

HCCA: Hot Survey Issues

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Objectives

- By the end of this presentation, participants should be able to:
- Identify CMS survey trends.
 - Demonstrate an understanding of the Emergency Preparedness Final Rule and general requirements for providers and suppliers.
 - Discuss tips for managing the CMS survey process.

Introduction



The CMS Regional Office (RO)

- Central Office (CO) staff develop national regulations, policy & guidance regarding all matters related to Survey, Certification & Enforcement.
- ROs are charged with implementing national policy, they do not develop separate regional policies.
- RO staff train, communicate and oversee State Operations in the implementation of national regulations, policy & guidance

RO Survey, Certification & Enforcement

- RO staff routinely work with: *[this is not an inclusive list]*
 - CMS Central Office;
 - State Survey Agencies
 - Regional OIG offices on Fraud & Abuse issues;
 - Regional Department of Justice staff;
 - Regional Offices of Civil Rights;
 - Quality Improvement Organizations (QIOs);
 - End Stage Renal Disease (ESRD) Networks;
 - Agency on Aging and Ombudsman Programs;
 - Beneficiary coalitions;
 - American Indian & Alaska Native groups;
 - Providers Associations;
 - Medicare Administrative Contractors (MACs);
 - Other CMS-CO groups such as Provider Enrollment, Division of National Systems, Office of Financial Management, Medicaid.

CMS Survey Trends

Hospital Topics

- Ligature risks
 - Psychiatric units/hospitals
 - S&C Memo: 18-06-Hospitals
- Primarily engaged
 - Development of micro hospitals and alternative models of care
 - S&C Memo: 17-44-Hospitals
- Co-locations
 - Providers desire to co-locate multiple facilities with the goal of shared services and expenses

Home Health Agencies

- New Conditions of Participation
- SOM Appendix B
 - Interpretive Guidelines - Complete
 - Survey Process - In Progress
- SOM Chapter 2: Certification Guidance
- SOM Chapter 10: Alternative Sanctions

End Stage Renal Disease Updates

- Dialysis in long term care
 - Integrated into core survey process
- Accreditation
- SOM Chapter 2 updates
- Appendix H revisions

Ambulatory Surgical Centers

- Infection Control Worksheets
- Electronic health records
- Distinct entity

Transplant Surveys

- Back to state agency jurisdiction: January 2, 2019
- SOM Appendix X

Emergency Preparedness

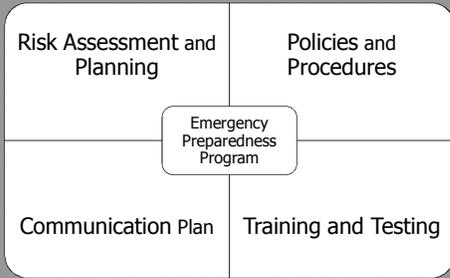
Emergency Preparedness Final Rule

- Published September 16, 2016 & applies to all 17 provider and supplier types; **Implementation date November 15, 2017**
- Compliance required for participation in Medicare (and Medicaid, as applicable)
- Emergency Preparedness is one new Condition of Participation/Condition for Coverage of many already required
- Appendix Z contains Interpretive Guidance and survey procedures
- The new Emergency Preparedness Tags are E-Tags
- If facilities are non-compliant, the same general enforcement procedures will occur as is currently in place for any other conditions or requirements cited for non-compliance

Conditions of Participation

- *5482.15, Condition of Participation for Hospitals*
- *5485.727, Conditions of Participation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services*

Four Provisions for All Provider Types



All-Hazards Approach

An all-hazards approach is an integrated approach to emergency preparedness planning that focuses on capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters, including internal emergencies and a man-made emergency (or both) or natural disaster. This approach is specific to the location of the provider or supplier and considers the particular type of hazards most likely to occur in their areas. **These may include, but are not limited to, care-related emergencies, equipment and power failures, interruptions in communications, including cyber-attacks, loss of a portion or all of a facility, and interruptions in the normal supply of essentials such as water and food.**

