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The New Appendix Q – CMS State Operations Manual Changes Overhaul Immediate Jeopardy For Providers And Suppliers

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OVERVIEW

The Centers for Medicare and Medicaid Services issued a Quality, Safety and Oversight Memo on March 5, 2019, which will change how state agency and CMS surveyors will analyze and identify situations of Immediate Jeopardy.

IN DEPTH

On March 5, 2019, the Centers for Medicare and Medicaid Services (CMS) issued a Quality, Safety and Oversight Memo, QSO-19-09-ALL (the Memo), which fundamentally changes the manner in which state agency and CMS surveyors will analyze and identify situations of Immediate Jeopardy (IJ) on survey. IJ generally refers to a situation where a provider or supplier's noncompliance with one or more regulatory requirements or conditions has caused, or is likely to cause, serious injury, harm, impairment or death to a recipient of health care services. While this general definition varies slightly within the regulations applicable to each type of provider and supplier, the common baseline principle confirms that IJ is reserved for serious situations involving harm. Seema Verma, Administrator of CMS, noted in the CMS release accompanying the Memo that it is "critical that federal and state inspectors accurately identify, thoroughly investigate, and ensure immediate jeopardy situations are resolved decisively and swiftly."

The survey guidance provided in Appendix Q, as is the case with the interpretive guidance throughout the CMS State Operations Manual (SOM), is "sub-regulatory" in nature, meaning that the usual provisions for changes in regulations, and most notably a public notice and comment period, are not required. CMS identified that the guidance changes described in the Memo are immediately effective, and that CMS staff and surveyors are to receive the information within 30 days and complete related training as soon as possible.

What's New in Appendix Q?

The Memo revises Appendix Q to the SOM, which provides survey guidance on Immediate Jeopardy, and introduces the use of a new survey tool and processes to help more consistently identify and

provide evidence of Immediate Jeopardy status during a survey. Additional changes in terminology and processes draw focus to serious adverse outcome or the likelihood of their occurrence, manner of calling and removing IJ and IJ's application to certain provider and supplier types.

New Key Components of IJ

The previous version of Appendix Q, implemented in 2014, identified three "key components" of IJ, and surveyors were instructed to consider these features along with a series of "triggers" that would trigger a further investigation to determine the presence of IJ. Numerous illustrative examples of IJ determinations were also provided. The Memo shifts this perspective, and revises the key components of IJ to align more closely to the general definition of IJ in the various regulations applicable to providers and suppliers, as depicted in the chart below.

Key Components of Immediate Jeopardy	
Prior Appendix Q (effective 2/14/2014)	**New Appendix Q (effective 3/5/2019)**
Harm - of a patient or resident, whether actual or potential	***Noncompliance*** - with one or more federal health, safety and/or quality regulations
Immediacy - that will occur in the near term if no action is taken	***Serious Adverse Outcome or Likely Serious Adverse Outcome*** - as a result of such noncompliance, including serious injury, serious harm, serious impairment or death
Culpability - which the entity knew or should have known about, investigated and corrected	***Need for Immediate Action*** - such that the noncompliance creates a need for immediate corrective action to prevent a serious adverse outcome from occurring or recurring

Likelihood v. Potential

One important change within the new components of IJ is the replacement of "potential" harm with the standard that surveyors identify the "likelihood" of a serious adverse outcome. IJ exists both when the noncompliance causes actual harm, and when the surveyor determines that the noncompliance makes serious harm, injury, impairment or death likely. This new perspective requires surveyors to determine whether a specific serious adverse outcome is "reasonably expected to occur", which is more specific than identifying the mere potential for harm to exist. The Memo specifies that surveyors determine likelihood based upon their professional judgment, taking into account the scope and nature of the identified noncompliance, the circumstances and vulnerabilities

of the individuals at risk, and any other relevant factors, including the magnitude of the actual or likely serious adverse outcome.

