CMS Hospital Surveys: The Legal Perspective

REGULATION, ACCREDITATION, AND PAYMENT PRACTICE GROUP*

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1. Background and Overview

Participation in the Medicare and Medicaid programs requires "certification" that the provider meets certain "Conditions of Participation." When these programs were first enacted (via the Social Security Act of 1965), Congress legislatively named a "proxy" for certification, in the form of an accreditation agency, such as the Joint Commission (at that time it was known as JCAH – Joint Commission on Accreditation of Hospitals and the American Osteopathic Association (AOA). By achieving accreditation, a provider is entitled to what is customarily referred to as "deemed status" – whereby an accredited hospital (or other healthcare organization) is deemed to meet the requirements for Medicare participation.

Over the years, it appears that healthcare providers have focused so profoundly on the accreditation standards that many have lost sight of the Medicare Conditions of Participation – apparently presuming either that the accreditation standards equaled or at least subsumed the Medicare Conditions, or that they somehow trumped the Medicare Conditions.

Any hospital caught in the relatively recent phenomenon of a Medicare "validation" survey has likely been disabused of any such perception. Because of recent legislative and public pressure and apparent questions about the Joint Commission survey process, the Centers for Medicare and Medicaid Services (CMS) has dramatically increased the rate of validation surveys by which it tests Joint Commission performance. Unfortunately, providers that have relied on Joint Commission accreditation are also being tested on their compliance with the Medicare Conditions of Participation. Every provider must now be prepared for a validation survey.

The purpose of this Toolkit is to assist hospitals' counsel that may not have focused on the subtle, but real, differences between the Joint Commission Standards and the Medicare Conditions of Participation or the differences between the Joint Commission and CMS survey processes. Thus, first and foremost, this Toolkit focuses on getting through the survey process. However, the additional goal is to educate and refocus attention on the requirements for Medicare certification. A similar analysis should be conducted as to the AOA Standards that apply specifically to facilities historically known as osteopathic. These Standards are now voluntarily ascribed to by many other hospitals, even some that were formerly Joint Commission accredited. In general, the AOA Standards are somewhat less prescriptive than the Joint Commission Standards; nonetheless, most of the recommendations in this document are equally applicable.

1.1 The Survey Options

By virtue of Section 1864 of the Social Security Act (42 U.S.C. § 1395aa), CMS has the option to delegate certification duties to an entity within each respective state known as the State Agency. CMS sets the standards for the certification process and funds the reasonable and necessary costs of carrying out these functions. Since the State Agency is an entity of each respective state government, the exact place in state government where the entity is housed may vary from state to state, but the State Agency function is usually performed by the same state department that is responsible for licensing under state law. There may also be some variation depending on whether a particular state has obtained waivers from CMS as to any part of the survey process. Nonetheless, compliance with the Medicare Conditions is a hallmark of each State Agency's functions, and there are not significant substantive differences from state to state.

1.2 What Is the State Operations Manual?

The State Operations Manual (SOM) provides guidance to State Agencies and sets out CMS policy regarding the survey procedures and certification activities prescribed by the Medicare statute and its effectuating regulations (42 C.F.R. §§ 488.1 et seq.). State Agencies are expected to refer to and comply with the SOM, and for this reason the SOM is an important resource to all providers. That said, it must be noted that despite the so-called "requirements" set out in the SOM, both CMS and the State Agency will sometimes (of late, frequently) disregard both the deadlines and the processes prescribed by the SOM, at least as to the performance of the State Agency, but not necessarily a provider.

The SOM is available electronically on CMS's website, as are updates and revisions, at: www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS019027&intNumPerPage=10

The SOM has 8 chapters, 200 plus exhibits, and 24 appendices. The most important portions of the SOM with regard to provider surveys are noted below:

- **Chapter 2: The Certification Process**
  - This chapter describes the certification and accreditation process.
- **Chapter 3: Additional Program Activitie**s
  - This chapter discusses termination and other sanctions for noncompliance as well as the termination process following the identification of an Immediate Jeopardy and noncompliance with Conditions of Participation.
- **Chapter 5: Complaint Procedures**
  - This chapter describes how complaints are evaluated and acted upon.
- **Exhibit 7A: Principles of Documentation**
  - This exhibit is designed as a tool to assist surveyors in drafting the statement of deficiencies and 2567 Report; however, it includes a disclaimer advising that it is "merely guidance" for surveyors and that it does not impose obligations on either providers or surveyors.
- **Appendix A: Survey Protocol, Regulations & Interpretive Guidelines for Hospitals**
  - This appendix outlines the survey process task by task, and describes the expectations for compliance with each Condition of Participation.
- **Appendix Q: Guidelines for Determining Immediate Jeopardy**
  - This appendix describes how the agencies identify and act upon circumstances posing an Immediate Jeopardy to the health and safety of patients.

It is important to emphasize that the SOM governs State Agency actions towards hospital providers as well as numerous other types of healthcare facilities such as hospices, home health agencies, and intermediate care facilities. This can be confusing because requirements for Medicare participation are different for each of these kinds of entities. Consequently, in referring to the SOM, be sure to look at the appropriate facility provision.

As discussed in greater detail below, a CMS/State Agency survey is aimed at measuring compliance with Medicare Conditions of Participation and associated Standards. There are 23 Conditions of Participation for hospitals, and each Condition is comprised of one or more component Standards. The section of the Code of Federal Regulations setting forth all of the

Conditions of Participation and their underlying Standards can be found at the following link: www.access.gpo.gov/nara/cfr/waisidx_04/42cfr482_04.html

Appendix A of the SOM provides particular insight into the agencies' evaluation process. That Appendix repeats the Conditions of Participation and the underlying Standards as set forth in the Code of Federal Regulations, and then follows each with "Interpretive Guidelines" and a recommended survey procedure.

For example, the Condition of Participation for Nursing Services (42 C.F.R. § 482.23) requires:

> The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.

The Interpretive Guidelines for this Condition restate and expand on the requirement, stating:

> The hospital must have an organized nursing service and must provide on premise nursing services 24 hours a day, 7 days a week with at least 1 registered nurse (RN) furnishing or supervising the service 24 hours a day, 7 days a week (Exception: small rural hospitals operating under a waiver as discussed in § 482.23(b)(1)).
>
> The Social Security Act (SSA) at § 1861(b) states that nursing services must be furnished to inpatients and **furnished by the hospital.** The SSA at § 1861(e) further requires that the hospital have a **RN on duty at all times** (except small rural hospitals operating under a nursing waiver). [emphasis in original]
>
> The nursing service must be a well-organized service of the hospital and under the direction of a registered nurse.
>
> The nursing service must be integrated into the hospital-wide quality assessment and performance improvement (QAPI) program.

The recommended survey procedures describe how the surveyors should go about determining compliance with the Nursing Condition, and provide as follows:

- Determine if the nursing service is integrated into the hospital-wide QAPI program.
- Interview the director of the service. Request the following items:
  - Organizational chart(s) for nursing services for all locations where the hospital provides nursing services;
  - Job or position descriptions for all nursing personnel, including the director's position description.
- Select at least one patient from every inpatient care unit. Observe the nursing care in progress to determine the adequacy of staffing and to assess the delivery of care. Other sources of information to use in the evaluation of the nursing services are: nursing care plans, medical records, patients, family members, accident and investigative reports, staffing, schedules, nursing policies and procedures, and QAPI activities and reports. Interview patients for information relative to the delivery of nursing services.

Another good illustration of how CMS walks the State Agency through the evaluative process and, perhaps more significantly, how CMS builds on the statutory requirements for Medicare certification, is the Condition of Participation for Infection and Control and its underlying Standards: www.cms.hhs.gov/manuals/Downloads/som107ap_a_hospitals.pdf (see page 231 of the pdf). Hospital managers need to be familiar with not only the Conditions of Participation and the related Standards, but also the Interpretive Guidelines.

1.3 The Joint Commission Accreditation Standards as a Comparison

As discussed in the introduction, hospitals tend to be comfortable with complying with The Joint Commission (TJC) accreditation standards and preparing for TJC surveys. It therefore often comes as a surprise to hospitals that the CMS Conditions of Participation and their accompanying Standards are not one-and-the-same. Rather, there are very real differences between these standards. **Exhibit 1.3** (located at the end of this document) details the most relevant differences.

1.4 Different Types of CMS Surveys

As described above, the State Agency is authorized by CMS to measure compliance with Medicare requirements. Compliance surveys generally follow the same overall process, though there are some differences depending on the type of survey and its objective. There are several categories of surveys:

- certification/recertification surveys
- complaint/allegation surveys
- validation surveys

Certification Survey

A certification survey is a comprehensive survey conducted after a hospital has submitted an application to become a Medicare provider to confirm that it meets all of the Medicare requirements (42 C.F.R. § 488.10(a)). Recertification occurs on a cyclical basis to confirm that the provider continues to meet the Medicare requirements. As described above, many hospitals are accredited by Joint Commission or other national accreditation organizations, meaning that they are "deemed" Medicare compliant. So long as a hospital remains "deemed" in compliance with Medicare Conditions, it would be subject to a validation survey (see below) rather than a certification survey.

Complaint/Allegation Survey

A complaint/allegation survey is conducted when CMS has received a complaint and determined that it raises a "credible allegation" of a Condition-level deficiency. CMS initially limits complaint/allegation surveys to Conditions related to the complaint. However, CMS or a State Agency have leeway to expand the scope of the survey if the surveyors identify additional problems. In addition, the SOM provides that, "if there are potential efficiencies in combining complaint and certification surveys and/or advancing the certification visit date without sacrificing the integrity of either, the State Agency should do so." If during a complaint/allegation survey, the State Agency substantiates a deficiency (either related or unrelated to the complaint) in a Condition of Participation, CMS will authorize a full Medicare survey (42 C.F.R. § 488.7).

Validation Survey

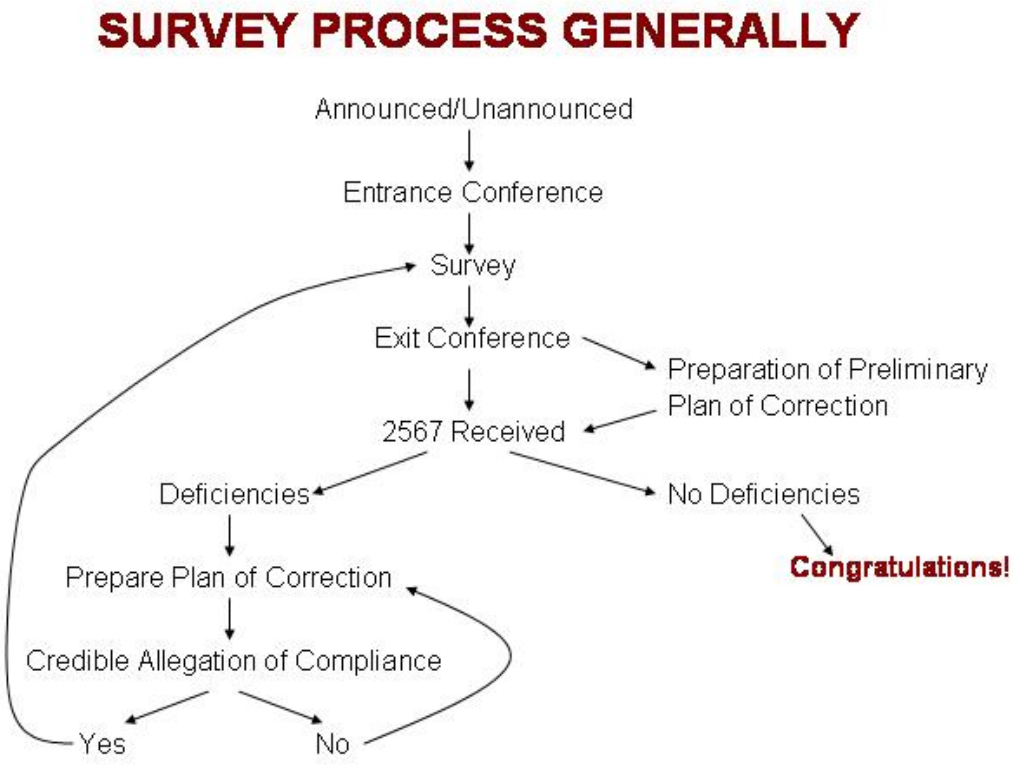
Validation surveys are conducted by State Agencies on a random sample basis to validate the accreditation process. In other words, a hospital that is accredited by Joint Commission, and therefore is "deemed" Medicare compliant, may be subject to a validation survey to confirm that it in fact meets Medicare requirements. Validation surveys may be comprehensive, or focused on a specific Condition or Standard. If an accredited hospital is found during a validation survey to have significant deficiencies, it will no longer be "deemed" to meet Medicare Conditions of Participation and CMS will authorize a full survey. 42 C.F.R. §§ 488.7 and 488.10(c).

The chart on the following page compares the various surveys.

Comparison of CMS/*State Agency* Surveys			
	Certification/ Recertification	**Complaint/Allegation**	**Validation**
Purpose	To determine whether a provider meets Medicare Conditions of Participation so that it may participate (or continue to participate) in the Medicare program.	To investigate whether a complaint alleging a Condition-level deficiency is valid.	To confirm compliance with Conditions of Participation, for providers that have already achieved "deemed status" through accreditation.
Trigger	Provider's application for enrollment in the Medicare program is recommended for approval by the fiscal intermediary/carrier, and the provider is ready to be surveyed for compliance with Conditions of Participation.	Conducted in response to a substantial complaint/allegation of noncompliance.	Conducted on a representative sample basis by a State Agency through authority delegated by CMS.
Scope	Comprehensive full survey.	Initially limited to Conditions related to the complaint/allegation, but CMS or the State Agency has discretion to expand the scope as it finds necessary. If a deficiency is substantiated and CMS determines that the provider is out of compliance with a Condition of Participation, then CMS will authorize the State Agency to conduct a full Medicare survey.	When conducted on a representative sample basis, the validation survey is comprehensive.
Announcement	Unannounced	Unannounced	Sample survey may be announced by notice letter, but CMS is embracing a policy that all surveys will be unannounced.
Entrance Conference	Purpose and scope of survey is explained, survey process is reviewed, and logistics are arranged.	same	same
Survey	Comprised of observation, interviews, and document review.	same	same
Exit Conference	Required by SOM, but the State Agency has discretion to cut it short [if hospital is obstreperous].	same	same

1.5 The CMS Survey Process

As explained in Section 1.2, the survey process is described in Chapter 2 of the SOM, as well as in SOM Appendix A. While the overall scope of the survey will depend upon the type of survey, the following general steps will apply to all surveys. A flowchart of the survey process follows.



When the surveyors arrive at the hospital, they will convene an Entrance Conference. The SOM instructs the surveyors to use the Entrance Conference as an opportunity to introduce themselves, describe the purpose of the survey, and provide an overview of the expected procedure.

In order to determine compliance with Medicare Conditions of Participation, the surveyors will conduct observations, interviews, and document review. The SOM sets out the following guiding principles of the survey process:

- Focus attention on actual and potential patient outcomes, as well as required processes.
- Assess the care and services provided, including the appropriateness of the care and services within the context of the regulations.
- Visit patient care settings, including inpatient units, outpatient clinics, anesthetizing locations, emergency departments, imaging, rehabilitation, remote locations, satellites, etc.

- Observe the actual provision of care and services to patients and the effects of that care, in order to assess whether the care provided meets the needs of the individual patient.
- Use the Interpretive Guidelines and other published CMS policy statements to guide the survey.
- Use Appendix Q (www.cms.hhs.gov/manuals/downloads/som107ap_q_immedjeopardy.pdf) [of the SOM] for guidance if an Immediate Jeopardy is suspected.

Survey team members will meet daily during the survey to assess the status of the survey and their progress. In the event concerns are identified, the team will coordinate their efforts to obtain additional information. The surveyors are encouraged to "maintain open and ongoing dialogue with the facility staff throughout the survey process."

At the conclusion of the survey, the surveyors will meet for preliminary decision making and analysis of findings. Their frame of reference will be the applicable Conditions of Participation, and the component Standards, and whether a hospital is "substantially" in compliance. This is a big question and it is made all the more puzzling because there is no definition of what "substantial" compliance is. The closest the SOM comes to defining this key term is in SOM Chapter 2:

> A deficiency is significant if it affects the ability of the institution to provide adequate care, or which adversely affects the health and safety of patients. A standard or an individual requirement (within a COP) not in compliance may or may not be a significant deficiency.

Additional guidance at 42 C.F.R. § 488.26(b) provides that:

> The decision as to whether there is compliance with a particular requirement, condition of participation, or condition for coverage depends upon the manner and degree to which the provider or supplier satisfies the various standards within each condition. Evaluation of a provider's or supplier's performance against these standards enables the State survey agency to document the nature and extent of deficiencies, if any, with respect to the particular function, and to assess the need for improvement in relations to the prescribed conditions.

Appendix A (www.cms.hhs.gov/manuals/Downloads/som107ap_a_hospitals.pdf) of the SOM builds on this regulation with the following insight:

> When noncompliance with a condition of participation is noted, the determination of whether a lack of compliance is at the Standard or Condition-level depends on the nature (how severe, how dangerous, how critical, etc.) and extent (how prevalent, how many, how pervasive, how often, etc.) of the lack of compliance. The cited level of the noncompliance is determined by the interrelationship between the nature and extent of the noncompliance.

