"Demystifying the FQAPI Process and the new Mitigating Factors Regulation"

David J. Reich, MD, FACS

Chair, ASTS Legislative Committee

David J. Cohen, MD

Co-Chair, AST Public Policy Committee

Danielle Miller, MS, RN, CCRN

Daniel Schwartz, MD, MBA

Michele Walton, RN, BSN

Centers for Medicare and Medicaid Services

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Demystifying FQAPI and the new Mitigating Factors Regulation

AST/ASTS Webinar

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Danielle Miller
Daniel Schwartz
Michele Walton

Today's Session

- **Transparency**
- **FQAPI**
- **Mitigating Factors**
- **CMS QAPI Webinar Series**

Goals of Transplant QAPI

- Provide a continuous learning infrastructure that promotes high quality transplantation services to the recipients and donors the program serves.
- Effectively stream performance information to the people who can and will act on the information to effect systemic improvement.
- Effectively analyze performance, identify and trace adverse events, and make sustained improvements to prevent future occurrences demonstrates an effective QAPI process.
- An effective QAPI program leads to sustainable good outcomes.
- There is a link between the Hospital QAPI program and the Transplant QAPI program. 42 CFR 482.21 + 482.96.

FQAPI Survey

Focused Quality Assessment and Performance Improvement Survey (FQAPI)

- Enables a more in-depth and comprehensive assessment of compliance with the Transplant Program QAPI Condition of Participation (CoP) at 42 CFR §482.96 and 482.21.
- Uses specially trained surveyors, called Quality Survey Educators (QSEs).
- QSEs provide tools and information that programs can use to improve the effectiveness of their QAPI program
- Is not an additional QAPI requirement for transplant programs

FQAPI Pre-Test

In the pre-test phase, FQAPI was a totally educational survey of 10 transplant programs selected based on various criteria in the summer of 2013.

Results of the pilot demonstrated that 8 of the 10 programs surveyed would have been cited with a condition level deficiency for QAPI, if the survey had not been a pre-test.

6 of the 8 programs demonstrating condition level non-compliance with QAPI were cited for outcomes non-compliance on the March 2014 release of SRTR data

FQAPI Beyond the Test Phase

Beginning 2014, the survey transitioned to an enforceable survey for which a total of 19 transplant programs would be surveyed.

Four basic criteria were used to identify the transplant programs to be surveyed:

- Programs that had previously completed a Systems Improvement Agreement (SIA)
- Programs that demonstrated non-compliance with patient and graft survival outcomes based on current SRTR data-programs
- Programs that demonstrated near non-compliance with patient and graft survival outcomes, but did not cross all three CMS thresholds
- Standard re-approval surveys using FQAPI survey process to assess QAPI CoP

FQAPI Results So Far

Results of the 19 FQAPI surveys demonstrated:

- transplant programs demonstrated condition level deficiencies for QAPI
  - 5 of 9 standard re-approval transplant surveys demonstrated condition level deficiencies for QAPI
  - 4 of 8 Outcomes non-compliance surveys demonstrated condition level QAPI deficiencies
  - 1 of 2 transplant programs completing an SIA demonstrated a condition level QAPI deficiency

Most Frequently Cited QAPI Deficiencies

- **X100- Objective Measures**
  - No objective measures in all phases.
  - No follow-up or evaluation for sustained improvement
- **X101-Performance Improvement Activities**
  - Data not collected as per written plan
  - Action not taken on collected data
  - No method for follow-up of improvements
- **X102- Adverse Events Policy**
  - Use of hospital policy only that did not address transplant-specific Adverse Events
  - No analysis or corrective action on patient death or graft failures to prevent recurrence.
- **X103 Thorough Analysis of Adverse Events**
  - No process for conducting thorough analysis
  - No documentation of RCA for Adverse Events
  - Review only of events that caused harm, not risk of harm
- **X104 Utilizing Analysis to Effect Change and Prevent Future Harm**
  - No evidence of strategies implemented or change sustained to prevent recurrence of actual or potential AEs
  - No action to prevent recurrence of AEs
  - No evidence of action taken based on analysis of AEs

