CMS Update

AHFSA Annual Conference

Orlando, Florida

August 23, 2017
Survey and Certification

David Wright, Director
Jan Tarantino, Deputy Director
Disclaimer

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Second Disclaimer

• Much of what I say next is Aspirational, with the intent of providing a context for our work or setting a goalpost for the future.
• I’ve learned, many times in the past year, that nothing happens by verbal fiat, even when I wish it could.
• Therefore, as with everything else, any aspirational or hopefully inspirational things I say have no force or effect unless and until codified in Statute, Regulation, or Guidance.
What are we about?

- Effective interventions that provide the appropriate amount of leverage to achieve our mission.
We’re effective when...

We move beyond anecdotes and focus on what is actually occurring. And then measure how we impacted that trajectory.
It’s easy to get distracted by the wrong things

* NOT Hugh Hefner
Where do we currently spend most of our time?

Living on the Edges
What am I happy about?

- Removing Right-Side POC Requirement
- Root Cause Analysis instead of POC Pilot
- Public Notice Revisions
- Voluntary during Involuntary Termination
- FOSS Workgroup
- State Performance System
What am I looking forward to?

New Survey, Certification and Enforcement System and the development process

Training flexibilities

Burden Reduction to allow for more targeted focus
CMS Regional Offices
Root Cause Analysis (RCA) Pilot

- 5 SAs participating: Arizona, Ohio, Oklahoma, Georgia, Massachusetts
- Pilot will test process for ESRD surveys
- Start date 9/1/17 for six months
- RCAs will be required for all Condition level deficiencies
- Providers will attest to completing the five components to the RCA process
- Providers will attest that they will complete the five components of the RCA process that we have identified and supply the date of correction for each tag
RCA Pilot

• Five Components:
  – Step 1: Review CMS 2567 and select a team
  – Step 2: Identify Contributing Factors
  – Step 3: Identify the root causes
  – Step 4: Design and Implement changes to eliminate the root cause
  – Step 5: Create a Sustainability Plan
Revised FOSS Pilot

• Two Stage process
  – Phase One: Training and support phase (Resource and Support Surveys)
    • Joint training opportunities
    • Targeted surveyor needs
  – Phase Two: Evaluative phase
    • Second half of the FY
    • Limited comparative surveys

• Has been piloted in three regions
SHIELD & PROTECT Projects

- Contagious pathogens are known to spread from healthcare facility to healthcare facility
- Containing spread is important for infection prevention and patient safety
- Regional interventions are a natural strategy for preventing the spread of contagious pathogens
SHIELD & PROTECT Projects
Orange County, California

– Shared Healthcare Intervention to Eliminate Life-Threatening Dissemination (SHIELD):

• Public health collaborative led by CDC, California Department of Public Health ((CDPH), Orange County Health Care Agency (OHCA) for hospitals, long-term acute care hospitals and nursing homes in Orange County;

• This regional collaborative will implement a decolonization strategy to reduce transmission of multidrug resistant organisms (MDROs) countywide and within healthcare facilities.

– Protecting Nursing Homes from Viral and Bacterial Pathogens (PROTECT):

• Project trial is a clustered-randomized study, funded by the Agency for Healthcare Research and Quality (AHRQ), that evaluates the feasibility (e.g., cost impact) of decolonization and antibiotic use among residents in nursing homes participating in this project;

• It uses the same decolonization process as the SHIELD project and monitors the prevalence of MDROs, infection-related hospitalizations and antibiotic use among residents in participating nursing homes.
Projects identified a need for CMS to clarify expectations for resident expectation and right to be informed for participation in infection prevention initiatives.

**Pertinent regulation: 42 §CFR 483.10**

“The right to be informed in advance, by the physician or other practitioner or professional, of the risks and benefits of proposed care, of treatment and treatment alternatives or treatment options and to choose the alternative or option he or she prefers. The right to request, refuse, and/or discontinue treatment, to participate in or refuse to participate in experimental research, and to formulate an advance directive.”
SHIELD & PROTECT

• Projects facilities are using infection prevention and control clinical practices that apply to all patients or residents. Therefore, there is no need to document resident notification and agreement to participate for these practices.

• CMS expects residents would be provided information about these decolonization practices. Examples include: admission packet, resident council, and other opportunities to share information about decolonization practices.