It is possible for a hospital to have some Standard-only deficiencies yet still be found in overall compliance with the Conditions.

If the hospital only has noncompliant Standards, but is found in compliance with all Conditions, the hospital will not be scheduled for termination. Rather, CMS will usually put the hospital on

State Agency monitoring until it can be determined that those Standard-only deficiencies are brought back into compliance.

On the other hand, it is possible that substantial noncompliance with one or more Standards will result in a finding that the hospital is out of compliance with a Condition. The absence of hard and fast criteria allows the State Agency significant latitude in determining whether any noncompliance is at the Standard or the Condition-level; however, CMS is the ultimate decision maker as to whether or not a deficiency will be cited.

The important thing to remember and accept is this: It is not possible to maintain Medicare participation if there is sustained noncompliance with ANY Condition.

At the conclusion of the survey, it is CMS policy to conduct an Exit Conference. According to the SOM, the purpose of the Exit Conference is to "informally communicate preliminary survey team findings and provide an opportunity for the interchange of information, especially if there are differences of opinion." According to section 2724 of the SOM:

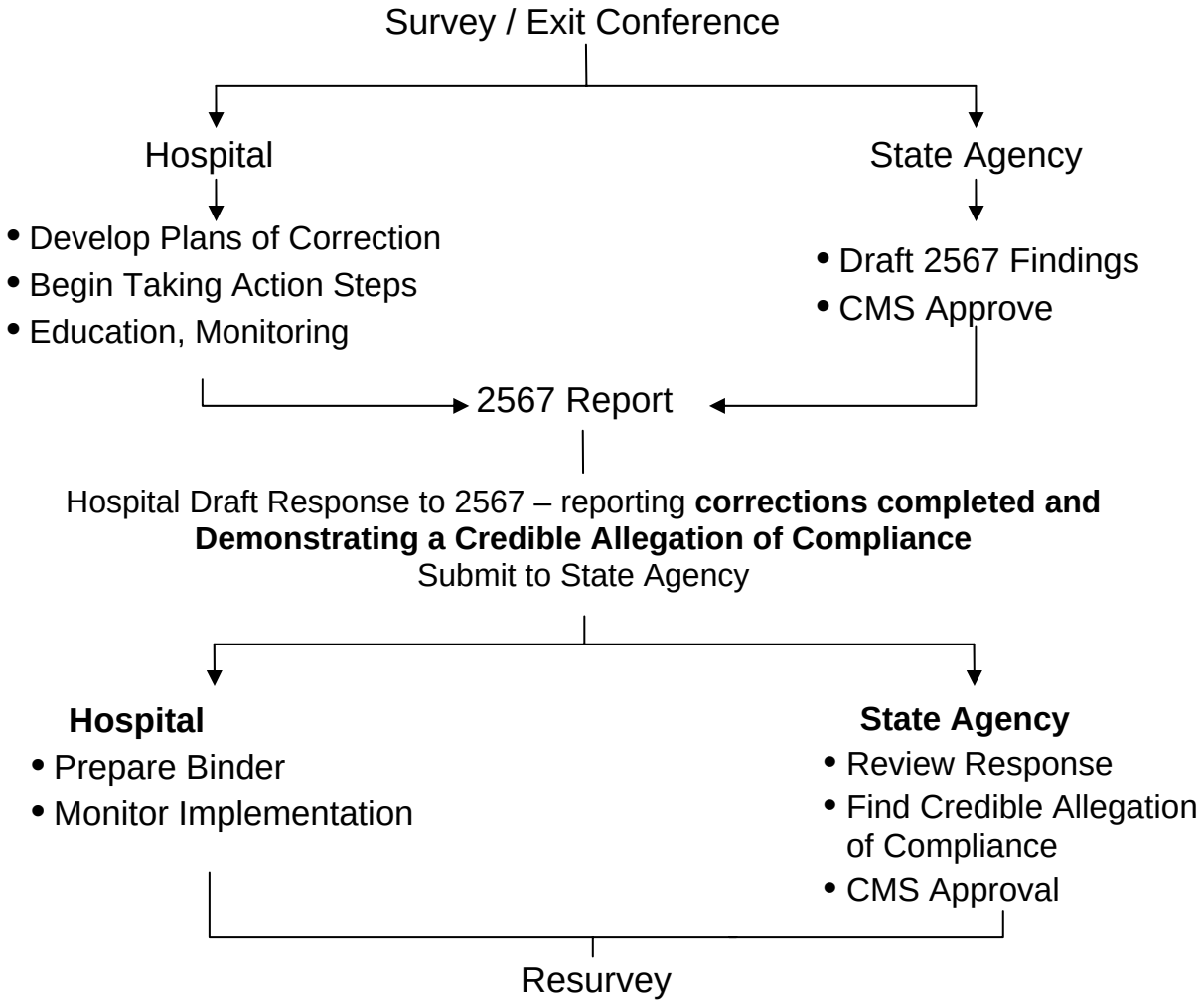
> The provider has a right to disagree with the findings and present arguments to refute them. Surveyors should be receptive to such disagreements. If the provider presents information to negate any of the findings, surveyors should indicate their willingness to reevaluate the findings before leaving the facility. The survey team's reasonableness demonstrates their fairness and professionalism. The degree of receptivity displayed by providers during the exit conference often depends upon the attitudes and survey style of the survey team. (See www.cms.hhs.gov/manuals/downloads/som107c02.pdf at page 349)

In spite of this directive, there are circumstances in which surveyors do not encourage a candid exchange of information at this point in the process. This sometimes depends on factors such as the tone that is established between the provider and the surveyors during the survey, the time of the day or the day of the week of the Exit Conference, and the surveyors' perceptions of whether any deficiencies are significant.

When it comes to the presentation of the survey team's initial findings during the Exit Conference, the SOM instructs that Tag numbers should not be revealed, and that deficiencies should not be identified as existing at the Condition or Standard-level. General impressions and statements of compliance or noncompliance are to be avoided. Most important is that the SOM directs surveyors to see that "all findings are discussed at the exit conference."

At the conclusion of the Exit Conference, surveyors should advise the hospital staff that a statement of deficiencies (prepared on CMS form 2567 (www.cms.hhs.gov/cmsforms/downloads/CMS2567.pdf), as discussed in more detail at Section 5.3) will be mailed to the hospital within 10 **working** days. Upon receipt, the hospital will have 10 **calendar** days (note the difference in the calculation of time, holidays and weekends notwithstanding) to submit a written 2567 Report (also prepared on CMS form 2567). The following flowchart generally illustrates the post-survey process.

Post-Survey



The surveyors are instructed to inform the hospital that the 2567 form will be disclosed to the public no later than 90 calendar days following completion of the survey. The purpose of disclosure is to notify the public of the hospital's deficiencies and what actions the hospital is taking to remedy them.

Note: This time frame can be significantly affected by the government's receipt of a Freedom of Information Act (FOIA – the federal law) or similar state equivalent request for documents. In case of a FOIA request, CMS's practice has been to release information to the public as soon as it receives the hospital's 2567 Response. (Indeed, in some instances, CMS representatives have spoken to the press even before receiving or fully evaluating the hospital's 2567 Response, and while they claim to be speaking only in generalities during these early interchanges, their disclosures may reveal information that has not yet been fully reviewed or corrected by CMS based on the 2567 Response, and may or may not be consistent with findings that eventually are made at the conclusion of the process.) Because of this, the hospital must also prepare itself for media inquiry, almost from the outset. (*See* additional discussion at Section 4.8.)

1.6 Survey Outcome

What to expect after a survey is entirely dependent on the surveyors' findings. In the best case scenario, no deficiencies are identified, and the provider can breathe a sigh of relief. If, on the other hand, the State Agency discovers one or more deficiencies, then the next steps are, according to the SOM, dependent on the type of survey and the level of the deficiency.

Caution: CMS has in some recent cases deviated from the usual processes and procedures, making it difficult for a provider to know for certain what to expect.

Standard-level Deficiency

If a hospital is found only to have Standard-level deficiency/ies, then 42 C.F.R. § 488.28 permits it to continue to operate so long as it has submitted to the State Agency an acceptable Plan of Correction for achieving compliance within a reasonable period of time. At section 2728B (www.cms.hhs.gov/manuals/downloads/som107c02.pdf at page 353), the SOM describes a reasonable period of time as "generally no longer than 60 calendar days." Depending on the nature of the deficiency, however, the SOM recognizes that some corrections may reasonably take longer than 60 days (for example, if construction is required), while other corrections may reasonably be accomplished in a much shorter time. The amount of time allowed for the hospital to achieve compliance is based on the nature of the deficiency and the State Agency's judgment regarding the capacity of the facility to provide adequate and safe care. The hospital remains at this State Agency monitoring cycle until it either achieves compliance, or it moves to a termination track (i.e., if during the monitoring process the State Agency finds the hospital out of compliance with a Condition, or discovers an Immediate Jeopardy).

Condition-level Deficiency

If the State Agency discovers a Condition-level deficiency in the course of a complaint/allegation or validation survey, and if CMS agrees, CMS will notify the provider of the removal of its "deemed status" and place the provider under State Agency survey jurisdiction. CMS will request a full survey of all Conditions of Participation at the State Agency's earliest convenience. If upon full survey, the State Agency determines that the provider is still out of compliance with one or more Conditions of Participation, the State Agency is to follow the 90-day termination track.

If a Condition-level deficiency is found during a recertification survey (or resurvey), CMS will put a hospital on a 90-day termination track. The SOM specifically provides that Condition-level deficiencies cannot be certified based on a plan of correction or acceptable progress, meaning that the hospital will be subject to a resurvey to confirm compliance based on an acceptable allegation of compliance.

When one or more Condition-level deficiencies are identified during a survey, the State Agency is required to send a warning letter and a 2567 Report to the hospital within 10 working days. The hospital then has 10 **calendar** days to submit its 2567 Response. The State Agency should conduct a resurvey within 45 **calendar** days of the survey provided the hospital's 2567 Response makes a credible allegation of compliance. The resurvey will determine whether the hospital is in fact in compliance, or if it has achieved acceptable progress. A second resurvey may be conducted between the 46th and 90th calendar days after the survey, if necessary, and if the hospital submits a second credible allegation of compliance.

Following is a flowchart illustrating how the 90-day termination track operates.

Sample 90-Day Termination Track

Applies when a hospital has condition-level deficiencies

Friday, July 1

Last day of survey

↓

Monday, July 18

10 working days past survey / (2 weekends & 4th of July holiday do not count) 2567 Reports Due

↓

Thursday, July 28

10 calendar days past survey Hospital's 2567 Response due

↓

Monday, August 15

45 calendar days past survey. If hospital's 2567 makes a credible allegation of compliance, then the State Agency should conduct a resurvey by this date

↓ If hospital has Condition-level deficiencies upon resurvey, it can use this time to submit a second 2567 Response. If a credible allegation is found, CMS may authorize the State Agency to perform a 2nd resurvey.

Friday, September 9

70 calendar days past survey, official termination notice sent by CMS, the hospital, AND the public. Notice most be AT LEAST 15 days before termination.

↓

Thursday, September 29

90 calendar days past survey

TERMINATION DATE

Immediate Jeopardy

An Immediate Jeopardy (IJ) is "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" (42 C.F.R. § 489.3). The SOM advises surveyors faced with a potential Immediate Jeopardy as follows:

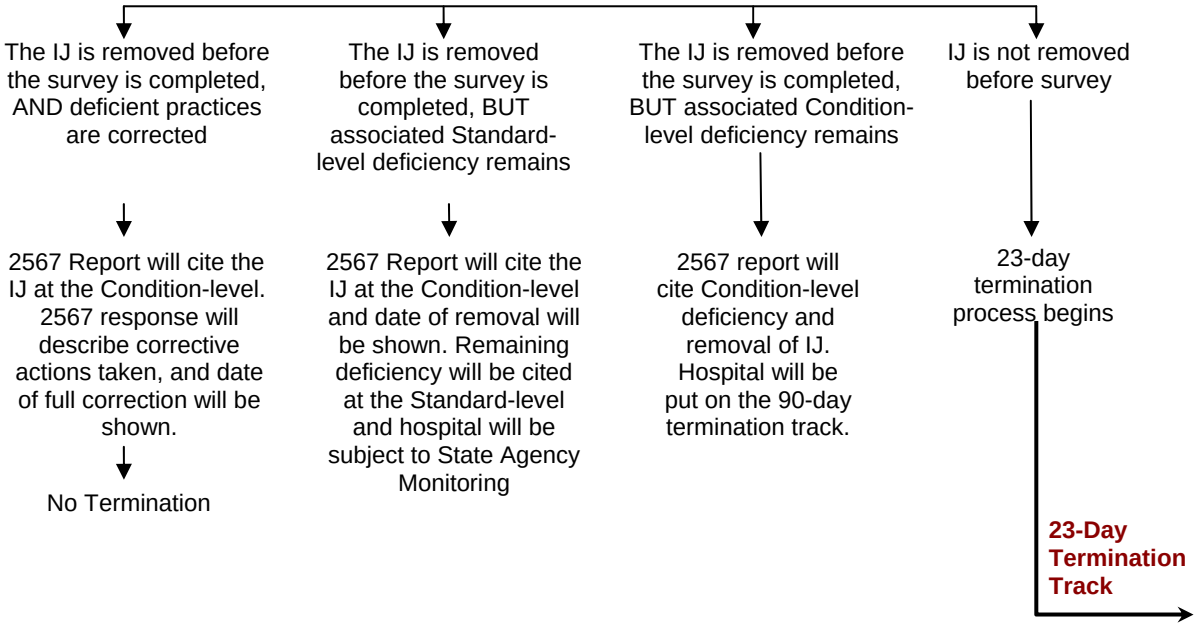
> The key factor in the use of the immediate jeopardy termination authority is, as the name implies, limited to immediate and serious. The threat must be present when you are onsite and must be of such magnitude as to seriously jeopardize a patient's health and safety. There should be no other application of immediate jeopardy terminations. Do not use these procedures to enforce compliance quickly on more routine deficiencies.

If the State Agency identifies a potential IJ during any type of survey, and CMS agrees, then an IJ will be called, and the hospital must immediately mobilize to address circumstances deemed to have created the IJ. A variety of things can follow:

- If the hospital corrects the IJ while the surveyors are still in house, and if that correction also **fully** addresses any Condition-level noncompliance associated with the IJ incident, then the IJ incident will be reported in a 2567 Report. If there is a full survey also under way, this will be incorporated into the full-survey 2567 Report. The hospital's response in this circumstance will describe what was done to correct the IJ, such monitoring as may be called for and the responsible person.
- If the hospital corrects the IJ while the surveyors are still in house, but the corrections were not sufficient to avert a determination that the hospital is still out of compliance with a **Condition**, notwithstanding resolution of the IJ circumstances, then CMS or the State Agency will include the IJ incident in the 2567 Report, and will place the hospital on a 90-day termination track.
- If the hospital corrects the IJ while the surveyors are still in house, but the corrections were not sufficient to avert a determination that the hospital is still out of compliance with a Standard, notwithstanding resolution of the IJ circumstances, then CMS or the State Agency will include the IJ incident in the 2567 Report, and (assuming no other Condition-level deficiencies exist) will place the hospital on State Agency Monitoring.
- If the hospital has **not** corrected the IJ while the surveyors are still in house, CMS or the State Agency will issue an IJ 2567, and will place the hospital on a 23-day termination track. If the hospital submits a credible allegation that it has corrected the threat, the State Agency is instructed to revisit before termination, if possible. A credible allegation is one that is realistic in terms of the possibility of the corrective action being accomplished by the time of the allegation and indicates resolution of the problem.
    - If the hospital does not alleviate the threat before day 23, then Medicare participation will be terminated effective day 23.
    - If the hospital alleviates the threat before day 23, but deficiencies still exist at the Condition-level, the hospital will shift "tracks" to the 90-day termination track (described above), in effect giving it 67 more days to bring itself into compliance.

The following chart illustrates the different outcomes that can result from an Immediate Jeopardy, and the subsequent flowchart illustrates the 23-day termination track.

What happens when an IJ is called during a survey



23-Day Termination Track

Applies when the hospital has not corrected IJ by the survey conclusion

Day 2

State Agency notifies hospital of IJ deficiency and it is recommending termination

Day 5

CMS notifies hospital AND the public of impending termination

Day 10
(working days)

2567 Report due regarding any additional non-IJ deficiencies

Termination will take effect on day 23 unless the hospital has achieved compliance OR removed the threat. If the threat has been removed BUT deficiencies exist at the Condition-level, the hospital will shift to the 90-day termination track.

Day 23
TERMINATION

Notice of Termination

As noted above, any Condition-level deficiency, as well as any circumstance found to create an Immediate Jeopardy, requires CMS to initiate termination of provider certification.

In such case, 42 C.F.R. § 498.20 requires the agency to notify the hospital. Such notification must include at least the following information:

- The basis or reasons for the decision to terminate.
- The effect of the decision to terminate.
- Information regarding the hospital's right to a hearing.

The hospital then has three options:

- Correct the deficiencies; **and/or**
- Informally contest the deficiencies; **and/or**
- Appeal the deficiencies.