Transplant Program Feedback on FQAPI

- Expressed appreciation for the opportunity to receive an in-depth evaluation of their QAPI program
- QSEs have provided transplant programs with additional knowledge and information to identify and implement strategies to improve their QAPI program
- FQAPI – generally resulted in more support and engagement of hospital administration toward transplant QAPI efforts

Recent Transplant Activities From CMS

- FQAPI surveys will continue in 2015 with a projected 20 surveys to be completed. Approx. 50% will occur during standard re-approval surveys.
- A recent transition to a 210-day timeframe to demonstrate compliance with QAPI condition level deficiencies will return to its original 90-day timeframe
- October 2014 publication of an improved mitigating factors regulation, found at:

ecfr.gov (browse to Title 42, click on 482-699, click on 488, click on 488.61)

Mitigating Factors Provision

- CMS Regulations - Permit Consideration of "Mitigating Factors"

- Main Types of Mitigating Factors
  - Natural Disasters (e.g. Hurricane)
  - Innovation (high HLA population, etc.)
  - **Improvement**
    - Robust Program Improvement
    - Evidence of Improved Outcomes

- Programs submit request for consideration to CMS Central Office (to ensure national consistency)

Favorable MF Decisions for Outcomes

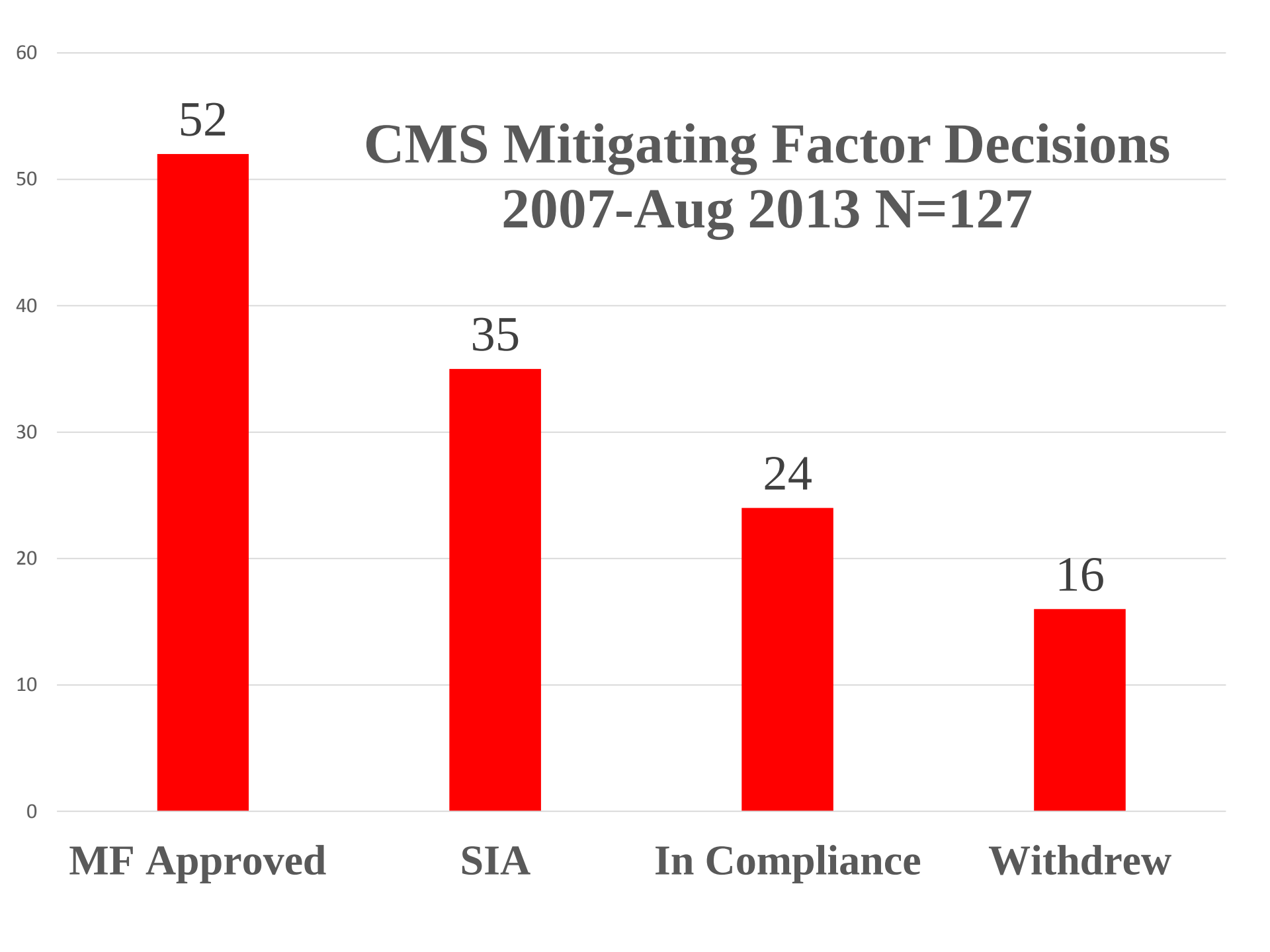
Five Elements – All Fulfilled

1. Program Improvements
2. Substantial
3. Address Root Causes
4. Implemented, Institutionalized, Sustainable (*not just plans*)
5. Evidence (Data) of Improved Outcomes to Support a Finding of Present-Day Compliance

Mitigating Factors Experiences

Majority of Programs Approved during 210 Day MF Review Period

Additional Programs Approved after System Improvement Agreement


CMS Mitigating Factor Decisions
2007-Aug 2013 N=127
60
50
40
30
20
10
0
52
35
24
16
MF Approved
SIA
In Compliance
Withdrew

Expanded Mitigation Factors (MF) Regulation 42 CFR 488.61 (f-h) Effective 10/22/2014

Reasons for Expanded MF Regulation: Since adoption of CoPs, CMS has expanded knowledge regarding:

- Factors and processes that promote improved outcomes;
- Additional MFs that merit explicit recognition;
- Recognition of substantial program and recent outcomes data improvements that leads to approval of MF;
- Desire for further transparency and clarity for expectations for Systems Improvement Agreement (SIA).

What's in the Regulation?

488.61(f)(1) Factors: consideration of mitigating factors

i. Extent to which outcomes measures are not met
ii. Availability of Medicare-approved transplant centers in the area