General Overview

- With the exception of Transplant Programs, that are incorporated under the Transplant Hospital's Emergency Preparedness Program:
- All 17 Providers and Suppliers are required to be in compliance with the four core elements/provisions with variations
- Variations may include areas such as:
 - Accountability for missing residents
 - Subsistence needs for inpatient providers only
 - Home health agencies and hospices required to inform officials of patients in need of evacuation

Four Provision Areas at a Glance

• Risk Assessment and Planning (Annually):

- Develop an emergency plan based on a risk assessment.
- Perform risk assessment using an "all-hazards" approach, focusing on capacities and capabilities.

• Policies and Procedures (Annually):

- Develop and implement policies and procedures based on the emergency plan and risk assessment.
- Policies and procedures must address a range of issues including subsistence needs, evacuation plans, procedures for sheltering in place, tracking patients and staff during an emergency.
- Update emergency plan

Policies and Procedures (cont'd)

Policies and procedures must address:

- How patients, staff and volunteers would shelter in place
- A system of medical documentation that maintains availability of records, protects confidentiality, etc.
- Staffing strategies and the use of volunteers
- Patient transfer arrangements with other facilities
- The provision of care at an alternate site (under an 1135 waiver)

E0013 Development of EP Policies and Procedures

42 CFR §485.625: The CAH must comply with all applicable Federal, State, and local emergency preparedness requirements. The CAH must develop and maintain a comprehensive emergency preparedness program, utilizing an all-hazards approach. The emergency preparedness program must include, but not be limited to, the following elements:

E0013 Development of EP Policies and Procedures

(b) Policies and procedures. [Facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually.

E0013 Development of EP Policies and Procedures

- (1) The provision of subsistence needs for staff and patients whether they evacuate or shelter in place, include, but are not limited to the following:
- (i) Food, water, medical and pharmaceutical supplies
 - (ii) Alternate sources of energy to maintain the following:
 - (A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.
 - (B) Emergency lighting.
 - (C) Fire detection, extinguishing, and alarm systems.
 - (D) Sewage and waste disposal.

E0013 Development of EP Policies and Procedures

- (2) A system to track the location of on-duty staff and sheltered patients in the facility's care during an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the facility must document the specific name and location of the receiving facility or other location.
- (3) Safe evacuation from the facility, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.
- (4) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

E0013 Development of EP Policies and Procedures

(5) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains availability of records.

(6) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

E0013 Development of EP Policies and Procedures

(7) The development of arrangements with other facilities or other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to facility patients.

(8) The role of the facility under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

E0013 Development of EP Policies and Procedures

Findings:

During record review with staff on 3/14/18, the P&Ps were requested.

1. At 11:55 a.m., the P&P provided for emergency water provisions indicated that the facility would keep two tank loads onsite. During a concurrent interview, facility leadership were asked to elaborate on the meaning of two tank loads. Adm1 and Maintenance Staff 1 stated they were unsure what that meant. Maintenance Staff 1 stated that the P&P was outdated.
2. At 12:05 p.m., there was no P&P provider regarding alternate sources of energy to maintain the temperatures for the health and safety of patients or to maintain the safe and sanitary storage of subsistence provisions.

E0013 Development of EP Policies and Procedures

3. At 1:50 p.m., there was a P&P for length of time paper-form medical records are retained in the facility. There was no P&P addressing the security of the electronic medical records system and a contingency plan for the system's failure. During a concurrent interview, Adm1 and Maintenance Staff 1 confirmed that there was no policy addressing the electronic medical system.
4. At 1:55 p.m., there was no P&P to address the role of the facility under a 1135 waiver during a nationally declared disaster.

Communication Plan

Facilities must develop and maintain a communication plan that complies with Federal, State and local laws. The plan must be reviewed and updated annually.