Correcting the deficiencies is the only safe alternative. However, a hospital can attempt to informally contest the accuracy of the findings, but generally success will only be had at this stage if it can be readily shown that the State Agency got its facts wrong. The trouble with waiting to appeal the deficiencies is that termination will likely take effect before the appeal can be conducted; thus, even if the hospital ultimately prevails, it will have a hiatus in Medicare certification – with concomitant confusion and significant undermining of public trust.

1.7 Appealing the Determination

A hospital has the right to appeal a final determination to terminate Medicare certification. Until such a determination has been made, the hospital is limited to pursuing such informal options as requesting meetings with key agency officers, seeking clarification of findings, and otherwise cooperating with CMS and the State Agency to achieve a mutually satisfactory outcome.

42 C.F.R. § 498.40 sets out the requirements for requesting an appeal hearing, and in relevant part requires the hospital to:

- File a request in writing.
- Submit the request within 60 days from receipt of notice of an initial or revised determination.
- Identify the specific issues, and the findings of fact and conclusions of law with which the hospital disagrees.
- Specify the basis for contending that the findings of fact and conclusions are incorrect.

Failure to comply with these requirements may result in dismissal of the hospital's appeal, because from the Administrative Law Judge’s (ALJ's) perspective, a hearing request could be the only submission that identifies the disputed issues. Consequently, in addition to meeting the above requirements, the request should:

- Put CMS on notice of all matters in dispute.

- Enable the ALJ to rule on the relevancy of evidence.
- Indicate whether facts are at issue, or whether the dispute is limited to legal issues, in which case a hearing would not be necessary.

At the appeal hearing, CMS will have the burden of demonstrating why the hospital should be terminated. At the conclusion of the hearing, both the agency and the hospital have the right to request Departmental Appeals Board (DAB) review if dissatisfied by the decision of the ALJ (42 CFR 498.80 et seq.). A request for review must be filed within 60 days from receipt of notice of the decision and must specify the issues, the findings of fact or conclusions of law with which the party disagrees, and the basis for contending that the findings and conclusions are incorrect. The DAB may remand the case to an ALJ or issue a decision. Judicial review is the final option if the hospital is dissatisfied with the decision of the DAB (42 C.F.R. § 498.5).

Once the option to appeal is under consideration, it is crucial that the hospital enlist the assistance of counsel, if that has not already been done. Counsel should participate in the drafting of the request and should monitor that no rights are waived and that all of the requirements for such a request are met. Furthermore, after the hospital receives notice of termination (either by way of the 90-day termination track or the 23-day Immediate Jeopardy track), the hospital should seriously consider submitting a request for an appeal right away.

1.8 Effect of an Early Appeal

Filing an appeal at the earliest possible time can shorten the period during which the hospital is technically ineligible to participate. In the best case scenario, the hospital will be found in compliance with all Conditions upon resurvey and the request for appeal can be withdrawn. However, the possibility always exists that the hospital will not be found back in compliance after the first resurvey, and since there are no statutory or regulatory provisions for securing an expedited appeal, its exposure is limited by getting the appeal process started early. It is highly unlikely (if not impossible) that an ALJ will have an opportunity to review the decision to terminate and issue a decision in time actually to prevent termination. Thus, retroactive reinstatement is the most the hospital can likely achieve. Limiting the amount of time that the hospital is decertified is the best way to mitigate damages, including less obvious damages such as the medical staff losing confidence in the hospital and an adverse public perception.

Submitting an early appeal may have the additional benefit of demonstrating seriousness on the part of the hospital. It may also cause the agencies to reconsider tenuous positions and to encourage compliance with timelines and procedures. It also may help maintain confidence both of the medical staff and the public.

The major circumstance in which it may not be feasible to file an early appeal is if the deficiency is one that will necessarily take time to correct or to get far enough in the correction process to make a credible allegation of compliance (e.g., a deficiency that requires entering into contracts and obtaining designs for construction; or a deficiency that requires training significant numbers of employees and staff members of a large facility). In such a case, it may be necessary to assess carefully the earliest point at which a credible allegation of compliance can reasonably be made. The good faith of the organization is at stake if the credible allegation of compliance is premature. Obviously, when a 23-day termination is at issue, the need to move expeditiously cannot be overemphasized.

2. The CMS Survey

CMS and/or the State Agency can show up at any time for an unannounced survey. The CMS State Operations Manual states that it is CMS policy to have unannounced surveys for all providers. (Section 2700A; but see 42 C.F.R. § 488.4 which suggests that accreditation organizations can choose to offer announced or unannounced surveys). There are many variables that affect the survey experience:

- The agency and number of the surveyors.
- The purpose of the survey.
- The extent of the survey.
- The outcome of the survey.

The Surveyors

Generally speaking, the size and composition of the survey team will depend on the type of provider and the purpose of the survey. Typically, a survey team conducting a full survey of a mid-sized facility would include two to four surveyors over a three- (or more) day period. Factors considered in assembling the team include:

- The size of the facility based on the average daily census.
- The complexity of services offered by the facility.
- The type of survey to be conducted.
- Whether the facility has special care units or off-site clinics or locations.
- Whether the facility has a historical pattern of serious deficiencies or complaints.
- Whether new surveyors are to accompany a team as part of their training.

Before the survey team arrives at the hospital, they will have already familiarized themselves with the hospital's ownership, layout, previous survey results, waivers and variances that might exist, and other information viewed as relevant. The survey team will arrive ready to get down to business.

Entrance Conference

Upon arrival, the surveyors should present identification and advise the hospital CEO of their intention to conduct a survey. The surveyors should also initiate an Entrance Conference during which the purpose and scope of the survey are explained, including:

- Clarification that all hospital areas and locations may be surveyed.
- Explanation that all interviews with patients, staff and visitors will be conducted privately unless otherwise requested by the interviewee.
- Discussion of how the facility will see that the surveyors are able to obtain copies of records and other documentation needed during the survey.
- Identification of the names and contact information of key staff members.
- Discussion of the estimated time, location, and possible attendees of any meetings that might be held during the survey.

- Proposal of a tentative date and time for the Exit Conference.

The Entrance Conference is also the time that the hospital can coordinate with the surveyors regarding its survey protocol. The hospital should take careful notes of the Entrance Conference. As deemed necessary to clarify and affirm why the survey is taking place, at the end of the Entrance Conference the hospital should (or it should request that the surveyors) restate key points.

The illustration at Section 1.4 identifies the main kinds of surveys and provides some guidance as to some of these variables. Regardless of the kind of survey in progress, the hospital must understand that the survey is only the starting piece to a much larger puzzle.

2.1 Key Points to Remember for Surveys

Advance Planning

The prospect for multiple unannounced surveys for licensing, certification, or accreditation has significantly increased. As a result, there should be careful planning for the prospect that a survey could happen any day. Preparation for surveys should include:

- Appoint an executive greeter – The chief executive officer and/or chief operating officer (or their designees in their absence) should always be available for the Entrance Conference and to lead the provider team.
- A policy or procedure regarding surveys that covers required training, procedures for survey, etc. Consider establishing a survey readiness steering committee to facilitate preparedness in accordance with policy.
- Establish a command center for effectuating communication throughout the survey.
- Establish a phone tree so that personnel at every hospital entrance point know whom to call when surveyors arrive. A phone tree should start with hospital administration and trickle down to every department. Be sure to include how to alert the next shift that a survey is in progress.
- Pre-identification of key leaders (or designees in their absence) from each department and service to be called if their department or service is at issue or if the surveyors want to round in that department. Establish checklists for each department to perform a quick review before surveyors reach the department.
- A plan to alert key medical staff leadership when medical staff issues are involved. There should be ongoing communication about emerging issues as to compliance with certification, accreditation, and licensing requirements, as well as how to respond during surveys. Careful attention needs to be given to making the medical staff leadership a part of the team both to maintain compliance and to avoid negative responses when surveyors raise questions.
- Establish and identify escorts, scribes, and runners:
    - **Escort** – accompanies each surveyor during the survey. The escort is key for announcing the surveyor's presence as they make their rounds in a cordial and welcoming manner.
    - **Scribe** – documents questions from the surveyors during the survey as well as medical records examined by the surveyor during the survey.

- **Runner** – Obtains documents and materials requested by the surveyor during the survey. Also alerts the next department or unit of the surveyor's anticipated arrival, things the surveyor is focused on, etc.

- Perform mock surveys and provide training for all affected personnel and medical staff leaders as to how to respond during surveys. Be sure to schedule training for medical staff officers and department and service chiefs as the leadership changes over time. Training should cover obvious do's and don'ts (e.g., do answer questions and provide facts; don't give your opinion or babble out of nervousness).
- Pay particular attention to training for documentation of everything that happens during the survey by the key leaders, as the most frequent problem providers have in preparing the 2567 Response is the inability to identify the precise individual or record to which a Tag relates. Be aware that the surveyors also may not keep adequate notes of the individuals or records at issue, or may lose them. It is almost impossible to prepare a 2567 Response or to correct obvious surveyor errors if no one has good notes.
- Prepare survey kits that contain the phone tree, files, and forms necessary for the survey.

During the Survey

- First impressions count! Be cordial and respectful of the survey process. Attend to appropriate amenities for surveyors – provide workspace, temporary badges, etc.
- Alert the staff – make the following announcement over the overhead speaker, "Our hospital welcomes the Survey Team from CMS [other]."
- Assemble key leaders for the Entrance Conference.
- Pay careful attention to the issues with which the surveyors seem particularly concerned or focused during the Entrance Conference and at each point in the survey.
- As the Entrance Conference proceeds, try to identify early the departments and services that are at particular issue. Include the applicable department and service leaders at the earliest appropriate time in the process.
- Assign an escort, scribe, and runner to accompany each surveyor on the rounds, making sure they offer whatever assistance and amenities the surveyor requires.
    - Within the bounds of the survey protocols for privacy for patients, staff and visitors, have the escort, scribe, and runner keep careful track and take notes of:
        - The identity of all individuals whom the surveyors interview or question.
        - All records the surveyors review, including patient records, logs, policies, procedures and protocols, and any surveyor comments that relate to a particular record.
        - All situations in which the surveyors take particular interest, and any comments surveyors make regarding particular issues.
    - As a finding is discovered, ask the surveyors to cite to the applicable Tag number (for a description of Tags, see Section 5.3), Standard and/or Condition. They are not required to provide this information, but it doesn't hurt to ask.
    - Don't be confrontational, but ask questions and advocate, when appropriate, for your facility's practices.

2.2 Special Guidelines for Handling an Immediate Jeopardy During the Survey

As discussed in detail at Section 1.6, a hospital should try to clear any IJ's found during a survey BEFORE the surveyors leave the facility. By doing so, the hospital can avoid formally being placed on the 23-day termination track and having to submit a separate written response to the 2567 write-up of the IJ. It is therefore crucial that the hospital be assertive and persistent in bringing all corrective action steps to the surveyors' attention in order to get their feedback on whether or not the IJ has been cleared and, if not, what else the surveyors require to be done. While constant communication will be needed during this period, an attitude of concern and cooperation is paramount.

3. Exit Conference

3.1 What Is It?

A survey can last anywhere from one hour to many days. Whatever the length, at the end of the survey, the hospital is entitled to an oral presentation given by the surveyors in which they present all of their findings. As described in Section 1.5 above, this discussion is referred to as the Exit Conference. Although it may appear casual, it is not. The hospital must take this meeting very seriously. At the Exit Conference, the surveyors are supposed to describe all the deficiencies they found during the survey. Sometimes, however, deficiencies that are mentioned during the Exit Conference will not be included in the final report because CMS may not agree with State Agency findings in the ultimate report.

In spite of the SOM's characterization of the Exit Conference as a forum for exchanging information , it is not unusual for the surveyors to discourage the hospital from providing substantive feedback during the Exit Conference. Sometimes they will ask if there are any questions. Usually, though, they expect any disputed items to have been dealt with during the survey or to await the 2567 Report. This problem can be especially difficult if the Exit Conference occurs late in the day, and surveyors have scheduling or transportation issues.

Nonetheless, if there are known errors of fact or missing information, the hospital should courteously attempt to get the correct information to the surveyors before they leave the hospital.

The SOM description of the Exit Conference is at page 21 at the following link: www.cms.hhs.gov/manuals/Downloads/som107ap_a_hospitals.pdf.

3.2 Checklist for Exit Conference

- Tape Record the Exit Conference. Because the hospital may not receive the agencies' 2567 Report for some time after the Exit Conference, it is imperative that the hospital tape record the entire meeting. This record will be the hospital's only complete and accurate source of the agencies' findings until it receives the 2567 Report. Handwritten notes and memories are not sufficient for this process. And, because it is illogical and inappropriate to wait until the 2567 Report is received, the hospital will need a detailed transcript of this meeting. **Be prepared to have two tape recorders available because the surveyors likely will not agree to record the Exit Conference unless they are allowed to leave with a copy as well** (the SOM supports their position on this issue).
- Take Notes During the Exit Conference. The hospital representatives sitting in on the Exit Conference should take note of the names of the surveyors and who is speaking to each deficiency or point described.
- Ask the Surveyors to Identify Tag Numbers. Although the surveyors are not required to disclose the Tag numbers that may be implicated at this stage of the survey process, it does not hurt to ask for this information. If there are particular patient records or interview situations involved, try to clarify the identity of the exact patient or interviewee involved.

4. The Survey Is Over; Now What?

4.1 What Is CMS or the State Agency Doing?

Once the survey has ended, and if deficiencies are identified, the State Agency is charged with drafting a detailed report of the hospital's deficiencies – the 2567 Report (www.cms.hhs.gov/cmsforms/downloads/CMS2567.pdf). Each surveyor involved in the survey will draft his/her section of the report. Thus, although the surveyors rely on templates, the style, detail, and format will vary throughout the final document. The State Agency is not required to include all of the deficiencies cited during the Exit Conference. In other words, the final authority on what is considered a deficiency is the report itself (approved by CMS), not the Exit Conference. It is important to note that the State Agency is not supposed to include any additional deficiencies in the final report that were not first mentioned at the Exit Conference. However, State Agency practice varies on this issue and the State Agency may include findings never described during the survey. (The tape recording of the Exit Conference is essential to documenting any such discrepancies, and may prove helpful in subsequent informal or formal appeals.)

As part of the final report, the State Agency will make a recommendation to CMS as to whether the hospital should be found "out" [of compliance] on any Conditions of Participation or whether the deficiencies are limited to Standards.

The SOM requires State Agency surveyors to submit their report to CMS within a specified time frame. In practice, however, the State Agency surveyors frequently miss these deadlines. Unfortunately, the hospital may not be afforded similar leniency when it comes time to produce the hospital's response.

Once CMS receives the report from the State Agency, the CMS regional office reviews the report and recommendations of the State Agency and determines what it will do. How much collaboration and editing by CMS actually takes place is unknown, but it is clear that CMS has authority to reject and/or modify State Agency recommendations. CMS makes the ultimate decision on which, if any, Conditions and Standards the hospital is out of compliance. CMS is responsible for sending the final report to the hospital. Depending on the situation, CMS may alert the hospital of the pending report via a phone call.

4.2 What Should the Hospital Do Following the Survey?

Once the surveyors have left the facility, there may be an inclination to wait for CMS's next move – i.e., to await the written survey results and see what they "really meant" by their exit comments. That would be a mistake. **The date of the Exit Conference (rather than the date the final 2567 Report is received) is the operative date that triggers the various corrective action timelines.** The agencies expect that the hospital has been given enough information during the Exit Conference to begin correcting its deficiencies immediately – and in most instances, requires the hospital to have completed its corrections **within 30 days from the date of the Exit Conference** rather than from the date the written report is ultimately received.

Keep in mind, too, that all of the hospital's deadlines are based on calendar days, rather than working days. Thus, the hospital's short clock starts ticking the day of the Exit Conference – very often a Friday – and the ticking does not lapse for weekends or holidays.

Thus, the Exit Conference is the hospital's only real source of initial direction – and a written transcription of the actual comments (rather than each participant's notes of what they think they heard) becomes a critical tool in guiding the next steps: development and implementation of an organized Plan of Correction. The Plan of Correction must be many-faceted – encompassing immediate measures to address the specific problem cited, as well as such structural and process measures as may be necessary to effectuate long-term correction and prevent recurrence. The hospital needs to create a Plan of Correction before the 2567 Report is received. This is done based on the deficiencies noted during the survey and the Exit Conference. Of course, the hospital has to make a lot of assumptions in preparing a Plan of Correction (e.g., whether the deficiencies will be noted in the final 2567 Report, how the surveyors will use each deficiency to support noncompliance of which standard and/or condition, etc.). However, Plans of Correction are essential because the hospital is required to take action as soon as it becomes aware of deficiencies and CMS requires that corrective plans be completed within 30 days from the time the deficiency is cited. The hospital should (but may not always) know of every deficiency that could be cited in the final report and it is expected to begin taking action immediately as opposed to waiting for the final report in order to make corrections. Keep in mind that in some instances the hospital may not even receive the 2567 Report for a month or two after the survey. The hospital cannot sit back and wait to take corrective action steps until that time. Instead, the hospital needs to keep detailed notes of all its corrective action steps so that, once the final 2567 Report is received, the hospital has detailed notes regarding its progress since the time of the survey.

