FEBRUARY 2019
PHC NEWSLETTER

PATTON HEALTHCARE CONSULTING, INC

NEWS FROM CMS AND JOINT COMMISSION

INSIDE THIS ISSUE:

PERSPECTIVES

Disease Specific Care Updates:

The lead article in this month's edition of Perspectives is about two new advanced disease specific care programs for ST elevation myocardial infarction, STEMI. The first program discussed is called PHAC, or "primary heart attack center" and the second is AHAR, or "acute heart attack ready," with a more basic set of requirements. Two links embedded in the article may be of interest to our readers. The first links you to the Journal Circulation where you can download a full PDF version of the findings about rapid STEMI treatment and the clinical practice guidelines for care. The second link will bring you to the Joint Commission's prepublication standards for both the PHAC and AHAR certification requirements. We encourage readers to download these resources now, so you have some of the tools you would need if you want to consider this version of certification at a later time.

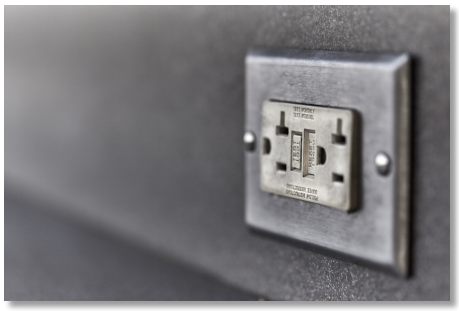
There is also second disease specific care article describing a reinstatement of the individual physician volume requirements for mechanical thrombectomy. We assume this discussion is related to the December Wall Street Journal article where they discussed outcomes being improved when volumes are higher. The prior volume requirement is being reinstated immediately for primary neuro-interventionists, and there is continuing analysis about volume thresholds for others who may be performing mechanical thrombectomy.

Hospital Accreditation Standards:

There are minor revisions to the hospital standard PC.03.01.01, EP 5 where the note about the required

qualifications of the circulating nurse in the operating room has been modified. The difference between the earlier note and the revised note seems subtle, we assume this was a request from CMS. The meaning is anything but subtle, CMS guidelines state that the circulator must be an RN. LPN or a surgical tech would not be acceptable in the circulating nurse role.

Consistent Interpretation Column:
This month's Consistent Interpretation column provides guidance to surveyors on where to score issues with missing ground fault interrupter outlets and access to electrical panels. The first guidance on GFCI outlets is clear on where they are required, however the second guidance does not explain what the surveyor saw and what the verdict is from TJC.



STERILE COMPOUNDING

USP Chapter 797:
A draft of the revised USP Chapter 797 was published in Pharmocopeial Forum in September and is undergoing final revisions based on public comments. Beginning to analyze that draft now is advantageous because some modifications you may need to take will require time. This draft is still subject to additional refinement, but the planned publication date in June 2019 will not provide much time to come into compliance prior to the published implementation date of 12/1/19. Section 5 of the draft version does a nice job of describing the microbiological air and surface monitoring requirements.

Today most organizations are doing viable and nonviable air sampling every 6 months and surface sampling at the same time. The requirement for surface sampling does intensify in the new USP Chapter 797 to a monthly requirement. They require written procedures for conducting air and surface sampling and these may need to be developed. The written procedures should also have a diagram of sampling locations, as well as details about the procedures for collecting samples, size of samples, time of day in relation to staff activities and action levels that will trigger corrective actions. There also is a clear requirement to document any corrective actions taken. This documentation is already an issue we see being scored on Joint Commission surveys today as a result of no actions, inadequate actions, or delayed actions taken. Section 5.3 of the draft USP Chapter 797 provides guidance on when to conduct surface sampling and they recommend at the end of compounding activities or shift, and before the area has been cleaned and disinfected. The reason for this advice is that appropriate techniques for moving people and drug products in and out of the classified spaces as well as the work practices in the classified space should prevent contamination from occurring, whereas inappropriate techniques are more likely to lead to contamination. Doing a thorough cleaning of the classified spaces immediately prior to sampling would give a false sense of confidence about contamination levels.

