SEPTEMBER 2018
PHC NEWSLETTER

PATTON HEALTHCARE CONSULTING, INC

NEWS FROM CMS AND JOINT COMMISSION

INSIDE THIS ISSUE:

PERSPECTIVES

As September arrives, we can start to feel a slight change in the weather as we gear up for another "academic year" trying to keep up with regulatory and accreditation changes. This month we will discuss new information from the Joint Commission in August and September's editions of *Perspectives* and other publications.

A Change in Quality and Patient Safety Reporting:
In August TJC announced that humans would no longer be responding to calls placed to the Office of Quality and Patient Safety complaint line. By policy TJC had required the complaint to come in writing, and now the hotline will have an automated message stating that the complaint must come in via fax, by mail or via their website. Our readers may not care that TJC is making it less easy to report a complaint about their organization, however there is an important change all readers will have to implement. The signage you currently have which includes the phone number for the complaint line is no longer compliant with the accreditation participation requirement. Your new signage should only advise use of the website, the fax number (630) 792-5636 and the mailing address for the Office of Quality and Patient Safety, The Joint Commission, One Renaissance Blvd, Oakbrook Terrace, IL 60181.

New Perinatal Care Measure:
The August *Perspectives* also announced a new perinatal care measure PC-06 that must be added to the measure set if your hospital has at least 300 live births per year, or you are seeking perinatal care certification. The newly

required measure identifies unexpected complications in term newborns. The specifications for the new measure are detailed in the Joint Commission's Specifications Manual available on their website.

New Guidance on Using Scribes:

Joint Commission also published new guidance on the use of scribes to assist with documentation. In this guidance document TJC eliminated their earlier advice that scribes are unlicensed individuals, now permitting licensed professionals to serve as a scribe. Another very significant departure from earlier guidance is that the scribes may now enter physician orders. Curiously Joint Commission differentiates these face-to-face verbally transmitted orders to a scribe from traditional telephone or verbal orders usually to a nurse. They do not mandate the write down and read back technique and the state that scribe entered orders are not really verbal orders at all. The logic of this conclusion is very hazy but if you use scribes you will want to read this August Perspectives article very carefully as you shape your policies and procedures. We would also advise checking with your state boards of nursing and pharmacy to verify that a nurse or pharmacist can act upon a scribe-entered order in your state. Some state boards may want the nurse or pharmacist to communicate directly with the physician.

Mandated Equipment in Operating Room Suites:

The August *Perspectives* also discussed some additional changes required by CMS to the nursing and provision of care chapter. The one change at PC.03.01.01 affecting hospitals and critical access hospitals with a distinct part psychiatric unit or rehabilitation unit is interesting. It mandates certain equipment be available in operating room suites and, after many years of working in healthcare, we had to look some of these terms up to identify what they were asking for.

1. Call in system (intercom?)
2. Cardiac monitor
3. Resuscitator (ambu-bag?)
4. Defibrillator
5. Aspirator (suction machine)
6. Tracheotomy set

Joint Commission stated the requirement as "At a minimum, operating room suites have the following equipment." So, the question may arise do they mean each OR room, or do they mean the suite as defined in life safety code, encompassing all of the OR's, has to have this equipment? The tracheotomy set can be quite extensive, so this could be a lot of stored and mostly unused surgical sets if every OR has to have them. The first response we received from TJC is every OR has to have all of this equipment, but at the recent Joint Commission Consultants Forum TJC leaders verbally indicated that the equipment needs to be available in the OR suite, not in each individual operating room. Don't forget that your c-section ORs will need their own set of the listed equipment if these ORs are located in a separate location from the main ORs. Readers may want to validate with the Standard Interpretation Group or wait until they publish an FAQ.

Top 10 Most Frequently Scored Standards Updated:

September *Perspectives* updates the Top 10 most frequently scored standards for each accreditation program and they are almost identical to the list published in April. One new standard breaks into the top 10 and that is IC.02.01.01. We most frequently see EP 1, which is somewhat of a catch all EP being scored. It basically requires infection prevention activities to be implemented. So, it does not specifically target high level disinfection and sterilization like IC.02.02.01 does, but other more general flaws in infection prevention practices can be scored here. Failures in hand hygiene, proper garbing in isolation rooms, dust and dirt and other breakdowns that might facilitate disease transmission are scored under this standard. The one standard that fell off the list is EC.02.05.09, but we are sure it did not fall far from the top 10. This standard discusses requirements for piped and cylinder medical gases including proper storage, labeling and the very frequently scored issue of blocking access to the medical gas shut off panel.