The plan must include:

- Contact information for staff, patient physicians, volunteers, contractors, other facilities as appropriate
- A primary and alternate means for communication
- A method for sharing patient information to other providers

E0031 Emergency Officials Contact Information

42 CFR §482.15(c)(2)

[(c) The [facility] must develop and maintain an emergency preparedness communication plan that complies with Federal, State and local laws and must be reviewed and updated at least annually.] The communication plan must include all of the following:

- (2) Contact information for the following:
 - (i) Federal, State, tribal, regional, and local emergency preparedness staff.
 - (ii) Other sources of assistance.

This STANDARD is not met as evidenced by:

The facility failed to ensure that an emergency preparedness communication plan that complies with Federal, State and local laws was developed and implemented.

E0031 Emergency Officials Contact Information

On 03/20/18 at 10:30 AM, the surveyor was provided with documentation by the Hospital Emergency Management Director, Engineering Director-ECHN and ECHN Environmental Safety Officer that didn't include call lists and numbers for Federal, State, tribal, regional, and local emergency preparedness staff and/or other sources of assistance.

Training and Testing

- Facilities must develop and maintain an EP training and testing program. The program must be reviewed and updated annually.
- Initial training required for all new and existing staff, volunteers and individuals providing services under arrangement (contractors, per diem staff, etc.)
 - Annual training required thereafter
 - Must maintain documentation of the training
 - Training may be tailored to specific staff roles

E0037 EP Training Program

- 42 CFR §485.727(d)(1)
- (1) Training program. The [facility, except CAHs, ASCs, PACE organizations, PRTFs, Hospices, and dialysis facilities] must do all of the following:
- Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected role.
 - Provide emergency preparedness training at least annually.
 - Maintain documentation of the training.
 - Demonstrate staff knowledge of emergency procedures.

E0037 EP Training Program

*[For Hospitals at §482.15(d) and RHCs/FQHCs at §491.12:]

(1) Training program. The [Hospital or RHC/FQHC] must do all of the following:

- i. Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles.
- ii. Provide emergency preparedness training at least annually.
- iii. Maintain documentation of the training.
- iv. Demonstrate staff knowledge of emergency procedures.

E0037 EP Training Program

This STANDARD is not met as evidenced by:

Based on review of documentation and interviews with facility staff, the facility failed to provide initial or annual training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected role. This failure could limit the ability of the facility staff, volunteers and individuals providing services under arrangement to react with proper knowledge and actions prior to, and during emergency situations.

E0037 EP Training Program

The findings were:

During the review of the facility's clinical employee records on the morning of 2/20/18, no documentation could be found or provided to surveyor to indicate that Staff #1, #2, or #3 received or participated in emergency preparedness training. In an interview with Staff #1 on the morning of 1/30/18, Staff #1 acknowledged the findings above.

Testing: Annual Exercises

Facilities must conduct exercises on an annual basis:

- Participate in a full-scale community based or individual based exercise (when a community based exercise is not available)
- Conduct a second exercise (may be full-scale community or individual exercise or tabletop exercise)

Integrated Healthcare Systems

Facilities that are part of a system consisting of multiple, separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program (EP), may choose to participate in the system's unified and integrated EP program.

If a facility elects to participate in the unified EP program, the facility must demonstrate/include:

- Active participation in the development of the unified program
- The facility's unique circumstances, patient populations, and services are part of the program
- It is capable of utilizing the unified EP program
- A community-based and facility based risk assessment specific to the facility
- Integrated policies and procedures that meet all requirements

Facilities with Multiple Locations

All locations of a Medicare certified provider or supplier must be included in the facility's EP program (all locations operating under the same CCN).

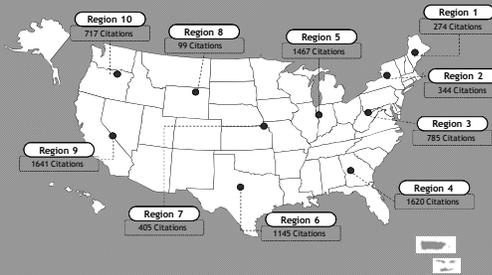
Off-campus locations of a Medicare certified provider or supplier that are co-located with another healthcare entity must be part of its facility's EP program but may collaborate with the co-located entity as part of each facility's community-based risk assessments and community-based exercises.

