be given an opportunity to correct, as described in §7304.

When the CMS Regional Office finds through a validation survey or review of the State's findings that any of the facility's deficiencies do not pose IJ to resident health or safety but the facility is not in substantial compliance, the CMS Regional Office must, as appropriate, take action itself to

terminate the facility's provider agreement (or stop Federal financial participation), or impose alternative remedies instead of terminating the provider agreement, or both; or direct the State Medicaid Agency to terminate the facility's Medicaid provider agreement. The authority for CMS to take enforcement action for any nursing facility, when CMS finds the nursing facility to be out of compliance, is at  $\S1919(h)(3)(A)$  and (B).

## 7313 - Procedures for Recommending Enforcement Remedies When Immediate Jeopardy (IJ) Does Not Exist (Rev.)

Once noncompliance is identified, the surveying entity *must first* determine whether to *immediately* impose remedies *in accordance with the criteria in §7304.1* or give the facility an opportunity to correct its deficiencies before *remedies* are imposed.

## 7313.1 - Facilities Given an Opportunity to Correct Deficiencies prior to the Immediate Imposition of Federal Remedies (Rev.)

A facility may be permitted to correct its deficiencies and delay the imposition of remedies only when the criteria outlined in §7304.1 of this chapter are not met. Facilities must submit an acceptable plan of correction for its deficiencies (other than Scope/Severity level A).

## 7317 - Acceptable Plan of Correction (Rev.)

Except in cases of past noncompliance, facilities having deficiencies (other than those at scope and severity level A) must submit an acceptable plan of correction. An acceptable plan of correction must:

- Address how corrective action will be accomplished for those residents found to have been affected by the deficient practice;
- Address how the facility will identify other residents having the potential to be affected by the same deficient practice;
- Address what measures will be put into place or systemic changes made to ensure that the deficient practice will not recur;
- Indicate how the facility plans to monitor its performance to make sure that solutions are sustained; and
- Include dates when corrective action will be completed. The corrective action completion dates must be acceptable to the State. If the plan of correction is unacceptable for any reason, the State will notify the facility in writing. If the plan of correction is acceptable, the State will notify the facility by phone, e-mail, etc. Facilities should be cautioned that they are ultimately accountable for their own compliance, and that responsibility is not alleviated in cases where notification about the acceptability of their plan of correction is not made timely.

The plan of correction serves as the facility's allegation of compliance and, without it, CMS and/or the State have no basis on which to verify compliance. A plan of correction must be submitted within 10 calendar days from the date the facility receives its Form CMS-2567. If an acceptable

plan of correction is not received within this timeframe, the State notifies the facility that it is recommending to the RO and/or the State Medicaid Agency that remedies be imposed effective when notice requirements are met. The requirement for a plan of correction is in 42 CFR 488.402(d). Further, 42 CFR 488.456(b)(ii) requires CMS or the State to terminate the provider agreement of a facility that does not submit an acceptable plan of correction.

A facility is not required to provide a plan of correction for a deficiency cited as past noncompliance because that deficiency is corrected at the time it is cited; however, the survey team must document the facility's corrective actions on Form CMS-2567.

## 7400 - Enforcement Remedies for Skilled Nursing Facilities (SNFs), Nursing Facilities (NFs) and Dually Participating Facilities (SNFs/NFs) (Rev.)

Sections 1819(h) and 1919(h) of the Act, as well as 42 CFR §§488.404, 488.406, and 488.408, provide that CMS or the State may impose one or more remedies in addition to, or instead of, termination of the provider agreement when the State or CMS finds that a facility is out of compliance with federal requirements. Enforcement protocols/procedures are based on the premise that all requirements must be met and take on greater or lesser significance depending on the specific circumstances and resident outcomes in each facility.

## 7400.1 - Available Federal Enforcement Remedies (Rev.)

*In accordance with 42 CFR §488.406, the following remedies are available:* 

- Termination of the provider agreement;
- Temporary management;
- Denial of payment for all Medicare and/or Medicaid residents by CMS;
- Denial of payment for all new Medicare and/or Medicaid admissions;
- *Civil money penalties;*
- State monitoring;
- *Transfer of residents;*
- *Transfer of residents with closure of facility;*
- *Directed plan of correction;*
- Directed in-service training; and
- Alternative or additional State remedies approved by CMS.

## 7400.2 - Enforcement Remedies for the State Medicaid Agency (Rev.)

Regardless of what other remedies the State Medicaid Agency may want to establish in addition to the remedy of termination of the provider agreement, it must establish, at a minimum, the following statutorily-specified remedies or an approved alternative to these specified remedies:

- *Temporary management;*
- Denial of payment for all new admissions;
- *Civil money penalties;*
- Transfer of residents;

- Transfer of residents with closure of facility; and
- State monitoring.

