



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 13-51-Transplant Programs

DATE: August 2, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Pilot-Test: Focused Quality Assessment and Performance Improvement (F-QAPI) Surveys for Organ Transplant Programs – *Informational Only*

Memorandum Summary

- **Pilot F-QAPI Surveys:** The Centers for Medicare & Medicaid Services (CMS) developed the F-QAPI survey to enhance assessment of the Transplant Program Quality Assessment and Performance Improvement (QAPI) Condition of Participation (CoP).
- **Purpose:** These initial F-QAPI surveys will pilot-test stand-alone surveys focused on QAPI. We will use the pilot to determine the extent to which a more in-depth review of QAPI may (a) improve surveyor ability to identify weaknesses in a QAPI program, (b) enable surveyors to offer improved feedback to hospitals, (c) provide tools that hospitals may use for internal risk assessment, and (d) offer CMS an option for a more focused survey for some transplant hospitals in lieu of more frequent, full, onsite surveys.
- **Educational Approach:** During the pilot-test phase, F-QAPI surveys will be educational. They will assess the risks that a transplant program's QAPI may not be in compliance with CMS requirements, but will not involve the issuance of deficiency citations. And CMS will learn more about the manner in which QAPI elements relate to program outcomes.

Background

The CMS will pilot test transplant program F-QAPI surveys as targeted surveys. The purpose of the F-QAPI survey is to provide an in-depth assessment of QAPI activities within a transplant program. This effort focuses on the important link between a highly functioning QAPI program and improved quality of care and patient outcomes.

The F-QAPI survey will assess the transplant program's compliance with 42 CFR482.96, QAPI Conditions of Participation (CoP), as well as improve the processes surveyors use in assessing compliance.

The F-QAPI surveys will be conducted by the CMS national contractor, using specially trained surveyors called Quality Survey Educators (QSEs) who have experience in survey and health care quality. Surveys conducted by QSEs will promote further insight into the assessment of transplant program QAPI. We expect that the survey will have the added value of providing an opportunity for programs to gain insights that can strengthen their improvement efforts. We plan to develop and test improved surveyor worksheets that may eventually be used by hospitals as a QAPI risk management self-assessment tool for transplant programs. While the survey is not designed to be consultative, prescriptive, or advisory in nature, feedback and other information that might be provided by QSEs may serve as an educational opportunity for the program.

Following a small number of pilot surveys, the F-QAPI survey will be revised. We then expect to expand the use of targeted surveys in FY 2014 and assess the extent to which these surveys may allow for a stretched-out timeline for full, onsite surveys. In a notice of proposed rule-making issued February 7, 2013¹, we proposed to amend the existing three-year survey frequency for full surveys in the existing CMS regulation to allow for a more flexible timeline where survey frequency may be more variable based on perceived risk (e.g., a 3-5 year range). The F-QAPI survey may offer one type of flexibility, in which we focus on key leverage points, and perhaps reduce the need for the more frequent full surveys.

The F-QAPI survey will incorporate assessment of the following key elements of a QAPI program:

1. ***Design and Scope:*** The transplant QAPI program is integrated within the broader hospital program (482.68(b)). The scope includes both a defined quality indicator selection and analysis system, and a patient safety system. The transplant QAPI program is implemented, effective, facility-wide, comprehensive, and data-driven.
2. ***Governance and Leadership:*** The hospital leadership, governing body, and transplant program leadership (482.21(e)) are clearly engaged in QAPI oversight and ensure that: 1) the QAPI program is adequately resourced; 2) a culture of transparency and inclusion exists that facilitates the gathering, reporting, and exchange of information; and 3) there is active leadership engagement with the program's QAPI.
3. ***Feedback and Data Systems:*** The transplant QAPI program includes effective feedback and data systems including: (1) a communications structure that ensures that QAPI information flows throughout the transplant program(s) and the hospital organization; (2) proactive identification of evidenced-based quality indicators; (3) an effective surveillance system to identify medical errors and adverse events and (4) effective systems to ensure ongoing data collection, tracking, and analysis related to all quality indicators and adverse events, (5).

¹ CMS 3267-P, Medicare and Medicaid Programs; Part II – Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Proposed Rule

4. ***Systematic Analysis and Systemic Action:*** The transplant QAPI program analyzes collected data to assess adverse events and quality indicator information, and uses the information to prevent or minimize problems. The result should be system-based interventions to improve quality of care and performance on an ongoing basis and to reduce risk of harm to patients.
5. ***Performance Improvement Processes:*** The transplant QAPI program defines, implements, and evaluates performance improvement interventions, including activities and distinct projects, with the objective of increasing quality of care on an ongoing basis.

Criteria for F-QAPI Surveys

CMS uses data from the Scientific Registry of Transplant Recipients (SRTR) to identify programs that have patient outcomes that are non-compliant with CMS regulations, as well as data from prior CMS surveys. CMS may seek to identify programs for F-QAPI surveys where CMS prior surveys, SRTR data, or other information indicate potential quality of care concerns.

The F-QAPI Protocol

The transplant F-QAPI protocol describes a more comprehensive review of QAPI compared to the standard survey process. While the standard survey reviews overall transplant QAPI to ensure compliance with the CoP, the F-QAPI survey evaluates each element of the QAPI process in more depth. QSEs may review the actual methodological soundness of the selection and implementation of the quality measures and tools employed. QSEs may not only look at quality measures, but further review the measure selection in relation to program outcomes or risks, whether the measures are related to systematically identified program operational issues, and whether the measures are benchmarked through a review of program data, current literature, industry standards, or best practices.

The F-QAPI protocol will use the methods of the standard survey, but with more depth to the QAPI inquiry. This will be done by examining documents showing analysis of adverse events, development of quality indicators, action plans, and dashboards, interactions between the transplant program QAPI program and hospital QAPI program, actions of hospital and transplant program leadership, and participation of all members of the multi-disciplinary team. Interviews with members of the transplant team and observation will also be used.

Since no citations will be issued, transplant programs will not be required to submit Plans of Correction as part of these pilot F-QAPI surveys. Surveyors will provide feedback, based on the draft surveyor worksheet, at the end of the survey to transplant program staff detailing QAPI areas at risk for non-compliance.

Effective Date: Pilot F-QAPI surveys began in July 2013.

Communication: This information should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

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/s/

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cc: Survey and Certification Regional Office Management