• Random subset of patients or residents are selected to undergo a screening effort to detect changes to MDRO prevalence. Specific documentation in the medical record that a resident/patient has been informed of the risks/benefits of the screening and has chosen to participate is needed.
SHIELD & PROTECT

• CMS views MDRO prevalence as an important issue.

• CMS will continue to work with CDC on guidance that addresses and support more broadly our ability to advance important infection control issues while ensuring that these efforts are consistent with and uphold the minimal health and safety requirements for participation in the Medicare and Medicaid Programs.
AHFSA HAI Workgroup Project and Infection Control Update

C. Diff In Nursing Homes
Infection Control Breaches
Legionella
SITUATION

CDI prevention as the choice for a collaborative project with AHFSA/CMS/CDC:

• Focus on Nursing Homes (NH) since all surveys in nursing homes are done by state surveyors

• CDC identified CDI as an infection with increasing prevalence and the target of NH NHSN reporting.

• CDI prevention includes: hand hygiene, contact precautions, antibiotic stewardship, and environmental cleaning and disinfection, transitions of care. These are all elements of infection control for which NH will be assessed for compliance.
Infection Control

AHFSA

CDC

CMS

Clostridium difficile infection

Contact Precautions
Hand hygiene
Cleaning and disinfection
Antibiotic stewardship
Transitions in care

1. Identify key stakeholders
   - State healthcare associations
   - Professional organizations
   - APIC
   - CMS regional collaborations
   - Ombudsman

2. Improve understanding of regulations
   - CMS tools
   - Infection control worksheet
   - Clinical pathways

3. Baseline data available
   - Nursing home citations from regional office
   - QIO data
   - Other data

4. Available assessment tools
   - NHSN (QIO)
   - ICAR (CDC)
   - Transition and care worksheet

5. Build trust with facilities
   - Open and honest communication
   - Form health advisory committee
   - Provider assistance
   - Best practice training

6. Communication channels and tools
   - State health department websites
   - Social networking sites
   - Provider associations
   - Skype and webinars
Update

Project Plan: By November 1, 2017

• Identification of additional partners on the national, state and local level to work on C Diff prevention and control in LTC facilities.
• Identification of existing tools through working with CDC, HAI/ICAR state health department representatives, QIN/QIO, and professional organizations.
• Compile a list of tools and resources that are currently available. Specific areas include:
  • Hand hygiene
  • Contact precautions
  • Antibiotic Stewardship
  • Environmental Cleaning
  • Transitions of Care
• Collect baseline data – this may come through the annual recertification findings – F441. Also, could look at self reported facility information available through the NHSN. Another suggestion would be to ask facilities to self report total annual number of cases of C Diff in their facility to the state HAI coordinator so that aggregate data could be compiled for each state.
• Provide listing of tools and resources to AHFSA Regional Representatives to share with states survey agencies within their region.
Update

• Work on finding available data to measure change
• Meetings with QIG on collaborating with QIN QIOs
• Further discussions at AHFSA Annual Conference
SUBJECT: Infection Control Breaches Which Warrant Referral to Public Health Authorities

***Additional Information has been added to Breaches to Be Referred. This policy memorandum supersedes policy memorandum S&C: 14-36-ALL***

Memorandum Summary

- **Infection Control Breaches Warranting Referral to Public Health Authorities:** If State Survey Agencies (SAs) or Accrediting Organizations (AOs) identify any of the breaches of generally accepted infection control standards listed in this memorandum, they must refer them as directed to appropriate State authorities for public health assessment and management.

- **Identification of Public Health Contact:** SAs should consult with their State’s Healthcare Associated Infections (HAI) Prevention Coordinator or State Epidemiologist on the preferred referral process. Since AOs operate in multiple States, the Centers for Medicare & Medicaid Services (CMS) strongly encourages them to notify the appropriate State public health officials to make the referral of information about serious infection control breaches on the part of healthcare providers they survey in that state. Contact information for each state’s health departments is identified on the Centers For Disease Control & Prevention’s (CDC’s) website at: https://www.cdc.gov/HAI/state-based/index.html
Breaches to Be Referred

When one or more infection control breaches, that could potentially expose patients to the blood or bodily fluids of another, are identified during any survey of a Medicare or Medicaid-certified provider/supplier, the SA or AO must make the appropriate State public health authority aware of the deficient practice. Examples of such infection control breaches that must be reported are unsafe injection practices and use of sharps, including:

- Using the same needle for more than one individual;

- Using the same syringe, pen or injection device (e.g. pre-filled, manufactured, insulin or any other medication or biological) for more than one individual;

- Re-using a needle or syringe which has already been used to administer medication or a biological to an individual, to subsequently enter a medication container (e.g., vial, bag), and then using contents from that medication container for another individual;

- Using the same lancing/fingerstick device for more than one individual, even if the lancet is changed.

