



*CMS TRANSPLANT PROGRAM  
QUALITY WEBINAR SERIES*

# **Writing an Effective Transplant Plan of Correction**



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*Enhancing Quality Assessment  
and Performance Improvement  
Programs in Transplant Programs  
and Hospitals*

*December 2, 2015*

# CMS Webinar Series

## Transplant Centers



1. Introduction to the Transplant QAPI: Regulatory Overview
2. Worksheet Overview
3. Comprehensive Program and 5 Key Aspects of QAPI
4. Objective Measures
5. Performance Improvements
6. Adverse Events
7. Transplant Adverse Event “Thorough Analysis”
8. QAPI Tools (part 1)
9. QAPI Tools (part 2)
10. Data display
11. Writing an Effective Transplant Plan of Correction
12. Interpretive Guidelines

# Learning Objectives



Upon completion of this session, the participant will be able to:

1. Recognize the components of the Form CMS-2567
2. Describe the process for responding to a CMS Statement of Deficiencies
3. Identify the requirements for an acceptable plan of correction (PoC)
4. Review common errors associated with an unacceptable Plan of Correction
5. Review some transplant-specific PoC examples

# The basics:

## Where do citations come from?

- On-site transplant surveys
  - Initial certification survey
  - Re-approval survey
  - Complaint survey
    - Outcomes Non-compliance
- Organ programs surveyed separately

# “Form CMS-2567”



- Form CMS-2567 is the official document that communicates the determination of compliance or noncompliance with Medicare Conditions of Participation for any survey
- It is the same form any program uses to submit a plan of correction
- The completed Form CMS 2567 is an official, legal record, available to any member of the public upon request
- The blank form is available at:  
[www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS2567.pdf](http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS2567.pdf)

# “Form CMS-2567”



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED  
OMB NO. 0938-0391

<b>STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION</b>	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: _____	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED _____
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NAME OF FACILITY	STREET ADDRESS, CITY, STATE, ZIP CODE
------------------	---------------------------------------

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY SHOULD BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERRED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See reverse for further instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
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# “Form CMS-2567”



- Form CMS-2567: used whether program is compliant or noncompliant

- If compliant, explicit statement of compliance

*Example: “Based on this transplant survey, there were no deficiencies found...”*

- If not compliant, includes corresponding citations of noncompliance

*Example: “This facility's (organ) program did not meet these Conditions of Participation based on...”*

# Plan of Correction (PoC) Receipt and Response



- All deficiencies on the Form CMS-2567 require a PoC
- Response is required within ten (10) calendar days of receipt of the CMS Regional Office notice
- NOTE: This is **CALENDAR** days - make sure to document the date of receipt



# How do I get the Form CMS-2567 Report from the Transplant Survey?



- The Form CMS-2567 is sent by your CMS Regional Office to whomever is listed as your program representative on the transplant program quarterly report (TPQR)

## *CMS Transplant Program Quarterly Report*

**Hospital's CMS Certification**      123456

**Hospital Name:**                      ABC Medical Center

**Address:**                              789 Hope Ave.                      **City:**                      Anywhere

**State:**                                    XX                      54321

**Hospital Representative:**      Ms. Mary Sunshine



# Requirement: Corrective Action Implementation



- The corrective action implementation dates must be no later than 45 days from the date of notice by the CMS Regional Office (RO)
- Note: This is 45 DAYS FROM DATE OF CMS RO LETTER that accompanies the Form CMS-2567

# Form CMS-2567 Components



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

<b>STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION</b>		(X1) PROVIDER/SU IDENTIFICAT	
NAME OF FACILITY		STREET ADDRESS, CITY, S	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY SHOULD BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE		TI	

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correct for further instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are

FORM CMS-2567 (02/99) Previous Versions Obsolete EF 11/2004

- Each cited deficiency and corrective action should be preceded by the identification (ID) prefix “tag.”
- The ID prefix tag is a reference label identified by CMS to specify components of conditions and standards.
- Transplant: “X” tags

# Form CMS-2567 Components



## Summary Statement of Deficiencies

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

<b>STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION</b>		(X1) PROVIDER/SUPPLIER IDENTIFICATION NUMBER: _____
NAME OF FACILITY: _____		STREET ADDRESS: _____ _____
(X4) ID PREFIX TAG	<b>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY SHOULD BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</b>	ID PREFIX TAG