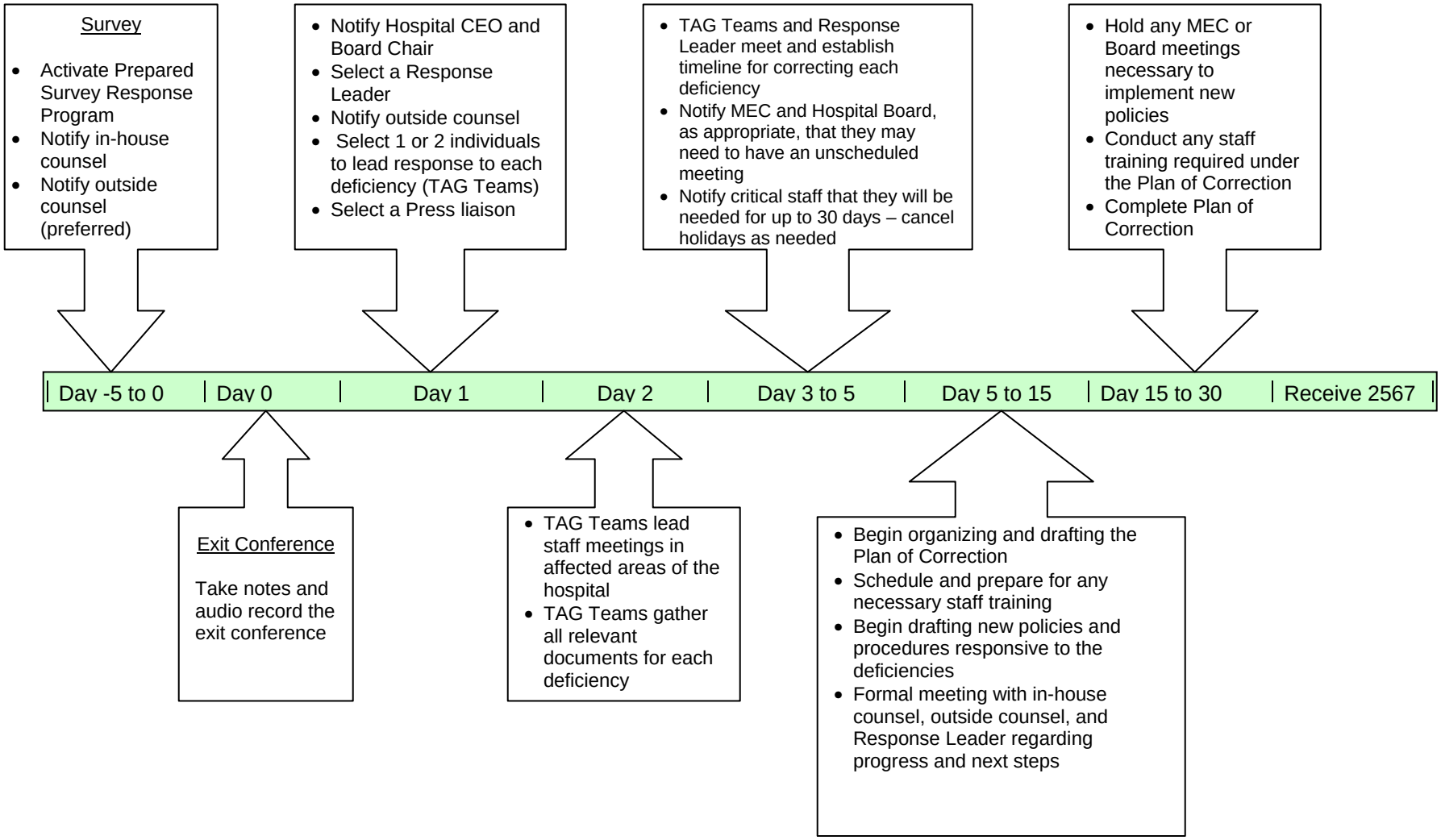
To create satisfactory Plans of Correction within the required time frames, the hospital needs to assemble a team immediately following the Exit Conference to dissect what occurred, why it occurred, what will be done to correct the occurrence, what will be done to prevent recurrence, and to implement the measures developed. Coordinate the matters raised in the Exit Conference with the notes key leaders made during the survey. Where there are particular records involved, carefully review the applicable records to identify any surveyor errors or missing information that might change the findings.

One question that has come up is whether the hospital may submit additional information to the State Agency for consideration after the Exit Conference but before the 2567 is prepared or even received. Unfortunately, there is not a formal avenue for doing so. Rather, the SOM contemplates that the provider will have an opportunity during the survey process itself to offer additional information, or that it will resolve outstanding issues in its Response to the 2567. Nonetheless, if there is a straightforward and documentable bit of additional information that was not originally available to the surveyors, but that might avert a final determination of a deficiency, the hospital should try to get that information to the surveyors as quickly as possible. Similarly, the hospital should try to get information to the surveyors of frank errors before the 2567 Report is issued.

Below is a sample timeline of what a hospital should do between the date of the Exit Conference and before the 2567 Report is received:

Sample Timeline

This timeline is an example of what a hospital might do if it had 30 days from a CMS exit conference to receipt of Form 2567*
***(note that the 2567 may not be issued in 30 days*)**



4.3 Checklist for Immediate Next Steps:

- Consolidate all of the notes and information gathered by staff members during the survey.
- Certainly at this point the hospital should consult with legal counsel to develop and/or confirm the specific strategy for the response. Having an attorney involved in the development of the hospital's Plan of Correction allows much of the work product to be protected by the attorney-client privilege. At the very least, the hospital's legal counsel should be immediately apprised, and direction sought as to marshalling additional legal and system support resources. See below at Section 4.9.
- Assemble a team of drafters and assistants. Ideally, try to limit the number of drafters so that there is a consistent voice throughout the response. However, make sure there are enough drafters who know and understand the Conditions or Standards for which they are drafting a Plan of Correction (as noted above, the hospital can only guess at which Conditions or Standards CMS finds deficient based on deficiencies found during the survey). Assistants should be identified who can gather documentation, implement corrections, and brainstorm ideas with the lead drafters. Include counsel in the drafting team or as a key advisor to the drafting team.
- Review the implicated Medicare Condition, its component Standards (insofar as they may be known at this time), and the associated Interpretive Guidelines, and try to assess how the specific problems cited in the Exit Conference may correlate with the specific Standards and Conditions. (Because individual occurrences can implicate many different Conditions and Standards, this task can seldom be fully completed until the actual 2567 Report is received. Nonetheless, an early review of the Conditions and Standards may help guide the hospital's responses and Plan of Correction.)
- Provide each drafter a template Plan of Correction.
    - A sample template is provided on the following page:

2567 Plan of Correction (POC) Template

ID#	DEFICIENCY	ID	POC	Comp Date

			• **Plan of Correction:**
			  • **Immediate**
			  • **Permanent**
			• **Responsible Person:**
			• **Monitoring:**	

Instructions:

- *use right three columns only*
- *sometimes immediate correction will be the same as the permanent; if full correction cannot be promptly implemented, need an immediate plan that will suffice to bring into minimal compliance and a permanent plan that will fully resolve. If there are both immediate and permanent actions, should also show dates that each will be effected. Right column (completion date) is for full completion date.*
- *Responsible person should be name and/or title.*
- *Monitoring – tell how compliance will be monitored; if monitoring to be conducted by other than responsible person, indicate who will be responsible for monitoring.*
- *To prepare final PoC, align PoC text with the Tag number (see* Section 5.3) *and Statement of Deficiencies (using extra pages – numbered as page 1a, 1b, ….3a,….etc. as necessary)*

- Conduct an orientation/training session including all of the staff members who will be involved in preparing the hospital's response.
  - Explain why corrective action drafting and implementation must take place now instead of waiting for the final document. Advise that the Plan of Correction serves two purposes–it starts the process of bringing the provider back into compliance AND it will serve as a tool for preparing the provider's ultimate 2567 Response.
  - Note that a separate Plan of Correction is needed for each deficiency cited.
  - Review each of the categories of the Plan of Correction and provide examples.
    - The main categories to include in the Plan of Correction are:

      1. Immediate corrective action steps taken and the dates of those actions.
      2. Permanent corrective action steps taken, including policy amendments, new policies created, education, and the dates of those actions. As to education sessions, keep syllabus materials, sign-in sheets, and records of times, dates, and places as to attendance by all trainers and attendees.
      3. Monitoring procedures that were created/revised ***to see*** that this same deficiency does not reoccur.
      4. The person(s) ultimately responsible for each fix – usually limited to one or two management-level individuals.
  - Instruct team members to gather all relevant documents for each deficiency, including any policies amended, any new forms created, etc. as a result of this corrective action process.
  - Remind team members that the corrective action process is fluid and will constantly be changing (dates will change, responses to deficiencies will change from what sounded like a good fix to what was actually feasible). Make sure the written plan of correction is continuously updated with the most recent information.
  - Establish a schedule for completing the Plans of Correction (at least as much as possible until the 2567 Report is received from CMS). Every effort must be made to **completely implement** the Plan of Correction within 30 days of the Exit Conference, even if the 2567 Report has not yet been received. Unfortunately, this may require canceling vacations and days off for key personnel. Also, the Medical Executive Committee (MEC), Governing Body, and other key committees may need to be alerted and emergency meetings convened as necessary to approve necessary policy changes. (Consider delegating authority to a smaller team – see Sections 4.6 and 4.7 below.)
- Draft and Implement the Corrective Action Plans.

4.4 Don't Waste Time on the "Ain't It Awfuls"

There is a tendency, especially following a bad survey, to circle the wagons and begin commiserating the unfairness and/or unreasonableness of the surveyors. However, there is little time for this, and engaging in "poor me" stories not only wastes time, it can undermine morale and impair the hospital's ability to effectively mobilize corrections. It thus becomes immediately important for the hospital CEO to set a tone of leadership and professionalism – to curtail bad attitudes and focus everyone on fixing the problems and getting back into compliance. Failure to curb negative energy will often result in a staff that is resistant to the changes that need to be enacted. Worse yet is that the surveyors, upon their return for the resurvey, may notice the attitude problem and mistake it to mean that the hospital is not taking the matter seriously.

4.5 Communicating with the Staff – Walking the Fine Line Between Mobilizing and Maintaining Confidentiality. Staff Briefings.

There is a definite need for hospital administration to address the results of the survey, its potential implications for ongoing Medicare certification, and the importance of prompt and effective corrective action. However, the hospital will not want to create an atmosphere of alarm or confusion. Moreover, the hospital must expect that anything said in open staff forums may ultimately make its way into the media and/or other venues. Thus, how and when the survey results are communicated is crucial to getting the staff on board with accepting and effectuating significant changes in a short period of time.

- The initial focus should be on pulling together as a team, to correct deficiencies and avoid blame. There is a real risk of back stabbing, which can undermine morale and interfere with the compliance process.
- CEOs must be quick to act. Staff meetings should be held to acknowledge the survey and the apparent negative results (based on the Exit Conference).
- The level of detail communicated will depend upon the scope of the problems, as well as the particular forum.
    - If many areas of the hospital's operations have been found deficient, general staff meetings will be necessary to generally communicate what is happening, answer general questions, and quash unnecessary rumors.
        - For these meetings, avoid specifics, as confidentiality issues are at play.
        - Try to speak of general areas that require improvement and what the general process will be.
        - Focus these discussions on how improvements will benefit hospital operations and patient care.
        - Encourage employees to ask their managers if they have any questions, but to be circumspect in speculating and discussing this unnecessarily.
    - Additional staff meetings will likely be necessary to "drill down" to the individuals whose actions and cooperation will be needed to effectuate corrections. For these meetings:
        - Be straightforward about areas of deficiencies (although confidentiality as to specific details is still important).
        - Give the staff an idea of what the process will be (Plans of Correction, new policies and procedures, more surveys, etc.).
        - Best yet, try to develop an "ownership" mentality, emphasizing the importance of their cooperation and active participation. Encourage the staff to be part of the solution by letting them know that as new draft policies and procedures are produced, their feedback and comments are a necessary part of the improvement process.

4.6 Medical Staff

Whenever the deficiencies involve issues within the purview of the Medical Staff, prompt notice to the Chief of the Medical Staff is necessary. Early convening of the Medical Executive Committee may also be needed. Hopefully, key leadership will have been previously trained as to maintaining compliance with certification, licensing and accreditation requirements, as well as the survey process including how to deal with surveyors, as described in Section 2.1. Similarly, if deficiencies involve issues within the purview of Medical Staff committee(s) or department(s),

the committee or department chair(s) need to be apprised and emergency meetings convened as early as possible. Each affected committee or department should consider whether delegation of immediate action authority to one or more representatives will be necessary to facilitate prompt corrective action.

The Medical Staff response to the survey is one of the more difficult issues to manage, and hence is an area where leadership is key. Early mobilization of key staff leaders is critical to effective corrective actions. And while it is generally true that the corrective measures will involve policy and procedure changes and other generic changes to Medical Staff operations, it is sometimes true that remedial action may require practitioner-specific corrective action pursuant to the Medical Staff bylaws.

Perhaps the most important thing for the hospital managers to keep in mind as it relates to issues within the Medical Staff purview is that administration, alone, cannot (and should not be expected to) resolve a Medical Staff problem. Thus, it is important early on to evaluate what is really at issue, and to work with the Medical Staff leadership to identify specific actions that effectively address **and resolve** the identified problem(s).

4.7 Governing Body

The survey results should be promptly communicated to the chair of the hospital's Governing Body. Together, the chair and the hospital CEO should determine how much and how soon additional communication to the full Governing Body may be needed. While there may be an inclination to spare the Governing Body specific details, and a reluctance to involve them in specific remedial actions, it is important to keep in mind their overall responsibility for the hospital, and that they may receive inquiries from a variety of sources (inside or outside the hospital). They will not want to be caught off guard.

Moreover, in some cases – and especially where the Governance Condition is or may be involved – early and proactive Governing Body participation may be called for. Key factors to look at are:

- If the Governing Body Condition of Participation, or any related Standards, are cited as out of compliance, then the Board must be made aware of these right away. In this circumstance, the Board will likely need to demonstrate improvement in its oversight functions in order for the Condition or Standard to be found back into compliance, and, as such, the Governing Board cannot take a passive role in the fix.
- Consider the need for a Board task force, or at least a delegation of authority to a group or committee as may be needed to effectuate prompt corrective actions.
- If the findings suggest that a lot of policies and procedures will need Governing Body approval, the Governing Body may need to be put on-call to be available, when needed, to approve these changes. (Check the meeting notice requirements of the hospital's corporate bylaws.)
- Here, too, consider whether the Governing Body should be asked to delegate approval authority to key individuals to alleviate the burden of seeking full approval. If there is a delegation of authority, there still needs to be ultimate accountability to the Governing Body. However, most actions can be implemented upon approval by the authorized representative(s), and later ratified by the Governing Body.

4.8 Dealing with the Press

The hospital should anticipate that sooner or later, the press will learn of the results of the survey. This is especially so if there has been an Immediate Jeopardy declared. A plan for communicating with the media should be developed.

- Identify a spokesperson and inform all managers who that spokesperson is. All managers should direct inquiries to the spokesperson. (Also, in meeting with the staff, a general discussion should direct staff to forward press inquiries to their managers or other designated individuals.)
- Communications with the media should not discredit the surveyors.
- If the hospital disagrees with the survey results, a matter-of-fact statement to that effect may be appropriate.
- The hospital should not concede mistakes, nor should it discuss specific findings. Rather, a simple statement such as: the surveyors identified issues that they believe indicate the hospital's noncompliance with Medicare Conditions of Participation. The hospital [is already assessing what actions should be implemented to assure the surveyors that the hospital does comply with the Conditions] – [has already taken measures to assure the hospital's ongoing compliance with the Medicare Conditions].
- Where serious issues have been identified, it is not helpful for the hospital to trivialize the results – that has the appearance of "sweeping things under the rug" and ultimately of undermining public confidence in the hospital.

4.9 Involving Counsel and Consultants When Termination Is Possible

Although not all providers adopt this practice, whenever it appears that the outcome of a survey could result in termination, a hospital should consider immediately involving counsel experienced in assisting providers to avoid or minimize the risk of termination. Except in rare cases, it is not usually a good idea to have counsel present at the Exit Conference (*see* Section 3 and www.cms.hhs.gov/manuals/Downloads/som107ap_a_hospitals.pdf); however, telephone or in-person consultation with experienced counsel can be very useful in assisting hospital leadership to assess the risks of termination and to prepare for and take best advantage of the Exit Conference.

In a termination track situation, it is highly advisable to involve counsel before the 2567 Response, the Plan of Correction, and the credible allegation of compliance, respectively, are finalized (ideally, counsel should be involved immediately after the Exit Conference or during the survey if an Immediate Jeopardy occurs). Primary roles of counsel are to review the documents with an eye to the specific Tags, the Conditions of Participation, Standards, and Interpretive Guidelines involved. Counsel can also advise on the best way to structure a credible allegation of compliance, especially when full compliance cannot be achieved immediately, such as when equipment purchases, construction, or major training efforts are required.

