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Certification Bureau Highlights

Public Protection | Communication | Consistency | Accurate Reporting | Continuous Education

current topics >>>

Quality, Safety & Oversight Memos (Formerly Survey & Certification Memos)

[19-01-AO/CLIA](#) 10/4/2018

Report to Congress: Review of Medicare's Program Oversight of Accrediting Organizations and CLIA

[18-25-HHA](#) 8/31/2018

Home Health Agency Interpretive Guidelines

[18-26-Hospital-CAH](#) 8/31/2018

Guidance to Hospitals and Critical Access Hospital (CAH) Surveyors for Swing Beds

[18-24-ESRD](#) 8/17/2018

Survey Process for Reviewing Home Dialysis Service in a LTC Facility

[18-22-ESRD](#) 8/10/2018

Revisions to the State Operations Manual, Chapter 2, ESRD

[18-23-OPO](#) 8/10/2018

New Organ Procurement Organization Survey Protocol and Guidance Revisions in Appendix Y of the SOM

Reusable Scopes & Reprocessing – An Ongoing Concern for Infection Control and Patient Safety

By: Liz Adams, LPN

In 2013, the Centers for Disease Control and Prevention (CDC) alerted the FDA to a potential association between multi-drug resistant bacteria and duodenoscopes. Focus was placed on cleaning and disinfecting methods per manufacturer recommendations. Current studies show there continues to be a large percent of reusable scopes deemed ready for use that have tested positive for bacteria.

In March 2018, the FDA issued [Warning Letters](#)¹ to duodenoscope manufacturers for “failing to comply with requirements of federal law under which they were ordered to conduct post market surveillance studies to assess the effectiveness of reprocessing.”

Regulatory requirements for Medicare-participating hospitals, CAHs, and ASCs are subject to Conditions of Participation under infection control practices in surgical and procedural settings and are required to provide a sanitary environment to avoid sources and transmission of infections.

Effective April 3, 2015 a CMS Survey and Certification Memo instructed surveyors, when surveying, to “ask during the entrance conference whether duodenoscopes are used. If the answer is yes, then surveyors must request a copy of the manufacturer’s instructions for use (IFU) for the duodenoscope(s) as well as any AERs the facility uses in reprocessing duodenoscopes. Further, surveyors must observe endoscopes being reprocessed and should ask the responsible staff to demonstrate and explain how they are adhering to manufacturers’ instructions and the Multisociety Guidance recommendations. Any

Reusable Scopes Continued from pg. 1...

identified noncompliance must be cited accordingly, and the increased risk to patient safety resulting from improper reprocessing should be taken into consideration when determining the appropriate level of citation.”² Facilities are also required to **not** use immediate use steam sterilization as a routine method of sterilization.

The survey process will include care and services to be followed from the procedure through the cleaning and disinfection processes to maintenance of the duodenoscopes and storage protocols. All manual and disinfection processes will be observed for adherence to current manufacturer guidelines, CMS requirements, to include professional organizations that include CDC and FDA recommendations.

All facilities should establish written protocols for instrument cleaning and sterilization. Policies and procedures should be based on the standards and guidelines commonly used i.e.: CDC, FDA, etc. There should be ongoing input from nursing and medical staff. All facility policies and procedures should be approved by the governing body of the facility and be available to the instrument processing staff.

It is important that facilities ensure their staff are specially trained and competent in performing reprocessing procedures to ensure the prevention of contamination and infection.

1. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm600388.htm> Act (the Act).
2. [Survey and Cert Letter 15-32](#)

Medication Reconciliation in Long Term Care

By: Dianna Bowling, NHA, LPN

Nurses are responsible to complete an accurate narcotic count at the end of each shift with another nurse. The facility staff are responsible for ensuring there is a system in place that ensures controlled medications are recorded, reconciled, and monitored for accuracy of dispensing the controlled medications.

During the shift change from one nurse to another, along with the shift report on the patient/resident, nurses are responsible for counting the controlled medications and checking the controlled medication log book. In doing this the nurses are required to not only look at the controlled medication book to verify the correct count for the correct person and medication and required to look at the package the medication comes in to verify the correct count is in the packaging.