Sentinel Events:

Perspectives in September summarizes the sentinel event statistics for first half of 2018. Falls is the most frequent sentinel event with 65 reported falls meeting the sentinel event definition in the first 6 months. We also noted 26 reported suicides in the first half-year. Given the focus on ligature elimination, this is sad to see. Unfortunately, many

organizations are still phasing in their elimination of ligature hazards based on a future date for an anticipated full survey. Some other organizations falsely hope TJC will not notice their remaining hazards. Given the awareness of these hazards by all the clinical and life safety code specialists this is less likely than your home team going to the Super Bowl this year.

Consistent Interpretation – More Guidance on Sterile Compounding:

The August and September Perspectives articles entitled "Consistent Interpretation" again focus on sterile compounding. In August they provided scoring advice if the hospital should fail to certify their primary engineering control (hood or Biological Safety Cabinet) every 6 months. They also discuss that if the surveyors should see this failure to certify the hoods and the organization is performing non-sterile to sterile compounding, also known as "high risk" compounding, then the surveyors should call SIG for advice. Our interpretation of this is that it could lead to SIG advising the surveyors of an immediate threat situation or other route to PDA. In addition, they mentioned that if the scheduled certification fails and the organization does not complete remediation, this too will be scored. We would add that the remediation must be timely and thorough. They also point out that the sterile compounding program should have reporting to the hospitals QAPI program. Our specific advice here is that any failures in PEC or SEC testing, viable surface or air sampling, finger tip or media fill testing for existing employees should all be reported. The August update also mentions that the primary engineering control or PEC should be placed inside of an ISO 7 environment if you want to take advantage of the full expiration dating permitted by USP 797. If it is not, you are limited to 12 hour dating for low and medium risk sterile compounds.

Air Pressure Monitoring and Documentation:

In the September article they discuss air pressure monitoring required for the compounding buffer area, ante area, and hazardous preparation area. Maintaining proper air pressure relationships has been a large problem for hospitals in decontamination areas, central sterile supply and other areas and this just expands upon the potential difficulty. USP Chapter 797 advises documenting these air pressures at least once each shift, and mandates documenting them at least once daily. We would encourage hospitals to also have these alarmed, so that staff working in the area will know if anything changes during their shift. TJC also advises hospitals that sinks are not permitted in the buffer area, walls must washable, ceilings must be solid, or if washable tiles, they must be caulked in place for form a solid ceiling.

Chemotherapy Compounding:

There is one really critical piece of information in this article and that is a prohibition on compounding of chemotherapy outside of an appropriate PEC. No more immediate use compounding of chemotherapy in a room or clinic outside of an appropriate containment device. They also advise readers that staff who perform chemotherapy compounding in an appropriate containment environment must wear 2 pair of chemo gloves, a chemotherapy safe gown, eye protection unless provided by the PEC and 2 pairs of shoe covers, the outer one which is removed when leaving the hazardous compounding area.

Lastly, there is one final reminder that single dose vials that staff might be using inside a PEC, can only be used for up to 6 hours, providing the single dose vial never leaves the PEC. If it leaves the PEC it must be discarded.

411 Initiative:

Joint Commission also sent a "Dear Colleague" letter out last month announcing their 411 Initiative. In this letter they advised that there are 4 high focus areas on survey, including suicide, dialysis, high level disinfection and sterilization and sterile compounding. This probably comes as no surprise to any of our readers, but these topics continue to be highly problematic on survey. Each hospital needs one or more content experts, who are reviewing every piece of literature on these subjects, keeping track of updates to existing clinical practice guidelines and inspecting every corner of the hospital for adherence to accepted practices. For sterile compounding in particular we know there will be a new version of USP Chapter 797 published later this year and there is already a new guidance document entitled USP Chapter 800 on hazardous medication preparation. These new USP

references will both become official December 1, 2019. You will want to start your path to compliance long before that date however.

TJC CONSULTANT FORUM NEWS

The Pendulum Swings, We *Think*:

The Joint Commission held one of its periodic "Consultant Forums" in August. TJC has multiple constituencies or group meetings with interested parties about changes and new initiatives. A very interesting directional change was discussed on a topic that has befuddled many - the mandate to pre-clean all surgical instruments at the "point of use" in the procedural area. They also hinted that surveyors will be trained to new expectations and that an announcement would be seen in the September *Perspectives*. Interesting, this announcement was not published in the September *Perspectives,* but they did issue one of their 411 publications on "Scoring Revisions for IC.02.02.01." The 411 publication states that they previously scored visible bioburden and dried blood found on instruments and they used to score if an enzymatic solution was not applied to maintain moisture on instruments. Now, the new scoring would occur only if the organization did not have a process for keeping used instruments moist. That is nice, simple and does not automatically mandate use of any sort of spray or enzymatic solution. Now the 411 states that surveyors will score if "wiping/flushing of soiled instruments is not observed during a case in the OR or procedure room and it is clinically appropriate." So, the term "not observed" is interesting phrasing as is the new phrase "clinically appropriate." What is clearly missing is the notion of strict adherence to a single evidence-based guideline such as AAMI. We also noted that TJC has pulled down the FAQ they had on the website that mandated pre-cleaning at the point of use. Unfortunately, removal of an FAQ is not easily noticed and does not adequately disseminate new information. We strive in this newsletter to cut through the fog and help advise readers on what they really need to do, but at this time there are too few details from TJC to give clear advice. We advise readers to refrain from changing policy or procedure until additional detailed direction is published on this subject. Until clear direction is published it may be advisable to have any proposed change to policy or procedure sent to SIG at the Joint Commission for vetting prior to implementation.

A second critical infection control requirement change was announced in the September issue of *Perspectives* and that deals with storage of semi-critical items. In this new advisory TJC states that semi-critical items that are processed in a peel pack such as a speculum, may be "opened and distributed safely to multiple clean drawers." This is a very significant departure from earlier guidance on other semi-critical items like laryngoscope blades where TJC mandated keeping them protected in some outer wrapping prior to use. We went looking for that FAQ and noted it too is missing from the website. However, we saved that FAQ in our files and we noted the date of publication was October 2013. In that FAQ TJC had stated the storage requirement as: "Laryngoscopes should be kept free from contamination until the time of use. Once opened, there is potential for microorganisms to settle on the equipment the longer it remains open and unused. An option would be to contain the individual blade in a closed plastic bag, placed in a clean storage location and if steam sterilized a peel pack may be used." We did note an FAQ that is still available on their website about storage of ETT tubes. Here they state there is no evidence that opening them ahead of time actually causes a problem, thus it would be acceptable for the organization to develop a risk assessment and policy that permits the pre-opening of these packaged items. The 411 article also references equipment that has been processed using high level disinfection. Here again the guidance in the 411 is ambiguous. They mention containers or storage locations that might be or are contaminated as a problem. However, they don't say if wrapped or unwrapped items stored in a dirty container is a problem. They also mention storage not being consistent with intended use would be scorable as non-compliant, (e.g. items that require minimum HLD may be stored in a way that protects from contamination, even if they were sterilized). Unfortunately, the meaning of that sentence is far from clear.

So, it looks like there is a philosophical change happening at TJC on some very difficult infection control requirements. Some of the issues in the 411 seem straight forward like the new guidance on instruments being transported in the building. Previously we saw surveyors scoring a failure to transport a non-sharp like an endocavity probe in a rigid container with a top. Now TJC makes it clear that a rigid container is not a requirement if you are not transporting sharps. They also clearly state TJC will not score issues relative to hang time for processed scopes, but if that is already in your hospital policy, we imagine they will still score it if you are not following your policy.

It looks like this may be headed in a direction that will focus less on minutia and based on what we heard at the consultant forum, we think hospitals will like the planned changes. When we see newly published information like this we act much like our readers do by vetting it with content experts. We distribute and discuss it with all of our consultants to make sure we are interpreting it correctly. Unfortunately based on what we have read thus far we are getting divergent opinions. We don't yet see clear guidance on the new direction where we could advise specific actions. We hope to read the details about these changes in an upcoming edition of *Perspectives* or hear about them at this falls Executive Briefings. Before taking action on the new direction, we encourage the Infection Preventionists in your hospital review the recent 411 and prepare your own analysis on what you believe TJC is saying, then seek confirmation before changing policies.

Adverse Decisions:
The Consultant Forum also provided insight into the increased number of adverse decisions, PDA and AFS, as well as immediate threat to life. They supplied data on the numbers of PDA, AFS and ITL from 2013 through early July 2018. We noted the ratio of AFS to PDA's has changed from more AFS to more PDA and the total number of PDA's has grown each year. In 2017 there were 54 PDA decisions and in the first 6 months of 2018 there have already been 66. The good news here is that TJC has a much-improved process for a time limited PDA, rather than the PDA automatically leading down the path to denial of accreditation absent a successful review hearing panel. Going back to the 411 discussion above, every PDA decision we have seen did involve problems with high level disinfection or sterilization, many involved suicide risks and quite a few involved sterile compounding. We have seen dialysis problems much less often, but that may just be the newest hot button issue soon to expand. We should also note every one of the PDA's we have seen did involve some aspect of pre-cleaning of surgical instruments, often including the same issue noted above on which they seem to have reversed course.

