

# The Role of CMS in Assessing Infection Prevention and Control Compliance

Karen Hoffmann RN BSN MS CIC FSHEA FAPIC  
 Infection Prevention Consultant  
 Centers for Medicare and Medicaid  
*No disclosures*


## Disclaimer

*The views and opinions expressed in this lecture are those of this speaker and do not reflect the official policy or position of any agency of the U.S. government.*

## Objectives

- Describe the evolution of CMS infection control regulations in the last decade.
- List most common IPC citations.
- Review CMS **survey** strategies for Infection Prevention and Control programs.
- *Not discussing payment systems!*

Field Guide for a CMS Survey



CMS covers 100 million people...

...through Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace.

- 1 of every 3 Americans;
- 105 million beneficiaries;
- paying out \$1.5 billion in benefits



Preceding Agency

Health Care Financing Administration (1977-2001)  
 www.CMS.gov

Website

Headquarters

Woodlawn, Baltimore County Maryland



## CMS Survey and Certification Group (SCG) Structure

Federal CMS Headquarters -----AOs

10 Regional Offices

State Agencies

<https://www.cms.gov/About-CMS/Agency-Information/RegionalOffices/RegionalMap.html>

## Organization of SCG

- Division of Acute Care Services (DACS)
  - Acute Care Hospitals, LTACs, CAHs, ASCs, Rehab, Psychiatric
- Division of Nursing Homes (DNH)
  - Nursing Homes
- Division of Continuing Care Providers (DCCP)
  - Home Health and Hospice, ESRD, Psychiatric Residential Treatment Facilities
- Clinical Laboratory Improvement Amendments (CLIA)

## Where to Submit a Question or Inquiry?

- Division of Acute Care Services (DACS)
  - [PFP.SCG@cms.hhs.gov](mailto:PFP.SCG@cms.hhs.gov)
- Division of Nursing Homes (DNHs)
  - [DNH\\_TriageTeam@cms.hhs.gov](mailto:DNH_TriageTeam@cms.hhs.gov)
- ESRD Survey & Certification Group
  - [ESRDSurvey@cms.hhs.gov](mailto:ESRDSurvey@cms.hhs.gov)
  - Find resources for compliance with the ESRD Conditions for Coverage here: [www.cms.gov/GuidanceforLawsAndRegulations/05\\_Dialysis.asp](http://www.cms.gov/GuidanceforLawsAndRegulations/05_Dialysis.asp)
- SCG General Information
  - <http://www.cms.gov/SurveyCertificationGenInfo/>

## Surveyor in the House!



## The Vision



*High quality health care system that ensures better care, access to coverage, and improved health.*

## Operationalizing the Vision



## Impacting the Vision

- Enhanced surveyor training
- Partnerships with AOs, CDC, FDA and stakeholders
- Updated/revised health & safety standards
- New & improved survey tools for building compliance, consistency, and facility self assessment

## CMS Conditions of Participation (CoPs) & Conditions for Coverage (CfCs)

CMS develops CoPs - (hospitals, CAHs, ASCs)  
CfCs - (ESRD, LTC/NH, ASCs)

- Minimum health and safety **standards** that providers and suppliers must meet in order to be Medicare and Medicaid certified and receive reimbursement.
- The Interpretive Guidelines (IGs) provide instructions to the surveyors on how to survey the CoP. *Note: key are "should" versus "must" statements*

cms.gov

## FAQ Example: Surgical Hair Covering-Skull caps- to be or not to be?

- Medicare-certified hospitals must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases.



## Example of Response to FAQ: Surgical Hair Coverings

- CMS does not support the American College of Surgeons statement on wearing skull caps in the OR as it is not a nationally accepted evidence based standard of practice.
- AORN
- CDC
- WHO
- Association of Surgical Technologists (AST).