Another important modification to USP Chapter 797 is the frequency required for gloved fingertip sampling and media fill testing. Fingertip sampling today is required 3 times for new employees, and a successful media fill test is initially required once. Both tests today must be repeated at least every year for what is currently called low and medium risk compounding. The new version of USP Chapter 797 moves the frequency for fingertip and media fill testing to every 6 months for any form of sterile compounding.

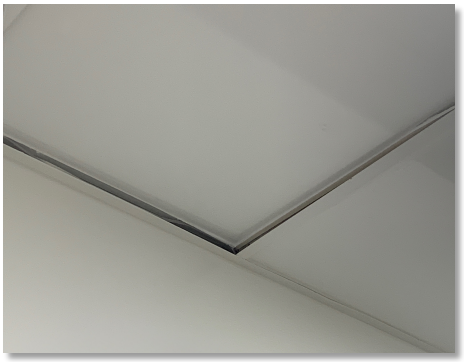
The current terms low-, medium-, and high-risk also are slated to disappear in the revised chapter. New terms will be category 1 and 2 sterile compounding. These new terms relate to the conditions under which sterile compounding is performed. Category 1 is assigned a beyond use date of only 12 hours when stored at room temperature and Category 2 is assigned full USP-permitted dating because they are compounded in an ISO 5 classified PEC, surrounded by an ISO 7 buffer room, and entered through an ISO 7 or 8 anteroom for non-hazardous sterile compounding.

What Can Go Wrong During the Evaluation of Sterile Compounding?
The FDA published a draft document in September 2018 entitled: "Insanitary Conditions at Compounding Facilities: Guidance for the Industry." A PDF copy of this guidance document can be obtained from:

https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm514666.pdf

The document provides an extensive list of what the FDA calls "insanitary conditions" they have found during surveys at organizations that perform sterile compounding. As you read through the examples you may have seen similar conditions at one point in time in your hospital setting. Some of the highlights include:

- Preparing drugs while construction is underway in an adjacent area without adequate controls to prevent contamination
- Standing water or evidence of water leakage in the production area or adjacent areas
- Open doors into classified spaces
- Loose ceiling tiles in classified spaces



- Engaging in sterile compounding wearing non-sterile gowns or gloves
- Putting on garb in a way that causes gowning apparel to become contaminated
- Failing to disinfect gloves frequently during sterile compounding
- Leaving and re-entering the classified space to perform sterile compounding without first replacing attire
- Conducting sterile compounding while blocking "first air" in the hood
- Lack of adequate environmental monitoring
- Lack of adequate personnel sampling
- Inadequate pressure differentials in classified spaces
- Air returns next to the HEPA filter rather than near the floor
- Overhangs and ledges in classified spaces that collect dust
- Sinks, drains or water sources in the buffer area / ISO 5 area
- Presence of particle generating equipment unnecessary for aseptic operations in the ISO 5 buffer zone
- Lack of, improper use of, or infrequent use of sporicidal agent in the classified spaces
- Failure to disinfect equipment or supplies moving from lesser quality air to higher quality spaces

This is just a sample of what they have seen, but the sample is of concern because it has too many similarities to hospital conditions we are seeing or TJC is seeing on survey.

What Can Be Done About It? Remediation:

If you identify air or surface microbial contamination above an actionable threshold you are going to need to go through at least 5 immediate actions.

1. Notify QAPI and or infection prevention of the finding for technical assistance and analysis of the pathogenicity of the growth.
2. Promptly analyze potential root causes and sources for this growth and trend analysis if it is a repeat finding.
3. Promptly undertake remedial actions including retraining, re-cleaning, retesting as well as corrective action on any other root causes identified in your analysis.
4. Document your swift and thorough actions taken in writing.
5. If found during a PEC or SEC certification, annotate the report you will provide to the surveyors to identify corrective actions.

