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Note: This educational material was prepared to assist providers in meeting the regulations. The information provided is intended to be summary and does not supplant either written law or regulations. Please refer to the statutes, regulations and interpretive guidelines for official guidance.

Issue:
Winter 2021



Healthy People. Healthy Communities.

Certification Bureau Highlights

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

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Hospital Survey Priorities

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FY 2019 Report to Congress (RTC): Review of Medicare's Program Oversight of Accrediting Organizations (AOs) and the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Validation Program

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New Platform for Submissions of 1135 Waiver Requests and Inquiries – Go Live

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Clinical Laboratory Improvement Amendments of 1988 (CLIA) Laboratories Surveyor Guidance for New and Modified CLIA Requirements Related to SARS-CoV-2 Test Result Reporting

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Above Ceiling Inspections

By: Rachelle Jewison MBA, NHA, CFI

As we all know, areas above the ceilings and behind the walls of every facility contain a large, hidden, intricate network made up of thousands of miles of pipes, ducts, wires, cables, and various lines. This extraordinary grid is segmented across multiple life safety compartments to reduce the risk of fire and smoke traveling from one area of a facility to another.

When conducting Life Safety Code inspections, adverse findings in almost any finished space include the results of both ceiling-level and above-ceiling observations.

Ceiling-level observations include items such as damaged ceiling tiles, gaps in ceiling tiles that exceed NFPA limitations, missing or dislodged sprinkler escutcheons, items hanging from sprinkler heads, and damaged or dirty sprinkler heads. Another common citation is caused by items being stored within the 18-inch clear area beneath the bottoms of sprinkler heads.

The most common above-ceiling observations include inadequately sealed penetrations of smoke barriers and fire-rated barriers, and a sprinkler pipe that is being used to support another object (data cables, wires, etc.).

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Abuse Prevention in Acute & Continuing Care Facilities

By: Jennifer Andersen LPN, OEC

Have you wondered if you're doing enough to prevent patient abuse in your facility or agency? Do you feel prepared for a state review of your abuse prohibition protocols, policies and procedures? Do you feel you are in compliance with the CMS regulations for abuse?

Abuse prevention is closely monitored and reviewed by surveyors in long-term care facilities, but what about in the non-long term care facilities also surveyed by CMS? The answer is yes; as a matter of fact, almost every facility type regulated by CMS, from hospitals to hospices, have regulations which outline the requirements for abuse prevention.

The intent of these requirements is to prohibit all forms of patient abuse, whether from staff, visitors, or other patients. The facility or agency must have mechanisms or methods in place which ensure those requirements.

Starting with the development, revision, and implementation of facility policy and procedures, which at a minimum, should incorporate the regulations outlined by CMS on abuse prohibition. The surveyor will review those policies to ensure they are routinely updated and revised by the facility according to the timeline directed by CMS.

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Ceiling Inspections... Continued

In the link below, for your reference, you can request an example of an Above Ceiling Inspection Form that many facilities across the state are utilizing. This form includes information about the following items and even includes the NFPA code reference for your review:

- Rated barriers
- Gypsum patches
- Embedded pipes
- Fire-stop materials
- Structural steel fire-coating
- Suspended ceiling tiles
- Water damage
- Sprinkler pipe and hangers
- Medical gas pipe
- Electrical wires, cable, and cords
- Electrical conduit & junction boxes

Link:

<https://www.complianceonegroup.com/lifesafety/above-ceiling-inspection-form>

Rural Health Clinics & Emergency Preparedness

By: Laura Carney, RHIT

This past year, 2020, saw some major changes in the way healthcare facilities were addressing infection control, personal protective equipment, and staffing. It's been a challenge across the Country and World. Our rural health clinics (RHC), in Montana, have played a major part in serving the people of this State. They have been one of the first lines of defense in addressing the pandemic within our rural communities.

A rural health clinic should be taking part in their county's emergency preparedness plans or be part of a CERT (Community Emergency Response Team). CERT was developed by FEMA (Federal Emergency Management Agency) to involve all aspects of a community in emergency response and preparedness. This information is found at www.ready.gov/cert.

There are multiple emergency preparedness programs available, developed and sold by companies, but if you are a rural health clinic and are certified by the federal government, there are Conditions for Certification the RHC must address to receive funding from the Centers for Medicare and Medicaid Services (CMS).

The State Operations Manual (SOM), Appendix Z, provides regulations and guidance for Emergency Preparedness in the RHC setting. Appendix Z can be found at the following link:

www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf

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Abuse Prevention, Continued...