The SA or AO should also refer other infection control breaches in addition to those described above if recommended by their State public health authorities or if they believe the breaches require public health assessment and management. Examples of such infection control breaches include, but are not limited to, the following:

- Improper cleaning and disinfection of endoscopy equipment; and,

- Improper cleaning and sterilization of surgical instruments.

The CDC works closely with States on HAI prevention activities, and many States have designated HAI Prevention Coordinators.
IC Breaches During CMS Surveys

• Are you aware of S&C 14-36 Revision?
• Are your surveyors reporting breaches to their State HAI Coordinator or SHD?
• Are they sharing critical survey findings?
• Is there a feedback loop?
• Has reporting led to outbreak prevention?
Reason for ITL:
- Infection control breaches identified in the Immediate Use Steam Sterilization (IUSS) process include the following:
  1. Premature release of implants through IUSS:
     a. One year look-back of records reviewed identified 18 patients who had IUSS of implants.
     b. There were 15 instances of premature release, prior to the biological indicator (BI) being read/finalized.
     c. Nine of 15 premature release occurrences had a documented physician premature release form, leaving 6 without a physician release form. IUSS as indicated for emergent circumstances was not followed per organization policy.
  1. Lack of adherence to sterilization evidence based guidelines specific to Immediate Use Steam Sterilization (IUSS).
  2. Lack of adherence to biological indicator (BI) manufacturer instructions for use.
  3. Lack of leadership oversight and accountability regarding evidenced-based IUSS indications and practices.

Immediately implemented mitigation strategy:
The organization states their intention is-
1. Memo/letter to the Dept. of Surgery from leadership regarding premature release of implants through IUSS, specifying evidence-based indications for IUSS to include immediate discontinuation of premature release of implants.
2. Face-to-face meeting with surgeons/medical staff regarding the gravity of the premature release of implants through IUSS.
3. Revised IUSS policy and procedure.
4. Departmental huddles to include IUSS discussion.
5. Focused surveillance of IUSS to include a detailed breakdown of frequency and indications of IUSS.
6. Central sterile processing has discontinued all IUSS of implants.
7. Increased instrument levels to minimize necessity of IUSS.
Reason for ITL:

- Using the same glucometer/lancet/fingerstick device for more than one individual/patient. Failure to follow manufacturer instructions for use.
  1. Two frontline nursing staff independently purchased their own glucometer/glucometer kits. One LPN was observed re-using the device on a second patient. Second LPN used the device on a patient and immediately placed the device in his bag with no device cleaning/disinfection observed.
  2. Lack of documented education, competency, training of staff that perform glucometer/lancing/fingerstick device testing.
  3. Lack of knowledgeable accountable supervisory oversight regarding the re-use of a glucometer/lancing/fingerstick device intended for single use that poses a risk of transmission of multiple infectious agents to patients.
  4. Leadership was unaware that the two frontline staff had purchased and were using their own glucometer/lancet/fingerstick devices.

Mitigation Strategies:

- Education of staff regarding use of patients glucometers & single use devices
- Revise policy to include cleaning of glucometers
  
*Increase Supervisory visits starting next week*
DATE: June 02, 2017

TO: State Survey Agency Directors

FROM: Director,
Survey and Certification Group

SUBJECT: Requirement to Reduce Legionella Risk in Healthcare Facility Water Systems to Prevent Cases and Outbreaks of Legionnaires’ Disease (LD)

***Revised to Clarify Provider Types Affected***

Memorandum Summary

- **Legionella Infections:** The bacterium *Legionella* can cause a serious type of pneumonia called LD in persons at risk. Those at risk include persons who are at least 50 years old, smokers, or those with underlying medical conditions such as chronic lung disease or immunosuppression. Outbreaks have been linked to poorly maintained water systems in buildings with large or complex water systems including hospitals and long-term care facilities. Transmission can occur via aerosols from devices such as showerheads, cooling towers, hot tubs, and decorative fountains.