Be Aware of Slight Differences in Requirements

- Outpatient providers are not required to have policies and procedures for the provision of subsistence needs.
- Home health agencies and hospices required to inform officials of patients in need of evacuation.
- Long-term care and psychiatric residential treatment facilities must share information from the emergency plan with residents and family members or representatives.

Number of EP Citations by HHS Region

SAMPLE TEMPLATE



Includes total number of citations (n=8497) issued between February 1, 2018 and June 29, 2018.

Observations and Lessons Learned

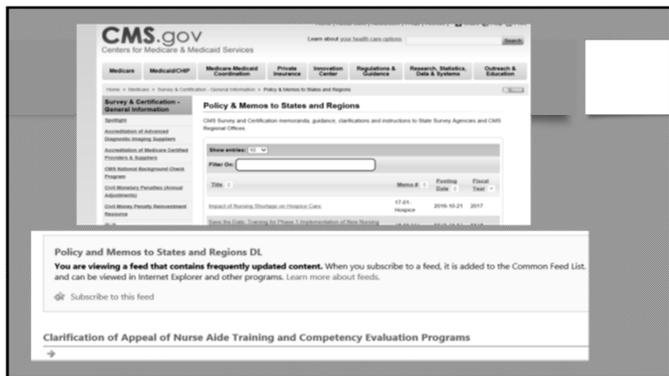
- Challenges evolve during different phases of disaster
- CMS works closely with State and other Federal agencies before, during, and after the disaster to ensure that safe, quality care is provided
- Communication, collaboration, and coordination among state and local emergency management, public health, and health care entities are essential to promoting effective emergency preparedness and response
- Remember, personal preparedness is your foundation to be best prepared!

How to Subscribe to S&C Policy Memos

For Associations and any public member to be alerted when CMS issues a Survey and Certification policy memorandum, please follow the following steps:

Website Option Only

1. Must have computer accessibility to RSS Feed (IT System).
2. Select <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html>.
3. Select RSS Icon (orange icon) on Right Side Corner
4. Select Subscribe to this feed at the top under the yellow box.



Other Resources

- State Operations Manual, Interpretive Guidelines: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107Appendicestoc.pdf>
- ESRD Center: <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis.html>
- Get CMS news at <https://www.cms.gov/Newsroom/Newsroom-Center.html>, sign up for CMS news [via email](#) and follow CMS on Twitter [@CMSgov](#)

EP Resources and Web Links

- Centers for Medicare & Medicaid (CMS) Survey and Certification Emergency Preparedness Website: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/index.html>
- Assistant Secretary for Preparedness and Response (ASPR) TRACIE Website: <https://asprtracie.hhs.gov/>
- State Operations Manual Appendix Z- Emergency Preparedness for All Provider and Certified Supplier Types Interpretive Guidance <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/Advanced-Copy-SOM-Appendix-Z-EP-IGs.pdf>

CMS Rule Health Sector Emergency Preparedness Course

The Center for Domestic Preparedness (CDP) at FEMA is offering a Health Sector Emergency Preparedness Course that will provide healthcare providers and suppliers with training in achieving the four core emergency preparedness elements outlined in the CMS Rule.

Course Goals: Understand specific emergency preparedness requirements as outlined in the CMS Rule and develop knowledge and skill in achieving these requirements.

- **Course Length:** 8 hours
- **Course Delivery Means:** Non-resident at a coordinated host location
- **Course Host Responsibilities:**
 - Provide a classroom or auditorium capable of seating the expected audience
 - Support recruitment of an appropriate audience from the 17 CMS identified providers and suppliers
 - Provide a point of contact to coordinate the class(es) with the FEMA Center for Domestic Preparedness Non-Resident Training Coordinator

Quality, Safety & Oversight Resources

- QSO Emergency Preparedness Website has an area with FAQs and resources available to the stakeholders.
- <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Emergency-Prep-Rule.html>
- ISTW EP Training Module: <https://surveyortraining.cms.hhs.gov/>.
NOTE: Surveyor Training is available to the public. Just select "I'm a Provider" upon logging into the system.

