CMS Webinar Series #1: Intro to Transplant QAPI

Question	Answer
Will this program have any impact on research, e.g., testing investigational drugs during transplantation in clinical trials? Will centers be more hesitant to participate in clinical trials?	The transplant QAPI regulations do not speak to research or clinical trials. Programs that participate in research or innovative practices should not be hesitant secondary to CMS regulations. A recent revision to the Mitigating Factors regulatory language recognizes that innovation is a factor that CMS can consider when a program has outcomes non-compliance.
Slide 23: If a transplant program is running continuous cycles of improvement but seeing no sustained improvement based on unsuccessful tests of change, would CMS cite the program for not successfully running improvement cycles despite clear documentation that cycles are being conducted?	It depends. The regulations require a written program that has a method for improvement. The continuous cycle(s) of improvement must be identified in the written transplant QAPI plan and the program must be performing these cycles as written. There must be evidence of continued assessment, reassessment and ongoing actions during performance improvement activities that are communicated to all the appropriate stakeholders, including the governance/leadership that has the authority and responsibility to oversee QAPI. There is no requirement for documented sustained improvement but if it does not occur, the program should reconsider the ongoing activates to achieve improvement.
We had a mini QAPI survey with our routine survey. Will we be surveyed for the FQAPI subsequently?	Programs that have a FQAPI survey, either during a recertification survey or as a standalone survey are subject to another survey at any time.
Can you give examples of contracts or agreements?	Examples often seen on survey are the HLA and dialysis contracts
Is the transplant QAPI program responsible for analyzing all adverse events (including level=0 no harm, level=1 no harm), or can the policy state QAPI will review and analyze adverse events level 2 and higher?	The program's written process can indicate how levels of events will be investigated. However, there should also be evidence the program is aware of, and evaluating or trending, non-harm events (as part of the "risk thereof" component of the CMS definition)

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Programs or centers? You said programs are per organ, so if 20 programs were deficient, does that mean you surveyed 5 centers with 4 programs each, or was this 20 centers and 10 were deficient?	Slides 8/9 referenced 20 surveys conducted and 10 programs non-complaint at condition level. Generally, FQAPI surveys assess compliance of one organ program but one center may have more than one organ program showing QAPI deficiencies in that survey. During 2014 FQAPI surveys, there were 20 centers totaling 24 programs surveyed.
When is the post-transplant phase completed? If the transplant recipient came in 1 year post transplant for an issue not related to their transplant and received a non-harm medication error, is that considered a transplant adverse event?	The program should define what is considered a transplant adverse event. The expectation would be if it involves a patient still active in your system, the event would at least be screened and investigated as appropriate.
Does CMS recommend that transplant programs be organized as service lines?	CMS has no recommendations regarding administrative management of transplant programs
Would a post-transplant measure of data integrity be adequate for compliance?	The issue would be: How is the measure being utilized and how does it affect processes or outcomes related to patient care in the post-transplant phase? Depending upon the response, there might be other high risk, high or very low volume or problem prone issues to consider that might be more appropriate.
How far back should we have adverse event records?	There is usually a state statute for adverse event record keeping CMS may request to look at events for the past three years.