CMS states unequivocally, the patient has the “right to be free from abuse, neglect, misappropriation of property, and exploitation, including abuse enabled through the use of technology. This includes but is not limited to freedom from corporal punishment, involuntary seclusion and any physical or chemical restraints not required to treat the resident’s medical symptoms.”

Abuse can also be verbal, mental, emotional, sexual, and physical. It can include the deprivation by an individual of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. The following components are identified by CMS as necessary elements to protect patients from abuse. Consider the following components in relation to the survey process; will your current abuse prohibition protocols pass muster?

1. **Prevent:** A critical part of prevention is ensuring adequate staff, who are qualified and trained, are on duty to provide for the care needs of every patient - especially during the evening, nights, weekends, and holidays shifts. **Survey Process:** Surveyors will assess if the needs of the patients are met, and review staffing levels across all shifts to determine if qualified staffing is sufficient to care for individual patient’s needs.
2. **Screening.** Persons with a record of abuse or neglect should not be hired or retained as employees. **Surveyor Process:** Surveyors will review personnel files to ensure the facility conducts criminal background checks as allowed by State law for all potential new hires. This is meant to ensure the facility does not employ individuals with a history of abuse, neglect, or harassment.
3. **Identify:** The facility creates and maintains a proactive approach to identify events and occurrences that may constitute or contribute to abuse and neglect. **Survey Process:** Surveyors will conduct observations, interviews, and record reviews to assess for situations which could contribute to abuse, such as staffing shortages, staff burnout, and lack of understanding of the facility’s abuse prohibition protocols. Patient/Family interviews will be conducted to determine staff treatment of patients, and if there are any patient care concerns. Any concerns identified during survey will be investigated.
4. **Training:** The facility should ensure staff are adequately trained on abuse prohibition during orientation, and through an ongoing training program by the facility. The training should provide all employees with information regarding abuse and neglect, and related reporting requirements, including prevention, intervention, and detection. **Surveyor Process:** The surveyor will review personnel files for validation of training on the facility’s abuse prohibition protocols, policies, and procedures, upon hire, and annually. Staff interviews will be conducted to verify understanding of the facility’s protocols, policies, and procedures.
5. **Protect.** The facility must protect patients from abuse during investigation of any allegation of abuse, neglect or harassment. **Surveyor Process:** The surveyor will validate through patient, family, and staff interviews to ensure patients were protected from further abuse during the investigation of any allegation(s) of abuse.
6. **Investigate.** The facility ensures, in a timely and thorough manner, objective investigation of all allegations of abuse, neglect or mistreatment. **Survey Process:** The surveyor will review necessary reports to ensure the facility thoroughly investigated any allegation(s) of abuse.
7. **Report/Respond.** The facility must assure that any incidents of abuse, neglect or harassment are reported and analyzed, and the appropriate corrective, remedial or disciplinary action occurs, in accordance with applicable local, State, or Federal law. **Survey Process:** The surveyor will review facility complaints, incidents, and reports, for validation that the facility reported to the appropriate agencies in accordance with State and Federal laws regarding incidents of substantiated abuse. And to ensure incidents of substantiated abuse resulted in appropriate action.

It is important to mention, although many of these regulations are standard level tags under the required Conditions of Participation, noncompliance with these standards can quickly rise from a Standard Level Deficiency to a Condition Level Deficiency based on outcome, severity, and occurrence.

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Abuse Prevention, Continued...

Also, failure to report serious injuries resulting from abuse or neglect have a greater probability of rising to an immediate jeopardy level finding. Immediate jeopardy procedures are outlined in Appendix Q of the State Operations Manual.

With the knowledge of the different forms of abuse, the components used to prevent abuse, and the different methods surveyors utilize to investigate a facility's compliance with CMS's abuse prohibition requirements, we hope we have addressed the earlier questions.

The following is a list of regulatory tag numbers under different Conditions of Participation (COPs) from each designated State Operations Manual (SOM) Appendix which outlines the regulatory language for compliance with abuse prohibition for each non-long term care facility type surveyed by the State Agency:

Facility Types & Related Abuse Tags:

Hospitals: Appendix A: Survey Protocol, Regulations, and Interpretive Guidelines for can be found under tags: A-0118 to A-0122, A-0145, A-0154 to A-0214, and, A-1566 Standard: Special requirements for hospital providers of long-term care services with swing-beds: Freedom from abuse, neglect, and exploitation. Note for (A-1566), refer to the Appendix PP of the SOM for interpretive guidelines and survey procedures.