In certain cases, especially where the hospital's staff may not have the requisite experience, it may be advisable to involve consultants. This is especially the case where complex processes are involved. Examples include a need to reorganize the medical records function or respond to laboratory deficiencies, and certainly if the experience or competence of the current director of the function is at issue. Consultants need to be selected carefully, but with such attention to speed as is commensurate with the potential termination schedule. Counsel may have worked with consultants in prior cases and may be helpful in identifying and contracting with them.

When outside consultants are used, confidentiality of the information the consultants obtain is always an issue. It is necessary to use business associate agreements that comply with the Health Insurance Portability and Accountability Act. Where state laws permit, it is advisable to structure the engagement to make the consultants a part of the hospital's quality review process and to take maximum advantage of state confidentiality laws relating to peer review and/or corrective measures involving staff, personnel or processes. Counsel can be helpful with these agreements. Consideration should also be given to whether consultants should be engaged by and report to counsel in order to take advantage of attorney work product privileges.

When consultants are involved, counsel can help assess whether it would be helpful to disclose their participation to CMS and/or the State Agency. If CMS or the State Agency are familiar with and have confidence in the particular consultants, that may improve the prospects for a finding of a credible allegation of compliance at a stage before the consultation process is fully completed. One cautionary comment must be made. Some consultants are former surveyors. There may be conflict of interest and other legal prohibitions that should be explored before a consultant is engaged, including the need to have a consultant certify that the consultant knows of no prohibitions. Providers should also be aware that recent Joint Commission practice is not to permit its part-time surveyors to act as consultants. Thus, in a validation survey, where the provider may be restored to "deemed status" if all the processes are successful, the issue of using part-time surveyors as consultants should be carefully evaluated.

5. Agency's Report to Provider – CMS Form 2567[1]

5.1 Receipt of CMS Form 2567

CMS will produce a final report of the hospital's deficiencies (2567 Report). This report is printed on a form template, CMS Form 2567. CMS will mail the 2567 Report directly to the hospital. CMS may also fax the report and/or call the hospital to give them a heads up that the report is on its way.

5.2 Cover Letter Accompanying the 2567 Report

The 2567 Report is usually accompanied by a Cover Letter from CMS. This too is usually a template that CMS tailors to fit the circumstances particular to the hospital in question. The Cover Letter is a critical document and must be reviewed very carefully.

- Termination Date – if the hospital is found out of compliance with one or more Conditions of Participation, the Cover Letter will state the ultimate date that the hospital's CMS certification will terminate if the Condition(s) are not brought back into compliance in the required amount of time. The Cover Letter will also include the date that CMS will give notice to the public regarding the termination (required by law).
- Date Hospital's Response Is Due – this date is usually a fairly quick turnaround (10 calendar days normally). If the date falls on the weekend or a holiday, be sure to get CMS confirmation that receipt of the hospital's 2567 Response by the next working day is acceptable.
- Review of Hospital's Response/Right to Resurvey – the CMS Cover Letter will explain that CMS will authorize the State Agency to perform a resurvey only if the hospital's 2567 Response is timely, responsive to all deficiencies and credible.
- Ability to Resurvey – Recent CMS Cover Letters also explained the process that would occur if authorities could not resurvey the hospital prior to the termination date. This language is especially disturbing because it ignores CMS prescribed timelines. By law, CMS is required to resurvey before termination if the hospital submits a credible allegation of compliance. See 42 C.F.R. § 488.18.
- CMS and/or State Agency Contact – The Cover Letter should include a contact name and number that the hospital should call with questions.
- List of Noncompliance Conditions – this list summarizes the Conditions with which the hospital is not in compliance. The report itself may include other Standards that, although they are deficiencies, do not cause the applicable Condition to be out of compliance.

  Elements to Address in the Hospital's Response - The Cover Letter will spell out specific elements that CMS expects the hospital to address in its 2567 Response, for each deficiency. Be careful - these elements vary with each Cover Letter. There is no one formula to a hospital 2567 Response because CMS sometimes alters the required elements for the hospital's response.

  These variances in Cover Letter instructions can further complicate the hospital's move from its preliminary Plan of Correction to its 2567 Response. The important

[1] [See SOM 2728, 2728A and 2728B and SOM Appendix 7A]

point here is that the hospital's 2567 Response must specifically address each category listed in the Cover Letter. (See below for further instructions about how to address each category.)

5.3 Form CMS 2567 (www.cms.hhs.gov/cmsforms/downloads/CMS2567.pdf)

Each Standard and each Condition of Participation has two numbers associated with it. The first is a code section citing to the requirement's location in the Code of Federal Regulations. The second number is a CMS generated "Tag" number associated with the particular code section.

- The CMS Form 2567 is a four-column document:
  - The first column and the third column (identical) include the ID Prefix Tag associated with each deficient Condition and Standard. These Tag ID numbers are found in the State Operations Manual at Appendix A.
  - The second column includes:
    - A cite to the full regulatory authority. The CFR citation refers to the actual Standard or Condition at issue as it is stated in the federal regulations.
    - An explicit statement that the Condition or Standard is not met and how that determination was made.
    - A detailed description of the findings. The statement of the evidence describes the circumstances the surveyors found that led them to conclude that a deficiency exists. The statement may be short or lengthy and may be broken out into separate findings that separately or together demonstrate noncompliance. It is not unusual for this statement to be highly repetitive and difficult to follow. Be careful to take the time to read each finding to ascertain what exactly is being cited as a deficiency and what may be superfluous information.
      - In a Condition Tag, each finding is usually followed by a reference to the Standard Tag implicated.
      - In a Standard Tag, if an interview supported the finding, the details of that interview will be described, but the form will usually not identify specific individual interviewees or patients because of confidentiality issues and the fact that the 2567 Report is ultimately a public document. That is why all of the suggestions for documentation during the survey, as made in Section 2.1, are so important. Also, if the hospital has failed to abide by a policy and procedure, then that particular policy will be mentioned and summarized to further demonstrate the deficiency.
  - The fourth and fifth columns of the CMS Form 2567 are blank when the 2567 Report is received. While column four is called "Provider's Plan of Correction," the actual response required for this column may be a Plan of Correction or a Credible Allegation of Compliance, depending on the type of survey, the findings and the instructions in the Cover Letter. See additional discussion at Section 1.5.

6. Provider's Response to 2567

6.1 Understanding the Termination Process and Responding to the Prospect of Termination

It is essential to understand the various types of termination tracks in order to prepare an adequate response. See discussion above at Section 1.5. There are significant differences in preparing a response to a prospect for termination on a 90-day schedule versus a 23-day schedule in cases involving Immediate Jeopardy. Seek advice from counsel to navigate the nuances of a 23-day termination track (obviously, time is of the essence in this situation).

6.2 Turning the Plan of Correction into the 2567 Response.

While the surveyors sometimes refer to the required response as a "plan of correction," the fact is that, depending upon the findings from the survey, a variety of responses may be called for.

- The facility puts together a **preliminary** Plan of Correction based on the Exit Conference, before it receives the 2567 Report.
- If Condition-level deficiencies are not involved, the hospital will be expected to present an acceptable Plan of Correction to the State Agency for State Agency monitoring.
- If one or more Condition-level deficiencies are found, the hospital will be required to present a "credible allegation of compliance." (*See, e.g* Ch. 3 section 3016A. www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS019027&intNumPerPage=10).

The precise terminology and expectations have varied from survey to survey. However, the gist is that if a Condition-level deficiency exists, the 2567 Response **must demonstrate what has been done**, not what will be done to correct the deficiency.

There can be some critical differences between the preliminary Plan of Correction (which is usually an immediate-response plan that is not necessarily tailored to the 2567 Report) and the very specific response that will be required to the 2567 Report (2567 Response). While the preliminary Plan of Correction is used as a resource for drafting the hospital's 2567 Response, it is a mistake to let it drive the 2567 Response. Rather, the 2567 Report should serve as the template for developing the 2567 Response. The hospital needs to reorganize the pertinent information contained in its Plan of Correction, as necessary, to show how its actions have addressed the specific findings cited by the surveyors. It is important to follow the exact order of the findings in the 2567 Report, and to respond to each and every finding.

One problem is the hospital team sometimes becomes wedded to its Plans of Correction. The hospital benefits from this ownership in that it helps get the deficiencies fixed right from the beginning. But the drafters' investment in their work can be counterproductive when it comes to drafting the actual 2567 Response. There is a tendency to want to simply restate the overall Plan of Correction rather than to isolate the specific issue involved in each finding, as well as the specific corrective measures that address the specific issue.

However, once the 2567 Report is received, the team needs to approach the issues differently. This is because the surveyors take general factual findings (which findings they have reported to the hospital at the Exit Conference), and they "unbundle" them into as many different

conclusions as they possibly can. A single fact, thus, may be used to support a conclusion that the hospital is out of compliance with a whole series of component Standards within a Condition, as well as a conclusion that the hospital is out of compliance with more than one Condition. Thus, even though the surveyors may repeat a certain fact throughout their 2567 Report, the gist of the conclusion will shift slightly from Standard to Standard, and significantly from Condition to Condition. The hospital's response must likewise be tailored, in each instance, to address the specific Standard and/or Condition at issue.

Too, despite the fact that the surveyors are supposed to have reported all findings during the Exit Conference, there may be new findings the hospital has never heard of, the report may exclude some findings the team was expecting to see and was prepared to respond to, and/or the report may present expected findings but with facts that are slightly different than anticipated. In sum, anything is possible.

The solution: Let the findings in the 2567 Report control.

- If there is a new issue presented, get working on a Plan of Correction and 2567 Response immediately.
- If a finding is excluded from the 2567 Report that the hospital worked on in its preliminary Plan of Correction, there is no need to (and the hospital should not) mention it in the 2567 Response.
- If the findings contain some surprises or different facts, adjust the hospital's 2567 Response to fit those facts and forget the old facts that were originally anticipated in the Plan of Correction. Be alert for frank error in the 2567 Report or the need for additional clarifying information, and correlate the findings and facts in the 2567 Response with the notes taken by key leaders during the survey.
- Most important – "rebundle" the information from the generic Plan of Correction as necessary to address each finding within the context of the specific Standard and Condition.

6.3 Manual, Not Electronic.

CMS will mail the 2567 Report directly to the hospital. If it is lucky, the hospital will also receive it by fax. That is as electronically savvy as CMS gets. The 2567 Report is **not** available electronically. CMS appears to rely on paper because it cannot guard against the possibility the recipient hospital might alter the CMS portion of the 2567 Report.

As a result, the hospital must produce its 2567 Response on paper. Ironically, in this age of computer-generated documents, one of the trickier problems associated with drafting the hospital's response is the logistics of getting a typewritten response into the far right column of the 2567. However, if the hospital's response is produced within a template document known to fit within the margins of the 2567 columns, it is possible to manually produce the required response. Using such a template, a new document can be created for every Tag in the 2567 Report. (Immediately upon receipt of the 2567 Report, the hospital should confirm that the columns in the 2567 Report match the columns in the 2567 Response Template. Adjustments to column widths are easy to do at the outset, but can be much more complicated down the line.) The hospital team should draft its response in the far right column only. The left column should always be left blank

For specifics on how to produce the response document, see Section 6.5.

6.4 Upon Receiving the 2567 Report, the Hospital Should:

- Make multiple copies of the report, and set aside the original for use in final production.
- Immediately contact legal counsel and enlist such assistance as needed to develop and produce the 2567 Response.
- Read and Analyze the full 2567 Report.
  - Identify which Tags are Conditions and which are Standard-only Tags.
  - Designate a team leader for each Condition. Key Conditions are usually pharmacy, infection control, surgery, nursing, medical staff, and medical records. The team leader is most likely the drafter of the preliminary Plan of Correction and will also be responsible for overseeing the drafting and implementing the 2567 Response.
  - Determine whether any findings are new and need to be addressed for the first time.
  - Determine which findings have already been addressed in the preliminary Plan of Correction and only need slight fact-specific modifications.
  - Identify whether there are findings addressed by the preliminary Plan of Correction (i.e., findings described during the Exit Conference that are not mentioned in the 2567).
  - Review again the actual Condition and Standard requirements and the associated Interpretive Guidelines.
- Calling CMS/State Agency – Pros/Cons
  - Strategize – assemble a team meeting to gather all the questions and how to approach each one.
  - Seek clarification from CMS/State Agency, if necessary.
  - Respect the chain of authority, but if it is not working for you, escalate the matter.
  - Make sure you get clear answers.
  - Identify who you should work with in the future if more questions arise.
- Create a General Template Outline or Formula for Responding.
  - Insofar as possible, each response to Standards and Conditions should have a similar outline. This can be especially tricky because the 2567 Report is often prepared by multiple people and is not consistently organized. Establishing a basic outline will provide ease of drafting for the hospital team and ease of reading for the surveyors. But form should never control over substance – there may be exceptions (based on how the 2567 Report is drafted) that require a particular Tag to take on a look or feel of its own. The ultimate goal is to communicate corrective action that can be readily identified as responsive to each and every one of the specific findings.
  - Look back to the Cover Letter for the specific elements required in the response, and tailor the outline accordingly - i.e., include a heading for each element, so that the drafters are sure to address each required element.

- Below is a Model Outline for a Standard Tag Response:

Actions Resulting in Correction	Date of Correction
[Summary statement that affirms the hospital's compliance and presents an overview of how the hospital addressed the overall issue. Then, if the surveyors use multiple findings in support of their conclusion, go on to address each finding as follows:] With respect to the findings: Immediate Actions: • [*use outline numbers only if specifically referring to a corresponding CMS numbered finding]* • • Other Permanent Actions: • • • **<u>Monitoring:</u>** **<u>Responsible Persons:</u>**	*[must be no later than the due date]*

- A Model Outline for a Condition Tag Response is included below:

Actions Resulting in Correction	Date of Correction
Statement using the deficiency's language that hospital is in compliance, i.e., "The hospital has taken effective measures to see that it . . ." Describe any immediate actions the hospital took to correct the deficiency – these are actions taken before the survey concluded. "The hospital immediately acted to . . . . Additional measures to achieve and maintain compliance are described below." If the findings are broken out into numbered findings, use the same numbers to list actions taken with respect to each finding. With respect to the findings: [*used numbers because they correlate to actual findings in the CMS report*] 1. The hospital . . . . These measures are more fully described below at Tag 121. 2. The hospital . . . . These measures are more fully described below at Tag 122. 3. The hospital . . . . These measures are more fully described below at Tag 128 . . . . **Summary of Actions Taken** Describe here all actions taken since the conclusion of the survey to correct the deficiencies. May be broken out under headings: Policies and procedures Education **Monitoring** Describe here how the hospital will see that new procedures are implemented and compliance is achieved and maintained. **Responsible Person(s)** Name one person who is responsible for achieving and maintaining compliance.	(must be no later than the due date)

- Revise the Production Schedule.
  - Know which track you are on (IJ – 23-day termination, 90-day termination, State Agency monitoring).
  - As noted, above, different elements are required by each track (and by each Cover Letter). Determine which elements are required.
- Create a Patient Matrix.
  - To see that actions taken with respect to particular patients are consistent AND to make sure that each patient is addressed, it is helpful to create a cross-referencing tool.
- Conduct a Second Orientation/Training Session.
  - Bringing together the response team as a whole is helpful in cultivating a "big picture" understanding of the process.
  - Specifically and completely answer each Tag. Advise the team not to rely on cross-references to other Tag responses as to any information integral to a full answer to the Tag.
- Alert Committees and the Board (or designated board members).
  - Key committees (or their designees) must be on stand-by to approve policies or take other actions within their purview.

6.5 Tips for Drafting the Hospital's 2567 Response

- Every response to a Tag must stand on its own (with rare exceptions). The entire answer, complete with all the detail, must be in the hospital's response to each individual Tag. This requirement can result in a lot of repetition. However, the surveyors require this formula because the hospital's 2567 Response may be broken up among the surveyors for review, therefore making cross-references difficult for them to evaluate. Naturally, there are exceptions to the rule:
  - Because a Condition Tag encompasses one or more Standard Tag findings, if the hospital followed the directions above, the hospital would have to repeat the entire response to each Standard Tag in the Condition Tag. To avoid such repetition, it is recommended summarizing the responses sufficiently to address the overall Condition, then referring to the Standard-level response for additional detail.
  - The hospital should make a determination whether there are other instances where it does not make sense to repeat the hospital's answer.
- The goal of the hospital's 2567 Response is to include enough detail about the action steps taken to correct a deficiency that the surveyors can envision the "fix" and understand its detail without having the actual documents (i.e., policies and procedures, training manuals, signage, etc.) in hand. There are several reasons for doing this: one is to focus the surveyors on the specific fixes undertaken (rather than giving them a document and expecting them to locate the fix). A second reason is the hospital does not necessarily want the surveyors to have its actual policies, procedures, and other documents sitting in front of them for prolonged dissection and critique. Third, there are confidentiality issues (even though the hospital may be entitled to claim certain documents are confidential and not to be released to the public, there is a danger that confidential or proprietary information will be disclosed). Finally, the availability of full documentation back at the hospital can even serve to entice the surveyors to return to the facility (remember the hospital's goal is to convince

the surveyors that the matter has been fixed, and get them to come back out to the facility to confirm compliance).