CMS Survey Process Response and Preparation

Conditions of Participations (CoPs)

Conditions of Participation (CoPs) are requirements which healthcare organizations must meet in order to begin and continue participating in the Medicare and Medicaid programs

- Focus on protecting the health and safety of patients and quality improvement

There are 23 CoPs:

Administrative Services

| | |
|-------------------------------------|--------------------------|
| 482.24 Health Assess Services | 482.13 Patient Rights |
| 482.15 Inpatient Care | 482.21 OSAs |
| 482.32 Medical Staff | |

Ancillary Services

| | |
|---|--------------------------------------|
| 482.09 Rehabilitation Services | 482.02 Nursing Medicine |
| 482.30 Utilization Review | 482.26 Radiology |
| 482.06 Dialysis Facilities | 482.27 Laboratory Services |
| 482.28 Food and Beverage Services | 482.25 Pharmaceutical Services |

Clinical Services

| | |
|----------------------------------|----------------------------------|
| 482.10 Emergency Services | 482.54 Outpatient Services |
| 482.12 Ambulatory Services | 482.37 Respite Services |
| 482.43 Outpatient Planning | 482.33 Respite Services |

Facility Services

| | |
|-------------------------------------|--|
| 482.17 Emergency Preparations | 482.18 Physical Environment |
| 482.42 Infection Control | 482.41 Physical Environment Facilities |

CoPs apply to many healthcare organizations:

- Ambulatory Surgical Centers (ASCs)
- Community Mental Health Centers (CMHCs)
- Comprehensive Outpatient Rehabilitation Facilities (CORFs)
- Critical Access Hospitals (CAHs)
- End Stage Renal Disease Facilities
- Federally Qualified Health Centers
- Home Health Agencies
- Hospitals
- Hospital Swing Beds
- Intermediate Care Facilities for Individuals with Intellectual Disabilities
- Organ Procurement Organizations (OPOs)
- Portable X-Ray Suppliers
- Programs for All Inclusive Care for the Elderly Organizations (PACE)
- Clinics, Rehab and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech Language Pathology Services
- Psychiatric Hospitals
- Religious Nonmedical Health Care Institutions
- Rural Health Clinics
- Long Term Care Facilities
- Transplant Centers

Sources: State Operations Manual, Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals
<https://www.cms.gov/Regulations-and-Guidance/EU-Implementation/CLIA/CLIA-Index.html#rdsrch-CFCAandCOP>

This is (Immediate) Jeopardy

A crisis situation in which the health and safety of patients and individuals are at risk



- CMS Form 2567: Statement of Deficiencies
- Immediate jeopardy, indicates "a situation in which the provider's noncompliance with one or more requirements of participation has caused or is likely to cause serious injury, harm, impairment or death."
- Immediate Jeopardy:
 - Protect from abuse
 - Prevent neglect
 - Protect from psychological harm
 - Protect from undue adverse medication consequences and/or failure to provide medications as ordered
 - Follow nationally accepted standards of practice for infection prevention
 - Correctly identify patients
 - Safely administer blood or blood products
 - Provide safety from fire, smoke and environmental hazards

Source: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Manual%20-%20L-1-10-14-0000.pdf>

Survey Response and Preparation Case Study

Case Overview



Problem

- Internationally recognized academic medical center (hereafter "Hospital")
- Majority of services are outpatient, also operates small inpatient hospital
- U.S. Centers for Medicare and Medicaid Services (CMS) and the State Department of Public Health (DPH) surveyed Hospital.
- CMS found that Hospital did not comply with six (6) Conditions of Participation (CoP)



Response

- Supported by Deloitte, Hospital replied to CMS/DPH with a Plan of Correction (POC) on November 30, 2016. The POC provided a detailed corrective action plan to fully comply with the noted CoP deficiencies.
- Hospital will be re-surveyed at an unknown date by CMS/DPH to monitor compliance with and progress towards the goals stated in the POC.
- Failure to meet Hospital CoPs results in loss of reimbursement for all Medicare and Medicaid patients with a state-sanctioned notice to the public in the local newspaper.