- **Facility Requirements to Prevent Legionella Infections:** Facilities must develop and adhere to policies and procedures that inhibit microbial growth in building water systems that reduce the risk of growth and spread of *legionella* and other opportunistic pathogens in water.

  This policy memorandum applies to Hospitals, Critical Access Hospitals (CAHs) and Long-Term Care (LTC). However, this policy memorandum is also intended to provide general awareness for all healthcare organizations.

Background

LD, a severe sometimes fatal pneumonia, can occur in persons who inhale aerosolized droplets of water contaminated with the bacterium *Legionella*. In a recent review of LD outbreaks in the United States occurring in 2000–2014, 19% of outbreaks were associated with long-term care facilities and 15% with hospitals. The rate of reported cases of legionellosis, which comprises both LD and Pontiac fever (a milder, self-limited, influenza-like illness) has increased 266% in the US during 2000–2014, with approximately 5,000 cases reported to the Centers for Disease Control and Prevention (CDC) in 2014. Approximately 9% of reported legionellosis cases are fatal.
infections and communicable diseases of patients and personnel.”

**Expectations for Healthcare Facilities and Surveyors**

CMS expects Medicare certified healthcare facilities to have water management policies and procedures to reduce the risk of growth and spread of *Legionella* and other opportunistic pathogens in building water systems. An industry standard calling for the development and implementation of water management programs in large or complex building water systems to reduce the risk of legionellosis was published in 2015 by American Society of Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE). In 2016, the CDC and its partners developed a toolkit to facilitate implementation of this ASHRAE Standard (https://www.cdc.gov/legionella/maintenance/wmp-toolkit.html). Environmental, clinical, and epidemiologic considerations for healthcare facilities are described in this toolkit.

Surveyors will review policies, procedures, and reports documenting water management implementation results to verify that facilities:

- Conduct a facility risk assessment to identify where *Legionella* and other opportunistic waterborne pathogens (e.g. *Pseudomonas*, *Acinetobacter*, *Burkholderia*, *Stenotrophomonas*, nontuberculous mycobacteria, and fungi) could grow and spread in the facility water system.

- Implement a water management program that considers the ASHRAE industry standard and the CDC toolkit, and includes control measures such as physical controls, temperature management, disinfectant level control, visual inspections, and environmental testing for pathogens.

- Specify testing protocols and acceptable ranges for control measures, and document the results of testing and corrective actions taken when control limits are not maintained.

Healthcare facilities are expected to comply with CMS requirements to protect the health and safety of its patients. Those facilities unable to demonstrate measures to minimize the risk of LD are at risk of citation for non-compliance with the CMS Conditions of Participation. Accrediting organizations will be surveilling healthcare facilities deemed to participate in Medicare for compliance with the requirements listed in this memorandum, as well, and will cite non-compliance accordingly.
Grants Closeout Process

Jeffrey Pleines
Closeout Requirements

For all Survey and Certification Grants (Medicare, Medicaid, CLIA):

• Final financial reports due 90 calendar days from the completion date of the award, consistent with the terms and conditions of award
  - Limited extensions with a fixed due date with case-by-case approval from CO, consistent with terms of award, with written requests due within 90 days of completion date.

• Full closeout no later than 270 days after completion of award
  - Must be closed in DHHS' Payment Management System and reconciled with CMS' accounting system.
  - Amounts authorized for expenditure, expended by State and drawn by State must reconcile in PMS and must reconcile with amounts shown as expended on the CMS 102/435 reports.

• If the requirements for closeout cannot be completed within the 270 day timeframe, CO may elect to complete unilateral closeout
  - CO will notify States in writing the basis for performing a unilateral closeout, and the amount at which the award will be closed.

• Enforcement commensurate with program needs and State actions
Why the Change?

Variety of reasons:

• Most importantly--proper business practice
• DHHS grants regulations (45 CFR 75.381) and Grants Policy and Administration Manual
• DHHS Undelivered Orders Policy
• Grants Oversight and New Efficiency Act (GONE Act, PL 114-117)
• GAO Audit Report 16-362
Where are we Now?

