FEBRUARY 2018
PHC NEWSLETTER

PATTON HEALTHCARE CONSULTING, INC

News from CMS and Joint Commission

INSIDE THIS ISSUE:

PERSPECTIVES:

This month's edition of *Perspectives* has a lot of announcements, but not a lot of substantive changes or new requirements that you might lose sleep over. The lead article is on changes made as part of their Phase IV EP Review process. This affects the IM, PI and RC chapters. There is a 12-page document you will want to download from the Joint Commission's website under the standards, prepublication page, that actually lists the changes. These changes become effective July 1, 2018. However, once you review the document you will note that essentially nothing changed other than some consolidation of EP's that were discrete topics, into new EP's that are now compound requirements. So, while there will be fewer elements of performance, don't get complacent, the actual requirements are essentially unchanged. While you are reviewing the 12-page document we would encourage you to take a look at PI.01.01.01 and its elements of performance. Each EP discusses some aspect of data collection and analysis of clinical processes and these issues can sometimes be discussed at the data use system tracer. EP's 3-7, EP 10, 12-14, 34, 35 and 40 all discuss what we define as mandatory PI data collection requirements. Surprisingly when we discuss these in preparation for survey at a data use system tracer it is not unusual to find that there

is no data and no process owner for some of these requirements. Our suggestion here is to self-assess 3 key questions:

1. Do we have a process owner for this data?
2. How often is this data reported to a hospital wide PI meeting?
3. Does the data demonstrate satisfactory performance and a valid/robust reporting process?

Elements of performance 34 and 35, which discuss MRI safety, were added back in 2015 and sometimes are discussed during tracers in the radiology department. It is likely that your hospital has not had one of these adverse events. But the follow-up question and response is sometimes less clear: Would one of these events result in completion of a hospital incident report? Lastly EP 40 is new, related to the new pain management standards and you want to make sure you have identified what data will be collected, by whom and how it will be analyzed to meet potential track record requirements on your next survey.

New Focus on Fluoroscopy Service:

There is also an article on new requirements for organizations performing fluoroscopy services. These also become effective July 1, 2018 and our assumption is that these requirements should not pose a significant challenge to any of our readers. The formatting of the article is a little confusing because it combines changes to the ambulatory care, critical access hospital, hospital and office based surgery accreditation programs. The change for the hospital program is in the "catch all" EP for radiation safety, under EC.02.02.01, EP 7. We used the term "catch all" because this EP requires the hospital to minimize risks associated with using hazardous sources of radiation. This EP is used for multiple different issues from failure to monitor lead shield integrity, to failure to wear or evaluate dosimetry badge use. Now TJC has added a Note 2 stating: "This includes the use of proper shielding during fluoroscopic procedures.". Since it is a "catch all" EP, we would have assumed it covered fluoroscopy previously. Never the less, do share this article with your radiology staff to verify they are aware of the requirement.

Update on Door Requirements:

Perspectives has yet another update on corridor door requirements and eliminating roller latches. This has been a focus of energy since 2003 when CMS first announced the intent to eliminate these latches. As a result of CMS and NFPA modifications, the Joint Commission has changed LS.02.01.30, EP 13 as of March 11, 2018. The change to the EP appears to be merely wordsmithing, but since some authorities would say that is not actually a word, we will say it is fine tuning. There are also 2 new notes added to the EP, the first of which describes a potential loophole to the requirement for positive latching, but the loophole is very narrow as the manufacturer of your door must verify that positive latching hardware is not an option for your door, and the door must still stay closed when 5 lbs. of pressure is applied. Potentially more interesting is note 2 which may be useful to hospitals working to become ligature resistant. Note 2 states that doors to toilets, bathrooms, showers, sink closets and similar auxiliary spaces that do not contain flammables are not required to have a device capable of keeping the door closed under 5 lbs. of pressure.