Implementation

- Provided project management office (PMO) support across the Hospital to come into compliance and prepare for re-survey.
- Worked closely with Hospital Leadership, Office of General Council, Compliance and Quality & Safety departments.
- Implemented POC measures and creating and disseminating training materials to modify procedures and needed behavioral changes.
- Supported 23 Hospital CoP teams to ensure that all possible areas covered by the re-survey are fully compliant.

Implementation
 Activities Pre- and Post-Plan of Correction (PoC) Submission

| Stage of Implementation | Activities |
|---|---|
| Pre PoC Submission | <ul style="list-style-type: none"> PoC Workgroup sections complete All sections ready for submission Attachments / supporting documentation complete Define and assess metrics QAPI Committee review |
| Post PoC Submission Activities (Implementation) | <ul style="list-style-type: none"> Approval from Board sub-committees, as applicable On-going implementation per PoC commitments <ul style="list-style-type: none"> Create dashboard to track quality metrics Ready access to supporting documentation Board sub-committee reporting and approval Execution of detailed work plan Communications to staff Monitoring per PoC (on-going) Survey readiness (on-going) <ul style="list-style-type: none"> Internal readiness assessment for preparedness for survey Develop project plan to address 23 CoPs |

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Response Org Chart and Team Structure
 Hospital team members focused on subject matter expertise

Survey Response and Preparation Org Chart



CoP Team Structure

CoP
 (42 CFR 482.XX):

Executive Sponsor(s):
 C-Suite

Work lead(s):
 Director/Manager

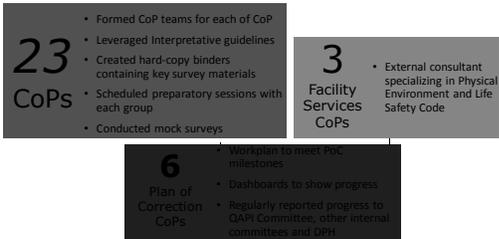
Counsel:
 OGC member

PMO:
 Deloitte team member

Workgroup Member(s):
 1-6 team members

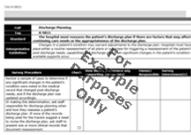
| | | | | | |
|----------------------------------|--------------------------------|---------------------------------|-----------------------------|-----------------------------|-----------------------------|
| 482.00 Behavioral Services | 482.03 Medical Services | 482.24 Medical Student Services | 482.13 Patient Rights | 482.55 Support Services | 482.26 Support Services |
| 482.20 Education Services | 482.26 Radiology | 482.12 Surgery | 482.21 X-ray | 482.02 Ambulance Services | 482.07 Laboratory Services |
| 482.40 Drug Formulation | 482.07 Laboratory Services | 482.22 Medical Staff | 482.02 Ambulance Services | 482.03 Pharmacy Services | 482.23 Nutrition Services |
| 482.28 Food and Dietary Services | 482.25 Pharmaceutical Services | 482.15 Emergency Procedures | 482.01 Physical Environment | 482.01 Physical Environment | 482.01 Physical Environment |

(Re)Survey Readiness
 Use readiness plan for responding to survey findings or regularly planned survey preparation



Tools
Leverage quality improvement, project management and mock survey tools and methods

Made Interpretive Guidelines into "Grids"



Dashboards helped track progress and report status of the PoC



Mock-survey sessions with all CoP teams during intensive weeks



Communication is Essential
Many stakeholders involved in a complex process



Key Takeaways

- Read, understand and share the guidelines and requirements
- Take advantage of available resources
- Preparation is your greatest strength
- Use survey experience to your advantage

Thank You



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