- Each Tag response should directly address every fact included in the Tag finding:
  - Thus, in addition to addressing the overall conclusion or issue, every finding must be acknowledged and addressed.
  - However, be prepared to distinguish relevant from irrelevant facts, as well as distinguish facts from opinions and suggestions. Some surveyors write elaborate descriptions that include truly irrelevant facts. Others include their observations of what they think could or should be done. The hospital is not required to accept these opinions (although it should develop at least a courteous acknowledgment of the opinion, and perhaps a statement of an alternative approach that has been implemented, if applicable).
- Keep in mind that the 2567 Report, and the hospital's 2567 Response will be public documents. This has many implications. The hospital will want to minimize adverse publicity, clarify misperceptions, and generally reassure the public about the facility. There may well be an inclination to challenge or otherwise debase the credibility of the findings. This must be delicately done, if at all. Care must be taken not to offend (remember, there is still significant agency discretion to be exercised), yet not to permit incorrect or unwarranted conclusions to go unanswered. The response should never be inflammatory or personally derogatory of the surveyors or any agency staff.
- Drafting the Hospital's Response – Condition Tag

  Recall that Condition Tags cite to one or more Standards that are deficient. There is no magic number of how many Standards a hospital can be found out of compliance with and still be in compliance on the Condition – rather, this is a subjective decision on the part of CMS, and is based on the nature and extent of each Standard-level deficiency as well as the collective effect of all of the Standard-level deficiencies.

  Sometimes the 2567 Response for a Condition Tag can be easily developed, with minimal repetition of information contained in other Tags, but in some cases this is not possible. Thus, the most appropriate response to a Condition Tag is really a judgment call. Where, for example, the surveyor's 2567 write-up itself cross-references to other, more specific Tags, it is usually possible to develop a summary-level response for the Condition Tag, and then cross-reference to the greater details that are contained in the more specific responses to the applicable Standards Tags. In other cases, this will not be possible. The key is to develop a complete enough answer to fully respond to the crux of the Condition, yet avoid, if possible, unnecessary redundancy. No small task, to be sure.

  Despite these general guidelines, the hospitals seem to have the most trouble developing a properly focused Condition-level Response. Accordingly, consultation with legal counsel is especially advised at this stage.

- Drafting the Hospital's Response - Standard Tag
  - Action Items:
    - **Immediate action response** – think of the most obvious fix to a problem. Below is illustration of how a hospital should and should not approach this response:

Finding included in 2567:	The light fixture in Closet X was burnt out.
INCOMPLETE RESPONSE:	• On [date], amended facility's policy and procedure as to how often light bulbs should be checked during rounds.
PREFERABLE RESPONSE:	• Burnt-out light fixture in Closet X was immediately replaced on [date] (date of survey).

    - Other action steps to describe:
      - New or amended Policies and Procedures or forms
        - As noted at Section 6.4 above, it is generally preferable to provide detailed descriptions of new/revised policies, rather than simply providing the revised policy and letting the surveyors find the fix.
        - Moreover, it is not enough to respond by including the title of a newly created policy and the date it was approved. Rather, specific descriptions of what is included (or different) in this policy and procedure are necessary to make the response complete. Alternatively, if there is relatively short language in an amended policy, it may be good to quote that language. After reading the response, the surveyor should be able to envision what the substance of the policy contains. The following is an illustration of this point:

Finding included in 2567	Nurses repeatedly found not complying with 8/24 hour medication checks. No hospital policy found relating to these requirements.
INCOMPLETE RESPONSE:	Drafted and implemented Nursing Structure Standard XX and 24 Checks on [date].
INCOMPLETE RESPONSE:	Drafted and implemented Nursing Structure Standard XX and 24 Checks on [date] to provide more definition on the 8- and 24-hour medication checks. Scheduled for MEC and Board approval.
PREFERABLE RESPONSE:	Drafted and implemented Nursing Structure Standard XX and 24 Checks on [date] to provide more definition on the 8- and 24-hour medication checks. These changes included:

	• A 24-hour worksheet is to be printed by each licensed nurse prior to the end of a shift; • All physician medication orders are compared to the 24-hour worksheet; • All unapproved abbreviations have been clarified and rewritten; • All medication orders for qualifiers are clarified; • There are no range orders for pain medications; • All late doses are charted as "late" or "not given"; • Patient allergy history is verified and is present on the MAR. These policy changes were immediately implemented and approved by the Nursing Department on [date]. They are scheduled for action by the MEC during its next scheduled meeting on [date] and by the Board of Directors during its next scheduled meeting on [date].

- If a policy or procedure goes through multiple drafts of amendments (i.e., a new nurses' medical record documentation policy is amended first after the survey, then after input from nurses during a training fair, and finally after a pilot form is used in one particular department), the hospital's response should reference all stages of the amendment process. These amendments can illustrate the hospital's quality improvement process at work, and can even turn a criticism (i.e., that the hospital did not achieve an immediate and fully effective fix) into a plus (i.e., that the hospital's continuous quality improvement activities didn't stop with the immediate fix, but were part of an ongoing activity aimed at continuous improvement).
- Do NOT include a copy of the policy and procedure in the 2567 Response. DO include a copy of the policy and procedure in the binder for surveyors to review in the hospital upon resurvey.
- Reasons NOT to attach the actual revised documents to the 2567 Response include:
  - It may not be possible to avoid redisclosure by the agency of proprietary or confidential documents.
  - Surveyors may take the opportunity to scrutinize the document and find other deficiencies.
  - Surveyors may use the documents as a reason not to do a resurvey, thereby depriving the provider of the opportunity to make a good appearance at the resurvey. Not producing the actual documents can therefore act as a hook to get the surveyors to come back out to the facility.

- **Disciplinary actions taken.**

Because of the potential for liability to medical staff members and employees, and the expectation of confidentiality under certain state laws, the provider is well-advised to have counsel opine on whether the hospital is permitted to disclose to CMS or the State Agency specific details of any corrective or disciplinary actions. In addition, whether there are exemptions under state or federal FOIA or other similar state laws, is usually a matter of (or affected by) state law.

In cases where counsel cannot opine favorably on hospital liability and FOIA or similar state law exemptions from disclosure of documents in the hands of CMS or the State Agency, it may be sufficient to put the following type of language in the 2567 Response:

> 'The hospital carefully reviewed and documented its review of any allegations made as to employees and/or medical staff members to determine whether any disciplinary or corrective action was warranted as to acts or omissions by or relating to such persons. These reviews were completed as to employees on _____,_____, and as to members of the medical staff on _____,____.
>
> 'Employee matters are reviewed under the policies and procedures of the Department of Human Resources (approved on _____,__, by the Board of Trustees). These include a system of progressive disciplinary action for which the Director of Human Resources is ultimately responsible. Complete records of any such actions taken during the period from _____, ____, to _____, ____, are maintained and are available for on-site inspection in the Office of the Director of Human Resources.
>
> 'Medical staff matters are reviewed by medical staff department and service chiefs and applicable committees under the direction of the Chief of Staff, and any actions are ultimately subject to approval or disapproval by the Board of Trustees, which has overall responsibility for the quality of care rendered in the institution. The medical staff has bylaws, rules and regulations that deal with peer review and corrective action as to medical staff members (approved by the medical staff on_____,___, and by the Board of Trustees on _____,___). Complete records detailing any corrective actions that took place during the time period from _____, ___, to _____,___, are maintained in the Office of the _____, and are available for inspection on-site. The Board of Trustees is subject to the procedures specified in the documents listed above, and is also bound by its own bylaws (approved by the Board of Trustees on _____,___). Complete records detailing any corrective actions undertaken by the Board of Trustees are maintained and are available for inspection in the administrative offices of the provider.'

Similar language should go into the Plan of Correction, which should also include reference to a review of the adequacy of the applicable policies, procedures, bylaws and rules and regulations and any amendments undertaken either by the Department of Human Resources or the medical staff and Board of Trustees. The Cover Letter should reference the fact that the hospital took seriously its

responsibility to consider whether to disclose in the 2567 Response details of any disciplinary or corrective action, and after consultation with counsel determined that the better practice would be to detail the applicable procedures in the 2567 Response, and to make available for on-site inspection the details of the decision making processes, and of any corrective or disciplinary actions undertaken.

In cases where counsel does opine favorably on hospital liability and FOIA or similar state law exemptions from disclosure of documents in the hands of CMS or the State Agency, the hospital's response should include, when applicable, each level of disciplinary action taken with regard to each individual cited in the findings. Where disciplinary action involves an individual not previously identified by the surveyors, the response might need to be more circumspect. Keep in mind; in any case, this is a public document. Counsel should assist in the strategy for any disclosure of disciplinary action, and also negotiate with CMS and the State Agency as to redisclosure issues. For example, when there are state laws that confer confidentiality as to records of disciplinary action, there is a federal FOIA exemption (and there may be a corresponding state exemption) for information exempted by other specific statutes, or there may be exemptions for certain information submitted with an expectation of confidentiality. It should never be assumed that CMS or the State Agency will be focusing on those exemptions, and the issue of redacting the exempted language and avoiding redisclosure should be specifically negotiated. Where necessary to preserve individual privacy, it may be necessary to allude to actions taken, being prepared and able to demonstrate specifics at the time of the resurvey.

- When it is determined to be appropriate to disclose details of disciplinary action in the 2567 Response, more than one level of discipline can be described. For example, if a nurse is first verbally counseled for failing to record vital signs, but later he or she is given a written counseling and required training, all three parts of the disciplinary action should be detailed, including the dates. Do NOT just describe the final action taken.

- **Procedures for Implementation/Education.** Sometimes the Cover Letter instructions ask the hospital to describe their "procedure for implementation." CMS has not been very instructive about what they are seeking through this request, but describing education activities is generally the best way to respond to this element. Include all types of education, whether individualized or group, whether the education is written or oral, whether it's planned or unplanned, etc. Include all dates that the education occurs, not just the first or last date. It is wise to keep sign-in sheets and the syllabus or curriculum, and to reference in the 2567 Report that these items are available.

- Monitoring:
  - Monitoring is where the hospital describes what review, quality assurance measures, monitoring procedures, etc. are being done so that the particular deficiencies cited in the findings do NOT/CANNOT happen again.

  - Here, too, hospitals often have difficulty knowing just how to structure this element of the response. The thrust should be what activities the hospital has undertaken and will continue to confirm the efficacy of its corrective measures. This also is an element that often needs to relate back to the hospital's ongoing quality improvement processes. Suggestions for developing this element include:

        - **Choosing the appropriate level of monitoring.** The type of monitoring chosen must be proportionate to the deficiency and the effect on patient care – i.e., the amount/type of monitoring must complement the deficiency.
        - **Determining specific monitoring responsibilities.** This includes describing who is responsible for monitoring to see that the deficiency isn't occurring (title of person(s)), how often they monitor, what they monitor for, who the results are reported to, what happens with the results (whether good or bad), what procedures are in place to alert key personnel if a problem occurs again so it can be stopped early in its tracks.
        - **Relating to the Quality Improvement Process.** This is also the time to assess how the results monitoring should be integrated into the hospital's larger QA/QI processes.
        - **Tiered monitoring.** When warranted (i.e., if patient care is at stake or a deficiency is not getting fixed after being monitored for a few weeks), a tiered monitoring plan should be considered. Here, the first layer of monitoring is intense and aggressive – whether the review is hourly or daily. After improvement is seen, monitoring can drop to a lesser scrutiny (i.e., weekly reviews). Finally, once ongoing [substantial] compliance has been achieved, monitoring can return to part of a general audit process.
- Person(s) responsible:
    - The surveyors want only one person ultimately responsible for compliance with each Tag. Usually this will be a key director or CEO. Look at the Tag to see if it is specific to a particular position's responsibilities (e.g., the director of nursing is responsible for . . . "). If so, the responsible person must be that individual in question.
    - In rare instances, a Tag will require more than one responsible person. This, however, is the exception to the rule.
- Date completed:
    - The 2567 form contains a column where the hospital is required to put a date by which the deficiency for each Tag was fixed.
        - Only one date should be included in the column, across from the first line of each Tag.
        - The date used should be the latest date when all of the collective actions that formed the response were completed. This date should be within 30 days of the Exit Conference, or in any case (with rare exceptions) no later than the date the 2567 Response is due. (Rare exception: certain actions, such as plant and equipment changes, may not be able to be completed until a later date. When that occurs, it is necessary to fully describe concrete steps already completed, and it may be possible to select the date the hospital formally initiated action [such as starting a construction project, or submitting documents for approval, or ordering equipment] as the completion date. This MUST be accompanied by an explanatory note as to when final completion is expected.)
        - All other interim dates should be embedded in the explanation of the action items.
    - **Further comments on how to deal with action steps that still need to occur after the required completion date.** As noted above, the hospital is generally required to have fixed the deficiency within 30 days of the Exit Conference, or in any case, by the time the 2567 Response is submitted. Thus, technically, there is no

room for dates beyond the due date for the 2567 Response. However, sometimes this is simply not possible to achieve. In these cases, it is important to have actually implemented sufficient measures to bring the day-to-day activities into compliance, such that the only actions remaining are, in essence, ratifying already-corrected practices. When this occurs, make sure to at least describe what committees or individuals have actually approved the document/action and then state, specifically, when the remaining approvals will occur (must be the next meeting) and note that their approval is already on the agenda for that meeting. An illustration is included below:

If the MEC or Board has not yet approved a policy and procedure, use the following language: *"These policy changes were immediately implemented and approved by the Department of Nursing on _____. They are scheduled for action by the MEC during its next scheduled meeting on _____ and by the Board of Trustees during its next scheduled meeting on _____."*

If an educational fair/training program will run for a number of days, state which dates of the fair have occurred prior to the due date and then state, *"Training will continue on 4/10-4/15 in order to achieve 100% attendance by all trauma nurses."*

- Troubleshooting the Hospital's 2567 Response:
  - **Outlining the response:** The hospital's 2567 Response can use an outline format for ease and clarity. The problem with this organization is that the findings in the 2567 Report often are written in modified outline format, usually using number "sequences" that vary from Tag to Tag and sometimes even within the Tag (this is usually because there are multiple surveyor/drafters that each use their own style). To avoid confusion, the hospital should refrain from using numbers in its response unless the hospital is specifically responding to the particular numbered finding in the 2567 Report. Instead, bullets and indented bullets should be used for outlining and organizational purposes.
  - **Apparent Omissions in the 2567 Report.** It is not uncommon for CMS or the State Agency either to omit something they meant to include, or to include something they meant to delete. The hospital has several choices: (1) ignore the error; (2) call and get clarification; or (3) acknowledge the error in the 2567 Response Cover Letter, and request that CMS advise if there is any further response expected from the hospital relative to the missing information. While the context of the error will have to guide which response is most appropriate under the circumstances, generally the third response is advised – i.e., acknowledging in the 2567 Response Cover Letter. It is not advised to totally ignoring the error, as CMS will likely hold that against the hospital. While, in some cases, it might be most appropriate to call and get clarification as soon as possible, this should be reserved for circumstances where it simply is not possible to develop a cogent response without getting the clarification. It is usually best to point out the error in the 2567 Response Cover Letter, and not otherwise address it in the 2567 Response – thereby shifting to CMS the onus of figuring out what they've omitted and deciding whether they want to back up the process and require a response. (This would generally require them rewriting that portion of the 2567 Report, then waiting for the hospital to develop the response to the revised 2567.) CMS will, more often than not, let the issue go – i.e., not issue a revised 2567, and not require a further response. The following examples illustrate the types of omissions:
    - The Condition Tag references a Standard that does not appear.
    - Patient Number is noted as being discussed somewhere else in the 2567 findings but in fact it is not otherwise discussed in the findings.

- Cross references do not pan out. The following is a suggested response for when this occurs:

Suggested Response: Note the error in the hospital's Cover Letter that accompanies their 2567 Response – e.g., *"At Tag A203, Condition for Pharmacy, four Standard Tags were referenced, A204, A205, A206, and A207 (see page __). However, in reading the remainder of the 2567, Standard Tag A205 was nowhere to be found. As such, hospital was unable to address any deficiencies related to this Tag. Please advise immediately if CMS requires further response relating to these."*

- **Disputed findings.** If the hospital disputes a **factual** finding, the hospital should courteously point out this discrepancy in the text of the response, and provide necessary clarification or supporting information. Illustrations are included below**:**

Hospital disputes findings:

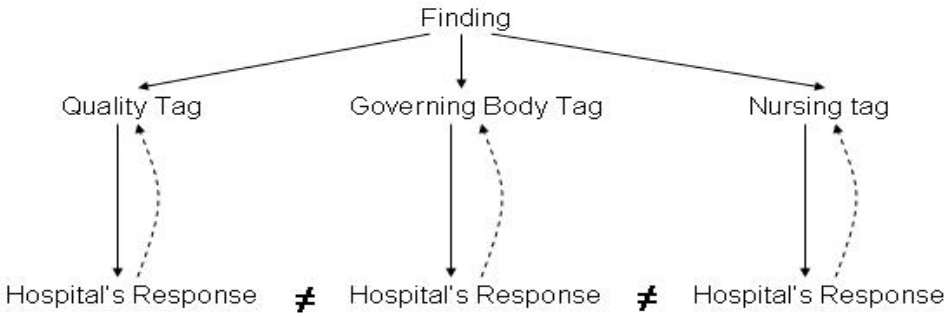
- For example, if the surveyor erroneously described a crack in the meat slicer, the hospital should respond; its 2567 Response should courteously correct the facts: *"The cracked plastic part mentioned in the findings was on the puree blender, not the meat slicer, which was replaced on [date]."*

- Another example: if the surveyor erroneously states that the hospital failed to document a new order on a follow-up form and the hospital can produce evidence that this finding is wrong, the hospital should attach evidence and then state in the response: *"Hospital disputes the finding that it failed to document the new antibiotic order on the ED follow-up form. There is documentation on the follow-up form that the new antibiotic was ordered and called to the patient's pharmacy. The patient was notified on [date], at [time]. See Exhibit A."*

  Note: this is one of the few instances where it is recommended to submit actual hospital documents as attachments to the 2567 Response.

