

# Bureau of Facility Standards

Understanding the Ambulatory  
Surgical Center Survey Process  
03/06/12



03/07/12

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Hello and welcome to today's section on understanding the Ambulatory Surgical Center (ASC) Survey Process.

# Objectives



- Identify where to find the ASC regulatory requirements.
- Identify the 2 levels of ASC regulatory requirements.
- Identify the 5 types of ASC surveys conducted by BFS.
- Obtain an increased understanding of CMS direction to State Agencies.
- Identify the 3 components of survey information gathering.
- Know where to locate surveyor documentation of deficient practice and facility response.
- Review most commonly cited deficient practices in Idaho.

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# Understanding the ASC Survey Process



- Regulatory Requirements:
  - 42 CFR 416, Subpart A - C
  - Appendix L

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The ASC program is a federal program as Idaho does not have state licensure rules for ASCs. The Federal Code of Regulation (CFR) includes the regulations an entity must follow in order to be a Medicare Certified ASC (42 CFR 416, Subparts A through C). The program is administered by the Centers for Medicare and Medicaid (CMS).

Based on the CFR, CMS develops, implements and monitors the State Operations Manual. Appendix L of the State Operations manual address the ASC regulatory requirements. It is based on the CFR and provides addition guidance to surveyors.

In January 2008, the Southern Nevada Health District identified a cluster of patients who had developed acute Hepatitis C infections. An investigation into the Hepatitis C outbreak found unsafe injection practices in ASCs. The reuse of syringes to access vials and then using those vials for subsequent patients resulted in the potential exposure of 63,000 patients to bloodborne pathogens.

Subsequently, in 2008 CMS began a pilot program to collect detailed data on 68 randomly selected ASCs in Maryland, North Carolina, and Oklahoma. As a result the CFR and the ASC survey processes and interpretive guidance found

in Appendix L were revised in an effort to improve ASC patient outcomes. The revised regulation took effect on 5/18/09.

# Understanding the ASC Survey Process



- Conditions of Coverage
  - Standards

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The ASC regulation set includes Conditions for Coverage and standards. Conditions represent the overall systems of the ASC. Under each Condition are the standard level regulations associated with that Condition. Appendix L includes all Conditions and standards, as well as interpretive guidelines, procedure and probes. The purpose of the guidelines, procedures and probes are to clarify the information that is relevant to specific requirements. While the guidelines, procedures and probes are used to assist surveyors, it does NOT replace professional surveyor judgment.

# Understanding the ASC Survey Process



- Surveys:
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  - Accrediting Organizations

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Survey is the process by which CMS ensures ASCs are achieving and maintaining compliance with the regulatory requirements. CMS contracts with state agencies to assist them in completing their survey work. In the state of Idaho, this is done by the Bureau of Facility Standards (BFS). CMS also contracts with Accrediting Organizations (AO). AOs are organizations that offer accreditation programs that are recognized by CMS for purposes of certifying the compliance. If an ASC successfully passes a deemed status survey conducted by the AO, then the ASC is deemed to be in compliance with the ASC Condition for Coverage.

# Understanding the ASC Survey Process



- **5 types of surveys:**
  - Initial
  - Recertification
  - Validation
  - Complaint
  - Follow up

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There are 5 types of surveys within the ASC program that can be conducted by BFS. Those are initial, recertification, validation, complaint, and follow ups. Initial surveys are conducted for facilities in order for them to become a Medicare certified ASC. Recertification surveys are conducted in order to recertify already established providers, validation surveys are conducted following a deemed status survey, follow up surveys are conducted in order to ensure deficient practices have been corrected and complaint surveys are conducted to investigate areas of alleged non-compliance with the regulatory requirements.