The State Medicaid Agency may establish additional or alternative remedies if the State has been authorized by CMS to do so under its State plan. Guidance on the review and approval (or disapproval) of State Plan amendment requests for alternative or additional remedies can be found in §7805.

Whenever a State Medicaid Agency's remedy is unique to its State plan and has been approved by CMS, then that remedy may also be imposed by the Regional Office against the Medicare provider agreement of a dually participating facility in that State. For example, where CMS has approved a State's ban on admissions remedy as an alternative remedy under the State plan, CMS may impose this remedy but only against Medicare and Medicaid residents; only the State can ban the admission of private pay residents.

## 7400.3 - Selection of Remedies (Rev.)

To select the appropriate remedy(ies) for a facility's noncompliance, the seriousness, scope and severity of the deficiencies must first be assessed. The purpose of federal remedies is to address a facility responsibility to promptly achieve, sustain and maintain compliance with all federal requirements. In addition to the required enforcement action(s), remedies should be selected that will bring about compliance quickly. While a facility is always responsible for all violations of the Medicare and Medicaid requirements, when making remedy choices, the CMS RO should consider the extent to which the noncompliance is the result of a one-time mistake, larger systemic concerns, or an intentional action of disregard for resident health and safety.

## 7400.3.1 - Matrix for Scope & Severity (Rev.)

Immediate jeopardy to resident health or safety	J	<i>K</i>	L
Actual harm that is not immediate	G	H	I
No actual harm with potential for more than minimal harm that is not immediate jeopardy	D	E	F
No actual harm with potential for minimal harm	A No PoC	В	C
	Isolated	Pattern	Widespread

Substandard Quality of Care (SQC) is defined in 42 C.F.R. §488.301 as one or more deficiencies which constitute either immediate jeopardy to resident health or safety; a pattern of or widespread actual harm that is not immediate jeopardy; or a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm, related to certain participation requirements.

# 7400.4 - Other Factors That May Be Considered in Selecting Enforcement Remedy Within a Remedy Category (Rev.)

Substantial compliance means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm. Substantial compliance constitutes compliance with participation requirements (42 C.F.R. §488.301).

Additional factors that may be considered to assist in determining which and/or how many remedies to impose within the available remedy categories for levels of noncompliance, include but are not limited to:

- The relationship of one deficiency to other deficiencies;
- The facility's prior history of noncompliance in general, and specifically with reference to the cited deficiencies; and
- The likelihood that the selected remedy(ies) will achieve correction and continued compliance.

**EXAMPLE:** If failure to spend money is the root cause of the facility's noncompliance, then any civil money penalty that is imposed should at least exceed the amount saved by the facility by not maintaining compliance.

## 7510.1 – Determining Citations of Past Noncompliance at the Time of the Current Survey (Rev.)

Past noncompliance may be identified during any survey. For the purpose of making determinations of current noncompliance or past noncompliance, the survey team is expected to follow the investigative protocols and surveyor guidance. To cite past noncompliance with a specific survey data tag (F-tag or K-tag), all of the following three criteria must be met:

- 1. The facility was not in compliance with the specific regulatory requirement(s) (as referenced by the specific F-tag or K-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 F-tag or K-tag.

A nursing home does not provide a plan of correction for a deficiency cited as past noncompliance because the deficiency is already corrected; however, the survey team documents the facility's corrective actions on the CMS-2567.

Regulations at 42 CFR 488.430(b) provide that a civil money penalty (*CMP*) may be imposed for past noncompliance since the last standard survey. CMS strongly urges States to recommend the imposition of a *CMP* for past noncompliance cited at the level of immediate jeopardy.

When a *CMP* is recommended, the State *Survey Agency* notifies the *CMS* Regional Office (*RO*) and/or State Medicaid Agency within 20 days from the last day of the survey that determined past noncompliance of its recommendation to impose a *CMP*. The *CMS RO* and/or State Medicaid Agency responds to the recommendation within 10 days, and if accepted, sends out the formal notice in accordance with the notice requirements in §7305 and §7520.

#### Class I, I/II, II, II/III, or III is noted in the Requirements column of the Inspection Results, usually at the end of the regulatory text

#### Class I

A violation which presents either an imminent danger to the health, safety or welfare of any resident or a substantial probability that death or serious physical harm would result. This is the most severe classification of State deficiencies. If an inspection results in any Class I violations, inspectors will revisit the facility within 20 days.

#### Class II

A violation which has a direct or immediate relationship to the health, safety or welfare of any resident, but which does not create any imminent danger. This is the intermediate classification of State deficiencies. If an inspection results in any Class II violations, but no Class I violation, inspectors will revisit the facility between 40 and 90 days.

#### **Class III**

A violation which has an indirect or a potential impact on the health, safety or welfare of any resident. This is the least severe classification of State deficiencies. If an inspection results in less than twenty Class III violations and no Class II or Class I violations, the facility is considered to be in substantial compliance and no revisits are required. These violations are not required to be corrected; therefore a correction date may not be displayed on the website. If an inspection results in twenty or more Class III violations and no Class II or Class I violations, inspectors will revisit the facility within 120 days.