Two common failure points are noted on both consults and TJC surveys. The first and most common failure point is forgetting to document your corrective actions. You should actually have a written remediation plan, so you know where to start on corrective action. The second most common failure point is starting corrective action too slowly, while waiting for the hospital content expert(s) to return to work to lead the implementation of corrective action. If you have a written remediation plan you will know where and how to start before your content experts return from vacation.

The Massachusetts State Board of Pharmacy has developed remediation advice for handling above-action-level environmental monitoring results. Massachusetts, you might remember was home to the New England

Compounding Center and they appear to be ahead of most states with improving practices. Their guidance document provides excellent advice on the detective work you need to do in order to help determine why you might have seen this growth. They suggest a re-evaluation of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency as part of the RCA. A copy of their advisory document can be downloaded from: https://www.mass.gov/advisory/remediation-considerations-for-handling-above-action-level-environmental-monitoring-em

A key last step in the remediation is always going to be a retest for microbial growth. You would anticipate that the retest is going to be clear but it is not always better so you may need to reanalyze all potential causes and improve your remediation strategy. In addition, as an organization you should discuss and decide upon additional potential actions such as not using USP 797 extended duration expiration dating, but rather reverting back to 12 hour dating as is used in a segregated compounding area, without sophisticated air handling and design features.

The important advice here is to do this as a team within the organization, involving leadership and using a formal hospital wide committee such as infection prevention, not in isolation. The repercussions of an inadequate remediation effort could affect patient care and your accreditation survey outcome, with an adverse decision a likely possibility.

TJC SURVEY PROCESS CHANGES

A-Tag Review:
Reportedly, CMS is looking for TJC to do a more comprehensive record review for all A tags that are identifiable in the medical record. TJC indicated at the recent consultant forum that they are developing a tool or checklist for surveyors to use and will make this available to consultants and clients as a resource. Until then we would suggest looking at the E-Edition COP-to-standards crosswalk. This document identifies each A tag and exactly where TJC has cross-walked their standards to that requirement. Seeing the A tag on the left side of the page and the corresponding standards on the right may make it easier to determine if you are comfortable that each of these A tags are addressed in your practices.

Additional advice, TJC will be required to review at least 30 medical records from "front to back" at your next full survey. TJC surveyors have been trained and are starting this review now. You can help your surveyor efficiently review the patient record by having a super user with their own computer assigned to each surveyor. The super user can be in the electronic health record at the same time as the nurse or other staff members are. Making a super user available to the TJC surveyor for any closed record review will also minimize the time required for this expanded activity.

Validation Pilot Survey Update:
Joint Commission announced that CMS will continue to perform both concurrent validation surveys on hospital surveys as well as perform the traditional retrospective validation survey. The CMS concurrent validation surveys will be unannounced so you should modify your Day One plan to include the potential need for more space and more staff to escort a joint CMS & TJC team.

It was also announced at the TJC forum for consultants that CMS will begin concurrent validation survey pilot for deemed ambulatory surgery centers. Following that pilot CMS will begin a pilot concurrent validation project for deemed home care organizations.

FSA Requirements Suspended for Some:
Hospitals do not have to submit FSA or submit any intra-cycle monitoring right now unless they have an adverse decision.

Pain Standards:
The pain standards were modified last year. Expect that the surveyors will be expecting compliance is in place this year. We saw very little scoring last year but understand that the TJC surveyors received additional training this year on the pain standards. Be prepared to show full compliance.

Survey Statistics from 2018:
The year end results are in. The number of PDA decisions in the hospital program doubled in 2018. There were 101 PDA decisions in 2018 compared to the 54 PDAs in 2017. The number of hospitals with an Accreditation Follow-up Survey (AFS) nearly doubled between 2017 and 2018. In contrast, the percentage of hospitals with a Condition Level Deficiency (CLD) remained fairly constant from year to year. Just half of all hospitals received a CLD last year.

