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# CMS Manual System

## Pub. 100-07 State Operations Provider Certification

Department of Health &  
Human Services (DHHS)  
Centers for Medicare &  
Medicaid Services (CMS)

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Transmittal 105

Date: March 21, 2014

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**SUBJECT: Revised Appendix A, Interpretive Guidelines for Hospitals, Condition of Participation: Quality Assessment and Performance Improvement**

- I. **SUMMARY OF CHANGES:** The guidance for the Quality Assessment and Performance Improvement (QAPI) Condition of Participation for Hospitals at 42 CFR §482.21 was previously organized into 34 separate subdivisions (“Tags”) in Appendix A of the State Operations Manual. The number of Tags has been reduced to eight by deleting and revising existing Tags and adding one new Tag. There has been no change in the wording of the regulation.

**NEW/REVISED MATERIAL - EFFECTIVE DATE: March 21, 2014**

**IMPLEMENTATION DATE: March 21, 2014**

*The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)**

**(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)**

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
D	Appendix A/A-0264 /§482.21(a) Standard: Program Scope
D	Appendix A/A-0265/§482.21(a)(1)
D	Appendix A/A-0266/§482.21(a)(1)
D	Appendix A/A-0267/§482.21(a)(2)
R	Appendix A/A-0273/Data Collection & Analysis/§§482.21(a), 482.21(b)(1), 482.21(b)(2)(i), & 482.21(b)(3)
D	Appendix A/A-0274/§482.21(b)(1)
D	Appendix A/A-0275/§482.21(b)(2)(i)
D	Appendix A/A-0276/§482.21(b)(2)(ii)
D	Appendix A/A-0277/§482.21(b)(3)
R	Appendix A/A-0283/Quality Improvement Activities/§§482.21(b)(2)(ii), 482.21(c)(1) & 482.21 (c)(3)
D	Appendix A/A-0285/§482.21(c)(1)(i, ii, iii)
R	Appendix A/A-0286/Patient Safety, Medical Errors & Adverse Events/ §§482.21(a)(1), 482.21(a)(2), 482.21(c)(2), & 482.21(e)(3)
D	Appendix A/A-0287/§482.21(c)(2)

D	Appendix A/A-0288/§482.21(c)(2)
D	Appendix A/A-0289/§482.21(c)(3)
D	Appendix A/A-0290/§482.21(c)(3)
D	Appendix A/A-0291/§482.21(c)(3)
R	Appendix A/A-0297/Performance Improvement Projects/§482.21(d)
D	Appendix A/A-0298/§482.21(d)(1)
D	Appendix A/A-0299/§482.21(d)(2)
D	Appendix A/A-0300/§482.21(d)(3)
D	Appendix A/A-0301/§482.21(d)(3)
D	Appendix A/A-0302/§482.21(d)(3)
D	Appendix A/A-0303/§482.21(d)(4)
N	Appendix A/A-0308/Standard Tag for requirements found only in Condition stem statement/§482.21
R	Appendix A/A-0309/Executive Responsibilities/§482.21(e)
D	Appendix A/A-0310/§482.21(e)(1)
D	Appendix A/A-0311/§482.21(e)(1)
D	Appendix A/A-0312/§482.21(e)(2)
D	Appendix A/A-0313/§482.21(e)(2)
D	Appendix A/A-0314/§482.21(e)(3)
R	Appendix A/A-0315/ Providing Adequate Resources/§482.21(e)(4)
D	Appendix A/A-0316/§482.21(e)(4)
D	Appendix A/A-0317/§482.21(e)(5)

**III. FUNDING:** No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2014 operating budgets.

**IV. ATTACHMENTS:**

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

\*Unless otherwise specified, the effective date is the date of service.

**State Operations Manual**  
**Appendix A - Survey Protocol,**  
**Regulations and Interpretive Guidelines for Hospitals**  
*(Rev.105, Issued: 03-21-14)*

**A-0273**

*(Rev. 105, Issued: 03-21-14, Effective: 03-21-14, Implementation: 03-21-14)*

*Data Collection & Analysis*

*§§482.21(a), 482.21(b)(1), 482.21(b)(2)(i), & 482.21(b)(3)*

*§482.21(a) Standard: Program Scope.*

*(1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes....*

*(2) The hospital must measure, analyze, and track quality indicators...and other aspects of performance that assess processes of care, hospital service and operations.*

*§482.21(b) Standard: Program Data.*

*(1) The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization.*

*(2) The hospital must use the data collected to--*  
*(i) Monitor the effectiveness and safety of services and quality of care; and...*

*(3) The frequency and detail of data collection must be specified by the hospital's governing body.*

**A-0283**

*(Rev. 105, Issued: 03-21-14, Effective: 03-21-14, Implementation: 03-21-14)*

*Quality Improvement Activities*

*§§482.21(b)(2)(ii), 482.21(c)(1) & 482.21 (c)(3)*

***§482.21(b)(2) Standard: Program Data***

*The hospital must use the data collected to--...*

*(ii) Identify opportunities for improvement and changes that will lead to improvement.*

***§482.21(c) Standard: Program Activities***

*(1) The hospital must set priorities for its performance improvement activities that--*

*(i) Focus on high-risk, high-volume, or problem-prone areas;*

*(ii) Consider the incidence, prevalence, and severity of problems in those areas; and*

*(iii) Affect health outcomes, patient safety, and quality of care.*

*....*

*(3) The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.*

**A-0286**

*(Rev. 105, Issued: 03-21-14, Effective: 03-21-14, Implementation: 03-21-14)*

***Patient Safety, Medical Errors & Adverse Events***

***§§482.21(a)(1), 482.21(a)(2), 482.21(c)(2), & 482.21(e)(3)***

***§482.21(a) Standard: Program Scope.***

*(1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will ... identify and reduce medical errors.*

*(2) The hospital must measure, analyze, and track...adverse patient events....*

***§482.21(c) Standard: Program Activities...***

*(2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.*

*§482.21(e) Standard: Executive Responsibilities. The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:...*

*(3) That clear expectations for safety are established.*

## **A-0297**

*(Rev. 105, Issued: 03-21-14, Effective: 03-21-14, Implementation: 03-21-14)*

### *Performance Improvement Projects*

*§482.21(d) Standard: Performance Improvement Projects.*

*As part of its quality assessment and performance improvement program, the hospital must conduct performance improvement projects.*

*(1) The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital's services and operations.*

*(2) A hospital may, as one of its projects, develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This project, in its initial stage of development, does not need to demonstrate measurable improvement in indicators related to health outcomes.*

*(3) The hospital must document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.*

*(4) A hospital is not required to participate in a QIO cooperative project, but its own projects are required to be of comparable effort.*

## **A-0308**

*(Rev. 105, Issued: 03-21-14, Effective: 03-21-14, Implementation: 03-21-14)*

### *Standard Tag for requirements found only in Condition stem statement*

*§482.21 Condition of Participation: Quality Assessment and Performance Improvement Program*

*... The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement)... The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.*

## **A-0309**

*(Rev. 105, Issued: 03-21-14, Effective: 03-21-14, Implementation: 03-21-14)*

### *Executive Responsibilities*

*§482.21(e) Standard: Executive Responsibilities*

*The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:*

- (1) That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained.*
- (2) That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety and that all improvement actions are evaluated...*
- (5) That the determination of the number of distinct improvement projects is conducted annually.*

## **A-0315**

*(Rev. 105, Issued: 03-21-14, Effective: 03-21-14, Implementation: 03-21-14)*

### *Providing Adequate Resources*

*§482.21(e) Standard: Executive Responsibilities*

*[§482.21(e) The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:]*

- (4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients.*