#### Class I/II

This violation may be cited as a Class I or a Class II. It will be cited at the lower classification, Class II, unless there is sufficient evidence to support the more severe classification of Class I.

#### Class II/III

This violation may be cited as a Class II or a Class III. It will be cited at the lower classification, Class III, unless there is sufficient evidence to support the more severe classification of Class II.

#### HOW TO WRITE A PLAN OF CORRECTION

#### 1. The first statement on the plan of correction should be a disclaimer such as:

"Preparation and execution of this plan of correction does not constitute admission or agreement by this provider of the truth of the facts alleged or conclusions set forth in the Statement of Deficiencies. The plan of correction is prepared and executed solely because it is required by the provisions of federal and state law".

#### 2. For each deficiency cited you must include in the POC the following information:

- a. How will you correct the deficiency for the residents who were cited? Explain what you did to correct the issues that were identified for each of these residents.
- b. What did you do to try to identify any other residents who may be affected by the same deficient practice? What did you do to identify other residents who have the potential to have the same issue? Audits, reviews, interviews, etc. If this is an environmental tag what did you do to identify any other issues in the facility related to this tag.
- c. What system will you put in place to correct the deficient practice and make surethat the problem remains fixed. This will include in-servicing, a change in the system approach, a change in the review process, etc. You must make some sort of change because whatever the facility was previously doing did not work.
- d. How will you monitor the system to make sure that the changes that have been made stay in place? You must include how you will monitor with your QA procedure. What type of monitoring, who will do the monitoring and how often will it be done.
- e. By what date will you complete this process. The Section for Long Term Care Regulations expects that no plan of correction date exceed *45 days* from date of exit.
- 3. Be careful not to put something in your POC that may be difficult or impossible for the facility to comply or keep in place.

#### PUTTING TOGETHER A "CREDIBLE ALLEGATIONS" BOOK

After the survey the facility should immediately start working on their plan of correction. The facility should have some idea what deficiencies the state has identified and why. A plan needs to be put into place for in-servicing, reviewing/updating chart information, completing assessments, auditing processes etc. Everything that is done after the survey should be documented and maintained for the "re-visit".

Once the 2567 (statement of deficiencies) is received and your plan of correction has been completed a "Credible Allegations" book should be put together. In this book there should be a divider for each deficiency. A copy of that specific deficiency and your plan of correction should be placed behind each divider. Everything that is done to clear that deficiency should be copied and added to the binder. This will include audits, reviews, in-services, updates of any information that may have been changed such as the care plan, assessments, physician orders, etc. The idea of the book is to provide the surveyor with all the information necessary to clear the tag without ever leaving the office. Most surveyors will still be on the floor and looking at the items, but they should not have to ask for any information. Everything they need to validate your plan of correction should be in the book. If an in-service is completed and it covers more than one deficiency, make a copy of that in-service for each deficiency covered. A copy of the facility employee roster should be obtained with any information other than name and job title erased. This can then be used as your in-service sign-in sheet which will ensure that all the employees for that respective deficiency has been in-serviced. For each deficiency, highlight the area that speaks of the specific deficiency and place a copy behind each divider. (Example: you in-service nursing staff on hand-washing for the infection control tag (F-880) and peri-care for the ADL tag (F-677) during the same inservice. You will make two copies of the in-service. You will highlight the first copy where you covered hand-washing and place that copy under F-880. Then highlight the 2nd copy where you covered peri-care and place that copy under F-677. Be sure to copy the signature sheet also.

If your plan of correction stated you would do daily audits, there should be an audit for each day of the week in the book. If you are doing weekly audits, there needs to be one for each week, etc. You should also create a list of items needed to make sure your book is complete and check them off as you receive and place in your book. Each day there should be a status update on each tag and any audits collected from the day before.

All Notebooks should be kept in a single place which is the Administrator's Office. Management staff should know where this information is kept, in case the re-visit occurs when you're not present.

#### **GETTING READY FOR RE-VISIT**

- 1. Be sure that everything is completed in your Credible Allegations Book by the deadline you set as your date of compliance.
- 2. Follow up on any issues that may have developed while working your plan of correction.
- 3. Monitor to assure no "new problems" arise that could result in a new deficiency. Do not let your current systems go down while working on your POC.
- 4. Be sure all staff are aware of the re-visit and are always prepared.
- 5. Continue your room rounds by department heads and your resident monitoring systems.
- 6. Review your POC, in its entirety, a minimum of weekly to make sure that you have not failed to review/correct an item. Status updates on corrective action(s) and completed audits should be reviewed daily and inserted in your "Credible Allegations Book.
- 7. Be sure to review you plan of correction at your monthly QA meeting.

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