There is also an update from the suicide prevention panel to recommendation 4 published in *Perspectives* in November 2017. This was the requirement to make the transition zone between patient bedrooms and bathrooms ligature resistant or ligature free. There is a new note added to the recommendation stating that while TJC does not

specify any particular solutions, some organizations may choose to use magnetic soft doors.

Oxygen Cylinder Storage – Change Effective *Now*:

Perhaps more important than the announcements in *Perspectives,* there are new or revised FAQ's on the Joint Commission website that reflect important changes. First, we would like to draw your attention to a new FAQ in the EC chapter on oxygen cylinder storage. This FAQ is surprising as it changes several years of consistent direction from TJC on storage of oxygen cylinders. For several years now TJC has been directing hospitals to store full oxygen cylinders separately from the less than full cylinders including partial and empty. See EC News December 2012 and EC News February 2014. Hospitals had a choice to use 2 racks, one with full cylinders only and a second with partial and empty combined, or to use 3 racks, one for full, one for partial, and a third for empty. Most organizations went the 2-rack route and for several years full cylinders have been stored separately from the partial and empty cylinders. This FAQ reverses that orthodoxy. The guidance in this FAQ now states "Those cylinders defined as empty by the organization shall be segregated from all other cylinders that are intended for patient use. Full and partially full cylinders are permitted to be stored together." Signage and training you have done to become compliant with the previous sorting on the partial cylinders will need to be updated. *Note*: A 3-rack process remains permitted under this new FAQ.

New FAQs on Sterile Medication Compounding and USP 797:

There are 11 new FAQ's about sterile medication compounding. We warned readers that this subject matter was becoming a focus of attention on hospital surveys in our July 2017 newsletter. In the September issue of *Perspectives,* TJC published its most frequently scored standards, including the most frequently scored issues in its new Medication Compounding Certification program. Joint Commission next published tips on survey preparation in its October 2017 edition of *Perspectives*. We also heard at the January *Consultants Forum* hosted by TJC, that they have hired a pharmacist in the Standards Interpretation Group to assist in interpretation and application of requirements. The genesis of this new focus is interesting as the source is a document called USP Chapter 797.

The USP is a standards setting body for pharmaceutical products including sterile compounds. The standards for sterile compounding have been in existence since 2004 and Joint Commission has taken a circuitous route to where we are today in terms of oversight. Initially TJC was going to enforce USP 797, then only a gap analysis would be required, then it would only be enforced in those states that had adopted USP Chapter 797 as part of their state board of pharmacy regulations. However, the article in the October *Perspectives* and these 11 FAQ's make it clear the new position is that all the expectations of USP Chapter 797 will now be enforced. In the past getting enough surveyors knowledgeable about these technical requirements was a challenge. Reportedly TJC has trained the entire hospital surveyor cadre this year, and as we mentioned in this newsletter in July, they also have pharmacist surveyors who will be assigned to hospital teams in some facilities. When one of these content experts participates on the survey you can expect a close examination of USP Chapter 797 standards.

We encourage our readers to print and discuss these new FAQ's, the October 2017 *Perspectives* article on sterile compounding, and the September listing of most frequently scored standards in medication compounding certification to determine your preparedness for survey on sterile compounding. In addition to gain further understanding about TJC's precise expectations we encourage readers to obtain a copy of the home infusion standards 2018, or the optional medication compounding certification standards. These documents have significant similarity to each other, and the EP format makes it easier to understand than the narrative format of USP Chapter 797 itself. While you may not have home infusion services, and you may not have volunteered for certification, these are very useful documents to understand issues that may be explored on your next hospital survey. If you are wondering why TJC is applying requirements not directly stated in the hospital accreditation manual, remember the CMS memo SC 16-01, dated 10/30/15 that stated hospitals should be compliant with "accepted professional pharmacy standards and principles including USP 797." The TJC hospital accreditation manual then states in LD.04.01.01 that the hospital shall be compliant with law and regulation. In addition, IC.01.05.01 requires the hospital to use evidence based national guidelines to prevent the spread of infection, and USP 797 is one example.