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from for further instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are identified by the LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

FORM CMS-2567 (02/99) Previous Versions Obsolete EF 11/2004

Each cited deficiency should be followed by full identifying information [e.g., transplant-specific Conditions of Participation at 42 CFR §482.68 through 482.104]

# Form CMS-2567 Components



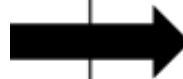
## Plan of Correction

- Describe the facility's plan for corrective action and the anticipated time of correction (an explicit date must be shown)
- Completion date and corrective action must be appropriate to the level of the deficiency(ies)
- Must include the individuals responsible for the actions to be implemented
- NOTE: This date must occur within 45 days of the date of the letter (NOT the receipt date)

FORM APPROVED  
OMB NO. 0938-0091

SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED _____
SS, CITY, STATE, ZIP CODE _____		
(X4) _____	PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERRED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE _____
If continuation sheet Page _____ of _____		
NAME	TITLE	(X6) DATE

do not correct providing it is determined that other safeguards provide sufficient protection to the patients. (See reverse side of form for instructions regarding the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are cited, an approved plan of correction is requisite to continued program participation.)



# Form CMS-2567 Components



## Authorized Signature

- This form must be signed and dated by the provider's designated leadership representative
- The original, with the facility's proposed corrective action, must be returned to the CMS Regional Office within 10 days of receipt
- Please maintain a copy for your records

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES  
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIVE ACTION**

NAME OF FACILITY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCY (EACH DEFICIENCY IS REGULATORY OR LEADERSHIP)
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Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See source for further instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

LABORATORY DIRECTORS OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
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FORM CMS-2567 (02/99) Previous Versions Obsolete EF 11/2004

If continuation sheet Page \_\_\_\_ of \_\_\_\_

# Structure of a Deficiency Citation: Example 1



482.96(b)(1) ADVERSE EVENTS

Tag X102 AHO

A transplant center must establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case. The policies must address, at a minimum, the process for the identification, reporting, analysis, and prevention of adverse events.



**Regulatory Reference**

This Standard is not met as evidenced by:

Based on policy review and staff interview, it was determined that the AHO program's staff did not have a written transplant-specific Adverse Event policy to address the process for the identification, reporting, analysis and prevention of adverse events.



**Deficient Practice Statement**

Findings:

1. A review on 05/22/15 of the AHO program's document, "Quality Assessment and Performance Improvement Plan" dated 04/01/14 did not address a process for the identification, analysis or prevention of adverse events during any phase of organ transplantation or donation. There were no other documents presented for review.



**Relevant Findings or Evidence**

# Structure of a Deficiency Citation (continued)



- The surveyor provides the documented reasons for non-compliance based on survey findings
- In the plan of correction, each deficiency must be addressed separately and “stand alone”
- Citations may be cross referenced but the PoC response must still be documented for each tag



# Acceptable PoC



An acceptable PoC must contain the following elements:

- The plan of correcting the specific deficiency
- The procedure for implementing the acceptable PoC for each specific deficiency cited
- The monitoring procedure
- The completion date for the implementation
- The title of the person responsible for implementing the acceptable PoC

# Condition Level vs. Standard Level Deficiency



- Condition Level
  - Acceptable PoC prior to revisit
  - Requires revisit prior to termination date
- Standard Level
  - Acceptable PoC
  - No revisit required

# Recap: The PoC Process



- A Plan of Correction (PoC) is required for all deficiencies cited
- The provider has ten calendar days from the date of the notification letter detailing how it will correct deficiencies
- Completion dates are not to exceed 45 calendar days from the date of the notification letter
- PoCs:
  - reviewed by the CMS Central (CO), Regional Office (RO) representatives
  - accepted or rejected based on the adequacy of the provider's written response

# After citation, consider the cause(s):



- Findings describe the evidence, not the cause
- Correcting the deficiency may or may not ensure the underlying cause has been addressed
- As a program, ask yourselves: What systems improvements are needed to ensure a lasting “fix”?

