

Understanding the 2567 & Writing Acceptable Plans of Correction

For Ambulatory Surgical Centers
(ASCs)

Welcome

This training covers the requirements for writing an acceptable plan of correction for Ambulatory Surgical Centers.

Main Menu

- This training is divided into four sections concerning the process surrounding the development of acceptable plans of correction.
- Use the menu below to navigate to each of the sections. At any time, press the “Main Menu” button in the bottom right corner of the slide to return to this page.
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Writing Acceptable Plans of Correction for ASCs

Section 1

Introduction

Target Audience

- This training was designed to help ASCs understand what constitutes an acceptable plan of correction (PoC) for identified deficient practices.
- This training was developed to improve the effectiveness of and promote consistency in writing plans of correction. The purpose of this training is to promote quality of care and services for ASC patients.

Objectives

When you have completed this training, you will be able to:

- List the elements required for writing an acceptable PoC;
- Evaluate a deficiency to determine if all the PoC elements have been addressed in the PoC; and
- Identify the requirements for submitting an acceptable PoC.

Additionally, you will have an understanding of how PoC are evaluated by the State Agency (SA) to determine it's acceptability.

Writing Acceptable Plans of Correction for ASCs

Section 2

The Provider and the Regulatory Process

Certification

- Federal certification is based on the Code of Federal Regulations (CFR) and requirements established through the Centers for Medicare & Medicaid Services (CMS).
- Providers must demonstrate compliance with Federal requirements, *and*;
 - Demonstrate an ability to remain in compliance continually; *and*
 - Implement corrective actions and follow-up measures to ensure that the deficient practice does not recur.

Certification

- Information related to certification requirements for ASCs can be found in *State Operations Manual Appendix L - Guidance to Surveyors: Ambulatory Surgical Centers*. Retrieved http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_l_ambulatory.pdf
- Information related to the survey process can be found in the *State Operations Manual Chapter 2 - The Certification Process* at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107c02.pdf>

Initiative and Responsibility

- Participation in Medicare mandates that facilities take the initiative and responsibility for monitoring their own performance continuously so that they are always in substantial compliance with Federal regulations.
- In Idaho, the Bureau of Facility Standards (BFS) is the (SA). SA surveyors conduct surveys of ASCs to determine if the care the facility provides meets minimum Federal requirements. When a surveyor finds evidence indicating requirements are not being met, a deficiency is written.
- Facilities should not rely on surveys or investigations to identify compliance problems.

Deficiencies

- A **deficiency** is a failure on the part of the facility to meet:
 - A federal standard specified in the State Operations Manual (SOM), Appendix L.

Deficiencies

- The Form CMS-2567, Statement of Deficiencies and Plan of Correction, specifies the deficient practice identified during a survey and supports the citation with evidence about how the facility failed to comply with federal requirements (Q tags for Health and K tags for LSC requirements).
- The Form CMS-2567 is sent to the facility within 10 business days from the date of exit.

Form CMS-2567

The Form CMS-2567 is important because:

- It is the official record of the survey;
- It is the official document of compliance/noncompliance with Federal regulation;
- It identifies the impact of the facility's noncompliance on the patients;
- It is available to the public; and
- The facility uses it to write its PoC.

Structure of a Deficiency

Deficiencies have three components:

- A regulatory reference;
- A deficient practice statement; and
- Relevant findings or evidence.

1st Component

The Regulatory Reference

The regulatory reference includes the survey tag; indicates the references (i.e., CFR, or LSC), and describes the requirements that are to be met by the facility.

Example of a regulatory reference:

Q01 - §416.25, Basic Requirements

Participation as an ASC is limited to facilities that-

- (a) Meet the definition in §416.2; and
- (b) Have in effect an agreement obtained in accordance with this subpart.

Regulatory Reference Categories

There are three categories that a regulatory reference can fall into.

Structure Requirements: These are initial conditions that must be present and are expected to remain as is.

- Example: Q40 – “The ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan.”

Process Requirements: These requirements specify the manner in which a facility must operate and do not allow the facility discretion to vary from what is expected.