Another change noted, but much less impactful, is the increasing percentage of hospital surveys where one or more Medicare Conditions of Participation are identified as noncompliant. This has gone from 31% in 2016 to almost 52% in 2018. The good news however is that this should lead to increased consistency on validation surveys conducted by the states for CMS and almost all organizations we have worked with are able to clear their condition level findings on the first try.

Joint Commission also announced that they have been conducting some concurrent validation surveys with CMS instead of the usual retrospective validation surveys. They report they are finding a higher degree of consistency in findings when the teams are simultaneously evaluating the organization. Thus far CPHQ and DNV have not been part of the pilot, but CMS perceives the outcome as very positive, so this concurrent activity is anticipated to be the future process.

EC NEWS

Hazardous Chemical and Medication Compliance:
The lead article in the August edition discusses hazardous chemical requirements and proven strategies for compliance. The individual at your hospital who is responsible for this section of the EC chapter and the preparation of your hazardous materials plan should certainly review this article. One problematic issue not discussed that we see as consultants is when a component of the organization purchases a hazardous chemical not previously in use in the hospital, it is not on the inventory of hazardous chemicals and the work area is not prepared with appropriate protective equipment to manage that hazardous chemical. Developing a system to block such ad hoc purchases would be very worthwhile.

Earlier we mentioned the publication of USP Chapter 800 discussing requirements for managing hazardous medications. The author of your hazmat plan should be reviewing that document now and collaborating with your pharmacy leadership to update your hazmat plan by December 2019.

BAS Compliance:
The August issue of EC News also has a good article on EC.02.05.01, EP 15 which establishes requirements for monitoring temperatures, humidity, air pressure relationships and air exchanges. This article points out the

capabilities and limitations of BAS, or building automation systems. Similar to the hazardous materials article they provide strategies for managing this requirement. One in particular is of paramount importance and that is step-by-step procedures that describe the actions to take when a temperature, air pressure, or humidity is out of your expected range. As consultants we see flaws in this process very often. Staff either don't react, or don't know how to react to "excursions." Staff need to know what must be documented and what actions to take to correct the situation, other than just calling facilities. Sometimes the air pressure relationship is off because of an open door, or an open pass through device and the call to facilities is unwarranted.

Fire Safety Requirements:
The lead article in the September EC News is about new life safety code standards for small behavioral health residential facilities. These new standards establish certain fire safety requirements, but we will not detail them here simply because most of our readers have hospital based behavioral health programs, not freestanding residential facilities. EC News also has an article on LS.02.01.30 which is the fifth most frequently scored standard in hospital surveys with 72% of hospitals being scored deficient. Unfortunately, this article only focuses on EP 19, and there are many other elements of performance in this standard that are more frequently scored. In past issues of this newsletter we have mentioned the very frequently scored problems with design and operation of smoke and fire doors.

CMS UPDATE

CMS Not Developing Ligature Risk Task Force!
On July 20th CMS published QSO:18-21 regarding psychiatric environmental ligature risks. This memo has particularly good news for the hospital industry. CMS announced that they will not be developing their own task force on ligature risks, as the Joint Commission has already done this and published their recommendations. At some point these task force recommendations will be incorporated into the Interpretive Guidelines. Not having parallel, redundant and potentially conflicting advice on this issue is a major win for the industry. However, there is still the significant challenge of coming into compliance with the recommendations from the Joint Commission task force.

Outpatient Dialysis Center Compliance Expected:
We would also like to draw your attention to a second QSO: 18-22 addressed to the End Stage Renal Disease industry. This memo points out that outpatient dialysis centers are expected to be compliant and certified as an ESRD program by CMS. The last page of the memo has some infection control related guidance on sterile syringes of saline and turning over the station between patients. The saline advice follows the CDC injection practices advice, recommending manufactured saline syringes. They do provide guidance on preparing sterile syringes of saline in the dialysis center, if you must, but there are so many difficulties in doing this from a single dose saline bag that we would recommend not going in this direction.

CONSULTANT CORNER

Dear Readers,

We hope everyone had a wonderful last two months and had the chance to have some end of summer fun! We're glad to be back to provide you with some pretty important updates for 2019. Keep an eye out for future Newsletters, as we are sure there is more to come for next year.

Please contact us if you have an adverse outcome—time is limited and our experienced PHC consultants will help you navigate through the process to a successful follow up survey.

Thank you,

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