# Example 2: Adverse Events



(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY SHOULD BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)
X 102	482.96(b)(1) ADVERSE EVENTS
ALO	<p>A transplant center must establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case. The policies must address, at a minimum, the process for the identification, reporting, analysis, and prevention of adverse events.</p> <p>This Standard is not met as evidenced by:</p> <p>Based on policy review and staff interview, it was determined that the ALO program's staff did not have a written transplant specific Adverse Event policy to address the process for the identification, reporting, analysis and prevention of adverse events.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. A review on 10/03/16 of the ALO program's policies, "XYZ Hospital Transplant Quality Assessment and Performance Improvement (QAPI) Program" dated 2/14, "Transplant Patient Safety Events Policy" dated 6/2014, and hospital policies, "Quality Assessment/Performance Improvement/Patient Safety Plan 2015" dated 01/14, "Safety Event Guidelines (Never Events)" dated 5/14, and "Report of Unusual Occurrence/Event Reporting" revised 2/14 revealed no evidence of written documentation of the following: <ul style="list-style-type: none"> <li>- A process for identification and screening of actual or potential transplant adverse events</li> <li>- The required time frame for reporting, investigating, and analyzing transplant adverse events</li> <li>- Who was responsible for conducting investigation of transplant adverse events</li> </ul> </li> </ol>

# Example 2: Regulatory Reference

- Regulatory tag reference
- Program affected
- Regulatory language
- “Not met” statement followed by specific deficiency

X 102

AHO

**482.96(b)(1) ADVERSE EVENTS**

A transplant center must establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case. The policies must address, at a minimum, the process for the identification, reporting, analysis, and prevention of adverse events.

**This Standard is not met as evidenced by:**

# Example 2: Deficient Practice Statement

- “not met as evidenced by”

X 102

ALO

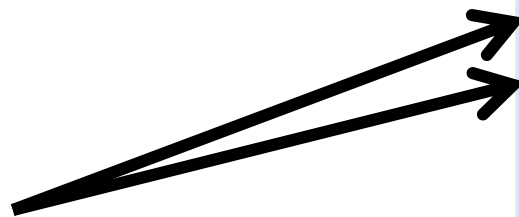
This Standard is not met as evidenced by:

Based on policy review and staff interview, it was determined that the AHO program's staff did not have a written transplant specific Adverse Event policy to address the process for the identification, reporting, analysis and prevention of adverse events.

**Findings:**

# Example 2: Deficient Practice Statement

- “not met as evidenced by”



X 102

This Standard is not met as evidenced by:

ALO

Based on policy review and staff interview, it was determined that the ALO and AHO program's staff did not have a written transplant specific Adverse Event policy to address the process for the identification, reporting, analysis and prevention of adverse events.

AHO

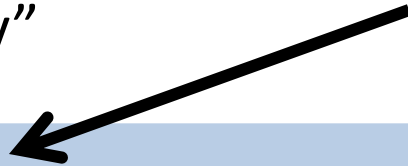
Findings:



# Example 2: Relevant Findings or Evidence



- “not met by”



X 102

Findings:

ALO

1. A review on 10/03/16 of the ALO program's policies, "XYZ Hospital Transplant Quality Assessment and Performance Improvement (QAPI) Program" dated 2/14, "Transplant Patient Safety Events Policy" dated 6/2014, and hospital policies, "Quality Assessment/Performance Improvement/Patient Safety Plan 2015" dated 01/14, "Safety Event Guidelines (Never Events)" dated 5/14, and "Report of Unusual Occurrence /Event Reporting" revised 2/14 showed no evidence of written documentation of the following:
  - A process for identification and screening of actual or potential transplant adverse events
  - The required timeframe for reporting, investigating, and analyzing transplant adverse events
  - Who was responsible for conducting investigation of transplant adverse events

# Example 2:

## What is the Compliance Issue?



- Look for the specific findings
- Identify the deficiency within each finding
- Make a list of what needs to be addressed
- Create the action plan
- Document it in the plan of correction including
  - **What** (identify specific issue, what needs to change, educate staff about change),
  - **Who** (responsible person)
  - **When** (implementation date),
  - **How** monitored

# Example 2: Address each one...

- Policy “fix” [revision]
  - Identification/screening of actual, potential transplant adverse events
  - Required timeframe for reporting, investigating, and analyzing
  - Who is responsible for conducting investigation (person not group)
- Approval
- Education to changes (all staff and team members)
- How this will be monitored to ensure systemic “fix”

