

# DECEMBER 2019

## PHC NEWSLETTER



NEWS FROM CMS AND  
JOINT COMMISSION

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### PERSPECTIVES

There is nothing dramatically new or difficult discussed in this month's issue of Perspectives, however there are multiple newsworthy announcements. The first announcement is that the National Patient Safety Goal for Suicide Prevention will now become applicable to critical access hospitals (CAH) effective July 1, 2020. It almost appears as if this was a nearly two-year oversight in not applying the NPSG 15 to critical access hospitals and that the omission is being corrected. Readers should also note that all of the NPSG 15-related FAQ posted for TJC's manual for hospitals (HAP) are now also posted for CAHs.

#### **Emergency Management:**

There is a worthwhile article in Perspectives outlining the process to obtain an 1135 Federal waiver during disasters. Current standards require that the hospital have a process designed to request such a waiver should disaster strike your area. TJC reports that this process is frequently not well developed, and staff are not able to articulate what they would do if they were to need such a waiver. This article helps to describe what such a waiver entails and the conditions which must be met for such a waiver to even be considered. It is important to note that a waiver cannot be preapproved or completely documented prior to the disaster, however as we reported in our February newsletter a skeleton can be developed. In addition, you would want to develop a written process for completion of the waiver application, obtaining internal approvals and how to process the actual waiver request. As TJC is reporting that this requirement is frequently scored noncompliant, it would be good to circulate this article to your emergency management team and verify that such a process is already described in your emergency operations plan.

**FSA Tool Temporarily Offline:**

Perspectives contains an announcement that the focused standards assessment tool will be temporarily unavailable from December 30th through January 9, 2020. If you were planning to use the tool or needing to submit data during this time, you will need to make alternative plans.

**Consistent Interpretation:**

This month's column focuses on LS.02.01.20, EP 1 concerning locking arrangements. The surveyor observations and the guidance sections identify multiple different problems that can arise leading to scoring this EP. The article serves as a useful reminder that in locked psychiatric units all staff have to have the keys to help expedite an evacuation. It also reminds us that there can be no secondary locking on an egress door, such as a thumb latch. Lastly if you have installed delayed egress doors, they must have required signage and most importantly they must actually work as designed. TJC reports that this EP has been scored in more than 17% of hospitals surveyed this year. While not coming close to hitting the top ten, this is the type of performance issue that can be found and managed prior to survey to prevent TJC from finding it for you.

**FAQS**

On November 14<sup>th</sup>, Joint Commission sent around an email alert to the posting of many new standards FAQs. As we are writing this newsletter two weeks later, we noticed the "NEW" label has already disappeared from the FAQs, so you won't be able to easily find them just by searching their FAQ pages. There were six new FAQs that appear important to hospital readers.

**Suicide Risk Monitoring:**

The first new FAQ is in the NPSG chapter and is entitled "What is the monitoring requirement for patients at high risk for suicide?" TJC provides two responses. The first is for hospitals with some environmental risks: the requirement is for 1:1 supervision for all patients identified at a high risk for suicide. The second response is for the perfect, ligature free hospital: the supervision requirement would be up to the hospital to determine. Since we have not yet seen a hospital that does not have any safety risks, for most readers the answer is going to just be that a 1:1 is required for patients at high risk for suicide.

**Essential Oils – A Medication?**

The second FAQ is in the MM chapter and provides what we view as an unusual response relative to the question; are essential oils used for aroma therapy considered a medication by TJC? TJC states that the FDA relies on the "intended use" to determine if it is a medication. TJC further states that if a product is intended for therapeutic purposes such as treating or preventing disease, it would be considered a drug. Our understanding of the FDA's position is that if the manufacturer wants to market and label a product for specific therapeutic purposes, then it is a drug. The FAQ seems to be implying if the hospital or treatment team is intending to use an essential oil not considered a drug by the FDA, for therapeutic purposes, then it is a drug. This has become important due to the new pain management standards which encourage the use of non-pharmacologic treatment for pain. Some organizations are using aroma therapy as one of their approaches in their pain management care plans. But if TJC considers it a drug, it is no longer non pharmacologic, and it requires a physician order. Hopefully there will be additional details forthcoming from TJC on this issue.

**IFU:**

The third and fourth FAQs are posted in the IC chapter and discuss manufacturer's instructions for use. One addresses the expectation for access to the IFU, and the second discusses how to manage conflict in different manufacturers IFU, such as a device IFU and a cleaning agent IFU. The first issue is easy, yes you have to provide access to the IFU and adhere to these IFU. But this FAQ raises the bar for IFU acquisition and retention. Most hospitals are not organized, equipped or staffed to handle this expectation. Currently in most hospitals, each departments "files" IFU in isolation. Often, we find the instruction manual still in its sealed plastic wrapper stuffed into a nearby drawer or cabinet, having never been read. A more centralized, procedure /standard work driven approach will be needed to meet this expectation reliably across the organization.