iii. Extenuating circumstances (for example, natural disaster)
iv. Program improvements that address root causes of outcomes (*new*)
v. Use of innovative transplantation practices (*new*)
vi. OPTN method of calculating outcomes (*new*)

488.61(f)(2) Content: request for consideration of MF must include sufficient information, with examples to be submitted listed. CMS looks especially for a good analysis and understanding of root causes matched with actions that address them, backed by evidence (e.g., QAPI program meeting minutes, quality dashboard, other performance indicators, implemented improvements).

488.61(f)(3) Timing: notification to CMS within 10 days, materials to be submitted within 120 days

What's in the Regulation?

488.61(g)(1) Actions: results of MF review

i. Approve initial approval or re-approval of a program's Medicare participation

ii. Deny a program's request

iii. Offer a time-limited SIA

488.61(g)(2) Limitation: will not approve any program with condition-level deficiency

What's in the Regulation?

488.61(h) Transplant Systems Improvement Agreement

1. Content, including but not limited to:

i. Patient notification

ii. External independent peer review team onsite assessment of program

iii. Action plan

iv. An onsite consultant

v. Comparative effectiveness analysis

vi. Demonstration of proficiency with patient-level data from SRTR

vii. Staffing analysis

viii. Activities to strengthen performance of QAPI program

ix. Monthly reporting and conference calls with CMS

x. Additional or alternative requirements tailored to the transplant program

Timeframe: SIA typically lasts12 months

SIA Lessons Learned

Transplant programs that have participated in SIAs have communicated to CMS:

- Independent Peer Review Team provides the foundation of improvement action plan
- Sustainability requires full support of transplant and hospital administration
- Comparing policies and processes to and visiting other successful transplant programs have lead to introspective change within their program
- The ability to critically examine program infrastructure determines the resources necessary to implement positive change.

How You Might Use this Information

- Proficient use of data allows programs to predict outcomes non-compliance;
- Reg provides clues of what might be done to have best chance of approval of MF application;
- Regulatory requirements of SIA can be used by programs to take effective proactive actions/interventions to quickly improve outcomes and demonstrate outcomes compliance;
- Full hospital support is essential.

