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Medicare Conditions for Coverage Alert:
Quality Assessment and Performance Improvement

In order to receive Medicare payment for surgical services furnished to program beneficiaries, an ambulatory surgical center ("ASC") must meet certain specific requirements referred to as Conditions for Coverage and set forth at 42 C.F.R. 416, Subpart C. This alert discusses the Quality Assessment and Performance Improvement ("QAPI") Condition for Coverage and provides a checklist based on the survey protocol outlined in the Medicare State Operations Manual to assist an ASC in evaluating whether it meets the condition's requirements.

Background

The QAPI Condition for Coverage requires an ASC to take a proactive and comprehensive approach to improving the quality and safety of the surgical services it delivers. It states that the ASC "must develop, implement and maintain an on-going, data-driven quality assessment and performance improvement … program."[1]

The QAPI Condition for Coverage presumes that an ASC employs a systems approach to evaluating its processes, identifying problems that have occurred or that potentially could occur from the ASC's practices and determining the root causes of the problems. The Centers for Medicare & Medicaid Services ("CMS") instructs surveyors to focus not on whether an ASC has any deficient practice, but rather on whether it has an effective system in place for identifying problematic policies, practices or events, taking remedial action, and following up to determine whether the remedial action was effective in improving quality and safety.

Program Scope

> *(a) Standard: Program Scope.*
> *(1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors.*
> *(2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC.*

CMS does not prescribe a particular QAPI program. However, each program must be ongoing, *i.e.*, the program must be a continuing one, not just a one-time effort. Evidence of an ongoing program includes collection of quality data at regular intervals, analysis of the updated data at regular intervals, updated records of actions taken to address quality problems identified in the analyses, and new data collection to determine if the corrective actions were effective. In addition, each program must be data-driven, *i.e.*, the program must identify in a systematic manner the data it will collect to measure various aspects of

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[1] 42 C.F.R. § 416.43; Appendix L to the Medicare State Operations Manual sets forth the "Guidance for Surveyors: Ambulatory Surgical Centers" and is available at www.cms.gov/GuidanceforLawsandRegulations/02_ASCs.asp.

quality of care, the frequency of data collection, how the data will be collected and analyzed, and evidence that the program uses the data collected to assess quality and stimulate performance improvement.

An ASC's QAPI program must improve both patient health outcomes and patient safety in the ASC. In order to achieve these goals, the ASC's QAPI program must be on-going, use quality indicators or performance measures associated with improved health outcomes in a surgical setting, and identify and reduce adverse patient events and medical errors.

Program Data

(b) Standard: Program data.
(1) The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC.
(2) The ASC must use the data collected to--
(i) Monitor the effectiveness and safety of its services, and quality of its care.
(ii) Identify opportunities that could lead to improvements and changes in its patient care.

An ASC must not only identify quality indicators or performance measures, but also actively collect data related to those indicators and measures at the intervals called for by its QAPI program. The staff responsible for collection of the data must be trained in appropriate techniques to collect and maintain that data.

CMS does not prescribe a certain set of indicators for an ASC to use.[2] However, the ASC must be able to demonstrate that the indicators it is using will enable it to improve health outcomes for its patients. The ASC is required to focus on high risk, high volume, and problem-prone areas. When selecting the indicators or measures, it is required to consider the incidence, prevalence and severity of problems.[3]

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[2] Indicators can be broken down into several types. "Outcomes indicators" measure results of care. "Process of care" indicators measure how often the standard of care was met for patients with a diagnosis related to that standard. "Patient perception indicators" measure a patient's experience of the care he or she received in the ASC.

[3] "Incidence" refers to the rate or frequency at which problems occur in the ASC related to the area measured by the indicator. "Prevalence" refers to how widespread something is in an ASC at a given point in time.

In addition, an ASC must track all patient adverse events and identify errors that result in near misses.[4]

Program Activities

(c) Standard: Program activities.
(1) The ASC must set priorities for its performance improvement activities that--
(i) Focus on high risk, high volume, and problem-prone areas.
(ii) Consider incidence, prevalence, and severity of problems in those areas.
(iii) Affect health outcomes, patient safety, and quality of care.
(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.
(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.

Once having collected the data, an ASC must analyze it to monitor ASC performance, *i.e.*, to determine what the data suggests about the ASC's quality of care and the effectiveness and safety of its services. Analysis must take place at regular intervals. In the case of data related to adverse events, the ASC must use the data to analyze the causes of the adverse events.

The staff responsible for this analysis must be qualified to interpret quantitative data. While CMS does not expect an ASC to engage in sophisticated statistical modeling of data, it does expect the ASC to conduct thorough analyses that focus on systemic issues. An ASC may elect to use contractors for technical aspects of the QAPI program, including analysis of data. However, the ASC is expected to actively involve its staff in the program, and the ASC's leadership is expected to retain responsibility for the ongoing management of the program.

Analysis of the data must be used to identify areas where there is room for improvement in the ASC's performance. Once an ASC's analysis has identified opportunities for improvement, the ASC

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[4] An "adverse event" is defined as "an injury caused by medical management rather than the underlying condition of the patient." An "error" is defined as "the failure of a planned action to be completed as intended (*i.e.*, error of execution) or the use of a wrong plan to achieve an aim (*i.e.*, error of planning)."

must develop specific changes to make improvements and also have a method to ensure that the improvements it makes are sustained over time.