## Teamwork: Collaboration & Alignment

- **CDC** - Interagency agreements (IA), surveyor and provider training, policy)
- **FDA** - device reprocessing, sterilization, compounding, enzymatic cleaners
- **AAMI** - standards ESRD, issue papers, summits
- **APIC, SHEA, AORN, AMDA** (stakeholders) - input and feedback)
- **State Agencies** (SAs) and **Regional Offices** (ROs)
- **Accrediting Organizations** (AOs) –(e.g. TJC, DNV) have a Memorandum of Agreement

## CMS Deemed Status and national accreditation organizations (AOs)

- AOs (e.g. TJC,) are approved by CMS for enforcing standards that meet the CMS CoPs/CfCs.
- CMS grants AO "deeming" authority as meeting the CMS certification
- CMS conducts random validation surveys and complaint investigations of HCO with deemed status.
- AOs must provide CMS with a listing of documentation for HCO receiving conditional accreditation, preliminary, and non-accreditation.
- AOs provide CMS with accreditation decision reports for HCO involved in CMS validation surveys and any other survey report CMS requests.


## CMS SCG IPC Training

- **Surveyor training to keep current:**
    - **APIC Courses and Annual Conference**
    - **IPC Webinars Division specific (e.g. ASCs)**
    - **Universal IPC Course (eta. Spring 2017)**
  - **Provider Training**
    - **Medical Learning Network (MLN) courses**
      - **Injection safety, Hand hygiene, Environmental cleaning**
- <https://learner.mlnlms.com>

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### State Agency's Role in Patient/Resident Safety

- Ensuring better care, access to coverage, and improved health.
- Compliance with minimal health & safety standards safeguards the vision
- Surveyors = win for patient safety




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### Surveyor's Role in Patient Safety


As integral parts of determining compliance with the CoPs/CfCs, the surveyor will:

- Verify an active and effective surveillance program
- Evaluate if the program is meeting the needs of patients and staff throughout the complex
- Verify a sanitary environment
- Verify comprehensive educational outreach
- Validate the program has been evaluated or revised if needed



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### Frequent Hospital Citations Dirty Environments



- Unsanitary sterile processing areas
- Layers of dust, tape, mold
- Leaking washers & sinks
- Holes in walls, missing floor & ceiling tiles
- Rooms, bathrooms and common areas with debris, spider webs, blood stains
- Clean instruments & scopes touching the floor, placed in dirty bins

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### Frequent Hospital Citations Untrained staff




- Reusing syringes
- Disregard for manufacturer instructions
- Staff not formally trained for their role
  - Housekeeping and cleaning products
  - Sterile processing techs cleaning instruments/scopes
  - Patient care staff not abiding by basic IPC practices
  - Cluster investigation process

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### Frequent Hospital Citations Improper Reprocessing Instruments

- Immediate Use Steam Sterilization (IUSS) used for all cases...not as urgent need only!
- Not verifying efficacy of the HLD solution before use
- Not following manufacturer's Instruction for use (IFUs)
  - Pre-cleaning of scopes
  - Exact step by step process
  - Improper tray loading



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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
 Center for Clinical Standards and Quality Survey & Certification Group

**CMS**  
Center for Medicare and Medicaid Services

DATE: August 29, 2014 Ref: SAC 14-44 Hospital/CAHAC

TO: State Survey Agency Directors

FROM: Director, Survey and Certification Group

SUBJECT: Change in Terminology and Update of Survey and Certification (S&C) Memorandum 09-55 Regarding Immediate Use Steam Sterilization (IUSS) in Surgical Settings

**Memorandum Summary**

- **Change in Terminology:** "Flash" Sterilization vs. IUSS: Instantly recognized or associated with expertise in infection prevention and control and autoclave sterilization, pressure, and other professional organization recommendations for use of the term "flash" sterilization, which is now considered outdated, and replacing it with the term "IUSS."
- **Update of S&C Memorandum 09-55 Regarding Standards for Immediate Use Sterilization in Surgical Settings:** The current version and update information regarding nationally recognized infection prevention and control guidelines and professionally acceptable standards of practice with respect to immediate use sterilization and updates S&C Memorandum 09-55.