SOLID ORGAN TRANSPLANT PROGRAMS

2015

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TRANSPLANT PROGRAM QAPI

QAPI Specialists/Quality Surveyor Educators (QSE's)/ Transplant Surveyors
James Ballard, MBA, CPHQ, CPPS, HACP
Eileen Willey, MSN, BSN, RN, CPHQ, HACP

CMS WEBINAR SERIES
Transplant QAPI Topics

1. Introduction to Transplant QAPI: A Regulatory Overview
2. FQAPI Worksheet Overview
3. Objective Measures – Monitoring & Evaluating Services
4. Performance Improvement Projects – Tools and Methods
5. Adverse Events
6. Transplant Adverse Event “Thorough Analysis”
7. QAPI Tools 1
8. QAPI Tools 2
9. Data Display - Tools and Methods
10. Comprehensive Program and 5 Key Aspects of QAPI
11. Interpretive Guidance
12. Writing an effective Plan of Correction & Other QAPI Resources

CMS WEBINAR SERIES
Transplant Programs

Transplant QAPI Series Introduction

A brief historical review and introduction to the Transplant QAPI training series.

Introduction to Transplant QAPI: A Regulatory Overview

A review of the Transplant QAPI Condition of Participation and Hospital Condition of Participation for Quality. This session will provide where Transplant programs are integrated into hospital QAPI activities and where distinct activities may occur.

FQAPI Worksheet Overview

An overview of the Focused Quality Assessment and Performance Improvement worksheet utilized by CMS surveyors.

Objective Measures – Monitoring & Evaluating Services

An insightful look into developing objective measures that allows monitoring and evaluations of transplantation activities in order to improve outcomes.

CMS WEBINAR SERIES
Transplant Programs

Performance Improvement Projects – Tools and Methods

A beginners guide to the different tools and methods that may be utilized to conduct Performance Improvement Projects and Activities.

Adverse Events

An in-depth review of what Adverse Events are, how Adverse Events can be identified, documented and acted upon in order to prevent future reoccurrences.

Transplant Adverse Event "Thorough Analysis"

An in-depth review of what a 'thorough analysis' should contain, a look at tools and methods that may be utilized and how the results of an analysis may be used to prevent re-occurrences.

QAPI Tools 1 & 2

A brief look at the 7 Basic Statistical Tools that may be utilized to conduct QA PI activities and a reference list of alternative tools/methods being used today.

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CMS WEBINAR SERIES
Transplant Programs

Data Display - Tools and Methods

A brief look into the different tools and methods that may be utilized to display data, to analyze data and to turn raw data into useful information

Comprehensive Program and 5 Key Aspects of QAPI

A review of the requirements for a Comprehensive QAPI program and the 5 key aspects that effective QAPI programs contain.

New Interpretive Guidance

A review of the new interpretive guidance for Transplant Programs.

Writing an effective Plan of Correction & Other QAPI Resources

A session devoted to writing Plans of Correction in relation to survey findings and 2567 reports along with other QAPI resources for programs to explore.

Dates for Webinars

1. February 11, 2015
2. March 11, 2015
3. April 8, 2015
4. May 13, 2015
5. June 10, 2015
6. July 8, 2015
7. August 12, 2015
8. September 9, 2015
9. October 14, 2015
10. November 18, 2015
11. December 9, 2015
12. January 13, 2016

All Webinars will start at 12:00pm Eastern Standard Time

DISCLAIMER

- This training series will contain Quality concepts, foundational and historical perspectives of Quality Assessment and Performance Improvement methodologies (as they were originally developed) and regulatory guidance to help transplant programs meet compliance with the Conditions of Participation.

- CMS understands that: 1) Healthcare has various definitions of what Quality is, 2) There are many methods that can be employed and 3) there are many tools that can be utilized within quality assessment and process improvement activities.

- CMS also understands that some organizations blend several quality concepts and tools together to provide for a more nimble and individualized QAPI program.

- CMS is never prescriptive to organizations in how to meet compliance. This training series does not support or advocate any particular QAPI method or tool. This training fully supports that QAPI activities include data driven decisions that lead to sustained improved performance and ultimately improved patient outcomes.