The 11 new FAQ's include:

1. Requirements for pharmacy compounding staff competency verification including annual media fill testing, fingertip sampling, didactic testing and competency evaluation of hand washing and donning of PPE. Those organizations that perform what is known as high risk compounding will need to perform media fill and fingertip testing every 6 months.

2. An exemption is permitted from media fill and fingertip testing for nursing staff who perform urgent sterile compounding. Thus, the ICU or ED staff involved in code or other emergency procedures would not need this additional competency.

3. An explanation that a closed system transfer device (or "CSTD,") is not approved by the FDA to extend the beyond- use-date of a single dose medication vial beyond a 6-hour maximum when compounded inside of a laminar flow hood. Remember these are single dose items medications, permitted to be used only once, and any residual amount discarded when drawn up outside of a laminar flow hood.

4. An explanation about permissible practices today for hazardous medications that would permit sterile compounding outside of a negative pressure room providing 2 levels of protection, such as a CSTD and a biological safety cabinet (BSC) or compounding aseptic isolator (CAI), are used. This will become a much more intense focus when the new USP chapter 800 is released in December 2019. This chapter focuses exclusively on compounding of hazardous medications. Drafts and guidance publications from USP and ASHP and JCR are already available if you want to start preparing for this.

5. This is an important one because intuitively you might think some portion of personnel cleansing and PPE would be exempted when using a compounding aseptic isolator (CAI) or compounding aseptic containment isolator, (CACI). However, this FAQ states that nothing is exempt from the same requirements as when using a laminar flow workbench unless the

manufacturer of the CAI or CACI specifically states what can be eliminated. Furthermore, TJC specifically notes that double gloving when preparing hazardous medications is still required in the CAI or CACI, unless the manufacturer of the device specifically stipulates that it is not needed.

6. This FAQ states what testing data is required every 6 months for the primary engineering control, (or "PEC") including your laminar air flow workbench, CAI or BSC. Remember also that this data should be made available with your day one documents. TJC requires:
   - ISO level of the PEC
   - Viable particle testing on the surface of the PEC
   - Viable particle testing of the air within the PEC
   - HEPA filter leak test for the PEC
   - Evidence of remediation and retesting if assessed levels were not in compliance

7. This FAQ details the 6-month testing requirements for the secondary engineering control, or the room surrounding room environment. TJC requires:
   - Air exchanges per hour of the buffer area
   - Pressure differentials between buffer and ante area, and ante to non-classified area
   - ISO level of the buffer and ante area
   - Viable particle testing of the surface of the buffer and ante area
   - Viable particle testing of the HEPA filtered air and leak test
   - Evidence of remediation and retesting in the event of a failure

8. This FAQ describes that low risk compounding can still take place in a segregated compounding area with a hood, however the beyond use date cannot exceed 12 hours.

9. This FAQ states that a single alcohol swab used during sterile compounding to clean a critical point such as a vial septum, ampule neck or injection port on an IV can only be used to clean one item, not multiple items or areas. Since surveyors may be observing sterile compounding this becomes an important compliance issue, because some staff may see this as a somewhat trivial point.

10. This FAQ is interesting in that it addresses an issue about what to do if your PEC fails its testing and certification. The advice provided seems unusual to us in that it says the determination to continue using the compounding area is up to the organization. Our advice would be to immediately remediate and retest, and to discuss with infection control and risk management and proceed with extreme caution or stop compounding in that location until that remediation is complete.

11. This last FAQ is similar to #10 above in that it addresses whether you may still use the PEC when testing/certification results show that either the PEC or SEC is outside of the acceptable range. The advice here is to remediate and retest while examining all issues including cleaning processes, products and air filtration efficiency.

CONSULTANTS FORUM:

TJC periodically hosts several group meetings with hospital constituencies, including accreditation consultants. In January, a meeting was held where there was additional conversation about ligature risks and strategies. The following information is

unofficial as we learned it from verbal presentations and we anticipate that TJC will be issuing another official *Perspectives* update soon. If you are at a decision point and anticipating a survey in the near future, we would encourage you to validate your plans with Joint Commission directly as this remains somewhat of a moving target.