In-Patient Rehabilitation Facilities: Must meet all the COPs specified in Appendix A. This includes tag #(s): A-0118 to A-0122, A-0145, and A-0154 to A-0214.

Psychiatric Hospitals: Appendix A: Regulations and guidance can be found under tags: A-1605 Standard: States Psychiatric Hospitals must meet all the COPs specified in Appendix A. Which includes tags: A-0118 to A-0122, A-0145, and A-0154 to A-0214.

PRTF: Appendix N: Psychiatric Residential Treatment Facilities (PRTF): Regulations, procedures, and guidance can be found under tags: N-0127 to N-128, N-0207 to N0224.

ICF/IID Facilities: SOM Appendix J: Regulations, procedures, and guidance can be found under tags: W127, W128, W148 to W157, W189, W191, W253, and W264.

CAH: SOM Appendix W: Includes tag: C-1612 Standard: Freedom from abuse, neglect, and exploitation. Regulations, procedures, and guidance can be found outlined by the Appendix PP, for Long Term Care Facilities, Sections: §483.12(a)(1), (a)(2), (a)(3)(i), (a)(3)(ii), (a)(4), (b)(1), (b)(2), (c)(1), (c)(2), (c)(3), and (c)(4) of the SOM for Long-Term Care, Appendix PP. Survey regulations, procedures and guidance can be reviewed under tags: F600, F604, F606, F607, F609, and F610.

Ambulatory Surgical Centers: Appendix L: Regulations and guidance can be found under tags: Q-0225, Q-0226, and Q-0233.

Home Health Agencies: Appendix B: Regulations and guidance can found under tags: G430, and G478 to G488.

Hospices: Appendix M: Regulations and guidance can be found under tags: L505, L508 to L511, L517, L737 to L760, and L771.

End Stage Renal Disease Facilities (ESRD): Appendix H: Regulation and guidance can be found under tags: V452, V465 to V467, and V520.

(Note: This list may not be all encompassing or cover all provider types)



Quality, Safety & Oversight Memos – Continued...

[OSO-21-09-ASC](#)

12/30/2020

Providing flexibility for exceeding the 24-hour time frame for patients in Ambulatory Surgical Centers (ASCs) during the COVID-19 Public Health Emergency

[OSO-21-08-NLTC](#)

12/30/2020

Revised COVID-19 Infection Control for Acute and Continuing Care

[OSO-21-07-Psych Hospital, PRTF & ICF/IID](#)

12/17/2020

COVID-19 Infection Control for Psychiatric and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs/IID)

[OSO-21-06-NH](#)

12/04/2020

Updates to the Nursing Home Compare website and Five Start Quality Rating System

[OSO-21-05-ESRD](#)

12/04/2020

FY2021 Quarter 1/Quarter 2 Dialysis Facility Report (DFR) – Update

[OSO-20-24-ASC-Revised](#)

11/25/2020

*Guidance for Processing Attestation Statements from Ambulatory Surgical Centers (ASCs) Temporarily Enrolling as Hospitals during the COVID-19 Public Health Emergency ***REVISED****

[OSO-21-04-CLIA](#)

11/6/2020

Clinical Laboratory Improvement Amendments of 1988 (CLIA) CMS Locations and State Agency Remote Survey Guidance – Optional Process

National Healthcare Safety Network – Required Reporting

By: Tina Smith, NHA, LTC Supervisor

Looking back, long-term care providers may not have realized the impact the requirements for the NHSN (National Health Safety Network) reporting, during the COVID-19 pandemic, would make. In 2020, the Centers of Medicare and Medicaid (CMS) notified long term care providers of the expectations for the NHSN reporting, and the outcome for the lack of reporting if it occurs.

The Centers for Disease Control and Prevention (CDC), National Healthcare Safety Network, is the most widely used system for tracking healthcare associated infections in our nation. Ultimately, the goal of the NHSN reporting would be to eliminate healthcare associated infections. NHSN provides data needed to identify problem areas related to infections and measures progress of prevention efforts. Facilities may also track blood safety errors or healthcare process measures, such as the influenza vaccine status and infection control adherence rates.

On May 8, 2020, the NHSN reporting requirements were rolled out by CMS, and the Quality Safety and Oversight (QSO) group, and included in QSO-20-29-NH update. Initially, long term care facilities (LTC) were provided a grace period for completing and meeting the minimum reporting requirements. Today, any long-term care facility that does not report the required data will in turn have a penalty imposed by CMS. During the last six months CMS has cited F884 – Reporting NHSN Requirements, at no less than 27 LTC facilities in Montana, and this number continues to grow. The process for review, citing deficient practice, and the imposition of remedies related to F886, is not investigated or cited by the Certification Bureau surveyors, but rather maintained and addressed through the various Regional Offices across the Nation.