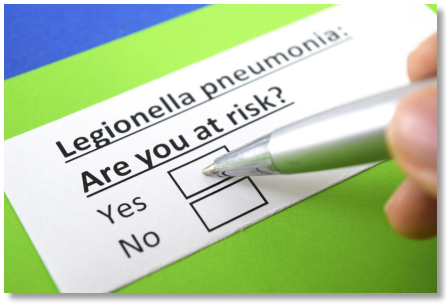
EC NEWS

Emergency Management and Preparing 1135 Waivers in Advance:
The lead article this month is about Emergency Management and preparing 1135 waivers. Such waivers are permitted by CMS during periods when there is a major disaster. The waiver would permit temporary deviation from some of the usual COP requirements. What is really unique in the article is the suggestion to draft the skeleton of your waiver ahead of time, not waiting until disaster strikes. This just seemed like such a great idea, not waiting until your basement is filled with four feet of water, or a neighboring hospital has the water and you are the receiving hospital for their transfers and have to exceed your normal bed capacity.

While you cannot anticipate precisely what kind of disaster may hit your hospital, you do have a hazard vulnerability analysis that gives your best prediction of the types of disaster situations you may have to manage. This seemed like a great suggestion so we would suggest sharing the article with your EM team, asking them to consider the advice. The article provides 10 detailed discussion points that should be addressed in your waiver request.

Legionella in a New CMS QSO Memo:
There is also another article on legionella in the hospital water supply. This has been discussed several times in EC News and our newsletter including September 2017 and again in July 2018. CMS has also issued a QSO memo on this subject in 2017. It is an issue however that continues to strike hospitals and patients with CDC reporting over 2800 cases in 2017. The article identifies that TJC is looking for water management plans that specifically address ANSI/ASHRAE standard 188/2018 and the CDC toolkit we have previously discussed. The ANSI/ASHRAE reference is a for purchase document available on the ASHRAE.org website.

Obtaining the appropriate references is of course a start point. In the EC News article TJC advises 15 specific tips to prevent a legionella outbreak in your hospital. There is some great advice in this article, and we would encourage you to share with your facilities leadership with later follow up to review what was done for each of the 15 recommendations.



Suicide Risk Assessment Tools:
The closing article in EC News provides one more environmental risk assessment checklist for suicide hazards. There are many different tools available for hospitals to use. This one has a good list of features to evaluate in the physical environment, however we have one caution. It asks users to identify if you have the feature, and then provides a column for comments. Our caution is "comments" is too general a term. If you have that environmental hazard, we would encourage you to re-label that comments column to "Immediate Mitigation Strategy". Remember, saying you will eliminate the hazard during a building renovation in some future year is not a mitigation strategy. You need to keep patients safe now and that may require 1:1 supervision to accomplish the almost hazard "free" environment in the behavioral health bedrooms and bathrooms.

There is also one item on the checklist that is far from consensus and that is about "bendable, plastic cutlery with accountability after meals." We have learned over the years that there is significant resistance to such items among many behavioral health professionals. The post-meal accountability feature can lead to crowding, delays and sometimes episodes of violence.

FREQUENTLY SCORED

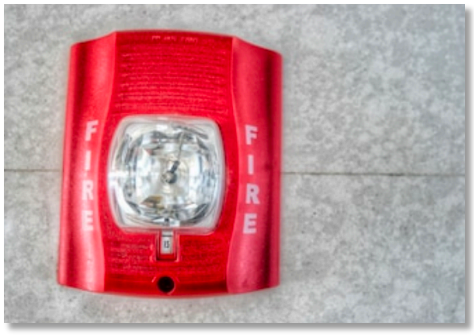
Testing and Maintenance of Fire Safety Systems:
In our last 3 newsletters we have been discussing actual observations from Joint Commission surveys identified in survey reports that have been shared with us. This month

we wanted to discuss EC.02.03.05, the standard that establishes requirements for testing and maintenance of fire safety systems. This standard is no longer on the Joint Commission's top 10 list, however that is not because it is being scored less often, it has just been supplanted by other standards that are being scored at even higher rates.