- Example: Q261 – “Not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician (as defined in section 1861(r) of the Act) or other qualified practitioner in accordance with applicable State health and safety laws, standards or practice, and ASC policy.”

Regulatory Reference Categories

Outcome Requirements: These requirements specify the results that must be obtained or events that must occur or not occur following an act.

- Example: Q227 – “The patient has the right to the following:
 - (i) Be free from any act of discrimination or reprisal.

2nd Component

The Deficient Practice Statement

The Deficient Practice Statement indicates the part of the requirement that is not met. It summarizes the issues that demonstrate the facility's actions or failures to act that resulted in noncompliance with the requirement.

It also includes the extent of the deficient practice. This is the number of patients (or items) affected or potentially affected by the deficient practice (e.g., 4 out of 6 patients were affected by the deficient practice, or 3 out of 7 patients whose records were reviewed, or 2 out of 3 operating rooms).

- Example of Deficient Practice Statement for Q162:

“Based on review of medical records and policies, and staff interview it was determined the facility failed to ensure medical records were complete and accurate for 8 of 11 patients (#1 - #3 and #5 - #9) whose records were reviewed. This failure resulted in a lack of complete comprehensive information being available in patient records.”

3rd Component

The Relevant Findings

Relevant findings are the “evidence” collected by the survey team which demonstrate the existence of the deficient practice.

Findings are the result of observations, interviews, and record reviews.

The findings allow the facility to compare what it did or failed to do against what is required.

The listing of the pertinent facts identified in the deficiency allows the facility to discover what caused the deficient practice.

Relevant Findings

- Example of relevant findings:

Records demonstrating that a quality improvement project had been developed, implemented, and monitored could not be found at the facility.

The physician owner of the ASC was interviewed on 2/03/10 at 2:00 PM. He stated the ASC had not developed or conducted a performance improvement project.

The ASC failed to ensure performance improvement projects were conducted.

Structure of a Deficiency Example

Q221 – 416.50(a) Notice of Rights

The ASC must provide the patient or the patient's representative with verbal and written notice of the patient's rights in advance of the date of the procedure, in a language and manner that the patient or the patient's representative understands.

← Regulatory Reference

The STANDARD is not met as evidenced by:

Based on record review and staff interview, it was determined the ASC failed to provide patients or their representatives with complete information regarding their rights for all patients receiving services at the facility, including 20 of 20 patients (#1 - #20) whose records were reviewed. This resulted in patients not being fully informed of their rights which had the potential to interfere with the patients' ability to make fully informed decisions. Findings include:

← Deficient Practice Statement

1. The ASC's "Patient Rights" policy, dated 4/01/05, stated "The patient is to receive, in writing, information on their rights..."

Upon request, the ASC's Medical Receptionist provided a sample packet of information given to patients in advance of their procedures. The medical records for Patients #1 - #20 were reviewed. None of the medical records nor the sample packet of information contained information regarding patient rights.

← Relevant Findings or Evidence

When asked during an interview on 8/18/10 at 11:40 AM, the Medical Receptionist stated that patient rights information was not provided to patients.

The ASC failed to provide patient rights information to patients in advance of care.

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Determining the Root Cause of a Deficiency

The PoC process mandates that facilities remedy deficient practices promptly and to ensure those corrections are lasting.

Facilities must take the initiative and responsibility for monitoring their own performance to sustain compliance.

To develop the PoC, the facility must first analyze the deficient practice to determine what happened and why the problem exists or occurred.

When the facility understands the root cause of the deficient practice, it can develop the solutions needed to correct the problem and sustain compliance. Deficient practice results from either system failures or discrete failures.

ASC Systems

Merriam-Webster's Dictionary defines a system as “a regularly interacting or interdependent group of items forming a unified whole.”

In an ASC, systems that promote patient care, comfort, safety, and well-being can include, but are not limited to:

- Daily management and operation of the facility;
- Provision of safe surgical practices;
- Protection of patient rights;
- Provisions for infection control prevention; and
- Ensuring staff competency.

Systemic Problems

When the failure is significant or involves many items within the system, then it is a system failure.

The system itself may be absent, or facets of an existing system may not be working. Even minor problems may be indicative of a systemic problem.