- **When one finding is used to support a number of deficiencies.** During the survey, it is typical for a surveyor to observe a finding that is then used to support a panoply of deficiencies in a number of Conditions or Standards. In other words, they will generally attempt to charge every possible offense they can derive from a single set of facts. Where it appears that the same set of facts supports an excessive number of deficiencies that should be courteously pointed out in the Cover Letter. The chart on the following page illustrates this concept:

One Finding Supports Multiple Deficiencies



- **Do NOT Cut & Paste**
- **Each Response Must Address the Tag in Question**

- **Responding to a Standard or Condition deficiency that was previously the subject of an Immediate Jeopardy.**

  If the hospital was previously subject to an IJ, the circumstances and declaration of the IJ will reappear in the full 2567 Report of deficiencies even though the IJ has been resolved. As noted at Section 1.6, the lingering repercussions of having been subject to an IJ will depend upon when the IJ was actually resolved, as well as the level of deficiencies that remained as of the time the IJ was resolved. Likewise, the hospital's 2567 Response will depend upon when and how sufficiently the IJ was resolved. For example:

  - If the IJ was immediately resolved, and the resolution brought the hospital fully back into compliance with the Condition, the IJ incident will be cited in the full survey 2567 Report, and the hospital's 2567 Response will describe what actions it took that brought the hospital back into compliance.

  - If the IJ was immediately resolved, but the resolution did not effect full compliance with a Condition, then the hospital's response will describe what was done to resolve the IJ, as well as what additional measures have been taken to correct the Condition.

  - If the IJ was not immediately resolved, the hospital will likely have developed a Plan of Correction that the surveyors have reviewed and approved. In such case, the hospital's 2567 Response will need to demonstrate how implementation of the Plan of Correction addressed the IJ circumstances, as well as how any residual Condition-level deficiencies have been or are being resolved.

- **How to address a finding that was not included during the Exit Conference** – (what if the fix can't occur by the due date, usually only 10 days?)

The statements of deficiencies in the 2567 Report should NOT contain any findings of which the hospital has not previously been made aware. The surveyors are supposed to summarize all findings during the Exit Conference at the conclusion of any survey. Nonetheless, the hospital may well see some new and unexpected findings in the 2567 Report. The problem with such surprises is that, unless the finding was coincidentally addressed as part of hospital's response to some other known problem, the hospital will not have taken any "immediate actions" to address the problem (indeed, by the time the hospital gets the first news of the problem, weeks or even months may have passed since the survey), so the hospital's response may look inadequate because the first action taken was so delayed.[2] Thus, it is important to state, in the text of the hospital's response, that the specific finding in question was not communicated to the hospital until receipt of the 2567 Report. The hospital should then state, "*Immediately upon learning of this finding, the following actions were taken . . . .*"

A variation on this approach is called for where the finding relates to a patient who has been discharged, or to a closed record, for example. In such cases, the hospital cannot take any action that will undo or correct the issue vis-à-vis that patient or that patient's record. Thus, the response will have to be something like this: *"Because this patient had been discharged before the hospital learned of this issue, corrective action specific to this patient could not be taken. However, the hospital has assessed the performance issues involved, and has taken the following specific measures to prevent any recurrence . . . ."*

6.6 Posing Objections

Upon reviewing the agency's 2567 Report, the provider may conclude that the statement of deficiencies is incomplete or inaccurate. While the hospital cannot challenge the agency's conclusion that a deficiency exits, it can challenge the accuracy of the findings that underlie an alleged deficiency. In the event the hospital has objections to the agency's findings, it has several options:

- Accept the deficiencies cited and submit a Response to the 2567.
- Record objections to the cited deficiencies, submit a Response, and provide convincing arguments and documented evidence that the findings are invalid.*
- Record objections to cited deficiencies, do not submit a Response, and provide convincing arguments and documented evidence that the findings are invalid.*

* If the hospital opts to object, supporting documentation should be attached to the Response.

Which option to select will depend upon the facts and circumstances. Generally, however, the second option – i.e., noting the objection and submitting evidence rebutting the finding – is the safest course.

[2] As mentioned previously, though the State Agency is required by the SOM to complete the 2567 Report within 10 calendar days, it is not unusual for the State Agency to take quite a bit longer.

6.7 Cover Letter from CEO

The CEO should prepare a cover letter to accompany the hospital's 2567 Response (The Response Cover Letter). The Response Cover Letter should be used to:

- Confirm the hospital's understanding as to what the next steps are (especially if this has been unclear).
- Capture, in writing, any intentions expressed verbally by the surveyors or CMS during telephone calls.
- Explain if there are any disputed findings in the 2567 Response and summarize how the hospital handled them.
- Explain any nuances about the 2567 Report (e.g., cross-references that were not accurate, Condition Tags that referenced a Standard not included in the 2567, references to patients not cited elsewhere, etc.).
- Note any omissions or errors (e.g., missing references or cross references).
- Request clarification regarding the process for the resurveys.
- A sample 2567 Response Cover Letter can be found on the following page.

HAND DELIVERED TO

To: [Address]

And: State Agency Office [Address]

Re: Termination Notice: Medicare Provider Number: xx-xxxx
Name of Facility

Ladies and Gentlemen:

Enclosed please find **[insert facility]** responses to the Statement of Deficiencies, Forms CMS-2567, that were issued as a result of the CMS Validation Survey that ended **[insert survey end date]**.

In responding to the deficiencies noted, **[insert facility]** has applied the "credible allegation of compliance" standard that is articulated in the State Operations Manual, and confirmed by telephone call with a CMS representative. We understand the protocol is that CMS will assess whether **[insert facility]'s** 2567 responses reflect a credible allegation of compliance sufficient to merit a resurvey to confirm that the corrections were in fact made in a manner that brings the Hospital back into compliance with the Medicare Conditions of Participation. The Hospital has prepared, and has available for review on-site, a compilation of the relevant supporting documentation (policies, forms, monitoring instruments, etc.). Please let us know immediately if some other protocol is expected, or if you have any questions about the Hospital's submission.

As you will see when you review the Hospital's submission, much work has been done to respond to each and every finding. The Hospital has elected not to challenge any of the facts at this time – although this submission should not be viewed as an admission [*insert if appropriate*, and the Hospital reserves its right to appeal, as described in CMS' State Operation Manual **[insert date]** letter].

On behalf of the many, many people at **[insert facility]** who have committed themselves to maintaining **[insert facility]'s** Medicare Certification so that the facility may continue to serve Medicare and Medi-Cal patients in our community, we ask that CMS and State Agency use their very best efforts to promptly review our submission, immediately let us know if you need any clarifications or additional documentation at this time, and conduct a resurvey as quickly as possible.

We are available to meet with you, in person or by telephone, to further explain our actions and/or provide any additional documentation you may require.

Very truly yours,

Chief Executive Officer

Enclosures:
(1) A-Tag Responses
(2) K-Tag Responses [if appropriate]
(3) Other attachments as appropriate (i.e., documentation supporting disputed facts)

6.8 Producing the Hospital's Response

As mentioned above, the 2567 Report is not made available electronically. The 2567 Report is provided in hard copy, and the hospital is expected to type its responsive measures into the appropriate columns. Since the actual responses always go through multiple edits and drafts, and since the reports are almost always very lengthy, it simply is not feasible to think that the final response could be completed in time to be manually typed onto the original report pages, using a typewriter. Complicating this logistical nightmare is the fact that CMS and the State Agency expect the hospital's response to each finding and each Tag to appear alongside the corresponding cited deficiencies. The reality is that the hospital's response is NEVER the same length as the cited deficiencies, and a fair amount of manual alignment, insertion of hand-numbered continuation pages, and the like are all needed in order to patch together a final 2567 Response. The only feasible way to accomplish all of this within the short time frames that are always involved is to develop the response on a template that can, once finalized, be printed out and photocopied onto the original report. All of this requires administrative assistance of someone very familiar with the reporting forms and CMS and State Agency requirements, and able to be dedicated almost exclusively to the production process as the document moves into its final states. Legal counsel can help the facility with all of these production challenges:

- A table is prepared to monitor the status of the Tags in the editing process and to see that each and every Tag, Condition, and Standard have been addressed.
- Editing process:
  - If a hospital is on a termination track, the hospital's legal counsel should retain primary responsibility for producing the 2567 Response.
  - However, the hospital should produce the first draft, and forward it to counsel for the beginning of the editing process. Remember that because of the time constraints involved (10 calendar days) and the need for counsel to clarify facts, perhaps research certain legal questions, and then edit and produce the final report, counsel should have been part of the drafting team from the moment the 2567 Report was received, and part of the earlier assessment process following the survey that resulted in the Plan of Correction.
  - There must be a clear path for communicating changes once the editing process is under way.
- Once the substantive edits to the 2567 Response are complete, the start of the response to a particular Tag is realigned on the page to be parallel to the start of the surveyors' findings on the 2567 Report.
- Any other Tags referenced on the sheet are crossed out.
- Multiple copies of the last page of a Tag are made to use as continuation sheets, when needed.
- After photocopying the final response onto the 2567 form, the extra pages are manually-numbered alphabetically (e.g., if the last page of the findings is Page 2, but the hospital's response runs over four pages, they should be numbered 2a, 2b, 2c, and 2d.).

6.9 A Complete Response Will Include:

- A Response Cover Letter that mirrors the CMS Cover Letter, notes any disputes, and advises of the availability of revised policies at facility.
- A signed 2567 Response. (Note: In lieu of including copies of supporting documents, such as revised policies or forms, it is suggested to present in the body of the 2567 Response a

detailed summary description of the substance of procedural changes, or changes in forms, together with notice that the actual forms are available for review at the hospital, but that they will also be sent to the agency, if requested).

- If appropriate, documents supporting disputed findings.

6.10 Who and Where to Send the Hospital's Response

- Follow the instructions in the CMS Cover Letter. Usually both the State Agency and CMS want a copy of the response.
- If the 2567 Response is being delivered on the due date, make sure to arrange for courier services.
- **The CEO must sign BOTH**:
  - Response Cover Letter (two copies).
  - Front page of the hospital's 2567 Response.

7. After the Hospital's 2567 Response Is Submitted.

7.1 Implementation of Plans of Correction

- The hospital needs to achieve full implementation of all steps described in the 2567 Response. This means any remaining action items must be completed within the stated time frames, and that all described monitoring is timely occurring.
- The drafters of the 2567 Response need to communicate to the responsible people identified in the 2567 Response what they are responsible for and help provide adequate resources to see that their requirements are being achieved.
- Document all monitoring, and results thereof.
- Continue to make improvements. As monitoring results come back, the hospital may need to continuously make changes and improve the processes discussed in the 2567 Response. Submitting the hospital's 2567 Response to the surveyors does not preclude the hospital from continuously making improvements as part of its QI process.
- Whether to notify the surveyors of changes in actions or monitoring activities will depend upon facts and circumstances. While sometimes it is sufficient to wait until the surveyors return on resurvey and at that time explain changes that may have evolved, there is a risk that the surveyors won't agree with the change in direction and will cite the hospital for failing to implement as represented. Generally speaking, any significant deviations from the activities described in the 2567 Response should probably be reported to CMS and the State Agency – either via a telephone call or a follow-up letter.

7.2 Prepare Binders and Evidence

As noted above, the hospital's 2567 Response to the 2567 Report is designed to get the surveyors to come back for a resurvey to confirm that the hospital has effectuated the corrections it has reported. The 2567 Response contains just enough detail so the surveyor can picture the change, but the response itself need not, and should not, include actual exhibits (unless there is a disputed finding). In other words, the 2567 Response tells the surveyors what was done, and when they come out to resurvey, the hospital needs to be prepared so the surveyors can quickly confirm that the hospital did what it said it would do.

Thus, supporting documents should be maintained in carefully organized binders so that the surveyors do NOT need to go searching for the documentation referenced in the hospital's response.

- Make multiple copies of the binders.
- Make sure the binders are kept up-to-date when any change to the forms takes place.
- Where appropriate, highlight specific changes or provisions designed to address the cited deficiencies.

7.3 What If the Hospital Forgets to Include Some Detail in Its Response?

In implementing the plan and monitoring processes, someone may determine that a key element of the hospital's 2567 Response was never included. The hospital should determine if an amended version of the Tag in question should be sent to CMS and the State Agency with a cover letter explaining the missing piece of material. If this is done:

- Make sure the date that the fix occurred is still prior to the date the hospital's 2567 Response was due (do NOT use the date the Amended 2567 was submitted).
- Make sure the missing piece does not affect another Tag – such as Quality or Governing Body.

The hospital may also determine that an amendment is not necessary and can instead either be shown upon resurvey or called in to the surveyor. Checking with CMS and the State Agency may be appropriate.

7.4 What Do CMS and the State Agency Do with the Hospital's Response?

Upon receiving the hospital's 2567 Response, the surveyors must determine whether the hospital has made a credible allegation of compliance. Remember, CMS only grants a resurvey if the State Agency determines that the hospital made a credible allegation of compliance in its 2567 Response. When the State Agency receives the response, each surveyor takes the Tags for which that surveyor is responsible. Thus, the document is not viewed as one document but many smaller responses.

According to the SOM, the surveyors have a deadline for determining whether the hospital made a credible allegation of compliance (see Section 1.5 above for further discussion). However, recent experience has demonstrated that while the hospital is strictly held to its timelines as laid out in the SOM, the surveyors may not adhere to their deadlines. As a result, it may be months before the hospital hears anything from the surveyors.

CMS and the State Agency are not required to communicate to the hospital whether or not it has determined there to be a credible allegation of compliance. Indeed, often the only confirmation that hospital has that such a determination has been made is when the surveyors show up to resurvey. Nonetheless, if too much time passes (how much is too much will depend on the circumstances, whether termination dates are impending, etc.) without word, placing a follow-up telephone call to CMS or the State Agency is recommended to determine the status of the survey process and to specifically ask if a credible allegation of compliance has been found or if any additional information or clarification is needed.

7.5 Follow-up Questions from CMS or the State Agency

While reviewing the hospital's 2567 Response, the surveyors may ask follow-up questions. These questions may come by way of a telephone call or a written notice. The hospital should try to ascertain as much information as possible about what level of detail is required for the response, what the response should look like, when the response is due, etc. If the inquiry is by telephone, the hospital should take excellent notes during such a call, so as to enable full compliance with the request for further information.

It is important to take these follow-up questions very seriously. In drafting a follow-up response, the hospital should carefully review its original 2567 Response as well as the initial findings cited in the 2567 Report. This background is essential for determining what the surveyor feels is missing in the response. Rereading the Tag is especially important to make sure the follow-up question asked is appropriate given the subject matter for the Tag.

In some cases, the answer to the follow-up question may already have been addressed in the original 2567 Response, but may have been overlooked by the reviewing surveyor. If the information was already communicated in response to the specific Tag at issue, then a letter

that clarifies the answer (e.g., showing where it appears in the 2567, and perhaps pulling out and restating the pertinent information) can be effective.

If the answer was not addressed in the original 2567 Response, or if it appeared only in response to another Tag, then the hospital should amend its 2567 Response and resubmit it with replacement pages to be inserted into its original 2567 Response. Note: If pagination is affected, it will be necessary to resubmit a corrected response for the entire Tag.

8. Resurvey or Other Types of Follow-up by Surveyors

8.1 Resurvey

Assuming the State Agency finds that the hospital's 2567 Response has made a credible allegation of compliance and that CMS approves this finding, the hospital may be entitled to a resurvey, depending on which survey track the hospital is on and where the hospital is in the investigation process. Because it is not always clear when the hospital is entitled to a resurvey, this is one of the essential facts that the hospital should pin down with CMS during telephone calls or during the survey itself.

The resurvey process is very similar to the initial survey. Ideally, there will be fewer deficiencies and therefore the survey team will be smaller, the length of the survey will be shorter, and the 2567 Report will be shorter. However, the hospital should not be lulled into a secure feeling by the scaled-back nature of a resurvey. The surveyors themselves may try to make the resurvey process more casual (e.g., coming out on different days rather than as a team, not doing an Exit Conference, etc.). The State Operations Manual does not support such actions, particularly with respect to the Exit Conference. This is not an optional meeting but rather it is CMS policy. If the surveyors fail to do an Exit Conference but still submit 2567 findings of deficiencies, then the hospital should work with its attorneys on how to best respond.

The scope of the resurvey will also vary depending on which track the hospital is on and where in the process the resurvey occurs. The resurvey may be a full survey of all Conditions of Participation or limited to only reviewing those Conditions of Participation previously found out of compliance. However, it is important to understand that even if the scope of the resurvey is limited to certain Conditions, the surveyors have the authority to cite the hospital for other deficient Conditions that they observe while in the hospital. This is because the hospital is required to be in compliance with all Conditions of Participation at all times.