The conflicting IFU issue is more complex and would require contacting the manufacturers to help resolve that conflict. Although not explicitly stated, we believe you would want to document your discussions, conclusions and guidance to staff on resolution of the IFU conflict. TJC cites

as an example a device where the hospital prefers to use a non-recommended disinfectant. Although the manufacturer of the device recommends against the alternative disinfectant the hospital believes it is more effective. The manufacturer of the device indicates the alternative disinfectant may shorten the life of the device. The hospital documents their discussion with the manufacturer of the device, and their conclusion to use the more effective but alternative disinfectant, knowing that the life of the device may be shortened. Using the risk assessment format, we have discussed often is the format we would recommend to document the analysis.

#### **Attire in the OR:**

The fifth new and quite lengthy FAQ is in the leadership chapter and addresses the controversial subject of operating room attire. The bottom line is in point #2 of the FAQ where TJC quotes the CMS Infection Control worksheet which states: “Surgical attire, e.g. scrubs and surgical caps/hoods covering all head and facial hair are worn by all personnel and visitors in semi restricted and restricted areas, and surgical masks are worn fully covering mouth and nose by all personnel in restricted areas where open sterile supplies or scrubbed personnel are located.” In addition, TJC advises organizations that a more stringent standard can be applied by surveyors if there is a state regulation establishing that higher standard, or if the organization has adopted a higher standard by stating it adheres to a specific clinical practice guideline.



## EC NEWS

#### **New Requirements:**

The lead article in this month’s EC News is essential reading and should be shared with your emergency management and facility teams. It summarizes new requirements in the EM, EC and LS chapters for 2020. These changes are as follows:

**EM.01.01.01:** They added a note to the standard to describe the CMS expectation to include “emerging infectious diseases” such as Ebola, Zika, or influenza to your hazard vulnerability analysis during emergency management planning.

**EC.02.05.01, EP 15:** This is the requirement that addresses airborne contaminants in critical spaces. TJC has further defined critical spaces this year to include all areas designated for the administration of general anesthesia, specifically inhaled anesthetics. They have also added content stating that new healthcare facilities or those renovated after July 5, 2016 must comply with heating, cooling and ventilation requirements as specified in ASHRAE 170 2008. They also added in Note 1 for this EP a reminder that organizations may adopt the CMS categorical waiver to reduce their relative humidity to 20%. TJC explains two essential requirements if you choose to do this. First you must include this information in your basic building information, or BBI. Secondly the hospitals equipment and supplies stored in the space where humidity is reduced to 20% must be compatible with this reduced humidity reading. This is the tricky or impossible part as it requires that each manufacturer or vendor be contacted and asked to provide documentation that their device or product is safe when stored or used in environments that may reach a 20% relative humidity level.

**EC.02.05.01, EP 27:** This change is simple as the reference to ASHRAE 170 was moved out of EP 27 and into the previously discussed EP 15.

**EC.02.05.09, EP 4:** This EP was changed to better match the current code in NFPA 99 2012 relative to storage of gases. The door signage for rooms containing gases other than oxygen and medical air must state: “Positive Pressure Gases: NO Smoking or Open Flame. Room May Have Insufficient Oxygen. Open Door and Allow Room to Ventilate Before Entering.” The door signage for rooms containing oxygen or medical air central supply manifold systems or cylinders should be labeled to state: “Medical Gases: NO Smoking or Open Flame”.

**LS.01.01.01, EP 7:** This is a new EP requiring the organization to maintain current basic building information within its statement of conditions (SOC). Although it is not stated here, the invisible requirement is that TJC is going to want a more precise square footage number for the hospital. TJC indicates in this article that while the EP is effective January 1, the more exacting square footage requirement is not required until some later and as yet unannounced date.

There is also a boxed and highlighted page at the end of this article which announces that TJC is now going to reference the 2018 edition of the FGI Guidelines for Construction or Renovation. Previously TJC addressed the 2014 edition. You will see this change in EC.02.06.05, EP 1 as of January. If you have not yet obtained a copy of the 2018 FGI, you will want to purchase it, as these requirements also apply to renovated spaces.

**Fire Risk in Hospital Kitchens:**

There is a great article in EC News this month about reducing fire risk in hospital kitchens and some very useful tips are provided describing some issues frequently seen on survey. This should be shared with your facility team and dietary leadership. The frequent flaws seen include:

- Vent hood baffles and filters improperly replaced after cleaning leaving gaps.
- Cooking appliances improperly covered by the fire suppression system because the stove has not been properly placed after cleaning.
- Blocked wall mounted pull station for the fire suppression system.
- Missing class K fire extinguisher, or missing signage which must accompany the class K fire extinguisher.
- Staff not trained to know the class K fire extinguisher is only to be used after the fire suppression system.
- Connection between the fire suppression system and automatic shut off of gas, ignition and electric.
- Adequate 16-inch separation between deep fat fryers and other open flame cooking appliances, or an 8-inch vertical baffle creating a separation.