**Introduction**

To assist surveyors in assessing compliance of sterilization practices in surgical settings with Medicare benefit and safety standards for hospitals, Critical Access Hospitals (CAHs) and Ambulatory Surgical Centers (ASCs), we are providing an update to S&C Memorandum 09-55 regarding the use of "flash" sterilization. In this document,

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## IUSS Sterilization S&C memo

*(released 8/29/14)*

### Change in Terminology and Update of Survey and Certification (S&C) Memorandum 09-55 Regarding Immediate Use Steam Sterilization (IUSS) in Surgical Settings

Key memo points:  
 Based current recommendations from nationally recognized organizations (AORN, AAMI, CDC) with expertise in infection prevention and control and other professional organizations  
 Applies to all settings using IUSS: (e.g. hospitals, CAHs, ASCs)

- Abandons use of "flash" terminology and replaces it with IUSS.
- Clarifies that routine or exclusive use for one instrument type is out of compliance.
- Must follow manufacturer's device IFU for IUSS.
- Must follow sterilizer IFU for IUSS
- Must use an FDA cleared rigid container or a tray with IUSS process.

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## S&C Alert: ERCP Outbreaks Guidance to Surveyors

DEPARTMENT OF HEALTH & HUMAN SERVICES  
 Center for Clinical Standards and Quality/Infection Control and Prevention  
 Center for Clinical Standards and Quality/Infection Control and Prevention

DATE: April 8, 2017  
 TO: State Survey Agency Directors  
 FROM: Division of Infection Control and Prevention  
 SUBJECT: Alert Related to Outbreaks of Clostridium Botulinum Enterotoxin (CBE) during gastrointestinal endoscopy, particularly Endoscopic Retrograde Cholangiopancreatography (ERCP)

**Message Summary:**

- Review recent newspaper articles, medical publications, and adverse event reports associated with endoscopic biliary infections caused by CBE with patients who have undergone ERCP. Endoscopes used to perform ERCP are difficult to clean and disinfect, and when multiple endoscopes are re-used, are difficult to clean and disinfect, and when multiple endoscopes are re-used, are difficult to clean and disinfect. The U.S. Food and Drug Administration (FDA) has issued a Safety Communication warning, with related updates, that the design of endoscopes may impede effective cleaning.
- Expectations for Reprocessing Endoscopes: Hospitals, critical access hospitals (CAHs), and ambulatory surgical centers (ASCs) are expected to automatically follow the manufacturer's instructions for reprocessing endoscopes, as well as adhere to the nationally recognized biosecurity consensus guidelines developed by multiple expert organizations and issued in 2011.

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## Frequent Hospital Citations Hand Hygiene and Glove Use

- Failure to clean hands after removing gloves
- Moving from patient to patient without cleaning hands and changing gloves
- Using ABHR on gloves rather than changing the gloves
- Thinking double gloving protects against puncture injury.
- Not having gloves accessible in locations where they are needed/used.

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## Dialysis Hand Hygiene and Glove Use Citations

Standard Surveys - 1928 surveys/6414 Active Providers

#	V-Tag	Tag Description	# Citations	% Surveys Cited
1	V113	IC-Wear Gloves/Hand Hygiene	648	33.6%
2	V122	IC-Clean, disinfect surfaces & equipment/written protocols	581	30.1%
3	V543	POC-Manage volume status	323	16.8%
4	V403	PE-Equipment maintenance- manufacturer's DFU	307	15.9%
5	V147	IC-Staff education re catheters/catheter care	269	14.0%

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## CDC and SCG Collaborate

Collaborative efforts to refine and expand IPC efforts and surveyor tools (and analyze findings)

- Ambulatory Surgical Centers (ASCs) – piloted in 2008 - final in 2009
- Hospitals -piloted 2011- final in 2014
- ESRD – Agency for Healthcare Research and Quality (AHRQ) pilot 2011- 2012 final 2013
- New Division of Nursing Homes– Pilot 2016 – 2018
- New draft Home Health IPC CoPs
- S&C Memos, Department of Health and Human Services (DHHS) activities – Reportable Breaches

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## What's coming soon from CMS...

- Updated Hospital IPC CoPs (closed September 15, 2016) will revise interpretative guidelines (IGs), and ICW.
- Revised Nursing Home IPC CoPs, IGs and availability of ICW.
- New CMS Emergency Preparedness Rule.
- New Home Health IPC regulation and interpretive guidance.