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NHSN – Required Reporting, Continued...

Long-term care providers quickly realized the failure to report was not always within their control. The access to report the required data requires an individual to enroll and have a background check completed by the SAMS (Secure Access Management Services). Once complete, SAMS will provide an approval/access for reporting the required data. It was found the NHSN reporting system struggled to take on all new LTC providers so quickly. Today, most LTC facilities have completed the enrollment process, but a few have encountered delays. When this occurs, penalties are imposed each week by CMS, regardless of the cause of the lack of reporting. CMS developed a process which allows a facility the opportunity to IDR any citation for F884 - NHSN Reporting. A facility may present evidence *showing consistent, accurate, and ongoing efforts to obtain the NHSN reporting approvals*. CMS reviews the evidence, and if the facility carried out the required steps accurately, but enrollment approval was not received timely, remedies may be removed.

Looking into the future, the State Survey Agency, and CMS, encourages each long-term care provider to have more than one employee designated and approved to access the NHSN reporting site. Since the enrollment has currently been delayed for some providers, signing up beforehand may be beneficial, rather than waiting until it is needed. If a long-term care facility needs assistance with the required NHSN reporting process they may contact Mountain-Pacific Quality Health at (406) 443-4020 | Toll free: (800) 497-8232. Mountain Pacific has designated employees assisting facilities as needed with education and resources for the NHSN reporting.

Bureau Chief Buzz

By: Todd Boucher, Bureau Chief

Thank you for all you are doing to keep your residents, patients, and staff safe during the COVID19 Public Health Emergency (PHE). We are waiting for additional guidance from CMS on visitation in nursing homes and any changes associated with certified provider operation of all facility types based on the COVID19 vaccinations. CMS have stated they will release any changes based on vaccinations when they can. While we both wait for their direction, please follow all existing requirements for COVID19 until told otherwise. If you have questions about requirements, please send us an email to mtssad@mt.gov or call me directly at 406-444-2038.

We wanted to remind long term care facilities to report any changes in the administrator or the director of nursing (DON) for your facilities. Non long-term care facilities will also want to report any changes in the CEO, administrator, etc. to us as well. We will need to know when the changes will occur and the new person's contact information. We will also need to have an emergency contact number, as CMS requires us to maintain that for emergencies. We suggest a cell phone as a secondary contact for this in case the facility number is not working. These changes can be addressed by emailing them with effective dates to mtssad@mt.gov or changes can be mailed into DPHHS QAD Certification Bureau, PO Box 202953, Helena MT 59620.

We are currently working on Focused Infection Control Surveys (FICS) and complaints. With numbers of active outbreaks in facilities getting lower, we will begin recertifications surveys soon. We will announce when recertifications will start via email, so again having your updated information for your facility will allow us to notify you timely.



Rural Health Clinics, Continued...

All Rural Health Clinics are required to establish an Emergency Preparedness (EP) program. The EP program must describe a comprehensive approach to meeting the health, safety, and security needs of its staff and patient population. The program also needs to identify how the RHC will coordinate with other healthcare facilities, and the community, during an emergency or a natural, man-made, or facility disaster. The facility's EP program must be reviewed and updated at least annually.

An RHC must have an emergency plan in place. This is one part of a facility's EP program. The RHC will conduct facility-based and community-based risk assessments to help the RHC develop the emergency plan. The RHC's emergency plan supports, guides, and ensures its ability to collaborate with local, tribal, regional, State, and Federal emergency preparedness officials.

The emergency plan is specific to the location of the RHC and the hazards most likely to occur in the surrounding area. These could include: Natural disasters, man-made disasters, facility-based disasters, and EID (Emerging Infectious Diseases) such as Influenza, Ebola, Zika Virus, and others. These EIDs will probably require modifications to the facility's protocols to protect the health and safety of the patients. Due to COVID-19, your facility has probably already made changes in its protocols: i.e. tele-visits, requiring patients to wear a mask for office visits, taking patient temperatures and completing exposure questionnaires, and requiring staff to wear PPE (personal protective equipment).

As we've seen during the COVID-19 pandemic PPE, for staff, has been in short supply in all healthcare settings. The RHC needs to evaluate the potential for interruption of supplies and essential services in the emergency plan. The RHC also needs to consider the possible length of such interruptions and address these issues. The RHC needs to talk with their contractors and service providers to determine possible delays of supplies and equipment during emergency situations. These discussions should lead to the development of policies and procedures to address these shortages in the clinic. The RHC's EP plan must address the types of services it can provide in an emergency, the continuity of operations, including delegations of authority and succession plans.