We are at the beginning of our process:

• Internally, we are currently working within CMS and the Department to ensure we’re following appropriate closeout practices and then documenting those practices.

• We are about to begin identifying root causes and tracking our progress in closing out expired agreements using LEAN tools and methods.

• We expect to notify States of the new and/or changing requirements via the upcoming Mission and Priorities Document and other vehicles, as necessary. Your current CO points of contact will not change.

• We expect to take further improvement actions with respect to the closeout process and SOM documentation as part of ongoing LEAN activities.
Division of Nursing Homes

Karen Tritz, Director
Evan Shulman, Deputy Director
Long Term Care Survey Process (LTCSP)

- Begins November 28, 2017 (includes Phase 1 and 2 requirements)

- Lessons learned from the Traditional and Quality Indicator Survey (QIS) processes
  - Best practices and opportunities for improvement
  - Identified slightly different quality of care/quality of life issues
  - Flexibility vs. prescriptiveness
  - Computer-aided vs. paper-based
  - Conference room vs. “out and about”

- Integrate finalized Requirements for Participation
Number of Surveyors & Time Onsite

<table>
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<th>Census</th>
<th>Sample Size</th>
<th>% of Census</th>
<th># of Surveyors</th>
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<tr>
<td>≤ 48</td>
<td>≤ 12</td>
<td>≥ 25%</td>
<td>2</td>
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<tr>
<td>49 - 95</td>
<td>13 - 19</td>
<td>20% – 27%</td>
<td>3</td>
</tr>
<tr>
<td>96 - 174</td>
<td>20 - 34</td>
<td>20%</td>
<td>4</td>
</tr>
<tr>
<td>≥ 175</td>
<td>35</td>
<td>≤ 20%</td>
<td>5</td>
</tr>
</tbody>
</table>

- Survey time onsite is expected to be similar to current time spent onsite
- Expect some lengthening while surveyors learn the new process
- Number of surveyors and time onsite also impacted by other factors such as State licensure, facility history, or complaints
- Continuous monitoring and dialogue
Interpretive Guidelines (IG)

• Revised format with consistent sections (e.g., Key elements of Non-compliance)
• Most of the IG has not been changed
• Revisions for phase 1 & 2 tags, and some existing tags where improvements were needed
• Revised CE pathways based on lessons learned (e.g., MDS focused surveys)
New Survey Process Readiness

Pre-November 28:
• Project plan, checklist, and equipment (Admin-info 17-21-NH)
• Manager support and training completion (including monitoring for completion)
• Practice, practice, practice!
• “How will I know I’m prepared?”

Post-November 28:
• Monitor findings, trends, and outliers
• How will I know care-related issues are not being missed? What are my trends and outliers? Why do they exist? “What is within my control, and outside?”
• Communicate with colleagues, AHFSA, and CMS.

Focus on intent!
Enforcement

- Revised Civil Money Penalty (CMP) Analytic Tool
- Evaluating other policies:
  - Immediate Imposition of Remedies
  - Multiple tags for same noncompliance (AKA “stacking”)
- Clarifying requirements for Nurse Aide Training Competency and Evaluation Programs
- Exploring improving care through other remedies (e.g., DPOC)
- Phase II Enforcement:
  - Focus on education for phase II requirements (e.g., facility assessment, antibiotic stewardship, etc.) such as Directed Plan of Correction or directed in-service training
  - Enforcement of Phase I requirements remains unchanged
- Long term: Revise SOM Chapter 7
Five Star Quality Rating System Update

Phase II Implementation (S&C 17-36-NH):
• Surveys conducted using the new survey process not included in five star quality rating system
• “Apples to Apples” comparison
• Transparency and user-friendliness to consumers

Other Five Star changes:
• Use of payroll-based journal (PBJ) staffing data
  • Staffing levels - 2018
  • Employee-level (tenure, turnover)
  • State access to data Q4 2017
• Continue to evaluate quality measures and explore new claims-based measures
National Partnership to Improve Dementia Care

• 2017 Q1 Long-Stay antipsychotic rate: 15.7%

• Reduction of 34.1% since program inception (2011 Q4)!