CMS defines controlled medications as *substances that have an accepted medical use (medications which fall under US Drug Enforcement Agency (DEA) Schedules II—V), have a potential for abuse, ranging from low to high, and may also lead to physical or psychological dependence.*

In F755 Pharmacy – Services/Procedures/Pharmacists/Records, §483.45(b)(2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and §483.45(b)(3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

INTENT §483.45(a) and (b)(1), (2), and (3)

The intent of this requirement is that:

- *In order to meet the needs of each resident, the facility accurately and safely provides or obtains pharmaceutical services, including the provision of routine and emergency medications and biologicals, and the services of a licensed pharmacist.*



Medication Reconciliation Continued from pg. 2....

- The facility utilizes only persons authorized by state or local, regulation, or other guidance to administer medications during the course of employment by a facility;
- The licensed pharmacist collaborates with facility leadership and staff to coordinate pharmaceutical services within the facility, guide development and evaluation of pharmaceutical services procedures, and help the facility identify, evaluate, and resolve pharmaceutical concerns which affect resident care, medical care or quality of life such as the:
 - Provision of consultative services by a licensed pharmacist as necessary; and
 - Coordination of the pharmaceutical services if multiple pharmaceutical service providers are utilized (e.g., pharmacy, infusion, hospice, prescription drug plans [PDP]).
- The facility, in coordination with the licensed pharmacist, provides for:
 - A system of medication records that enables periodic accurate reconciliation and accounting for all controlled medications;
 - Prompt identification of loss or potential diversion of controlled medications; and
 - Determination of the extent of loss or potential diversion of controlled medications.

Achieving Compliance on a Health Revisit Survey

By: Tina Smith, NHA, LTC Supervisor

After a long-term care survey, a facility receives a *Statement of Deficiencies on the CMS Form 2567*. This form, includes any deficiencies identified and cited from the survey. The facility is then required to determine when and how they will correct the identified deficient practices. The corrections will be documented on a plan of correction. The facility must choose a date, referred to as the date of compliance, and all corrections will be completed, before or on, this date. You may hear the date of compliance referred to as the facility's **X5** date. The X5 reference corresponds to the ePOC (electronic plan of correction) entry box. The compliance date is entered in the X5 entry box for each deficiency submitted to the State Survey Agency.

Once the State Survey Agency approves a plan of correction, a revisit survey will be scheduled. A surveyor will be assigned to complete the revisit survey, at their earliest availability. This means, revisit surveys may be conducted at any time, on or after, the compliance date. *This includes evening and weekend hours.* The goal for the facility, and the Certification Bureau, is to have the facility achieve compliance on the first revisit survey, and if this occurs, the penalty track initiated by CMS will be stopped as of the date determined the facility was in compliance. A facility must provide evidence that all aspects of the plan of correction were completed by the date of compliance.

A trend identified by the Certification Bureau over the last year, has shown some facilities have not completed the necessary actions they identified and documented as needing to be done on the plan of correction. Other facilities have struggled with maintaining the necessary documentation for the revisit.

One best practice, commonly used across the State of Montana and Nation, includes the use of a *revisit survey binder*. The purpose of the binder is to maintain and organize the evidence and documentation of tasks completed, by the facility, for the plan of correction. Binders are typically set up in the following manner, but there are various ways a facility may maintain the information:

Achieving Revisit Compliance Continued from pg. 3...

- a. Each deficiency cited includes a separate tab or divider page to identify the specific area of deficient practice.
- b. Copies of documented evidence, held behind each tab, is added in the same order as it is documented in the facility Plan of Correction.
- c. Documentation pertaining to the information relating to the corrections made, are highlighted or marked in some fashion, to bring attention to the detail provided.
- d. The revisit binder allows the surveyor to review and gather the facility's documented evidence, in one location, which decreases time spent by the facility and surveyor, gathering or searching for the evidence.

The surveyor is also required to complete observations and interviews relating to the deficient practices identified and corrected, which may be done anytime during the revisit survey. If concerns are identified by the surveyor, due to a deficient practice continuing, or not all the Plan of Correction steps are carried out, the facility may be recited on the deficient area(s).

During a revisit survey, a surveyor may decide the date of correction occurred earlier than the facility alleged. If this happens, the surveyor may change the date of correction, to the earliest date identified. If a facility identifies, on their own, prior to the revisit survey, that all corrections were made on a date prior to the alleged date of compliance, we encourage the facility to notify the surveyor of this right away.