As part of the RHC's physical building, all exits must be identified by an exit sign. The signs need to be illuminated and need to remain so during a power failure. The RHC must also have an evacuation plan in place. A floor plan, showing the nearest exits from exam rooms, offices, reception areas, breakrooms, nurse stations, and ancillary areas are usually the most easily understood by the staff and patient population.

The RHC's emergency plan must include policies and procedures for how it will provide for patients, staff, and volunteers to shelter in place if they remain in the clinic. During emergency situations, an RHC may need to utilize volunteer support from individuals with varying levels of skills and training. If the RHC has healthcare professionals volunteering in emergency situations, the RHC must ensure those volunteers are performing within their scope of practice and training. The RHC's EP plan must address the necessary privileging and credentialing processes necessary for the volunteering healthcare professionals. Non-medical volunteers would do non-medical tasks.

In Montana, a large number of the rural health clinics are in truly rural areas, and as we all know, communications in those areas can be limited. The RHC's EP plan needs to address communication concerns that would arise during an emergency. RHCs with limited connectivity to the internet or cellular capabilities need to ensure their plan identifies and addresses other methods of communications for communications with State and Federal emergency officials. Emergency communications methods include, but are not limited to, satellite phones, citizen band radios, and short-wave radios.

The RHC's communication plan must include the following: Names and contact information for staff, entities providing services under arrangement, patients' physicians, other facilities, and volunteers. It must also contain contact information for Federal, State, Tribal, Regional, and local emergency preparedness staff, the State Licensing and Certification agencies, the Office of the State Long-Term Care Ombudsman, and other sources of assistance. The EP communication plan must contain a primary and alternate means for communicating with the professionals and agencies listed above. The RHC must maintain an EP communication plan that complies with Federal, State, and local laws, and must be reviewed and updated at least annually.

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Rural Health Clinics, Continued...

As part of the RHC's EP communication plan, it must develop a method for sharing information and patient medical documentation necessary to ensure continuity of care for patients. In the event of patient evacuation, the RHC must be able to release patient information as permitted under 45 CFR 164.510. The RHC must also have a means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4). The RHC must have a communication system in place to generate timely, accurate information that could be disseminated, as permitted, to family member and others. The RHC has the flexibility to develop and maintain their own system in a manner that best meets its needs. HIPAA requirements are not suspended during a National, State, or public health emergency. However, HIPAA privacy regulations at 45 CFR 164.510(b)(4) states, "Use and disclosures for disaster relief purposes," establishes the requirements to assist in disaster relief effort, of notification to family members, personal representatives, or specified others of the patient's location and general condition.

RHCs must develop and maintain an EP training and testing program. The training and testing program must be reviewed and updated at least annually. **Training-** The facility's responsibility to provide education and instruction to its staff, contractors, and volunteers to ensure the individuals are aware of the EP program. **Testing-** That in which the RHC's training is operationalized, and the RHC can evaluate the effectiveness of the training. Testing should include drills (exercises) to test the emergency plan to identify areas of improvement.

The RHC must conduct exercises to test its emergency plan at least annually. This includes tabletop and full-scale exercises. The RHC should participate in full-scale community-based emergency exercises. If community-based emergency exercises are not available to the RHC, the RHC needs to document its efforts. The RHC must document its facility-based training and testing efforts.

If the RHC is part of an integrated healthcare system, the RHC may choose to participate in the healthcare system's coordinated emergency preparedness program. If the RHC does make this choice, a unified and integrated emergency preparedness program must: show each facility within the system actively participated in the development of the program; consider each facility's unique circumstances, patient populations, and the services offered; show each facility can use the unified and integrated EP program and is in compliance with the program. The unified and integrated emergency plan must include a documented community-based risk assessment, and a documented individual facility-based risk assessment utilizing an all-hazards approach. The integrated policies and procedures must have a coordinated communication plan, and training and testing programs. The RHC must have documentation showing it is actively involved in developing the unified EP program, and the annual reviews of the program requirements and program updates.

A complete, effective, receptive, and current emergency preparedness program and emergency preparedness plan, in the RHC setting, is important for responding to and providing essential services in any community in the event of a pandemic, catastrophe or disaster - natural or man-made.

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final thoughts...

Special thanks to:

- Brittney Nelson, Certification Specialist
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