New IJ Template

The Memo also introduces the use of a new IJ Template as a means for surveyors to provide notice to providers and suppliers of an IJ determination in a manner that is more transparent and timely than the prior process. Under the prior process, IJ could be called at any point during a survey or at an exit conference verbally, with no set form for written communication of the determination. In this structure, providers and suppliers would sometimes be left to figure out the potential IJ basis for themselves, with little guidance, or be told of the IJ determination long after the fact—even after the survey exit conference. The IJ Template identifies the three key components of IJ, requires surveyors to identify their substantiation of each as "yes/no" and to provide a preliminary fact analysis which demonstrates where a key component exists. The IJ Template is to be provided to the provider or supplier as soon as possible once an IJ is identified. The content of the IJ Template is "preliminary" and not a replacement for whatever survey findings will be noted in the Form 2567 issued as a result of the survey. How the IJ Template might be utilized or made available to the public, as compared to the Form 2567 from the same survey, is not discussed in the Memo.

Expanded Focus and Process on Psychosocial Harm

While the prior Appendix Q identified and established a requirement for surveyors to consider non-physical harm—psychosocial and mental harm—when assessing the key component of Harm, the new Appendix Q will expand on those concepts and place additional investigatory obligations on surveyors. Accordingly, surveyors are instructed to discern how an individual responds to noncompliance, including changes in mood or behavior, and investigate as needed to determine if a change in mood or behavior is a significant factor of the noncompliance. In certain care settings and patient populations, this investigation will require surveyors to determine whether any such changes are due to the noncompliance, or due to the individual's baseline status or disease process. Of interest, where the surveyor cannot determine a response to noncompliance from the individual affected, the Memo indicates that the surveyors are to undertake a fulsome investigation on the issue—including making an attempt to interview family, legal representatives or others involved in the affected individual's life to "understand how [the individual] reacted or would have reacted" to the noncompliance and if such data cannot be obtained, to use a reasonable person approach. The reasonable person approach considers how a reasonable person in the individual's position would be impacted by the noncompliance. This expanded scope and applicable of a "reasonable person" standard places the surveyor in an almost diagnostic capacity in determining psychosocial/mental impact of noncompliance, and provides a level of discretion for the survey team that could continue to yield inconsistent results. In addition, the process of investigation on these issues, involving interviews with third parties and the like, may expand the timeline for those surveys where the more robust psychosocial/mental process is determined to be necessary.

How IJ is Called and Removed

The Memo specifies that going forward, surveyors must use the IJ Template to determine if IJ exists, and to communicate the determination to the entity under survey. Survey teams who identify the key components of IJ are to consult with the state agency to confirm that IJ exists and to seek direction. In some cases, the CMS regional office is also contacted for confirmation. The provider/suppler administrator is then "immediately" notified and the IJ Template delivered. While the basic

confirmatory processes with the state agency and regional office are unchanged from typical procedures under the prior Appendix Q, the imposition of the IJ Template requires surveyors to use a more structured approach in communicating this information. Of interest, the Memo acknowledges that while the IJ Template is to be delivered “when IJ is called,” it acknowledges that this occurs before the surveyor or survey team exists “in most cases.” Accordingly, it remains possible for an IJ to be called after a survey exit conference. Though CMS indicates these circumstances are “rare” when they occur, the new Appendix Q will require that the survey team return to the provider/suppler in person to validate the findings using the IJ Template (which then would need to be provided to the surveyed provider or supplier).

Removal of IJ will still only occur after a provider/supplier provides an acceptable Removal Plan to the surveyor or survey team, ideally before the time the survey exit conference occurs. Because IJ status brings with it the threat of expedited termination of the provider/supplier’s enrollment agreement with CMS, it is important for the IJ Removal Plan to be prepared and submitted as promptly as possible. The IJ Removal Plan as described in the Memo must identify the individuals who have “suffered, or are likely to suffer, a serious adverse outcome as a result of the noncompliance” and the actions the entity will take to “alter the process of system failure to prevent a serious adverse outcome from occurring or recurring” along with a completion date. The surveyor must accept the Removal Plan and confirm that the actions described therein have been fully implemented in order to move forward, as is the case today.