Example of Systemic failure: If one out of seven patients observed was not provided with personal privacy during pre-surgical preparations, the problem could be systemic if the facility has no policy for providing patient privacy and none of the staff knew who was responsible for ensuring the patient's privacy.

A systemic problem requires a PoC that:

- Describes what changes in the system will occur to fix the problem; or
- Plans for the development and implementation of a new system.

Discrete Problems

Discrete Problems may be more difficult to identify. Discrete problems may occur within a system but may only affect a small portion of the entire system.

For example: the problem may reflect an isolated incident, affect one or fewer individuals or staff, or be present at one or a limited number of times or locations.

Because even relatively isolated problems could result from a systemic problem, it is imperative that the facility examine all problems carefully to determine whether there is a system failure before assuming the problem is discrete.

When there are minor or few problems within a system, then the deficiency may be related to a discrete problem, rather than a systemic problem.

System or Discrete Failure?

Let's look at an example of a situation in which a Registered Nurse confessed that he had been abusing patients.

This could represent a system failure OR a discrete failure.

How could it be a system failure?

- Other staff suspected or observed the abuse and failed to report the incident to administration due to a lack of training.

How could it be a discrete failure?

- Perhaps the RN was alone with a combative patient, there were no physical signs of abuse, his victim did not report the abuse to the facility, and the facility had systems for prevention of abuse but were not aware of this instance of abuse.

Differentiating Between Deficiencies

- Differentiating between deficiencies that represent a breakdown in a system and those that represent a discrete problem is not always easy, but if the facility does not identify the source of the failure, it probably will NOT succeed in correcting it.

Things to Consider?

- Investigate the reason why the deficient practice occurred.
- Is there a pattern of other similar incidents?
- Was this an isolated situation caused by unusual circumstances?
- If there is a pattern, how could present systems be modified, or could new systems be implemented to correct the problem?

Writing Acceptable Plans of Correction for ASCs

Section 3

Developing an Acceptable Plan of Correction

Examining the Plan of Correction Elements

Let's examine the elements for writing a PoC.

Plans of correction provided must address 6 core elements.¹

Those elements require the development of very specific strategies that delineate exactly what actions will be taken to correct deficiencies and are essentially the same steps taken when implementing an ASC QAPI plan.

Once the facility has gathered answers for its questions and analyzed its problems, it can begin to develop a PoC.

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Plan of Correction Elements

These six elements apply to all PoCs:

- Element 1: What corrective action(s) will be taken to correct each specified deficiency;
- Element 2: How the actions taken will improve the processes that led to each deficiency;
- Element 3: What the process is for implementing the corrective action for each deficiency;
- Element 4: How the corrective action(s) will be tracked and monitored to ensure the PoC is effective in bringing the ASC into compliance, and that the ASC remains in compliance, i.e., what quality assurance program will be put into place;
- Element 5: The title of the person responsible for implementing the PoC; and,
- Element 6: Include dates when corrective action will be completed.
- 42 CFR 488.28(a) states ordinarily a provider is expected to take the steps needed to achieve compliance within 60 days of being notified of the deficiencies.

Element 1

Deficiencies With and Without Identifiers

Element 1 asks: What corrective action(s) will be taken to correct each specified deficiency;

Element 1 applies to deficiencies that impacted specific patients and deficiencies that are violations of certain operational requirements that have the potential to affect all individuals of the facility. Typically, the deficiency will identify those individuals directly impacted along with those potentially impacted. On rare occasions, no specific individuals will be identified (i.e., condition level deficiencies).

Examples of deficiencies with identifiers:

- Failure to ensure hand washing occurred as indicated for 2 of 2 patients (Patients #1 and #2) whose procedures were observed; and
- Failure to ensure discharge orders were signed by the physician for 15 of 15 patients (Patients #1 - #15) whose records were reviewed.

Examples of deficiencies without identifiers:

- Failure to ensure development of a disaster preparedness plan; and
- Failure to post Patient Rights information.

In either case facilities must state what they have done about the identified issue(s).

Element 1

Deficiencies That Include More Than One Example of Relevant Findings

Occasionally, the deficient practice statement will include more than one example of a relevant finding.