**X**  
**102**  
**ALO**

## **Findings:**

- .....showed no evidence of written documentation of the following:**
- **A process for identification and screening of actual or potential transplant adverse events**
  - **The required timeframe for reporting, investigating, and analyzing transplant adverse events**
  - **Who was responsible for conducting investigation of transplant adverse events**

# Critical First Steps



- Relate specific actions to the same identifiers as used in the Form CMS-2567
- Address only what is in each citation
- What is the fundamental issue that was cited?
- Is it “what IS being done” or is it “what IS NOT being done”?
- Is the deficiency a matter of policy/procedure, implementation, or both?

# Noncompliance: Considerations for Action



## Step 1:

Clearly address the problem or weakness, including the root cause

- Consider the Problem:
  - What is happening, what is the effect?
- What should be happening?
- How can it be fixed?
  - Individuals affected?
  - Processes affected?
  - Systems affected?

# Noncompliance: Considerations for Action



## Step 2:

Create simple, measurable solutions that address the root cause

- What are the regulatory requirements?
- How will this be accomplished?

## For Documents:

- Address names of policies/procedures, etc.
- Identify the specific changes, content that will be revised

## For Training & Education:

- Address who, when, and how: content, how it will be done in the future if ongoing
- How will the program make sure everyone gets the information (staff, providers)?

# Noncompliance: Considerations for Action



## Step 3:

Each corrective action should have a person that is accountable for it (title not name), individual responsible for corrective action and frequency of monitoring

## Step 4:

Set achievable deadlines

- What is a reasonable time frame to develop, revise, approve, educate/train, and implement?
- **(Correct within 45 days: revisit for condition-level findings would be between 60-90 days of initial letter identifying findings)**

# Noncompliance: Considerations for Action



## Step 5:

Monitor the progress of your plan

- How will you measure success?
- Reported to whom, how often?
- Consider how this information might integrate with existing hospital reports (or those of other organ programs within your hospital)



# Monitoring: Required



Considerations for monitoring implementation and compliance:

- Method (Audit, measurement, other)
- Definition of the measure
- What (population), how many (sample size), when/how often
- Who is responsible for the data: measurement, analysis
- Where it will be reported, when/frequency
- How monitoring is integrated into the transplant program

# Example 3

## PoC Response Examples

- Practice change was implemented immediately post survey
- Policy was revised to reflect change in practice
- Compliance monitoring to be reported monthly at transplant program specific QAPI meeting.

## Better Responses Would Be...

- Specify what the practice change was. Identify specific date “when” implemented
- Name the policy. When was it approved (date), by whom?
- How were all staff and other team members educated to changes? When (date)?
- What is actually being monitored as “compliant,” what is the population, sample size, target goal? Will information be integrated with reports to hospital QAPI as well?
- Who is responsible for oversight and/or monitoring of the action items?

# On-site Correction of Deficiency



- If deficiency corrected while on-site, the citation must still be documented on the Form CMS-2567 as “NOT MET”
- The PoC must still address it:
  - the systems fix
  - the date of correction
  - monitoring
  - person responsible, etc.

# The PoC: Acceptable vs. Unacceptable



- Corrective action plan/completion dates must be acceptable to all reviewers
- CMS will notify program: acceptable or unacceptable
- If PoC not acceptable:
  - facility will be contacted for clarifications and modifications
  - Acceptable PoC must be submitted and correction of all deficiencies made **prior to any revisit or termination date**
  - The program must be aware of deadlines and contact the CMS RO for any questions regarding their PoC

# The PoC Resolution Process - Think Quality Cycle

- Define opportunity
- Investigate the cause
- Identify the solution
- [Verify the solution]
- Plan and educate to the solution
- Implement the solution
- Evaluate effectiveness



# Sample Format:

## Make sure you address the issue....



- [Citation issue here]

Action/Implementation  
(what, by whom/when)

Education  
(what, by whom/when)

Monitoring  
(what, by whom/when)