For questions relating to the revisit survey process, please contact the Certification Bureau LTC Supervisor, Tina Smith at (406) 444-4463.

Question & Answer

Q: How can I get help with my *Plan of Correction*?

A: Every time you receive your Statement of Deficiencies (CMS-2567) the Bureau includes with it a *Plan of Correction Guidance*.

For Non-LTC facilities, this *Guidance* will be in the form of an attachment through the file transfer system.

For Long Term Care facilities, this *Guidance* will be in the form of an attachment within the ePoC system. You must save this attachment to your computer, as it will be automatically deleted from the system.



Certified Dietary Manager – F801

By: Tina Smith, NHA, LTC Supervisor

Change is inevitable, and as each day passes, all departments within long term care are affected. Changes to the State Operations Manual, Appendix PP Guidance to Surveyors For Long Term Care, F801, §483.60(a)(2) Food and Nutrition Services, went into effect on 11-28-17, and was implemented on 11-28-17.

F801 now includes the requirement for education and training for a certified dietary manager, and the coverage of nutritional services, when a full-time dietitian is not available. Now, if a facility “... **does not have a qualified dietitian or other clinically qualified nutrition professional employed full time, the facility must designate a person to serve as the director of food and nutrition services...**.” This means, dietary managers not previously certified, in a manner which meets the regulatory requirements, will need to seek the higher level of education and training, for the provision of nutritional services. CMS provided the following guidance:

Each resident brings forth a multitude of contributing factors to be considered to ensure nutritional services are adequately met for the SNF/NF resident. Some of the previous certified dietary manager courses failed to include the necessary **clinical** training, now required. Because of this, CMS included a grace period within F801. Regulatory language shows, “**For designations prior to November 28, 2016, meets the following requirements no later than 5 years after November 28, 2016, or no later than 1 year after November 28, 2016 for designations after November 28, 2016.**” Therefore, a dietary manager, who did not meet the requirements prior to the implementation of the regulation, could complete the training which includes the clinical components necessary for comprehensive nutritional services.

It was found not all nationally certified dietary manager courses meet the requirements of the F801. CMS identified and provided guidance on the following for nationally recognized programs, which may not meet the regulatory requirements:

- a. *At times, a course may require training in the importance of food safety, good personal hygiene, time and temperature control, preventing cross-contamination, cleaning and sanitizing, safe food preparation, receiving and storing food, methods of thawing, cooking, cooling and reheating food, HACCP (Hazard Analysis and Critical Control Points), food safety regulations, and more. These are important topics relating to long term care. **Some courses do not address Food Service Management** which is a requirement under the Regulation 483.60(a)(2)(C).”*
- b. *Some programs do not meet the Regulatory Requirements under 483.60(a)(2)(C) Has similar national certification for food service management and safety from a national certifying body; or*
- c. *The course is a Food Safety and Food Protection Managers Course that is one course within a block of courses required to meet the regulation.*
- d. *Some courses are only one of four mandatory courses (passage of all four plus one foundation are required) by the National Restaurant Association.*
- e. *A dietary manager must have the education to meet the scope of practice as stated in the Association of Nutrition & Foodservice Professionals and the Food Management Professional (FMP) certification through the National Restaurant Association’s websites.”*

The Director of Food and Nutrition Services national accrediting bodies are: Association of Nutrition & Foodservice Professionals (ANFP), CDM, CFPP Credential <http://www.anfonline.org/become-a-cdm/cdm-cfpp-credential>

International Food Service Executives Association (IFSEA) <https://www.ifsea.org/>

Food Management Professional (FMP) certification through the National Restaurant Association <http://www.restaurant.org/Restaurant-Careers/Career-Development/FMP-Credential> The FMP exam has no specific training course. It assesses candidates on knowledge and skills directly related to job activities. Find how to begin the FMP credentialing process at the ManageFirst website.

For questions or further guidance and interpretation, please contact the LTC supervisor, Tina Smith.

Non-Survey Bureau Visits

By: Todd Boucher, Bureau Chief

Since I first was hired as the Life Safety Code Survey Supervisor with the State Survey Agency in Montana over 10 years ago, I have always had a desire to reach out to facility providers in a nonconfrontational format that would allow the providers to speak to us directly with questions. A process where Providers would feel comfortable to discuss any issues they would like with us without fear of some sort of citation. We have started this process internally and it has been well received so far.