• Continued focus on improving dementia care:
  • New requirements (behavioral health services)
  • New goals
  • Focused surveys
  • Minimum Data Set assessment items (gradual dose reduction, position change alarms)
State Performance Standards System (SPSS)

Long Term Care Measures
FY 2017
• Q9 Waived

FY 2018
• SPSS requirements remain in effect
• Balance expectations:
  • Flexible due to new process and requirements
  • Ensure noncompliance is identified and resident safety
• Analyze performance for FY 2018 SPSS decisions (expectations and consequences)
• FOSS pilot underway
Civil Money Penalty (CMP) Reinvestment

  • Sample application, FAQs, State contacts, examples of projects
• OIG starting to look at required use of State CMP funds
• CMS Central Office reinvestment contractor
Division of Continuing Care Providers

Peggye Wilkerson, Director
Davis Escobedo, Deputy Director
Home Health

- New Conditions of Participation
- Interpretive Guidance
- Training on New Conditions of Participation
- Survey Protocol
- ASPEN TAGs
- Subunits
- OASIS
Hospice

• Impact Act
  – Status
    • % States in Compliance
    • % Facility Survey Intervals in Compliance
    • Federal Contractor
  – Implementation Date – April 18, 2018
  – States Projected to be Out of Compliance
  – Requests for Compliance Plans
  – Need to Maintain
  – Funding
ESRD

- Revised SOM Chapter Two
- Dialysis Services in Nursing Homes
- CMS-3427
- Addition of Services/Modalities Requiring On-site Survey
- Updating the Tier List
- FAQs
Transplant Centers
Transition Date January 1, 2019

• Interpretive Guidance
• SOM
• Survey Protocol
• Transition Plan-September 15
  – Prep Package
  – HMS Overlap
• 2018 Training Plan Release in November (12 webinars)
• Use of Both Transplant and Hospital TAGs on Survey
• Funding
Focused Survey Processes

• ICF/IID (On Track for Implementation by the end of 2017)
  – Draft process is almost complete:
  – Associated work aids being developed:
  – Projected for entering clearance by early fall.

• Home Health (Delayed due to new regulations)
  – New target date January, 2018:

• Hospice
  – In progress
  – Plan for a pilot in early spring 2018:
Division of Laboratory Services

Karen Dyer, Director
Regina Van Brakle, Deputy Director
# Current Statistics - Enrollment

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
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<tr>
<td>Total Number of Laboratories</td>
<td>257,263</td>
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<tr>
<td>Total Non-Exempt</td>
<td>248,405</td>
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<td>Compliance</td>
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<td>WA</td>
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CMS data base 6/2017
IQCP Survey Findings*
(*Surveys from 1/1/16 – 12/31/16)

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<tr>
<th>Laboratories surveyed</th>
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<tr>
<td>Labs implementing IQCP</td>
<td>761</td>
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<tr>
<td>Labs with IQCP Citations</td>
<td>154</td>
</tr>
<tr>
<td>Percent of labs implementing IQCP with IQCP citations</td>
<td>20%</td>
</tr>
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CLIA Outreach - Goals

The Division of Laboratory Services (DLS) CLIA Outreach Program – Academic (COPA) had its formal GO-Live in February of 2017

Goals for Outreach:

• Increase knowledge of and visibility of CMS/CLIA
• Demonstrate the link between quality healthcare and the regulated clinical laboratory industry
COPA Outreach

• Spring and Fall semesters 2017
  – To date, contacted 17 local/regional universities and community colleges within 120 miles of CMS

• Audience: Allied health students, 2-4 year Clinical laboratory programs (ex. MT, MLT, CLS)

• Eight schools had CLIA 101 presentation
  – 78 Students and 17 Faculty members total
Outreach - Feedback

• Received high evaluations from participants (average 4.8 points out of 5)
• In all situations, schools have asked us to come back!
• New challenge is to vary the presentation method from live to on-line audio-visual to reach off-campus students
COPA Expansion Ideas

• Develop presentations for local high school science programs: junior and senior students.

• Collaboration with Healthcare Students of America (HOSA) to focus on high schools within HOSA state chapters across the country.

• Offer program(s) to CMS CLIA Regional Staff or State Agencies to present to their area’s academic institutions.