Following a resurvey, the State Agency and CMS again produce a 2567 Report detailing any deficiencies found. Upon receiving the report, the hospital must undertake all the same steps to respond to the findings as they did with the original report.

SPECIAL NOTE: In preparing a response to a Tag cited in the Resurvey 2567 Report, the hospital should also review any prior response(s) to that Tag. If prior corrective action steps and monitoring were not sufficient to correct a problem, then the same response will not suffice. Rather, the hospital will be expected to take a more aggressive approach to solving the deficiency or eliminating the problems.

SPECIAL NOTE: The standard for compliance with the Conditions of Participation is SUBSTANTIAL COMPLIANCE. Because the State Operations Manual defines "substantial compliance" as "compliance," CMS or the State Agency sometimes take the position that 100% compliance is necessary to clear a Condition. When this occurs, the hospital must be prepared to vigorously and effectively argue that 100% compliance is neither required nor reasonable. By referring to – and integrating the hospital's actions into – the hospital's continuous quality improvement activities, it is generally possible to get CMS or the State Agency to back off on this expectation. Along this same vein, the surveyors have been known to question continued improvements as though such actions are a sign of continued weakness and deficiencies at the hospital instead of viewing these actions as part of an effective quality improvement process (required by Medicare and Joint Commission). Here, again, a vigorous defense of the hospital's quality improvement processes is called for. Hospitals should consult with their attorneys on how to effectively refocus CMS or State Agency expectations.

8.2 No Actual Resurvey

Certain survey tracks, namely State Agency monitoring, may not require an actual resurvey. The 2567 Response and acceptance of the hospital's 2567 Response may be sufficient to the surveyors. Although not contemplated in the State Operations Manuel, the surveyors may ask that the hospital forward the supporting documentation in order to avoid a revisit to the hospital. Such a request should be carefully considered to make sure compliance with the requests fits the hospitals needs. Questions to ask are:

- Do the documents tell the full story? By supplying the documents directly to CMS or the State Agency, is the hospital missing an opportunity to demonstrate some improvements that are integral to the surveyors understanding that cannot be demonstrated in documentation?
- Are the documents self-explanatory, or do they need, or would they benefit from, further explanation?
- Does the hospital want CMS or the State Agency to have copies of all the documents? If confidential or proprietary information are involved, the hospital needs to get assurances that confidentiality will be maintained – and in particular that the documents will not be released to the public, even pursuant to a FOIA or similar state law request. It is usually essential that assurances be obtained in advance that CMS or the State Agency will not release documents pursuant to FOIA requests. Even then, if CMS or the State Agency gives these assurances in error, the documents may be released in any event if court proceedings are brought by the requester (often the press or a competitor). As a result, a provider is well advised to seek advice of counsel as to the specific documents CMS or the State Agency requests.

8.3 Multiple Surveys Overlapping

It is crucial to understand that more than one survey process can be occurring at a hospital at the same time. For example, in one case, the State Agency is acting as CMS's agent as part of a termination survey process that eventually moved into State Agency monitoring on behalf of CMS. Simultaneously, the State Agency may be conducting surveys on other complaints in its role as the state licensing body. While the State Agency is at the hospital performing complaint investigations, it is not precluded from following up on the hospital's compliance with the Medicare Conditions of Participation. Moreover, one of the customary practices of some State Agency offices is to go into the facility wearing one hat – e.g., state licensing – then "observe" a likely violation of a Medicare Condition, call CMS with a "complaint," get CMS authority to put on its State Agency complaint survey hat, and proceed under federal auspices.

Whenever hospital officials speak with surveyors, it is important for them to clarify with the surveyors what hat they are wearing.

It is also very important to keep careful track of all pending investigations, so that the hospital and its counsel can try to guard against (or at least get a record of for appeal purposes) process violations that **may be** occurring as the agencies perform multiple roles.

9. Potential Repercussions

Early on in the process, the hospital needs to carefully assess the variety of potential repercussions of loss of Medicare Certification. These include:

- The most obvious repercussion is loss of Medicare payments.
- Medicaid payments will also be terminated.
- Depending on the facts, decertification may also result in Office of Inspector General (OIG) exclusion from all federal healthcare programs. OIG has oversight over this issue and it enjoys enormous discretion in deciding whether to exclude a provider since the regulations do not describe factors for consideration and ALJs do not have the authority to review OIG's exercise of discretion to exclude an entity under § 1128(b).
- Third-party payor contracts may contain a requirement of Medicare certification, and even if they don't, coordination of benefit provisions are implicated and significantly complicated.
- Physicians who contract with an excluded provider and provide services to federal beneficiaries may be subject to civil monetary penalties and will not be paid. **According to the OIG, "an exclusion from Federal health care programs effectively precludes an excluded individual or entity from being employed by, or under contract with, any practitioner, provider or supplier to provide any items and services reimbursed by a Federal health care program."** *See* OIG Special Advisory Bulletin, *The Effect of Exclusion from Participation in Federal Health Care Programs*, September 1999 (http://oig.hhs.gov/fraud/docs/alertsandbulletins/effected.htm).
- Inability to serve Medicare and Medicaid patients might jeopardize bond financing. (Whether this is so would depend, in part, on whether the hospital could still be found to meet the good faith requirements of the bond convenants.)
- Inability to serve Medicare and Medicaid patients might jeopardize tax exemption.
- Inability to serve Medicare and Medicaid patients might cause a violation of the Hill-Burton community service obligation, which continues in perpetuity for hospitals that obtained Hill-Burton funds.
- Reinstatement may not be possible for at least 90 days from the date of exclusion – CMS claims it expects the hospital to have a sustained period of demonstrated compliance before it will reinstate. This is, however, a discretionary decision for CMS, and it is not clear whether exigent circumstances will change this position.

EXHIBIT 1.3

This Attachment provides a description of areas of discrepancy between the Medicare Conditions of Participation and The Joint Commission (TJC) Hospital Accreditation Standards.

Please note that the Conditions of Participation and Hospital Accreditation Standards are lengthy documents with numerous differences. This Attachment only provides a description of material differences where meeting the Hospital Accreditation Standards might not result in fully satisfying the Conditions of Participation; this Attachment does not identify differences in which the Hospital Accreditation Standards have greater requirements than the Conditions of Participation. Further, both the Conditions of Participation and Hospital Accreditation Standards are dynamic sets of rules that are revised frequently. Changes to the Conditions of Participation or Hospital Accreditation Standards may affect these issues and are not reflected herein. Finally, both CMS and TJC, and surveyors for both organizations, may interpret the Conditions of Participation or Hospital Accreditation Standards differently than as provided herein and hospitals should always consult these authorities for their interpretations.

This comparison was prepared on February 1, 2007. Note also that TJC does not allow free access to their materials. In order to obtain TJC's manuals, please follow the instructions at this link – www.jcrinc.com/77/.

TELEMEDICINE	
Conditions of Participation	**TJC Hospital Accreditation Standards**
§ 482.11(c) The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws. **Interpretive Guidelines:** When telemedicine is used and the practitioner and patient are located in different states, the practitioner providing the patient care service must be licensed and/or meet the other applicable standards that are required by State or local laws in both the state where the practitioner is located and the state where the patient is located.	**MS.4.120 Licensed independent practitioners who are responsible for the care, treatment, and services of a patient via telemedicine link are subject to the credentialing and privileging process of the originating site.** **EP 1(c):** [One option is] The originating site uses the credentialing and privileging decision from the distant site to make a final privileging decision if all of the following requirements are met: (1) The distant site is a Joint Commission-accredited hospital or ambulatory care organization; (2) The practitioner is privileged at the distant site for those services to be provided at the originating site; (3) The originating site has evidence of an internal review of the practitioner's performance of these privileges and sends to the distant site information that is useful to assess the practitioner's quality of care, treatment, and services for use in privileging and performance improvement. At a minimum, this information includes all adverse outcomes related to sentinel events considered reviewable by the Joint Commission that result from the telemedicine services provided; and complaints about the distant site licensed independent practitioner from patients, licensed independent practitioners, or staff at the originating site.
Description: MS.4.120 permits hospitals to credential/privilege telemedicine providers using the credentialing and privileging decision from the distant site to make a final privileging decision (subject to certain requirements). MS.4.120 EP1(c) does not specifically state that the telemedicine practitioner must be licensed in both the state where the practitioner is located and the state where the patient is located, which is required by the Conditions of Participation. However, it should be noted that the Introduction to MS.4.120 does state: "these standards assume that the organization is following applicable law and regulation such as appropriate licensure to practice medicine or telemedicine in the states where the originating and distant sites are located."	

OVERALL CARE OF PATIENT BY MEDICAL STAFF MEMBER	
Conditions of Participation	**TJC Hospital Accreditation Standards**
§ 482.12(a)(5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients. **Interpretive Guidelines:** All hospital patients must be under the care of a member of the medical staff or under the care of a practitioner who is directly under the supervision of a member of the medical staff. **Survey Procedures:** Verify that any individual providing patient care services is a member of the medical staff or is accountable to a member of the medical staff qualified to evaluate the quality of services provided, and in turn, is responsible to the governing body for the quality of services provided.	**MS.2.20 The management and coordination of each patient's care, treatment, and services is the responsibility of a practitioner with appropriate privileges.** **EP 1:** Licensed independent practitioners with appropriate privileges manage and coordinate a patient's care, treatment, and services.
Description: MS.2.20 recognizes the distinction between medical staff appointment and clinical privileges and, accordingly, permits practitioners with appropriate privileges, who may not necessarily be medical staff members (e.g., a practitioner with locum tenens or temporary privileges) to manage the care of a patient. The Conditions of Participation technically do not recognize this distinction and require every patient to be cared for by a member of the medical staff.	

QUALIFICATIONS OF MEDICAL STAFF PRESIDENT	
Conditions of Participation	**TJC Hospital Accreditation Standards**
§ 482.22(b)(3) The responsibility for organization and conduct of the medical staff must be assigned only to an individual doctor of medicine or osteopathy or, when permitted by State law of the State in which the hospital is located, a doctor of dental surgery or dental medicine. **Survey Procedures:** Verify that an individual doctor of medicine or osteopathy is responsible for the conduct and organization of the medical staff through review of the organizational structure and interviews with members of the medical staff.	**No corresponding standard.**
Description: The individual responsible for organization and conduct of the medical staff (e.g., medical staff president or chief of staff) must be a doctor of medicine or osteopathy or a doctor of dental surgery or dental medicine. This requirement does not appear in TJC hospital accreditation standards, which do not contain any requirements for qualifications of medical staff officers.	

FREQUENCY OF VERBAL ORDERS	
Conditions of Participation	**TJC Hospital Accreditation Standards**
§ 482.23(c)(2)(i) If verbal orders are used, they are to be used infrequently. **Interpretive Guidelines:** Verbal orders, if used, must be used infrequently. This means that the use of verbal orders is not a common practice. Verbal orders pose an increased risk of miscommunication that could result in a patient adverse event (which includes medication errors). Verbal orders should be used only to meet the care needs of the patient when the ordering practitioner is unable to write the order himself/herself. Verbal orders are not to be used for the convenience of the ordering practitioner.* [*Note: 42 C.F.R. § 482.23(c)(2) was revised on November 27, 2006. The State Operations Manual has not been updated since those revisions and the Interpretive Guidelines language relates to the previous version of 42 C.F.R. § 482.23(c)(2); however, the revised version of the regulation continues to contain the requirement that verbal orders be used infrequently, which is the subject of the Survey Procedures language. Nevertheless, it is possible that the State Operations Manual Interpretive Guidelines will be modified regarding this requirement.]	**IM.6.50 Designated qualified staff accept and transcribe verbal or telephone orders from authorized individuals.** **NPSG 2A For verbal or telephone orders or for telephonic reporting of critical test results, verify the complete order or test result by having the person receiving the information record and "read back" the complete order or test result.**
Description: TJC hospital accreditation standards do not contain a rule regarding frequency of use of verbal orders.	

AUTHENTICATION OF VERBAL ORDERS	
Conditions of Participation	**TJC Hospital Accreditation Standards**
§ 482.24(c)(3) All verbal orders must be authenticated based upon Federal law and State law. If there is no State law that designates a specific timeframe for the authentication of verbal orders, verbal orders must be authenticated within 48 hours.	**IM.6.50 Designated qualified staff accept and transcribe verbal or telephone orders from authorized individuals.** **EP 3:** When required by law or regulation, verbal or telephone orders are authenticated within the specified time frame. **FAQ Authentication of Documentation – April 13, 2005:** Q: Do the standards specify the time frame for authentication of documentation? A: The Joint Commission standards do not specify the time frame for authentication of documentation. The organization is free to determine the time frame for completion of authentication. The time frame must comply with any applicable laws or regulations. If the organization is silent on the issue for specific types of documentation, the time frame defaults to the time frame that the organization adheres to for completion of the medical record. For example, the standard IM.6.10 in the AMCAH, CAMH, CAMLTC, and CAMBHC while requiring the organization to establish a time frame for completion of the medical record, specifically limits the time frame to no more than 30 days.
Description: Some organization may use 30 days as a requirement for authentication of verbal orders under TJC FAQ on Authentication of Documentation. However, the revisions to the Conditions of Participation (released November 27, 2006) require verbal orders to be authenticated within 48 hours. Please note that TJC standard does not conflict as IM.6.50 EP 3 cross-references federal and state requirements, which includes the Conditions of Participation.	

<table>
<tr><th colspan="2">MEDICAL RECORD ENTRIES MUST BE TIMED</th></tr>
<tr><th>Conditions of Participation</th><th>TJC Hospital Accreditation Standards</th></tr>
<tr><td>§ 482.23(c)(2) All orders for drugs and biologicals must be in writing and signed by the practitioner or practitioners responsible for the care of the patient.

Interpretive Guidelines: [§ 482.23(c)(2)] "All entries in the medical record must be legible, timed, dated and authenticated. All orders for drugs and biologicals, including verbal orders, must be legible, timed, dated and authenticated with a signature by the practitioner or practitioners responsible for the care of the patient." (Emphasis added.)

§ 482.24(c)(1) All entries must be legible and complete, and must be authenticated and dated promptly by the person (identified by name and discipline) who is responsible for ordering, providing, or evaluating the service furnished.

Interpretive Guidelines: [§ 482.24(c)(1)] ". . . All entries in the medical record must be timed, dated, and authenticated, and a method established to identify the author." (Emphasis added.)

Survey Procedures: [§ 482.24(c)(1)] "Verify that entries are legible and complete and appropriately authenticated, timed and dated by the person who is responsible for ordering, providing, or evaluating the service provided." (Emphasis added.)

§ 482.24(c)(1)(i) The author of each entry must be identified and must authenticate his or her entry.

Interpretive Guidelines: [§ 482.24(c)(1)(i)] ". . . The author of every entry must take a specified action to identify himself/herself as the author (or responsible person) of the entry, the time and dating of the entry, that the entry is accurate, and that he/she takes responsibility for accuracy of the entry." (Emphasis added.)</td><td>IM.6.10 The hospital has a complete and accurate medical record for patients assessed, cared for, treated or served.

EP 4: "Medical record entries are dated, the author identified and, when necessary according to law or regulation or hospital policy, authenticated, either by written signature, electronic signature, or computer key or rubber stamp."</td></tr>
<tr><td colspan="2">Description: TJC hospital accreditation standards do not contain a requirement that entries in the medical record be timed; however, this is required by the Conditions of Participation.</td></tr>
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INFORMED CONSENT	
Conditions of Participation	**TJC Hospital Accreditation Standards**
§ 482.24(c)(2)(v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent. **Interpretive Guidelines:** [§ 482.24(c)(2)(v)] ". . . Informed consent would include that the patient is informed as to who will actually perform surgical interventions that are planned. When practitioners other than the primary surgeon will perform important parts of the surgical procedures, even when under the primary surgeon's supervision, the patient must be informed of who these other practitioners are, as well as, what important tasks each will carry out. We recognize that at the time of the surgery, unforeseen circumstances may require changing which individual practitioners actually are involved in conducting the surgery. . . ." **§ 482.51(b)(2) A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies.** **Interpretive Guidelines:** [§ 482.51(b)(2)] ". . . Furthermore, informed consent would include that the patient is informed as to who will actually perform surgical interventions that are planned. When practitioners other than the primary surgeon will perform important parts of the surgical procedures, even when under the primary surgeon's supervision, the patient must be informed of who these other practitioners are, as well as, what important tasks each will carry out."	**RI.2.40 Informed consent is obtained.** **EP 3:** A complete informed consent process includes a discussion of the following elements: • The nature of the proposed care, treatment, services, medications, interventions or procedures. • Potential benefits, risks, or side effects, including potential problems that might occur during recuperation • The likelihood of achieving goals • Reasonable alternatives • The relevant risks, benefits, and side effects related to alternatives, including the possible results of not receiving care, treatment, and services • When indicated, any limitations on the confidentiality of information learned from or about the patient
Description: CMS requires the consent to identify all practitioners performing important parts of the surgical procedures. This requirement, which has proved difficult for hospitals to satisfy, is not found in TJC hospital accreditation standards.	