EC.02.03.05 has many different elements of performance, almost all of which we see scored, however EP 28 is the one that we are seeing scored most often in this standard. This is the EP that requires testing reports to indicate the NFPA references/specifications that were used to conduct the test. Two problems frequently arise, the first being the vendor inspection report has failed to provide any reference, and second when the vendor inspection report identifies an NFPA reference that is now outdated. This is an easy one to check and prevent however as the Joint Commission standards manual, right at the end of each EP lists the required NFPA reference and year. You can share this information with your vendors and make it part of the bid specifications.

Other elements of performance scored in this standard deal with failure to conduct a required test as scheduled, or failure to document an inventory of devices tested when conducting the evaluation. Issue 1, failure to conduct the test requires planning and organization to ensure that tests are conducted when due. A master tickler or work-order schedule is needed and as an organization you need to make sure that momentary budget issues do not delay cutting the purchase order to have your vendor conduct the test. To avoid this budget issue some organizations cut the purchase orders far in advance for the full year, but you may still have to remind your vendor to come on schedule. A finding that a test was missed is sometimes due to a failure to file the test report in the appropriate location or binder. Unfortunately, failing to bring forth the documentation upon surveyor request counts the same as an actual failure to conduct the test. Examples of missed testing documentation seen in these survey reports includes failure to test the supervisory signal devices in the fire pump, failure to transmit and document time for the fire alarm signal to transmit to the offsite monitoring site, failure to test the kitchen's Ansul fire suppression system, failure to test a fire shutter door for appropriate closing, and a failure to test elevator fire fighter recall operations.

Many of the devices or fire safety systems that you test for this standard include many devices scattered throughout your organization. For example, fire alarm devices including both visual and audible alarms, smoke dampers, air handling shut down devices and electronic door closing devices. For more than a decade TJC has required an inventory of these devices. It is not acceptable to say "all" devices were tested, however many vendor reports still contain this language. TJC expects that all devices are listed in an inventory, and all devices are clearly marked as tested and passing. One other risk point here is that sometimes the vendor does not find and test the entire inventory, so one report identifies 150 devices tested and the next 6-month report identifies 152. There must be a logical and documented explanation for this discrepancy, and it can't be they only found 150, if there really are 152 devices.



CMS

There is one new QSO memo's published by CMS for the hospital industry this month. CMS posted QSO19-16 on February 1. It contains some updates to appendix Z of the State Operations Manual dealing with emergency management. CMS is adding "emerging infectious diseases" such as Ebola or Zika to the list of emergencies that should follow the all hazards approach. The specific change from CMS on this aspect is as follows: (italicized, blue text on page 7 identifies the new content).

All-Hazards Approach:
An all-hazards approach is an integrated approach to emergency preparedness that focuses on identifying hazards and developing emergency preparedness capacities and capabilities that can address those as well as a wide spectrum of emergencies or disasters. This approach includes preparedness for natural, man-made, and or facility emergencies that may include but is not limited to: care-related emergencies; equipment and power failures; interruptions in communications, including cyber-attacks; loss of a portion or all of a facility;

and, interruptions in the normal supply of essentials, such as water and food. *Planning for using an all-hazards approach should also include emerging infectious disease (EID) threats. Examples of EIDs include Influenza, Ebola, Zika Virus and others.* All facilities must develop an all-hazards emergency preparedness program and plan.

Appendix Z covers many different types of CMS approved providers, not just hospitals. There is also specific guidance in this memo that organizations that do not have emergency generators, need not obtain one if their solution is to obtain one, or evacuate during an emergency that affects heat, light and power. Hospitals standards already require such devices.

Your emergency operations plan may require some minor modifications if emerging infectious diseases are not already discussed in your plan. If it's not there in your EOP, you may have valuable content in your infection control plan that can be transferred to the EOP.

CONSULTANT CORNER

Dear Readers,

Please join us in congratulating Kurt Patton on publishing his fifth book! We are thrilled to announce *USP <800>: How to Prepare for the New Hazardous Drug Handling Requirements*.

As many of you know, USP 800 will take effect this December. This book details the current state of regulations and standards and provides a step-by-step process to help with compliance as you prepare for these requirements.

You may find this book at the *HC*Pro Store at http://hcmarketplace.com/usp-800.

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