• Given the growth of Point of Care testing across all healthcare venues expand the list of schools with nursing and medical resident programs.
CLIA Virtual Basic Training

• All Surveyors (RO and SA) are required to take the virtual training courses

• New surveyors (those with less than 2 years experience) have 3 months to complete the training

• Remaining surveyors have up to one year to complete the training
CLIA Virtual Basic Training Update

• Went live - May 2017
• Basic made up of 14 Lessons (24 modules)
• All modules available 24/7
• Pre / Post Test for each module
• As of July:
  – Number of surveyors enrolled: 101
  – Training Completed: 22 (21.8%)
Interagency Coordination

• CMS, along with CDC and the FDA, formed tri-agency response teams to keep each agency informed of potential issues involving CLIA laboratories

• Develop process where by each agency informs the other of potential issues so that response can be proactive rather than reactive.

• Allows CLIA to determine the immediate need for sending surveyors into the laboratory.
Interagency Coordination

• CMS, CDC and the FDA, have formed an additional tri-agency workgroup that will review Emergency Use Authorizations (EUAs) for testing for emergent diseases/infections.

• Goal is the standardization of information, policies and procedures for EUAs to assist laboratories and surveyors.
Emergency Use Authorization (EUA) Authority (FD&C Act § 564)

- A legal mechanism that allows the FDA to strengthen the nation’s public health protections against Chemical, Biological, Radiologic, and Nuclear (CBRN) threats.

- Facilitates the availability of Medical Counter Measures (MCM). The term MCM means the medical products that might be needed during public health emergencies to diagnose, prevent, or treat diseases or other conditions resulting from CBRN emergencies.

- HHS Secretary has to make a declaration of emergency or threat justifying emergency use.
Division of Acute Care Services

Marie Vasbinder, Director
Patricia Chmielewski, Deputy Director
DACS Mission

• To ensure compliance with Medicare quality and safety requirements for the care provided to patients by Providers and Suppliers through the oversight of Accrediting Organizations.
DACS OVERVIEW

10 Accrediting Organizations (AOs)
22 Programs

- 2 Non-certified programs:
  - ADI – 4 AOs
  - DSMT – 2 AOs
Goals

• Strengthen Oversight of AOs

• Collaboration between AO/SA/RO to ensure quality and safety for patients

• Consistency with survey process to ensure compliance to CoPs
Major Initiatives

- Liaison Project
- Validation “SWAT TEAM”
- SHIP Project
- PSYCH Task Force
- Fully updated SOM and Guidance
Pending Regulations

• Advanced Diagnostic Imaging (ADI)
• Home Infusion Therapy (HIT)
Pending SOM Guidance

• RHC
• CAH
• Chapter 2
• Primarily Engaged
• Co-Location
• Appendix A
• Appendix AA
Surveyor Training

- RHC - New
- CAH - New
- ASC - Revised
- Emergency Preparedness - New
- LSC - New
**Hot Topics**

- Ligature Risks – Psych units/hospitals
- Disparity Rates – Validation Surveys
- Primarily Engaged – Micro Hospitals
- Co-Location
- Emergency Preparedness
# Validation Survey Results

<table>
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<tr>
<th></th>
<th>FY 2012</th>
<th>FY 2013</th>
<th>FY 2014</th>
<th>FY 2015</th>
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<tbody>
<tr>
<td><strong>HOSPITAL</strong></td>
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<tr>
<td>60-Day Validation Sample Surveys</td>
<td>102</td>
<td>96</td>
<td>103</td>
<td>102</td>
</tr>
<tr>
<td>Disparity Rate</td>
<td>44%</td>
<td>46%</td>
<td>38%</td>
<td>39%</td>
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<tr>
<td><strong>PSYCHIATRIC HOSPITAL</strong></td>
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<td>60-Day Validation Sample Surveys*</td>
<td>8</td>
<td>10</td>
<td>12</td>
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<tr>
<td>Disparity Rate</td>
<td>75%</td>
<td>60%</td>
<td>75%</td>
<td>69%</td>
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<tr>
<td><strong>CRITICAL ACCESS HOSPITAL</strong></td>
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<tr>
<td>60-Day Validation Sample Surveys</td>
<td>33</td>
<td>35</td>
<td>27</td>
<td>33</td>
</tr>
<tr>
<td>Disparity Rate</td>
<td>36%</td>
<td>40%</td>
<td>52%</td>
<td>45%</td>
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<tr>
<td><strong>HOME HEALTH AGENCY</strong></td>
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<tr>
<td>60-Day Validation Sample Surveys</td>
<td>102</td>
<td>80</td>
<td>75</td>
<td>104</td>
</tr>
<tr>
<td>Disparity Rate</td>
<td>19%</td>
<td>14%</td>
<td>15%</td>
<td>16%</td>
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<td><strong>HOSPICE</strong></td>
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<tr>
<td>60-Day Validation Sample Surveys</td>
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<td>18</td>
<td>16</td>
<td>34</td>
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<tr>
<td>Disparity Rate</td>
<td>10%</td>
<td>6%</td>
<td>6%</td>
<td>9%</td>
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<td><strong>AMBULATORY SURGERY CENTER</strong></td>
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<td>60-Day Validation Sample Surveys</td>
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<td>61</td>
<td>54</td>
<td>69</td>
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<tr>
<td>Disparity Rate</td>
<td>32%</td>
<td>39%</td>
<td>31%</td>
<td>42%</td>
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</tbody>
</table>
Update on SETI Working Sessions