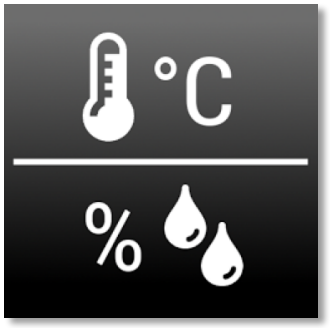
- Ligature risks on behavioral health units with no plan to correct and no mitigation strategy will likely be scored as an immediate jeopardy situation
- Ligature risks on behavioral health units with a mitigation strategy and a plan to correct would likely be scored as a condition level deficiency
- The Columbia Suicide Scale which results in three levels of outcome, high, moderate and low risk levels can be used and the hospital can choose to define the moderate and low as not a serious suicide risk, using only the high to correlate to the TJC term serious suicide risk
- On gero-psychiatric units you can forego the 1:1 as a mitigation strategy if you have completed a documented patient risk assessment that concludes the patient is not capable of self-harm
- When using sitters for 1:1 suicide prevention, be sure to train and validate competency and include in your plans coverage for breaks for the sitter

We also learned that the leadership session on survey is going to focus to a much greater extent on the culture of safety. Surveyors may be asking about your culture of safety questionnaire and analysis of results, goals you were working on prior to the most recent survey and goals you will be working on in the coming year. Surveyors may be asking you about or showing you a video they have developed entitled "Zero Patient Harm is Achievable" along with discussing the TJC Center for Transforming Healthcare's ORO 2.0 survey and your hospital's model and approach to differentiating blame and accountability. The TJC video can be viewed through https://vimeo.com/211533916.

EC NEWS:

The lead article this month is about ligature safety when serving behavioral health patients, but most of the content is a reiteration of content already published in *Perspectives*.

There is also a detailed article on managing temperature, humidity and air pressure in specialized environments. This article links some of the issues that can be identified with specific elements of performance, and scoring trends in the EC chapter. The article contains an important reminder about the categorical waiver available from CMS for humidity in anesthesia settings to as low as 20%. The reminder is not to set the 20% threshold unless you have first conducted and documented a risk assessment to verify the supplies and medical equipment you have in this area can be safely maintained between 20 and 30% relative humidity. The author also includes 11 specific strategies for better compliance on this issue. The article is well worth sharing with your facilities staff and to conduct an assessment of your implementation of those 11 tips.



CMS UPDATE:

Important Changes – After CMS Removes Deemed Status:

On January 12, CMS issued what they are now calling a QSO memo, or Quality and Safety Oversight group memo, formerly known as a Survey and Certification (S&C) memo. This memo describes actions to be taken when CMS temporarily removes deemed status from an accredited healthcare organization. There are

three important features to this enhanced process. First, the organization and the accrediting body must be notified by the CMS regional office that deemed status is being removed at this point in time. This is particularly beneficial given what we read in the Wall Street Journal last fall about perceived flaws in the accreditation process. Now the accreditation organization (AO) will know exactly what CMS is doing and be able to react accordingly. The second important aspect of this process is that anything the accreditation organization does relative to issuing an accreditation decision during this period, will have no impact on deemed status. The accreditation organization after being notified by CMS of the issues and loss of deemed status may decide to survey in order to investigate the issue, but that survey would not reinstate deemed status. Thirdly the temporary removal of deemed status will authorize the accrediting body to delay a planned triennial survey. Currently CMS expects surveys to be conduct on or before due dates. This temporary loss of deemed status would be an approved reason to delay a survey beyond the usual 36-month limit. So, the net result will probably be better coordination of effort and information sharing between the accreditation organization and CMS, which sounds like a good thing.

CONSULTANT CORNER

To our CAS clients: don't forget to log in to access our Tools & Resource Library. We have added two new tracer tools on the new compounding requirements. You can use these to begin asking the right questions in your hospital.

Have a wonderful month!

Thank you,

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