DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-08-Transplant Programs
REVISED 04.11.14

DATE: **December 20, 2013**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: QAPI Condition-Level Deficiency in Transplant Re-approval, Complaint and Focused Quality Assessment and Performance Improvement (F-QAPI) Surveys for Organ Transplant Programs – ***Informational Only***

"Revised to extend the prospective termination date for all §482.96 Condition: Quality Assessment and Performance Improvement (QAPI), to 210 days"

Memorandum Summary

- **F-QAPI Surveys:** In July-August 2013, the Centers for Medicare & Medicaid Services (CMS) conducted a pilot of the new transplant F-QAPI survey, and will now proceed with full implementation of this survey, including the issuance of citations.
- **Purpose:** The transplant F-QAPI survey provides CMS an opportunity for a more comprehensive assessment of compliance with the Transplant Program QAPI Condition of Participation (CoP) at §482.96. Additionally, the survey team may provide tools and information that programs can use to improve the effectiveness of their QAPI program.
- ***UPDATE:*** *The timeframe for prospective termination due to a QAPI condition-level deficiency will be 210 days regardless of the survey type (re-approval, complaint or F-QAPI).*

Background

The purpose of the Focused Quality Assessment and Performance Improvement (F-QAPI) survey is to provide an in-depth assessment of QAPI activities and improve the process of surveyor assessment of compliance with 42 CFR 482.96 QAPI Conditions of Participation (CoP) within a transplant program. This effort focuses on the important link between an effective QAPI program and improved quality of care and patient outcomes. The CMS pilot-tested F-QAPI surveys during the summer of 2013 and revised supporting instruments based on surveyor and program feedback.

A CMS contractor will conduct the transplant program F-QAPI survey using specially trained surveyors, called Quality Survey Educators (QSEs), who have experience in survey and health care quality. This survey is not consultative, prescriptive or advisory in nature; however, tools and other information provided by QSEs may serve as an educational opportunity for the program to improve the effectiveness of the transplant QAPI program.

Criteria for F-QAPI Surveys
In FY 2014, transplant program F-QAPI surveys will assess compliance among programs in the following categories:

1. Completed a Systems Improvement Agreement (SIA)
2. Shown by prior CMS surveys, Scientific Registry of Transplant Recipients (SRTR) data, or other information that indicate problems that could lead to outcomes non-compliance
3. Applying for mitigating factors as a result of outcomes non-compliance in the most recent Programs Specific Report (PSR) from the SRTR
4. In conjunction with an initial survey or re-approval of standard organ transplant survey process (SOTP)

Process for Confirmation of Compliance and Enforcement
Similar to all CMS surveys, F-QAPI surveys will be unannounced. For condition-level QAPI deficiencies, programs that are found to have a condition-level deficiency will be given a prospective 210-day termination date rather than the standard 90-day period that applies for most other condition-level deficiencies. These termination timeframes, 90- and 210-days, do not apply to situations where there is immediate jeopardy. Dates of correction in the PoC must be no later than 45 days from the date of the letter of non-compliance. A revisit will occur between 160-190 days to assess compliance with the CoPs. Programs will have the opportunity to implement needed QAPI improvements and demonstrate compliance with CMS requirements prior to the end of the 210-day period.

Effective Date: F-QAPI surveys will begin in January 2014.

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.

Contact: For additional information, please contact Annette Snyder at 410-786-0807 or by email, annette.snyder@cms.hhs.gov.

/s/
Thomas E. Hamilton

Attachment: Process for Follow-up after a Transplant Survey with a Finding of a Condition-Level Deficiency

cc: Survey and Certification Regional Office Management

Attachment 1: Process for Follow-up after a Transplant Survey With a Condition-Level Deficiency

Days	Steps	CMS Actions/Termination Indicators	Comments
1	Letter and CMS form 2567 sent to the program.	The CMS form 2567 is generated by the surveyor and sent to the program from the Regional Office (RO).	The date of the initial 2567 letter begins the overall countdown to achieve compliance where there are cited deficiencies.
10	Program must submit a Plan of Correction (POC), detailing how it will address deficiencies identified in the 2567.	The POC is jointly reviewed and agreed upon, by the surveyor, and the CMS Regional and Central Office (CO) representatives.	
45	New Language Timeframe within which required modifications of the PoC must be implemented. Dates of correction in the PoC must be no later than 45 days form the dated of the Form 2567 notification letter.	New Language During this time (day 45-160) CMS Central Office will be available to address any questions the transplant center may have, by contacting: Sherry Clark Centers for Medicare and Medicaid Services 7500 Security Boulevard, Mailstop C2-18-03 Baltimore, MD 21244 Sherry.clark@cms.hhs.gov	
New Language 160-190		New Language A revisit will occur during this timeframe to assess whether the program has achieved compliance with the Conditions of Participation.	
210		Termination takes effect if compliance is not achieved with CoP 42 CFR 482.96	