# Understanding the ASC Survey Process



- CMS Direction to State Agencies:
  - Mission & Priorities Document FFY2012

| Tier 1  | Tier 2  | Tier 3                  | Tier 4  |
|---|---|-------------------------|---------|
| Validations:<br>5 to 10% as<br>assigned by<br>CMS<br><br>Immediate<br>Jeopardy (IJ)<br>Complaints | 25% Targeted<br>Surveys<br><br>& Non-IJ<br>complaints | 5.0<br>Year<br>Interval | Initial |

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Each federal fiscal year (FFY), CMS provides the State Agencies with a Mission and Priorities Documents which directs how the work is to be prioritized. Please understand the Mission and Priorities Document directs all work for all provider types under the CMS umbrella. For FFY 2012, ASC surveys have been given the priorities indicated on the slide.

Tier 1 includes Validation surveys of 5% - 10% of deemed ASCs: States conduct validation surveys of deemed ASCs assigned by CMS based on AO survey schedules. Tier 1 also includes complaint allegations with the potential for immediate jeopardy, which means the alleged deficient practice is placing the patients at risk for serious harm, impairment or death.

Tier 2 includes targeted surveys. The State performs surveys totaling 25% of all non-deemed ASCs in the State. Also included in Tier 2 are complaints that do not include an immediate jeopardy component.

Tier 3 work states surveys are done to ensure that no more than 5.0 years elapse between surveys for any one non-deemed provider and initial surveys for new providers are Tier 4 work.

That is CMS direction on when ASCs surveys will be conducted, now let's look at CMS direction regard how the surveys are to be conducted.

## Understanding the ASC Survey Process



- Observation, Record Review & Interview
- Full survey of all CfC or focused surveys

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During the survey process, surveyors conduct observations, review records and interviews of facility staff and patients. Once all information is gathered through those 3 methods, surveyors review the information in light of the regulatory requirements. If the facility's practices are consistent with the regulation then the regulatory requirement is considered "met." If the facility practice is inconsistent, then the regulatory requirement is considered "not met."

During Initial, Recertification, and Validation surveys, all regulatory requirement (condition and standard level) are reviewed for compliance.

Complaint surveys are conducted as the result of allegations of non-compliance with regulatory requirements. These allegations can arise from multiple sources, and all must be investigated when there is a regulatory basis relating to the allegation. Complaint surveys are focused and may not include a review of all regulatory requirements. Complaint surveys only investigate areas of alleged non-compliance with the regulatory requirements. However, surveyors may identify other areas of non-compliance during the course of the complaint survey, which may be unrelated to the original allegation. For example, if an allegation is made that the ASC is not keeping patient medical records, then a survey would be conducted focusing on patient records. However, if while conducting the survey, surveyors observed the ASC was not clean, then Environment and

Infection Control would also be reviewed as they relates to the unsanitary conditions.

Follow-up/revisit surveys are conducted to ensure compliance with regulations which were determined out of compliance during a previous survey. Similar to complaint surveys, follow-up/revisit are focused, however surveyors are not precluded from addressing other deficiencies noted at the time of the follow up.

## Understanding the ASC Survey Process



- CMS form 2567
  - Condition Level Noncompliance
  - Standard Level Noncompliance

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Any deficient practice, regardless of the level of the tag, be it a condition or standard will be documented on the 2567 or Statement of deficiencies. If a Conditional level citation was issued, the ASC is placed on a 90 day termination track. This means the clinic has 90 days from the date of the exit to come back into compliance with the Condition. Additionally, any referenced standard level deficiency would need to be found met before the Condition level citation could also be found met. If the ASC can not achieve compliance, then its participation in the ASC program is terminated by CMS. Typically, the 90-day timeframe is divided into two 45-day periods, allowing the ASC two opportunities to achieve compliance. Timelines related to a specific survey are included in the cover letter which accompanies the 2567. Please note, when a Condition-level citation is due to a determination based upon immediate jeopardy, the termination track changes from 90-days to 23-days. Please refer to the “Appendix Q: Guideline for Determining Immediate Jeopardy” coming soon to the BFS website for additional information related to Immediate Jeopardy.