Example of multiple relevant findings under Administration of Drugs (Q181):

The facility failed to:

- Ensure expired medications were discarded.
- Ensure multi-dose vials were properly labeled.
- Ensure pre-drawn syringes were properly labeled.
- Ensure single use vials were only used for one patient.
- Ensure drugs were kept secure.

Address EACH Instance of Noncompliance and ALL Evidence!

Facilities must state what corrective actions they have taken or will take for EACH instance of noncompliance.

- To meet the PoC Element 1, the ASC must address what specific changes have or will occur. Changes may include changes to policies, procedures, equipment, the environment, staff training, etc.
- The facility must address EACH specific example listed for each deficiency.

Element 2

How Has the Process Improved

Element 2 asks: How the actions taken will improve the processes that led to each deficiency.

- To meet Element 2, the facility must address: How the specific changes are expected to improve patient care and services and compliance with the regulatory requirements.

For example if the ASC developed a policy and procedure designating a particular staff to check all medications for expiration on a daily basis, the expected outcome would be a decrease in the possibility patients receive expired medications and an improvement in patient care and regulatory compliance.

Element 3

Changes to Prevent Recurrence

Element 3 asks: What the process is for implementing the corrective action for each deficiency.

- To meet PoC Element 3, the facility must state how the corrective actions will be implemented.

For example, if the ASC developed a policy and procedure designating a particular staff to check all medications for expiration on a daily basis, the implementation of that policy may involve training of staff and documentation of the daily checks.

When identifying in-service training as part of a PoC, the facility should indicate:

- Who will conduct the training;
- What the content of the training will include;
- When and how often the training will be provided; and
- How performance will be monitored to ensure elements addressed in the training were implemented accurately and consistently.

Element 4

Tracking and Monitoring

Element 4 asks: How the corrective action(s) will be tracked and monitored to ensure the PoC is effective in bringing the ASC into compliance, and that the ASC remains in compliance, i.e., what quality assurance program will be put into place;

- To meet PoC Element 4, the facility must state how the correction has been incorporated into the ASCs QAPI program to prevent the deficient practice from happening again.
- For this element, facilities should include the specific quality indicator, the data which is to be collected, the frequency of the data collection, and the frequency of data analysis (monitoring) to ensure compliance.

Element 5

Title of the Person Responsible

Element 5 asks: What is the title of the person responsible for implementing the PoC.

The person responsible is not always the same for each deficiency.

For example, an ASC may identify the Infection Control Nurse as responsible for Infection Control deficiencies and the Administrator responsible for Patient Rights deficiencies. However, in accordance with the ASC regulations, the Governing Body has overall responsibility of achieving and sustaining compliance.

Staff who have been determined to have contributed to a deficient practice should not be solely responsible for implementing the corrective action(s), or for monitoring the corrective processes or actions.

Element 6

Date of Completion

Element 6 states: “When corrective action must be accomplished.”

The PoC must identify the date of completion or the expected date of completion for each deficiency.

Facilities should consider the significance and seriousness of each deficient practice.

- The amount of time for correction should vary, depending upon the nature of the deficiency.
- Many deficiencies, especially those involving health and safety, can and must be corrected within shorter time frames.

Element 6:

“Reasonable” Date Of Completion

Even though the amount of time for corrections should vary depending on the nature of the deficiency, there are other considerations.

According to the State Operations Manual, 2728B, a “reasonable period of time” to achieve compliance is generally not longer than 60 calendar days. The correction date certainly could be fewer than 60 days after the survey, depending on the circumstances of the deficiency.

- BFS/CMS will not routinely accept time frames longer than 60 days for compliance when a deficiency can reasonably be corrected before that date.

The PoC must also be dated and signed by the Administrator or other authorized official.

Important Points

- To ensure that facilities are properly addressing the deficient practice, the PoC must be specific, realistic, and complete. The PoC must state exactly how the deficient practice has been or will be corrected.
- A general statement indicating that compliance has been achieved or will be achieved is not acceptable. The PoC must identify the nature of the corrective action (i.e., how the corrective action will address the concerns identified in the Form CMS-2567) .
- Achieving and maintaining compliance relies on:
 - Detecting problems;
 - Implementing actions to correct the problems; and
 - Monitoring and evaluating the corrective actions to ensure that the problems will not recur.