### Notice of Proposed Rule Making (NPRM) for Hospitals

- June 13, 2016 - Proposed new regulations to improve the quality of care including IPC.
- Estimates new requirements could save hospitals up to \$284 million annually, plus improving care and potentially saving lives.
- Proposed rule includes: Reducing readmissions; Reducing the incidence of hospital-acquired conditions (including HAIs); and follow nationally recognized guidelines.

Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care (CMS-3295-P)

### NPRM Hospital and CAH Changes to Promote Innovation, Flexibility, and Improvement in Patient Care

- Hospital-wide IPC and antibiotic stewardship programs (ASP);
- Designate leaders of the IPCP and the ASP respectively, **who are qualified through education, training, experience, or certification.**
- Quality Assessment and Performance Improvement (QAPI) program **incorporate quality indicator data related to hospital readmissions and hospital-acquired conditions;**
- Competencies documented for IPC training
- Assess for IPC during Transitions of Care

### Notice of Proposed Rule Making (NPRM) for Nursing Homes

- LTC proposed rule was published in the Federal Register on July 16, 2015.
- <http://www.gpo.gov/fdsys/pkg/FR-2015-07-16/pdf/2015-17207.pdf>
- Have not been comprehensively updated since 1991 despite significant changes in the industry.
- 3 month comment period ended on September 15, 2015



### CMS Division of Nursing Homes(DNH) F880: Infection Prevention and Control ("Old F441")

Phased Implementation: 1-3 by year  
 Phase 1: November 28, 2016  
 Phase 2: November 28, 2017  
 Phase 3: November 28, 2019

New Interpretive guidance estimated to be released in May 2017.

### F880: Infection **Prevention** and Control

New §483.80 (a)(1-2)(4)(e-f)

- Implement in Phase 1 with the following exception:  
 As linked to the **facility assessment** conducted according to §483.70(e) - **Implement in Phase 2** (Nov. 28, 2017).

### F881: Antibiotic Stewardship Program (New)

- §483.80 (a)(3)
- Implement in Phase 2 (Nov. 28, 2017)
- Residents should be prescribed antibiotics appropriately (i.e., correct indication, antibiotic, dose, and duration)
- Training and education for nurses, attending practitioners, residents, and families on the ASP

### F881: High Level Overview of the ASP Interpretive Guidance

- Antibiotic use protocols must include the following:
  - How to identify the presence of an infection:
    - Guidelines recommend infection assessment tools, such as SBAR tool for UTI assessment and/or Loeb minimum criteria;
    - Where documentation of infection is recorded and tracked
  - Review laboratory report for resistance and need to change antibiotic; can the antibiotic be de-escalated to narrow spectrum?

### F881: High Level Overview of the ASP Interpretive Guidance

- Antibiotic use protocols must include the following:
  - Monthly drug regimen review to evaluate antibiotic use and document and report any irregularities/incidents to clinician and DON;
  - That attending practitioner must document in the medical record the rationale for medication irregularities.

### F881: High Level Overview of the ASP Interpretive Guidance

- Facility wide system to monitor antibiotic use including who will conduct the monitoring, how and where documented, including:
  - Reports on antibiotic usage and antibiotic resistance (i.e., antibiogram) based on laboratory data (i.e., created within the past 18 months) are provided to the Quality Assessment and Assurance Committee (QAA)
  - Reports on antibiotic prescribing practices and resistance data are provided to attending practitioners

### F882: Infection Preventionist Qualifications/Role (New)

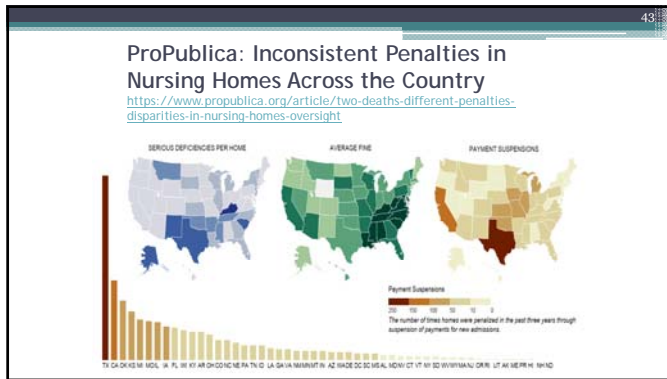
- §483.80 (b-c)
- Infection Preventionist (IP)—Implement in Phase 3 (Nov. 28, 2019)
- IP participation on quality assessment and assurance committee (QAA) committee—Implement in Phase 3 (Nov. 28, 2019)