Bear in mind that surveyors are also using a new kitchen tracer tool recently developed by TJC to help remind them of these common pitfalls, so be sure to prepare.

**PCRA and ICRA:**

The second part of the article on PCRA and ICRA started last month is published this month. TJC provides 8 steps to help think through and manage this process. These steps are as follows:

1. Describe the project work in detail so that you can begin to evaluate the risks.
2. Identify the areas surrounding the project so you can determine the areas that might be affected and the risk in those areas.
3. Identify the construction activity type from inspection only to minor to major so that you can identify the hazards that might be created.
4. Identify the infection prevention and control activities that should be present.

5. Identify other issues or impacts beyond just infection prevention including noise.
6. Identify the mitigation measures that will be put into effect to prevent the risks identified in step 5.
7. Complete ILSM assessment and choose enhanced safety measures as appropriate.
8. Monitor the project on an ongoing basis.

While this sounds simple, we often see steps skipped or neglected. For example, step 5, looking beyond just the infection prevention issues is often missed. Similarly step 6 is often missed either by itself or in addition to missing step 5. An example is when the surveyor arrives in the NICU and there is jack hammering in an adjacent space making basic conversation and more importantly patient care difficult. Step 8 is another one that is often missed or falls apart during the construction project. If you say you are going to inspect at some frequency, or you are going to abate noise, dust or construction debris, then you must adhere to your plan. This article is well worth sharing with your facilities and infection prevention teams, as well as the administrative leaders who perform unit rounding so everyone can be better prepared to identify developing problems.

**CMS****Restraint Death Reporting:**

CMS published QSO-20-04 on December 2nd discussing a new electronic death reporting form #10455 that coincidentally they want you to start using as of December 2nd. CMS does mention that they will continue to accept paper forms until December 31 only. The requirement on which deaths must be reported remains the same, it is only the way in which you report them to CMS that is changing.

The deaths that must be reported include death: While in restraint, seclusion or both excluding those in which only 2-point soft wrist restraints were used and the patient was not in seclusion at the time of death.

Within 24 hours of the removal of restraint, seclusion or both excluding those in which only 2-point soft wrist restraints were used and the patient was not in seclusion within 24 hours of their death;

Within 7 days where the use of restraint, seclusion or both is reasonable to assume contributed to the patient's death.

Attached to the QSO memo is a slide show describing how to access and use the new electronic form. CMS has created an instructional video on how to complete the form that can be accessed on their surveyor training website.

[https://surveyortraining.cms.hhs.gov/pubs/ClassInformation.aspx?cid=0CMSRHDRS\\_ONL](https://surveyortraining.cms.hhs.gov/pubs/ClassInformation.aspx?cid=0CMSRHDRS_ONL)

The QSO memo also details the specific fields of information which must be submitted, but this becomes somewhat easy in that you are filling in the blanks on the form.

CMS also describes what the regional office will do with the information submitted including evaluating it for a potential survey and sharing of information with the accrediting bodies. Since this new process is effective immediately you will want to review the QSO memo and slide deck and make sure that the individual responsible at your hospital for reporting such deaths has the information.

**Omnibus Burden Reduction Final Rule 3346-F:**

CMS had published some program efficiency rules in September that became effective November 29th, 2019. These rule changes are intended to help “cut the red tape” in healthcare and create efficiencies for healthcare providers from burdensome regulations. While governmental agencies often oversell changes like this, there are some changes that will be of interest to our readers. You can download the entire text of changes for all provider types as published in the Federal Register at:

<https://www.federalregister.gov/documents/2019/09/30/2019-20736/medicare-and-medicaid-programs-regulatory-provisions-to-promote-program-efficiency-transparency-and>

The change we believe has the most potential benefit for many readers is an opportunity for multihospital systems to have an integrated QAPI and or infection prevention program. Previously multihospital systems had to operate these functions independently. CMS also added a new requirement to have antibiotic stewardship programs, but since most readers are also accredited by Joint Commission which has had this requirement in place for several years, this should not be at all difficult.

There is also a change that would allow a hospital’s medical staff to develop bylaws permitting the use a presurgical assessment in lieu of a comprehensive medical history and physical prior to certain outpatient surgical procedures. We are less sure that this is a major improvement because many hospitals we see already have so called “short form” histories and physicals in place for some outpatient procedures. But do take a look at the reference to histories and physicals as well as the comments received by CMS on this issue. Be careful to focus on the specific provider-type changes as they are different in ambulatory surgery settings from hospitals.

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CONSULTANT CORNER

Dear Readers,

Happy Holidays from all of us here at PHC! We hope you and your families have a great holiday season and a wonderful new year!

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