All Parts of the PoC Must Be Acceptable

An acceptable plan of correction is required for all deficiencies to be in compliance.

When more than one deficiency is cited, the plan of correction for each deficiency must be acceptable in order for the overall plan of correction to be deemed acceptable.

It is acceptable to reference plans of correction for different deficiencies if the corrective action is identical. For example: the plan of corrective action for Condition level deficiencies may refer to the standard level deficiencies under that Condition.

All deficiencies cited on the Form CMS-2567 must be individually addressed in the plan of correction.

A [PoC Review Checklist](#) may be used prior to submission.

Use of Names or Titles

The PoC must not:

- Include proper names,
- Allude to another supplier/provider,
- Or malign an individual.

(SOM 2728B)

It is acceptable to use staff designated titles. For example:

- The facility LPN,
- The RN,
- The Medical Director,
- The facility Administrator,
- The facility's contracted CRNAs, etc.

Accessing PoCs

- Remember, 42 CFR 401.133 requires that Form CMS-2567 must be made available for disclosure to the public within 90 days of the last day of the survey.
- Survey results may be viewed at the SA website: www.facilitystandards.idaho.gov
- The cover letter to the facility, the CMS-2567, and submitted PoC are available to the public via the website.

Writing Acceptable Plans of Correction for ASCs

Section 4

PoC Submission and On-site Revisits

Consequences

Failure to submit a PoC, or to submit an acceptable PoC, could result in termination of the supplier agreement as authorized by 42 CFR §488.28(a), §488.456(b)(1)(ii), and §489.53(a)(1).

If the PoC is NOT Acceptable

After the PoC is submitted, BFS determines whether the PoC is acceptable.

If a PoC is not acceptable, BFS rejects it and seeks an acceptable PoC by contacting the facility. If only minor revisions are required, Pen & Ink changes may be made at the request of the facility. If significant revisions to the PoC are required, it may be necessary for the facility to re-submit an amended or revised PoC.

The facility must submit an acceptable PoC in order for the SA to recommend recertification to CMS.

Other Plan of Correction Issues and Reiteration

Facilities need to ensure that they received all the pages of the Form CMS-2567.

- In some instances, the federal data system prints a blank last page due to the set up for the last printed line at the bottom of the previous page.
- The page format is not adjustable. It is set within the Federal software system.
- The document must be returned the same way it was received.

All pages (including blank pages) must be returned to the BFS.

Onsite Follow-up Revisits

Because the survey process focuses on the care of the patients, onsite follow-up visits are conducted to ensure that deficiencies have been corrected.

BFS surveyors will follow up on deficiencies cited in the Form CMS-2567.

The purpose of the follow-up visit is to confirm that the facility has regained compliance and has the ability to remain in compliance.

The facility can show evidence of monitoring by summarizing what steps it has taken to ensure the deficient practice remains corrected.

More than Correcting Deficiencies

Developing a successful PoC involves more than just reading a deficiency and developing a plan to correct it.

It requires the provider to analyze the statement of deficiencies and determine the underlying problem that generated the deficiency.

When systems are in place for each type of service and when the facility consistently monitors its practices and makes adjustments as necessary, through its QAPI system, compliance will be achieved and maintained.

When a system or part of the system isn't working, it is the facility's responsibility to recognize and correct the problem, preferably before the survey team identifies a deficient practice.

When deficient practice is identified and cited, the provider is required to correct the identified deficient practice and ensure that it does not recur.

Conclusion

The importance of developing a good, acceptable plan of correction cannot be over-emphasized.

Submitting and following an acceptable plan of correction goes a long way toward ensuring continued quality care for the patients receiving the facility's services.

References

¹ *State Operations Manual Chapter 2 - The Certification Process*. Retrieved from <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107c02.pdf> (p 369).

² *State Operations Manual Chapter 2 - The Certification Process*. Retrieved from <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107c02.pdf> (p 370).