The Certification Bureau managers and Bureau Chief have begun some road visits with a variety of providers to introduce ourselves and open up an opportunity for provider staff to speak to us directly while in their own surroundings without the fear of a survey going on. We are accomplishing this with onsite visits to the facility to introduce ourselves.

Before you read on, understand that my expectations of our visits are as follows:

- We will not be conducting surveys – revisits, complaints, recertifications for all categories of health, life safety, Clinical Laboratory Improvement Amendments (CLIA), or Emergency Preparedness
- You decide who should be present when we meet with you
- We will call ahead to make sure someone will be available
- These are not mandatory and can be denied by you

We have developed some topics to discuss with providers as follows:

- ePOC System
- Incident Reporting System
- Items for our Newsletter
- Regulations specific to your provider type
- Updates to Administration of the facility
- State Survey Agency oversight areas identified by CMS
- Any other questions you may have

Secondly, I wanted to discuss the areas that CMS will be evaluating the Montana State Survey Agency on for the federal fiscal year 2019 (October 1, 2018 to September 30, 2019). They have confirmed with us the following four areas will be evaluated by them as we conduct the survey process and after, if a comparative survey is conducted.

- Staffing
- Abuse/Neglect
- Pain Management
- Infection Control

This is a slight change from what we were told in October 2018, but these are the final areas. You can be assured that these areas will be areas of concentration for the Certification Bureau. This is based on a new process CMS is utilizing to evaluate the State Survey Agency as described in Survey & Certification Admin Info 18-06-NH Revised Federal Oversight Support Survey (FOSS) Process National Pilot, January 5, 2018. These Administrative Info sheets were not provided to the public in the past but have been made available.

coming soon >>>

- *Pain Management*
- *Critical Access Hospital Swing Bed Regulations Update*



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special thanks to >>>

- Becky Yancy & Brittney Nelson, Certification Specialists
- Liz Adams
- Dianna Bowling

Holiday Decorations and LSC Compliance

By: Tony Sanfilippo, LSC Supervisor

The Life Safety Code requires specific compliance for use of decorations for holiday events. Compliance for these requirements can be found on the QAD website at dphhs.mt.gov/qad/certification. The Compliance Readiness Bulletin is provided for any holiday decoration activity and not only Christmastime.

Certification Bureau Compliance Readiness Bulletin CRB 02 17, Date of Issue: 11/9/17
Christmas Trees and Holiday Decorations

The Life Safety Code considers Christmas trees highly flammable decorations. The Certification Bureau provides the following guidelines and precautions for the use of trees and decorations in Health Care Facilities:

Live Trees [Trees must be fresh cut]:

Live trees must be flocked with a fire retardant.

A staff person must be designated to water the tree. Logs must be maintained to indicate the date and time the tree was watered and by whom.

Lights are not permitted on flocked or aluminum/metal trees. Indirect flood lights may be used.

Live trees must be located in a room that can be closed from corridors, (e.g. a dining room or lounge) and supervised by staff.

Live trees must be limited to one per building.

Live trees should be located near sprinkler heads or smoke detectors.

Artificial Trees [Underwriters Laboratory (UL) or Factory Mutual (FM)]:

Lights may be used on UL or FM approved artificial trees in accordance with manufacturer's directions.

Artificial trees, factory wired with lights are acceptable if UL or FM tested.

Lights on artificial trees should be unplugged at night.

No limit is placed on the number or type of artificial trees in the building as long as they are UL or FM tested and approved.

Only UL or FM approved multi plug adaptors/power strips with surge/circuit breaker protection are acceptable

Holiday Lights:

UL approved lights may be installed on the exterior of the building and on outside trees and shrubs. Exterior lighting circuits must have ground fault circuit interrupter (GFCI) protection.

Only UL approved multi plug adaptors with surge/circuit breaker protection are acceptable.

Holiday Decorations:

The use of live evergreen boughs for decoration inside a health care facility is prohibited.

The exception is floral arrangements, using evergreens in a water source.

Wrapping paper is combustible and must not be used to decorate doors and wall surfaces.

Open flames and/or candles are prohibited.

If you have any questions regarding safety issues, please contact the Certification Bureau at (406) 444 2099 or email the Bureau at MTSSAD@mt.gov. For additional Holiday and winter heating safety tips, please visit www.nfpa.org/education

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