### F883: Influenza and Pneumococcal Immunizations (“Old F334”)

- §483.80 (d)
  - Implement in Phase 1 – minor changes
  - August 2014, the Advisory Committee on Immunization Practices (ACIP) updated pneumococcal immunization recommendations.
- Both 23-valent pneumococcal polysaccharide vaccine (PPSV23) and 13-valent pneumococcal conjugate vaccine (PCV13) vaccines should be administered routinely in series to all adults aged ≥65 years.

### Survey Tools for Assessing Infection Control Compliance

- Hospitals: SA/RO/CO workgroup in process of updating worksheet.
- ASCs: FY16 worksheet collection from 450 randomly selected facilities – new electronic submission process
- ESRD: In use since 2013 on all surveys
- NHs: IC worksheet draft in pilot testing – hospitals & NH pilot.



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### Hospital and Nursing Home CMS IPC Pilot

CMS has begun a 3 year pilot project to improve assessment of IPC regulations in nursing homes, and hospitals including during transitions of care.

The screenshot shows a CMS document with the following details:
 

- DATE:** November 30, 2016
- BY:** Robert Mays, Agency Executive
- FOR:** Compliance
- PROGRAM:** Health and Compliance Group
- RELEVANT TO:** Medicare and Medicaid Programs

 The document title is 'Improving the Clinical Assessment and Quality/Process & Compliance Group'.

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### CMS IPC Pilot Project

- CMS Survey and Certification Group (SCG) and(CDC) Division of Healthcare Quality Promotion History
- Ebola funding
- New Regulations
- Combating Antibiotic Resistant Bacteria (CARB)

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### CMS IPC Pilot Goals

- Improve assessment of infection control and prevention regulations in nursing homes, hospitals, and during transitions of care.
- Develop and test new surveyor tools
- Promote transparency of regulations
- Prevent infections in nursing home residents

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### CMS IPC Pilot Surveys

- Unannounced surveys
- Educational surveys – no citations (except IJ)
- Facility selection
- 2016: (beta test)10 pilot nursing home surveys
- 2017: 40 hospital and 40 nursing home surveys
  - Review findings
  - Technical assistance
  - 2018: Revisit surveys

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### New CMS Processes

- Analyze hospital and nursing home survey results
- Develop action plans for improvement
- Provide technical assistance
- Perform revisit surveys
- Observe National Health Safety Network (NHSN) data as metric for outcome



## Katrina 2005 to Ebola Threat 2014



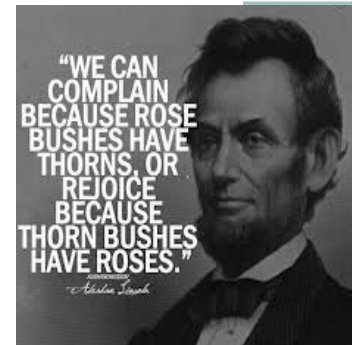
## New CMS Emergency Preparedness Rule

- 1) Emergency plan based on a risk assessment of the emergency preparedness program...utilizes an all-hazards approach,
- 2) Policies and procedures based on the plan and the risk assessment,
- 3) Communication plan to maintain continuity of patient care and coordination with state and local Public Health Departments (PHD); and Emergency management (EM) systems;
- 4) Personnel training and annual testing of the emergency preparedness program.

<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-06-08.html>

## Summary of CMS Survey Process

- Moving away from significant surveyor time spent on document review
- Assessing basic IPC in all areas of ASC, hospital, nursing homes, home health, and dialysis facilities
- Observing patients and procedures where there is high risk of infection transmission
- Focusing on prevention efforts for HAIs in HHS HAI Action Plan and Patient Safety Initiatives.



## Thank You!..Questions



**Contact Information**  
KHoffman@med.unc.edu