• Co-Location & Provider Based Criteria
• Micro Hospitals - Primarily Engaged
• Immediate Jeopardy
• Focused surveys
Questions and Comments
Training Division

Anita Segar, Director
Immediate Current & Future Environment

- Increased Needs/Demand
- Increased Growth
- Continuous Improvement
- Implementation of Strategic Initiatives
NEW NEEDS - New Regulations Training

• Develop new training or update existing training based on new regulations and scheduled publication dates.

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course Title</th>
<th>Details</th>
</tr>
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<tbody>
<tr>
<td>CMS-3277-F</td>
<td>Basic Life Safety Code Course</td>
<td>Available online by March 2018</td>
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<tr>
<td>CMS-3260-N</td>
<td>Reform of Requirements for Long-Term Care Facilities</td>
<td>New regulation implementation is being rolled out in phases.</td>
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</tbody>
</table>
Continuous Improvement - ISTW

Single portal – Integrated Surveyor Training Website (ISTW)
Name change to Quality and Safety Education Portal (QSEP)

State-of-the-art training and management platform
- Centralized, Cloud-based
- Flexible & Adaptable – Advanced functionality, Reports
- Application – Training Needs, Schedule, Information Center
- Training accessible 24/7, 365 days/year to surveyors AND providers/public
Accreditation Timeline (CEU)

- Total number of courses offered by the Training Division: 146
- Total number of current courses with CEUs: 10 (6.8%)
- Our goal is to have 100% of our courses accredited by 2025
  - 15 new courses will be accredited each year to reach our goal

Current Courses with CEUs
- EMTALA Basic (2.3)
- Basic Home Health Agency (2.7)
- Basic Hospice (1.7)
- Basic ICF/IID (2.8)
- Basic ESRD (2.7)
- Advanced EMTALA (2.1)
- Universal Infection Prevention and Control Training (2.47)
- Hospital Basic 1 & 2 (5.4 & 2.8)
- Basic Writing Skills for Survey Staff (.25)

Timeline:
- Currently: 6.8%
- 2018: 17%
- 2019: 27%
- 2020: 38%
- 2021: 48%
- 2022: 58%
- 2023: 68%
- 2024: 79%
- 2025: 89%
- Goal: 100% by 2025
Strategic Initiatives: Three-phase approach

- **Phase 1A**: All basic training will be available via self-paced, online courses so that new hires can take training immediately upon hire. No wait times for Training.

- **Phase 1B**: Quarterly calls for surveyors that have taken the online training, with program leads, to allow Q & A and discussion opportunities for new learners (starting May 2018)

- **Phase 2**: Development of Refresher Training, as a means of providing continuing education, for all surveyors (starting May 2018)

- **Phase 3**: Development of Competency Testing for all surveyors, who have completed the basic and refresher courses (Starting November 2018)
Strategic Initiative: Quality Improvement Training

Provide needs/deficiency-focused training for providers from our existing training portfolio

Tailor training based on survey findings to providers’ individual training needs

Support S&C to ensure compliance and improve quality
Questions and Comments
Thank you

Save the Date

• State Executives Training Institute
• April 16-20, 2018
• See you in Baltimore!!!