The ASC also must implement preventive strategies designed to reduce the likelihood of adverse events throughout the ASC and must make all staff aware of the strategies it has adopted for prevention of adverse events.

Performance Improvement Projects

> *(d) Standard: Performance improvement projects.*
> *(1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations.*
> *(2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results.*

Every ASC must undertake one or more specific quality improvement projects per year. Large, complex or high volume ASCs are expected to undertake more or more complex projects.

An ASC must keep records on its performance improvement projects. The records must include an explanation of why the project was undertaken. The explanation must indicate what data (collected in the ASC or based on recommendations of nationally recognized organizations) leads the ASC to believe that the project's activities will actually result in improvements in patient health outcomes and safety in the ASC. For projects that are still underway when the ASC is surveyed, the ASC must be able to explain what activities the project entails and how the impact of the project is being monitored. Unless the project has just begun, the ASC must be able to provide evidence that it is collecting data that will enable it to assess the project's effectiveness. For projects that are completed, the ASC must be able to provide documentation that explains what the results of the project were, and what actions, if any, the ASC took in response to those results.

Governing Body Responsibilities

> *(e) Standard: Governing body responsibilities.*
> *The governing body must ensure that the QAPI program--*
> *(1) Is defined, implemented, and maintained by the ASC.*

> *(2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness.*
> *(3) Specifies data collection methods, frequency, and details.*
> *(4) Clearly establishes its expectations for safety.*
> *(5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.*

A successful QAPI program requires the direction and support of an ASC's leadership. CMS expects that the ASC's governing body assume responsibility for all aspects of the design and implementation of each phase of the QAPI program. The governing body must ensure that the ASC's QAPI program: 1) is defined in writing (*e.g.*, in the minutes of a meeting where the governing body established the program), 2) is actually implemented, 3) is implemented on an ongoing basis, 4) employs quality and safety indicators, 5) describes in detail the indicator data to be collected, how it will be collected, and how frequently it will be collected, 6) uses the data collected and analyzed to improve the ASC's performance, 7) evaluates changes designed to improve the ASC's performance to determine whether they are effective, and 8) takes appropriate actions to make further changes as needed.

Quality Assessment and Performance Improvement Checklist

Program Scope

□   Can your ASC's leadership describe the QAPI program, including staff responsibilities for QAPI and the indicators your ASC tracks?

□   Is there a rationale for the particular indicators that your ASC has chosen to track? Are the indicators based on nationally-recognized recommendations? If not, does your ASC have evidence that the indicators are associated with improvement in patient health outcomes and safety? Do the indicators include measures appropriate for surgery? Do the indicators include infection control measures?

□   Does your ASC have a system for tracking adverse events?

□   Can the staff responsible for QAPI articulate the method for data collection for each QAPI program indicator? Can the staff articulate the frequency for data collection for each QAPI program indicator?

Program Data and Program Activities

□ Is your ASC collecting data on all of the indicators it identified for its QAPI program? Is it collecting the data at the frequency specified in its QAPI program?

□ Can your ASC identify who is responsible for the data collection and analysis and articulate what their qualifications are? In particular, can your ASC explain who determines the causes of adverse events, including the immediate cause and the underlying root causes?

□ Does the ASC staff that handles data collection and analysis have appropriate education or training?

□ Can your ASC provide examples of instances where it used QAPI data to identify opportunities for improving processes for providing care? Can your ASC demonstrate that it evaluated whether the improvements were effective and sustained?

□ Can the ASC staff explain how it trains staff on ways to prevent adverse events from occurring?

□ Can the ASC staff explain what they know about the ASC's QAPI program?

Performance Improvement Projects

□ Can your ASC provide documentation for performance improvement projects currently underway and for projects completed in the prior year? If a large, complex, or high volume ASC with only one project underway, is the scope of that project such that it is likely to have a significant impact on your ASC's quality of care or patient safety?

□ Does your ASC's documentation indicate the rationale for undertaking each project? Does your ASC have data indicating it had a problem in the area targeted for improvement, or could your ASC point to recommendations from a nationally recognized expert organization suggesting the activities?

□ Does the documentation for the completed projects include the project's results? If a project was unsuccessful, can your ASC explain what actions it took as a result of that information? If the project was successful, can your ASC explain how it is sustaining the improvement?

Governing Body Responsibilities

□ Can your ASC's leadership explain how the governing body is involved in the QAPI program? Can your ASC's leadership display ready knowledge of the program's structure and activities? If a contractor is used for some portions of the program, can your ASC's leadership demonstrate that it monitors closely the contractor's activities?

□ Is there evidence of a governing body review of all elements of the QAPI program, *e.g.*, meeting minutes?

□ Can your ASC's leadership articulate how it uses the program to improve performance? Can your ASC's leadership provide evidence of changes made as a result of QAPI program activities?

□ Can your ASC's leadership provide documentation of the details of the resources that are dedicated to the QAPI program? Is there evidence that these resources were actually made available as planned?

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