# Understanding the ASC Survey Process



- Plans of Correction
  
- Credible Allegations of Compliance

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When deficient practices are cited, the clinic is required to submit a response. Plans of Correction (PoC) and Credible Allegations of Compliance (Credibles) identify how the facility plans to correct non-compliance as identified on the 2567. A PoC is submitted in response to standard or element level deficiencies and a Credible is submitted in response to Condition level deficiencies. Both PoCs and Credibles must be submitted to the State Agency within 10 calendar days of the date the 2567 was received and both PoCs and Credibles must include these elements for *each* citation:

- Action that will be taken to correct each specific deficiency cited;
- Description of how the actions will improve the processes that led to the deficiency cited;
- Procedure for implementing the acceptable plan of correction for each deficiency cited;
- A completion date for correction of each deficiency cited;
- Monitoring and tracking procedures to ensure the PoC is effective in bringing the ASC into compliance, and that the ASC remains in compliance with the regulatory requirements;
- The plan must include the title of the person responsible for implementing the

plan of correction; and

- The administrator's signature and the date signed on page 1 of the 2567 form.

While general requirements and submission time lines are the same for both PoCs and Credibles, timeframes for the correction of the deficient practices vary. Within a PoC, the correction date may be a "future" date, normally less than 60 days. However, within a Credibles the correction date must be a date prior to the date specified in the cover letter. That is, for a PoC the clinic is saying they will have a corrective plan in place by a certain date in the future, but for the credible the ASC is saying the issue has been resolved as of this date and we are ready to be resurveyed to determine compliance at the Condition-level. Timelines related to a specific survey are included in the cover letter which accompanies the 2567.

Once survey staff receive the PoC/Credible, they will ensure the administrator's signature and the date in on page 1 of the 2567 form are present. Surveyors then review the plan for each deficiency for adequacy and appropriateness. If additional information is needed, survey staff will contact the clinic Administrator, or designated representative.

It should also be noted that when complete, 2567s and PoCs/Credibles are posted to the BFS web site at [www.facilitystandards.idaho.gov](http://www.facilitystandards.idaho.gov) However, due to privacy and proprietary consideration, we are prohibited from releasing any information that may identify a patient or anyone else not employed by the entity. Nor will we publish to the internet any documentation regarding financial documents, such as vouchers, professional licenses, etc.

# Understanding the ASC Survey Process



- Idaho Trends:
  - Q0043: Disaster Preparedness Plan
  - Q0181: Administration of Drugs
  - Q0241: Sanitary Environment
  - Q0225: Submission and Investigation of Grievances
  - Q0162: Form and Content of Records
  - Q0084: Governing Body Responsibilities

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This slide and the next 2 slides include the most frequently cited deficiencies in Idaho from 2010 to present. We are not going to review each of them and they are simply being provided for your reference. For specific information, please refer to the ASC survey 2567s posted on our web site.

# Understanding the ASC Survey Process



- Idaho Trends Continued:
  - Q0222: Posting Written Notice of Rights
  - Q0082: QAPI data and activities
  - Q0104: Safety from Fire
  - Q0267: Discharge with Responsible Adult
  - Q0240: Infection Control
  - Q0242: Infection Control Program
  - Q0221: Notice of Rights

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# Understanding the ASC Survey Process



- Idaho Trends Continued:
  - Q0260: Patient Admission, Assessment & Discharge
  - Q0101: Physical Environment
  - Q0264: Post-Surgical Assessment
  - Q0081: QAPI Program Scope and Activities
  - Q0202: Radiologic Services
  - Q0060: Surgical Services

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## Contact Information

- Bureau of Facility Standards:
  - Web Site: [www.facilitystandards.idaho.gov](http://www.facilitystandards.idaho.gov)
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Should you have any questions, need additional information, or have suggestions regarding future trainings, please feel free to contact BFS.