Once the IJ Removal Plan is accepted, the IJ is “abated” and the provider or supplier would shift to the longer termination track for the remainder of the survey cycle. For example, a hospital provider that is determined to have an IJ situation would be placed on a 23-day termination track (meaning their provider agreement would be terminated if compliance is not achieved by the 23rd day after the survey exit), and would be shifted to a 90-day termination track upon resolution of the IJ (meaning that the full resolution of remaining non-IJ findings may occur on a longer time frame). In situations where the IJ Removal Plan is not accepted in advance of the exit conference, the Memo provides that surveyors must return to the facility once it is received, to verify that the IJ has been removed. The confirmation of removal cannot be done via a “desk audit” or other process that does not include an on-site visit (though the Memo refers to additional onsite investigations as permissive in a later section, and historically regions have varied in how they have handled this).

It is important to differentiate between the IJ Removal Plan and the Form 2567 and plan of correction (PoC) that a provider or supplier must complete to resolve outstanding survey issues. The IJ Removal Plan is specific to actions to identify those at risk of serious adverse outcomes as a result of the noncompliance, and to prevent occurrence or recurrence of such outcomes. The PoC must address corrective actions, procedures put in place, monitoring efforts for all condition-level findings (and, in good practice, standard-level findings) and completion dates.

IJ Removal Plan Required Elements	PoC Required Elements
Identify those individuals who have suffered, or are likely to suffer, a serious adverse outcome as a result of noncompliance	The plan of correcting the specific deficiency, addressing the processes that lead to the deficiency cited
Specify the action the entity will take to alter the process or system failure to prevent a serious adverse outcome from occurring or recurring	The procedure for implementing the acceptable plan of correction for the specific deficiency cited
When the action will be complete	The monitoring procedure to ensure that the plan of correction is effective and that specific deficiency cited remains corrected and/or in compliance with the regulatory requirements
	The title of the person responsible for implementing the acceptable plan of correction
	Completion date (for each action, and overall for each survey tag cited)

Both must identify implementation/completion dates within the survey timelines set forth in the CMS State Operations Manual, and the IJ Removal Plan dates must be as soon as possible in order to abate the IJ.

The Memo specifies that the Form 2567 issued to a provider/supplier with a determination of IJ must contain the "core components" of the IJ determination and the actions taken by the provider to remove the IJ are documented on the Form 2567, including the date the IJ began, the date the provider/supplier was notified, the specific requirement that surveyors determined was violated (including a description of the noncompliance and serious adverse outcomes), identification of the individuals at risk, the date of IJ removal. The Form 2567 must also include a statement of the seriousness of any remaining noncompliance (*i.e.*, which findings are condition-level or standard-level, or scope and severity, depending on provider/suppler type).

Disagreements between State Agency and Regional Office

As is the case today, the Memo notes that where a regional office determines there is IJ, its determination trumps the stage agency's determination.

Subparts for Long Term Care and Lab

The Memo indicates that the new Appendix Q will focus on “core guidelines” applicable to all providers and suppliers, and that specific subparts will be issued for provider and supplier types that have different or additional IJ concepts to consider. The first two subparts provided relate to long-term care facilities (SNFs and NFs) and CLIA laboratories. The key components of IJ for these providers/suppliers are slightly different, and reference resources specific to the survey processes for each, for example, survey F-Tags for long-term care facilities.

For long-term care facilities, the Memo further articulates a set of triggers for which further investigation is called for. The list of triggers is lengthy, and while their presence in a SNF or NF does not automatically mean there is an IJ situation, some of them may be common enough in the long-term care resident population that their inclusion on the triggers list leads to more frequent or robust investigations during the survey process (*i.e.*, behavior changes, fear of a person or place, disturbed sleep).

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The changes to Appendix Q described in the Memo make clear that CMS has recognized that determining IJ has sometimes been an unevenly applied and poorly communicated survey finding, and that patient safety demands close scrutiny and investigation of the key components of IJ and a consistent process to address and resolve the findings. Whether this will lead to more surveyor determinations of IJ overall is not yet known. The full extent of the changes to Appendix Q will become more clear as surveyors roll out the use of the IJ Template, and the IJ processes described in the Memo.

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