# Example 4: Generic Findings X099



## Findings:

1. A review on \_\_\_\_\_ of [program type] program's QAPI documents, "Transplant Quality Assurance and Performance Improvement (QAPI) Policy", dated \_\_\_\_\_, supporting documents, emails, personal notes, minutes, QAPI reports, and dashboard data from 2013 to present revealed the documentation did not reflect an active, implemented, comprehensive data-driven QAPI program. The XYZ program's staff was not currently functioning as addressed in the Transplant and Hospital QAPI Plans i.e., committee structure, documentation of meetings, oversight of PI initiatives, objective measures data review, analysis/actions taken in response, and communication of performance improvement activities. The XYZ program's staff was not integrated with the hospital quality program as described in its policies. This determination was based on, but not limited to, the following factors:

# Example 4: X099 Generic Findings



## Findings:

- **The QAPI program structure described in the plan was not the current structure** used for meeting and reporting QAPI information.
- The plan **did not identify title, role or responsibilities of QAPI team.**
- The plan **did not identify when or how often transplant program performance would be reviewed and reported** to the Transplant QAPI Committee or the hospital-wide QAPI program.
- **Objective process and outcome measures were not identified** for all phases of transplantation.



# Example 4: X099 Developing the Plan of Correction



What/where were the deficiencies?

## QAPI Structure

## Membership

## Meeting frequency and reporting

## Objective Measures

**Actions Needed:** Revise existing Transplant QAPI Policy/Plan to reflect the following:

- QAPI Structure
- QAPI team members, roles, responsibilities
- Meetings
- Reporting

Add specifics here

**Education and Communication about Plan:**  
[leaders, team, staff]

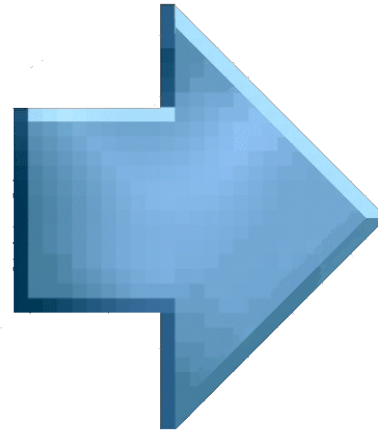
**Implementation\*:** [within 45 days,]

**Monitoring\*:** [identify how you will know this is fixed]

\*Address the title of staff responsible/accountable

**The next few slides are examples of  
common citations from the field...**

**Next**



# Action/Implementation (What, Who, When)



- The plan of correcting the specific deficiency. The plan should address the processes that lead to the deficiency cited;
- The procedure for implementing the acceptable plan of correction for the specific deficiency cited;
- The monitoring procedure to ensure that the plan of correction is effective and that specific deficiency cited remains corrected and/or in compliance with the regulatory requirements;
- The title of the person responsible for implementing the acceptable plan of correction.

# Example 5: Tag X101



Based on program document review and staff interviews, it was determined that the [organ] program's staff was not ensuring that improvements were sustained by establishing a process to track performance improvements.

## Findings:

1. A review on 12/16/14 of [organ] program's documents of four major performance improvement initiatives identified by staff; 1) Evaluation to listing, 2) Organ offer declinations, 3) Immunosuppression therapy, and 4) Missed appointments, showed there was no evidence of how/why issues were identified, baseline data collection, analysis of data, actions taken in response, or monitoring of improvement. There was no evidence of quality improvement activity reported to any transplant committee, hospital quality/safety committees, or the governing board.

# Example 5: Tag X101

Fundamental issue:

QAPI Activity  
Documentation

- Evidence of QAPI cycle (how/why identified, data collection, analysis, actions taken in response, monitoring/evaluation)
  - Communicate performance
- Action/Implementation (What, Who, When)**
- Revise transplant QAPI plan to include addendum/tool to report PI projects to reflect how/why issues were identified, baseline data collection, analysis of data, actions taken in response, and monitoring of improvement (by whom/date)
  - Implemented standardized Transplant QAPI Committee agenda to include “QAPI Activities Report” at each quarterly meeting. (by whom/date)
  - Transplant QAPI minutes will reflect the QAPI activity documentation including any recommendations (by whom/date)
  - [organ] transplant reports to hospital quality committee and governing board will include QAPI activity documentation a minimum of annually (by whom/date)

# Example 5: Tag X101



Fundamental issue:

QAPI Activity Documentation

- Evidence of QAPI cycle (how/why identified, data collection, analysis, actions taken in response, monitoring/ evaluation)
- Communicate performance

**Education (What, Who, When)**

- Re-educate transplant program leaders, QAPI personnel and clinical staff on revised TQAPI plan, tools
- (Transplant QAPI Manager/date)

**Monitoring (What, Who, When)**

- Quarterly audit of transplant QAPI minutes X 4 to ensure new process for reporting is consistent and corrective action is sustained.
- Compliance reported at TQAPI meetings and documented in minutes.
- (Transplant QAPI manager/date)

# Example 6: Tag X103



Based on policy review, document review, and staff interview, it was determined that the [organ] program's staff did not address a process for a thorough analysis of an adverse event.

## Findings:

1. A review on \_\_\_\_\_ of the [organ] program's document, "Quality Assessment and Performance Improvement Plan: Comprehensive Transplant Center" dated \_\_\_\_ did not include a process to conduct a thorough analysis of adverse events that may have occurred during any phase of organ transplant. An investigation and analysis process was not defined in any other policies provided for review.

# Example 6: Tag X103



Fundamental issue:  
Thorough analysis  
process

## Action/Implementation (What, Who, When)

- Revise transplant QAPI plan to include description of thorough analysis process for transplant-specific adverse events. The revised plan will be approved by the transplant QAPI committee, hospital QAPI committee and the governing body (by whom/date)
- The transplant quality manager will ensure the thorough analysis is performed within a defined timeframe and will maintain documentation of all analyses in progress and completed (date)
- Implemented a standardized transplant QAPI agenda including “Adverse Events.” Transplant-specific adverse events will be monitored and discussed at Transplant Committee and incorporated into the transplant QAPI dashboard (by whom/date)



# Example 6: Tag X103

Fundamental issue:  
Thorough analysis  
process

## **Education (What, Who, When)**

Re-educate transplant program leaders, QAPI personnel and clinical staff on thorough analysis process. Process will be included in annual transplant update for staff on an ongoing basis  
(Transplant QAPI Manager/date)

## **Monitoring (What, Who, When)**

Created checklist of thorough analysis process steps to accompany each investigation performed. Audit and compliance report of each checklist by Transplant QAPI manager on quarterly basis X four quarters. (Transplant QAPI manager/date)

# Additional Thoughts...



- Each deficiency must have its own PoC
- Action items cannot be referenced from one citation to another
- The response to each finding must “stand on its own”
- Put the response item on the same page as the citation tag - if it goes longer than the page, clearly note the tag number on each page

# Summary: Some “Do’s”



- Address the underlying systems issue for the citation
- Make sure you educate...
- Make sure you identify deadlines and staff responsible for oversight
- Make sure you have a monitoring plan
- Meet all deadlines noted in the cover letter
- Contact the CMS Regional Office with any questions

# Summary: Some “Don’ts”



- Don't use names of individuals
- Don't write the PoC without leadership involvement – they are ultimately responsible for the compliance plan
- Don't make the time deadlines too soon - make sure they can be met
- Do not make the PoC too complicated, or unrealistic

# Publically Available Information



Hospital and Transplant Form CMS-2567 citations are found here:

- <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Hospitals.html>

death reporting requirements related to restraint and seclusion.

#### Downloads

[EMTALA \[PDF, 23KB\]](#)

[Patient's Rights Regulation published 12/8/2006 \(PDF, 335 KB\) \[PDF, 334KB\]](#)

[Chapter 2 - The Certification Process \[PDF, 1MB\]](#)

[Full Text Statements of Deficiencies Hospital Surveys - Updated 7/16/2015 \[ZIP, 16MB\]](#)

[Full Text Statements of Deficiencies Transplant Surveys - 7/16/2015 \[ZIP, 1MB\]](#)

#### Related Links

[Hospitals](#)

[Survey & Certification - Enforcement](#)

[Emergency Medical Treatment & Labor Act \(EMTALA\)](#)

[Section 1867 of the Social Security Act](#)

[Section 1861 of the Social Security Act](#)

[42 CFR 482.1 - 482.66](#)

[Related Regulation - 42 CFR 489.13\(c\)\(2\)](#)

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# Questions & Answers

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